IN THE HIGH COURT OF JUDICATURE AT BOMBAY

CIVIL APPELLATE JURISDICTION

PUBLIC INTEREST LITIGATION NO. 85 OF 2021

Yohan Tengra .... Petitioner

Vs.

State of Maharashtra & Ors. ...Respondents

INDEX FOR AFFIDAVIT IN REJOINDER

Sr. No	Particulars	Page Nos
1.	Affidavit In Rejoinder	1149 – 1408
2.	**Exhibit "RA-1"** A copy of study published by World Health Organization titled as **"Coronavirus disease (COVID-19): Herd immunity, lockdowns and COVID-19"** dated 31 December, 2020	1409
3.	**Exhibit "RA-2"** A copy of article published in **The Indian Express** titled as **"Over 85% Mumbai population has Covid-19 antibodies: Latest BMC Sero survey"** dated 18th September, 2021.	1414
4.	**Exhibit "RA-3"** A copy precaution issued by The Department of Health and Family Welfare Services Govt of Karnataka.	1417
5.	**Exhibit "RA-4"** A copy of article published in Times of India titled as **"8 more Omicron cases found in**	1418

NOTARY M. M. PADALE Mumbai Maharashtra Reg. No. 15/23 Expiry Dt. 27-1-2024 GOVT OF INDIA

	Maharashtra: 6 in rural Pune, 2 in MMR" dated 18th December, 2021.	
6.	**Exhibit "RA-5"** A copy of **RTI** reply dated **20.09.2021** given by the Ministry of Health & Family Welfare.	1420
7.	**Exhibit "RA-6"** A copy of the news published in Times of India titled as **"10 months on, Chief Secretary of Maharashtra takes his first shot"** on 4th December, 2021	1423
8.	**Exhibit "RA-7"** A copy of complaint against Shri Sanjay Raut by Shri Amber Koiri dated **2nd December, 2021.**	1425
9.	**Exhibit "RA-8"** A copy of the RTI reply received from a small district in Kerala **(Mallapuram)** district medical office has acknowledged that 11 people died only in Mallapuram due to side effects of vaccine till **25.09.2021.**	1428
10.	**Exhibit "RA-9"** A copy of Central Government letter dated **1st December, 2021** sent by Mr. Rajesh Bhushan to Dr. Pradeep Vyas, Additional Secretary, Government of Maharashtra	1429
11.	**Exhibit "RA-10"** A copy of article published titled as **"Maharashtra: Over 1.6 lakh people took jab**	1430

	after 'No vaccine, no entry' order in Beed" dated 28 November, 2021	
12.	**Exhibit "RA-11"** A copy of news published in Mid-Day titled as **"BMC's pro-mask drive is just an extortion racket"** dated 20th December, 2021	1432
13.	**Exhibit "RA-12"** A copy of RTI reply dated **27th May, 2021** to Mr. **Sourav Bysack** Being **RTI Application No. F. No. Z.28016/133/2021-DM CELL**	1441
14.	**Exhibit "RA-13"** A copy of RTI reply dated **19.05.2021** to **Shri. Amit Chauhan** Being **RTI Application No. F. No. INCMR/R/E/21/00355.**	1443
15.	**Exhibit "RA-14"** A copy of RTI reply dated **17.07.2021** Being **RTI Application No. F. No. NIOVP/R/E/21/00046**	1447
16.	**Exhibit "RA-15"** A copy of article published titled as **"47 studies confirm ineffectiveness of masks for COVID and 32 more confirm their negative health effects"** dated 23rd July, 2021	1448
17.	**Exhibit "RA-16"** A copy of **"Summary of frauds related with Covid-19 pandemic exposed by Bhartiya Janta Party's former M.P. Dr. Kirit Somaiyya"**	1477
18.	**Exhibit "RA-17"**	31501

	A copy of Sero-Survey shows Delhi has 97% antibodies, Mumbai over 85%, and India over 67%.	
19.	**Exhibit "RA-18"** A copy of Indian studies regarding Natural Immunity & Indian Expert Opinion.	1504
20.	**Exhibit "RA-19"** A copy of 138 papers published in pre-print servers & peer reviewed medical journals confirm natural immunity is equal to or better than vaccine immunity.	1506
21.	**Exhibit "RA-20"** A copy of studies which show that vaccinated people have just as much, or more viral load than the UN-vaccinated.	1596
22.	**Exhibit "RA-21"** A copy of latest Government Data on AEFI in India.	1598
23.	**Exhibit "RA-22"** A copy of comparison of deaths and serious adverse events in India and other countries.	1601
24.	**Exhibit "RA-23"** A copy of under reporting in VAERS & India.	1604
25.	**Exhibit "RA-24"** A copy of letters from Indian Experts opining on the state of AEFI reporting in India.	1617
26.	**Exhibit "RA-25"** A copy of Covid Deaths in India and Infection Fatality Rate.	1624
27.	**Exhibit "RA-26"**	1626

NOTARY
M. M. PARAL
Mumbai
Maharashtra
Reg. No. [illegible]
Expires on [illegible]
GOVT.

	A copy of studies & Data which link AstraZeneca (Covishield) to serious adverse events.	
28.	**Exhibit "RA-27"** A copy of research showing that giving vaccines to person with earlier infection causes serious harm.	1632
29.	**Exhibit "RA-28"** A copy of Covishield banned/age restricted in 15 countries.	1633
30.	**Exhibit "RA-29"** A copy of how vaccines don't reduce Covid cases even at a country level.	1642
31.	**Exhibit "RA-30"** A copy of vaccinated people are at higher risk of testing positive, hospitalization & death.	1645
32.	**Exhibit "RA-31"** A copy of research shows vaccinated people are 13 times more likely to get infected than those who are naturally immune.	1649
33.	**Exhibit "RA-32"** A copy of evidence that Covid Vaccines compromise Natural Immunity.	1651
34.	**Exhibit "RA-33"** A copy of ways other than vaccines of reducing Covid infection, hospitalization & death.	1654
35.	**Exhibit "RA-34"** A copy of Maharashtra Govt Order dated 27th November 2021.	1663
36.	**Exhibit "RA-35"**	

NOTARY
M. No. 1670
Maharashtra
Reg. No. 19220
Expiry Dt. 30-10-2024
GOVT. OF INDIA

	A copy of Cowin API lets anyone know a persons vaccination status using their phone number.	
37.	**Exhibit "RA-36"** A copy of National Disaster Management Authorities website contains advisories from Ministry of Home Affairs & Ministry of Health & Family Welfare.	1673
38.	**Exhibit "RA-37"** A copy of fully vaccinated people in India testing positive for Omicron, one of them even had a booster.	1674
39.	**Exhibit "RA-38"** A copy of CDC announces 79% of Omicron cases have occurred in the fully vaccinated.	1679
40.	**Exhibit "RA-39"** A copy of Indian experts suggest booster doses not needed to tackle Omicron Variant.	1684
41.	**Exhibit "RA-40"** A copy of how mass vaccination is giving rise to new variants.	1690
42.	**Exhibit "RA-41"** A copy of possible consequences of using boosters in an Omicron wave.	1694
43.	**Exhibit "RA-42"** A copy of study suggests T-cell immunity from natural infection will work against Omicron.	1703
44.	**Exhibit "RA-43"**	1712

	A copy of natural Immunity 75% effective against Omicron, vaccine only 33%.	
45.	**Exhibit "RA-44"** A copy of examples of Immunity that lasts for decades in other viral respiratory infections like Sars & the 1918 Flu.	1714
46.	**Exhibit "RA-45"** A copy of all trials done to approve Astrazeneca (Covishield) were done in foreign countries.	1715
47.	**Exhibit "RA-46"** A copy of studies when asked under Indian Evidence Act 1976, ICMR sent foreign studies to support their position on Masks, RT-PCR testing, Lockdowns and social distancing, & said that no studies have been done by them.	1743
48.	**Exhibit "RA-47"** A copy of Japan Health Ministry's Stand Regarding Vaccination.	1747
49.	**Exhibit "RA-48"** A copy of our Response to Affidavit filed by State Japan Health Ministry's Stand Regarding Vaccination Government.	1754
50.	**Exhibit "RA-49"** A copy of Natural Immunity vs. Vaccine Immunity Comparison table.	1757
51.	**Exhibit "RA-50"** A copy of article published in **'Outlook'** titled as **"Will Omicron End the Pandemic? Top Experts**	1760

GOVT. OF INDIA

	Say Omicron May Act As 'Natural Vaccine' For Covid-19" dated **22.12.2021.**	
52.	**Exhibit "RA-51"** A copy of one such written application to the officials of Respondent No. 1 for providing them compensation as per above provision.	1764
53.	**Exhibit "RA-52"** A copy of Parliamentary Committee's 72nd Report dated **23rd August, 2013.**	1770
54.	**Exhibit "RA-53"** A copy of Complaint against PHFI dated 18th October,2021.	1829



IN THE HIGH COURT OF JUDICATURE AT BOMBAY
CIVIL APPELLATE JURISDICTION
PUBLIC INTEREST LITIGATION NO. 85 OF 2021

Yohan Tengra .... Petitioner

Vs.

State of Maharashtra & Ors. ...Respondents

AFFIDAVIT IN REJOINDER ON BEHALF OF PETITIONER

I, **Yohan Tengra,** Petitioner above named, residing at Building No. 21, 1st Floor, Flat No. 3, Old Khareghat Colony, Hughes Rd, Mumbai – 400007., do hereby state on solemn affirmation as under;

1. That, the reply affidavit filed by the Respondent No.1 i.e. chief Secretary of State of Maharastra is out and out false & misleading. It is filed by suppression, twisting and dishonest concealment of material facts with ulterior motive to misguide this Hon'ble Court.

2. It is ex-facie clear that the reply affidavit is prepared with one motive of giving wrongful profit to vaccine companies and wrongful loss to public exchequer, with further putting the life and liberty of the citizen in to jeopardy.

3. That there are two Affidavits filed by the Respondent No. 1.exhibit

i) Dated 15.12.2021

Affirmed by Dr. Sadhana Tayade, Director of Health Services, Public Health Department.

ii) Dated 21.12.2021

NOTARY
M. M. PABALE
Mumbai
Maharashtra
Reg. No. 15230
Expiry Dt.
30-10-2024
GOVT. OF INDIA

1150

Affirmed by Shri. Debashish Chakrabarty, Chief Secretary, Government of Maharashtra.

4. That the affidavits and connected documents submitted by the state are itself sufficient to prove that the submissions of Petitioner are correct and the submission by the Respondent State is false and misleading and actuated with ulterior purposes and malafide intention.

5. That, the present Rejoinder Affidavit is sub-divided into following parts for the sake of convenience:

Sr. No	Particulars	Para Nos	Page Nos
1.	The affidavit filed by the Respondent No 1 Chief Secretary is against the mandates of law laid down by Hon'ble Supreme Court & this Hon'ble Court regarding contents of the reply affidavit to be filed by the state authorities.	6	9
2.	Detail of facts suppressed, not disputed and conveniently ignored by the Respondent No.1. State, in their reply affidavit.	7	15
3.	As per law laid down by the Full Bench of Hon'ble Supreme Court, vague and omnibus denial in reply affidavit is not sufficient. Failure of the Respondent No.1 state in not disputing the serious allegations in the petition with specific answer, proves the malafides of the state authority. In such cases Court can pass order in favor of the Petitioner on this ground.	8	21

4.	Reasons given by Respondent No.1 to defend their act of discrimination between vaccinated & unvaccinated in the affidavit dated 15.12.2021 and 21.12.2021 are incorrect, wrong, irrational, illogical and improper. The falsity of reply is proved from their own documents. Such decisions are called as 'Fraud on Power' and are vitiated as per law laid down by the Full Bench of Hon'ble Supreme Court	**9**	**26**
5.	Other false and misleading submissions on the part of Respondent No.1.	**10**	**34**
6.	Health Ministry of Central Government said, the longevity of the immune response in vaccinated individuals is yet to be determined.	**11**	**42**
7.	Subsequent order dated **27.12.2021** is so impractical that the Respondent No.1 Chief Secretary himself is not following it.	**12**	**42**
8.	Question is regarding violation of fundamental rights of the Crores of citizen and it cannot be curtailed by passing an arbitrary order on the basis of incomplete data without any scientific proofs.	**13**	**44**
9.	Proofs of suppression of data by state regarding vaccine deaths and side effects which proves the concerns expressed by Hon'ble Justice Dr. D.Y. Chandrachud that court cannot rely only on state to determine	**14**	**45**

NOTARY
M. M. PARDALE
Mumbai
Maharashtra
Reg. No. 16220
Expiry Dt.
30-10-2024
GOVT. OF INDIA

1152

	truth in the cases related with Covid-19.		
10.	Defense taken by the state (Respondent No.1) on the basis of false and incorrect data does not pass the Scrutiny of Article 14 and intelligent differentia as laid down in the case of **Madan Mili Vs. UOI 2021 SCC OnLine Gau 1503.**	**15**	**49**
11.	As per Hon'ble Supreme Court judgment, when public servant files false affidavit with suppression of material and relevant facts then such public servant should be punished under section 2 (c) & 12 of Contempt of Court Act,1971 and also under section 191, 192, 193, 199,200,471,474,120(b), 34 etc of IPC as per section 340 of Cr.P.C.	**16**	**63**
12.	The rules made by the Respondent No.1 state authority are not with the approval of National Platform for Disaster Risk Reduction (NPDRR) as mandates in sub. rule (3).	**17**	**82**
13.	The impugned order are vitiated as said orders/rules/regulations are not placed before the House of State Legislature nor it is approved by the both the House as mandated under section 78(3) of Disaster Management Act, 2005	**18**	**83**
14.	Executive order cannot become the law. The liberty of citizen cannot be curtailed on the basis of orders passed by the authority. There is a need of creating a law by the legislation as	**19**	**84**

Maharashtra
Reg. No. 152
GOVT. OF INDIA

	per Article 19(6) of the Constitution of India as explained by the Hon'ble High Court in **Re Dinthar Incident Vs. State of Mizoram and Others 2021 SCC OnLine Gau 1313.**		
15.	Disaster Management Act, 2005, National & International Law applicable in India and our Constitution does not permit any discrimination between vaccinated and un-vaccinated.	**20**	**86**
16.	False & incorrect objection about non-joinder of parties.	**21**	**98**
17.	Reliance on the judgement passed by the Gujarat High Court is in Contempt of Hon'ble Supreme Court judgement in **Pradip J. Mehta v. Commissioner of Income-tax, Ahmedabad (2008)14 SCC 283 & Dwarikesh Sugar Industries Ltd. v. Prem Heavy Engineering Works (P) Ltd., (1997) 6 SCC 450.**	**22**	**100**
18.	Unauthorized access of personal data of the Petitioner is an offence on the part of the Respondent No.1. Unlawful and irrelevant objection raised in contempt of the order dated **15.12.2021** passed by this Hon'ble Court.	**23**	**107**
19.	Act of Respondent No. 1 Chief Secretary is not protected by the element of good faith but actuated with legal malice and in bad faith.	**24**	**113**
20.	Omission to prevent illegality makes the Respondent No.1 Chief Secretary liable for	**25**	**120**

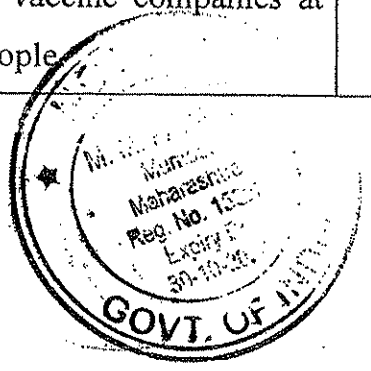
	action under section 218,201,202 etc. of IPC.		
21.	The doubt created by the State i.e. Respondent No. 01, regarding possible shortage of oxygen is not only irrelevant for defending discrimination but also a dishonest statement because said problem which may be faced in future can only be because of wrong mandates of the State. Because the shortage of oxygen in the body is mainly due to the mask mandate as proven in the research which is explained in the earlier paragraphs.	**26**	**127**
22.	As per Supreme Court judgment in **Common Cause Vs. Union of India (2018) 5 SCC 1**, the state authority cannot put questions to any citizen regarding his decision to refuse to take vaccines. Therefore, the program 'Ghar Gahr Dastak' or any such attempts to collect information or put pressures are contemptuous.	**27**	**128**
23.	Order dated **27.11.2021** relied by Respondent No.1 is more aggravated form of the unlawful Act. It is also contempt of court as per law laid down by the Full Bench in the case of **S. Abdul Karim (1976) 1 SCC 975** which mandates for keeping equanimity till matter is subjudice.	**28**	**129**
24.	Criminal liability of Respondent No.10 Shri Udhhav Thackery, Chief Minister of Maharashtra and Chairman of State Disaster	**29**	**136**

NOTARIAL M. M. PABALE Mumbai Maharashtra Reg. No. 15220 Expiry Dt. 30-10-2024 GOVT. OF INDIA

	Management Authority.		
25.	As per Supreme Court judgment Government officials opposing meritorious case on the basis of false and frivolous grounds needs to be saddled with heavy cost.	**30**	**156**
26.	The data relied by the petitioner in support of his submissions to prove the falsity and dishonesty of the Respondent No.1.	**31**	**166**
27.	Omicron is the blessing as explained by the experts and proved from the scientific data but the Respondent No.1 state & Respondent No.4 Shri Iqbal Chahal is deliberately creating panic and spreading misinformation suppressing the truth in connivance with some media persons to spread fear amongst the public and therefore it is an offence under Section 54, 55 of the Disaster Management Act, 2005 on the part of all the public officials involved.	**32**	**170**
28.	Sponsored, biased, one-sided reporting by some media is contempt of court and also make them co-accused in the conspiracy.	**33**	**173**
29.	State authority was duty-bound to publish the side effects of vaccines and also to publish that there cannot be any force or mandate for taking vaccine. If anyone is forced to take vaccines then the public should be given a grievance cell to complain as done by the Japan Government. But Respondent No.1	**34**	**182**

NOTARY
M. M. PUBALE
Nashik
Maharashtra
Reg. No. 15220
Expiry on
30.10.2024

	adopted unlawful, unconstitutional approach thereby putting the citizen at the mercy of correct officials. This Hon'ble Court can direct Respondent No.1 to publish the side effects and readdress grievance cell.		
30.	The insistence of the state authority i.e. Respondent No. 1 by asking the citizens to get immunization only through vaccines is contempt of the Supreme Court Judgment in **Dr. AKB Sadbhavan Mission School of Homeo Pharmacy Vs. Secretary (2021) 2 SCC 539**, and other law applicable in India.	**36**	**197**
31.	State cannot bring any prohibitions or lockdown without making arrangements for compensation as mandated under Section 2 of the Epidemic Act, 1897. But Respondent No. 1 maliciously not followed the said provisions.	**37**	**203**
32.	Respondent No. 1 – State of Maharashtra was duty bound to follow the Constitution Bench judgment in **Mineral Development Ltd. Vs. State (1960) 2 SCR 609** and remove the persons from committee, who are directly or indirectly getting funds from the vaccine/pharma companies more particularly from Bill & Melinda Gates Foundation, Rockefeller Foundation, whose aim is to give wrongful profits to the vaccine companies at the cost of killing the people.	**38**	**208**



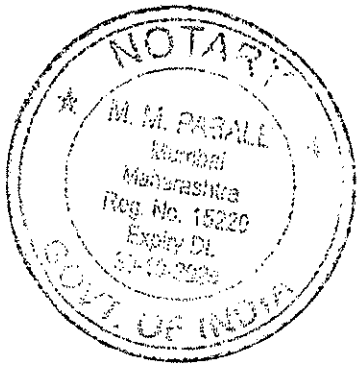
33.	Duty of the Government Pleader.	**39**	**238**
34.	Summary Of Submission	**40**	**251**
35.	Concluding Paragraph	**41**	**257**

5.1. That, the emphasis to the important paras from the reported judgments is by the petitioner for sake of convenience.

6. The affidavit filed by the Respondent No 1 Chief Secretary is against the mandates of law laid down by Hon'ble Supreme Court & this Hon'ble Court regarding contents of the reply affidavit to be filed by the state authorities.

6.1. That, Hon'ble High Court in the case of **Seethalakshmi v. State of Tamil Nadu, 1989 SCC OnLine Mad 272**, it is ruled as under

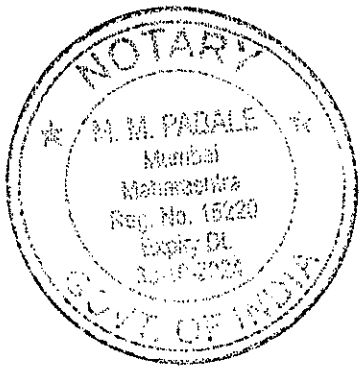
> *"18. This Court has on several occasions pointed out that affidavits should not be treated in a light-hearted fashion and prepared in a hap-hazard manner. Every litigant should understand that an affidavit is a sworn statement and it takes the place of deposition. Responsibility of Government officials is much more in this regard. Their affidavits are not intended just to point out the flaws in the case of the opponent. Their affidavits should always place all the facts before the Court whether such facts would support the contention of the Government in the case or not."*



6.2. That, in the case of **Amardeepsingh Baswantsingh Thakur Vs. Deputy Inspector General (Prisons) (East) Nagpur 2020 SCC OnLine Bom 6621**, it is ruled as under;

"3. The reply filed on behalf of the respondent No.2 is far from satisfactory, rather it borders upon interfering in the administration of justice. We say so with all sense of responsibility. The least that is expected from the state is to be correct on facts and straight forward in submissions. The reply filed on behalf of the respondent No.2, does not fulfill any of these parameters. The reply is misleading and also takes a ground which is not stated in the impugned order, for resisting this petition..... This time we would not pass any order which may be adverse to the interest of respondent No.2, but, we would like to put respondent No.2 and the officers like him who are public servants on guard by what we have said just now."

6.3. Full Bench of Hon'ble Supreme in a recent judgment in the Case of **Manohar Lal Sharna Vs. Union of India 2021 SCC OnLine SC 985,** has also ruled that omnibus and vegue denial by state in reply affidavit is not sufficient. In such case Court will accept the contention of the petitioner. The state is bound to place all the information before the court when the question is about violation of fundamental rights of the citizen. It is ruled as under;



*"53. In the present matter, as we have indicated above, the Petitioners have placed on record certain material that prima facie merits consideration by this Court. There has been no specific denial of any of the facts averred by the Petitioners by the Respondent-Union of India. **There has only been an omnibus and vague denial in the "limited affidavit" filed by the Respondent-Union of India, which cannot be***

sufficient. In such circumstances, we have no option but to accept the prima facie case made out by the Petitioners to examine the allegations made.

48. *Such a course of action taken by the Respondent-Union of India, especially in proceedings of the present nature which touches upon the fundamental rights of the citizens of the country, cannot be accepted. As held by this Court in Ram Jethmalani v. Union of India, (2011) 8 SCC 1, the Respondent-Union of India should not take an adversarial position when the fundamental rights of citizens are at threat. This Court in that case observed as follows:*

> *"**75.** In order that the right guaranteed by clause (1) of Article 32 be meaningful, and particularly because such petitions seek the protection of fundamental rights, it is imperative that in such proceedings the petitioners are not denied the information necessary for them to properly articulate the case and be heard, especially where such information is in the possession of the State. To deny access to such information, without citing any constitutional principle or enumerated grounds of constitutional prohibition, would be to thwart the right granted by clause (1) of Article 32.*

76. Further, inasmuch as, by history and tradition of common law, judicial proceedings are substantively, though not necessarily fully, adversarial, ***both parties bear the responsibility of placing all the relevant information, analyses, and facts before this Court as completely as possible. In most situations, it is the State which may have more comprehensive information*** *that is relevant to the matters at hand in such proceedings...*

77. It is necessary for us to note that the burden of asserting, and proving, by relevant evidence a claim in judicial proceedings would ordinarily be placed upon the proponent of such a claim; however, ***the burden of protection of fundamental rights is primarily the duty of the State. Consequently, unless constitutional grounds exist, the State may not act in a manner that hinders this Court from rendering complete justice in such proceedings****. Withholding of information from the petitioners, or seeking to cast the relevant events and facts in a light favourable to the State in the context of the proceedings, even though ultimately detrimental to the essential task of protecting fundamental rights, would be destructive to the guarantee in clause (1) of Article 32...*

NOTARY
M. M. PISALE
Mumbai
Maharashtra
Reg. No. 15220
Expiry Dt.

☞

*78. **In the task of upholding of fundamental rights, the State cannot be an adversary. The State has the duty, generally, to reveal all the facts and information in its possession to the Court, and also provide the same to the petitioners**. This is so, because the petitioners would also then be enabled to bring to light facts and the law that may be relevant for the Court in rendering its decision. In proceedings such as those under Article 32, both the petitioner and the State, have to necessarily be the eyes and ears of the Court. Blinding the petitioner would substantially detract from the integrity of the process of judicial decision-making in Article 32 proceedings, especially where the issue is of upholding of fundamental rights."*

46. That said, after we indicated our reservations to the Petitioners regarding the lack of material, various other petitions have been filed in Court, including by individuals who were purportedly victims of the alleged Pegasus spyware attack. These subsequently filed petitions, as well as additional documents filed by others, have brought on record certain materials that cannot be brushed aside, such as the reports of reputed organizations like Citizen Lab and affidavits of experts. Additionally, the sheer volume of cross-referenced and cross-verified reports from various reputable news organizations across the world along

NOTARY
M. M. PADALE
Mumbai
Maharashtra
Reg. No. 15220
Expiry Dt.
30-10-2024
GOVT. OF INDIA

with the reactions of foreign governments and legal institutions also moved us to consider that this is a case where the jurisdiction of the Court may be exercised. Of course, the learned Solicitor General suggested that many of these reports are motivated and self-serving. However, such an omnibus oral allegation is not sufficient to desist from interference.

47. It is for this reason that this Court issued notice to the Respondent-Union of India and sought information from them. We would like to re-emphasize what is already apparent from the record of proceedings. This Court gave ample opportunity to the Respondent-Union of India to clarify its stand regarding the allegations raised, and to provide information to assist the Court regarding the various actions taken by it over the past two years, since the first disclosed alleged Pegasus spyware attack. We had made it clear to the learned Solicitor General on many occasions that we would not push the Respondent-Union of India to provide any information that may affect the national security concerns of the country. However, despite the repeated assurances and opportunities given, ultimately the Respondent-Union of India has placed on record what they call a "limited affidavit", which does not shed any light on their stand or provide any clarity as to the facts of the matter at hand. If the Respondent-Union of India had made their stand clear it would have been a different

M. M. PABALE
Mumbai
Maharashtra
Reg. No. 15220
Expiry Dt.
30-10-2024
GOVT. OF INDIA

situation, and the burden on us would have been different."

6.4. Needless to mention that in a similar case, the Union of India in **Writ Petition 607 of 2021** have filed a **447 pages** detailed reply with all the available data which can be produced.

7. Detail of facts suppressed, not disputed and conveniently ignored by the Respondent No.1. State, in their reply affidavit.

7.1. That, the petitioner in his petition and also in the Additional Affidavit dated **20.11.2021** have pointed out various studies, evidences and suggestions given by renowned experts including Dr. Sanjay Rai, AIIMS, New Delhi proving that the natural immunity developed due to Covid-19 infection is 13 times better, more robust and long lasting than the vaccine immunity. Recent studies shows it is 27 times better than the vaccines.

7.2. The World Health Organization in its directives also clarified that the herd immunity can be achieved either by the vaccination or **through previous infection.**

(A copy of study published by World Health Organization titled as **"Coronavirus disease (COVID-19): Herd immunity, lockdowns and COVID-19"** dated 31 December, 2020 is marked and annexed herewith **Exhibit "RA-1") (Page No. 261)**

7.3. As per Sero Survey conducted by the ICMR, MCGM and other Government bodies, it is clear that, more than two third of the country's population is having developed antibodies due to their contact with SARS-CoV-2 virus.

NOTARY M. M. PARALE Mumbai Maharashtra Reg. No. 15220 Expiry Dt. 30-10-2024 GOVT. OF INDIA

1164

(A copy of article published in **The Indian Express** titled as **"Over 85% Mumbai population has Covid-19 antibodies: Latest BMC Sero survey"** dated 18th September, 2021 is marked and annexed herewith **Exhibit "RA-2") (Page No. 266)**

7.4. Hence, the majority of the population having developed antibodies need not be given vaccines as it is not only harmful for their body but also it causes loss of thousands of Crores of public money.
Link: https://www.mdpi.com/2075-1729/11/3/249/html

7.5. The summary of the all-research papers and opinion of domain experts as mentioned in additional affidavit filed by the petitioner and in annexed documents, regarding the comparison between natural immunity and vaccine immunity is as under;

Natural Immunity Vs. Vaccine Immunity Table

Sr. No.	Points of concern and comparison	Vaccine Generated Immunity	Immunity developed due to Covid-19 infection i.e. Natural Immunity
1	Protection from infection	Double Dose of vaccine having no guarantee of person not getting infected or spreading the infection. Vaccinated person is 13-27 times more likely to get infected than a naturally	Person is fully protected and safest. He is 13-27 times less likely to get infected than a vaccinated person. He is highly unlikely to spread the infection as he is highly unlikely to get infected in

GOVT. OF INDIA Mumbai Maharashtra Regd. No. 15220 Expiry Dt. 30-10-2024

		immune person. (Pg No 960 Pt 23 of reply affidavit by State)	the first place. (See Exhibit on Page 147, Point no 15)
2	Longevity of immunity developed	As per reply affidavit filed by the State at Pg. No. 960 Point No. 24, there is no study of longevity of such immunity in vaccinated people. (But dishonest officers try to give the credit of natural immunity to vaccines)	Immunity development due to infection lasts for decades (as witnessed from other viral respiratory illnesses of the past like Sars and spanish influenza). (See Exhibit on Page 149, Point no 28)
3	A] Expense of public money required B] Who will be benefited more if given the preference.	A] Thousand of crores B] Only vaccine companies and corrupt officials will be benefited	A] Free of cost. As it is already developed in the body. Already two third of Indias population is having antibodies. (See Exhibit on Page 146, Point no 1) B] Country's money will be saved and economy will grow up as such persons are treated as protected, which they actually are.
4	Side effects	Serious death causing side effects. Person may	No question of any side effects, because the

GOVT. OF INDIA
Mumbai
Maharashtra
Reg. No. 15220
Expiry Dt.
30-10-2024

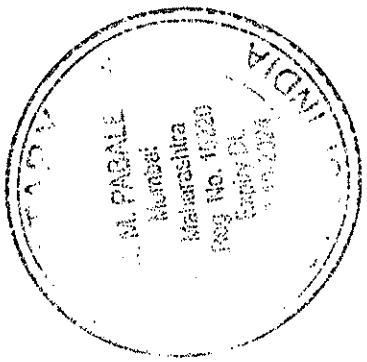
		die due to side effects of vaccines or there is possibility of serious side effects such as G.B.S. causing paralysis, deafness, blood clotting, blindness loss of voice, Ect.	person is having antibodies. But if naturally immune person is vaccinated he faces worse side effects compared to someone who is not naturally immune (See Exhibit on Page 147, Point no 11)
5	Public benefits or reasons for recommending.	**A]** No guaranteed public benefit of protection from infection or death or saving the public money is found. Cannot be recommended over natural immunity or for persons having risks. B] Giving vaccines to the person with natural immunity is causing much harm and with no additional benefits. Therefore not recommended for more than two third population	A] Since already more than 2/3rd of the population have developed antibodies therefore herd immunity is developed. Scientists recommends that the persons with natural immunity are the safest and recognizing them will be helpful for everyone and also for the economy of our country. (See Exhibit on Page 146, Point no 1, 2 & 3)
6	Variants	Very less efficacy against variants, as immunity is developed only against	Offers protection against almost all variants, as immunity is developed

GOVT. OF INDIA
Mumbai Maharashtra Reg. No. 15249 Expiry Dt. 31-10-2024

		the spike protein.	against all parts of the virus.(See Exhibit on Page 149, Point no 26 & 27)
7	Immunity Location	Generates antibodies in the blood, whereas sars-cov-2 infection takes place via the mouth and respiratory tract.	Generates immune cells at the point of entry of the virus, to preemptively stop an infection before it happens.

7.6. That, in **Para 15** of the Additional Affidavit by the Petitioner it is specifically mentioned as under;

> ***"15. The decision taken by the authority apart from its legality also amounts to an offence of misappropriation of thousands of crores of public money for giving vaccine to the persons with natural immunity when from the suggestions given by the domain experts and research proved that the natural immunity is 13 times more robust and long lasting than the vaccine immunity and giving vaccine to such people will cause harm to the person and also causes a loss of thousands of crores to the public money.***
>
> *15.1 The research data shows that the persons with natural immunity are* ***13 times*** *more robust and protected than the fully vaccinated person because*



they cannot get re-infection and they cannot spread infection.

Dr. Sanjay K. Rai, President of Indian Public Health Association (IPHA) and Proessor at Department of Community Medicine at AIIMS , Delhi in his interview at

Link: https://www.youtube.com/watch?v=-btDk0eSi5U&feature=youtu.be

He made it clear that;

"the best protection and possibly life time immunity only comes from Natural immunity/natural infection i.e. those who have recovered from COVID-19. He further stated that death due to Covid-19, among those who acquired Natural Immunity is nearly zero and possibility of re-infection is rare. Further those vaccines could cause harm or result in adverse effects if administered to those who have already acquired natural immunity and are also non-susceptible.
(A copy of excerpt of comments of Dr. Sanjay K Rai, Proffessor at Department of community Medicine at AIIMS, Delhi in conversation with Girijesh Vashistha of Knocking News is annexed as Annexure AA")

7.7. However, in the reply affidavit **dated 15.12.2021,** filed by the Dr. Sadhana Tayade, and also subsequent Affidavit dated **21.12.2021** by Shri. Debashish Chakrabarty, Chief Secretary, there is having no mention about the abovesaid serious issues.

7.8. Hence, the only responsible conclusion that can be drawn is that the submissions of petitioner are correct and Respondent No.1 is having no reply for the same.

8. As per law laid down by the Full Bench of Hon'ble Supreme Court, Vague and omnibus denial in reply affidavit is not sufficient. Failure of the Respondent No.1 state in not disputing the serious allegations in the petition with specific answer, proves the malafides of the state authority. In such cases Court can pass order in favor of the Petitioner on this ground.

8.1. That when petitioner in **Para 15** of the Additional Affidavit and also in various paras has made the allegations of malafides by the State Authorities and accused them of having been committed an offence of misappropriation of public money then it was bounded duty of the State Authority to come forward with an explanation rebutting the same. Failure to reply will lead to only one conclusion that the allegations are correct and admitted by the State. Full Bench of Hon'ble Supreme Court in the case of **Express Newspaper Pvt. Ltd. Vs. Union of India (1986) 1 SCC 133,** had rued as under;

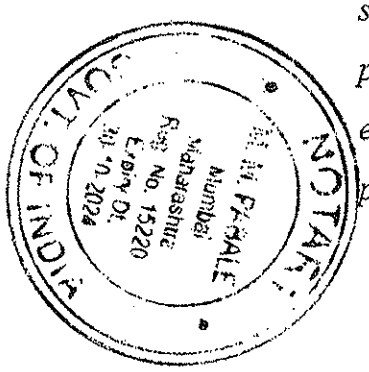
> *"(A) Constitution of India, Art.226- Petition alleging mala fides - Pleadings of parties - Where mala fides are alleged against public servant, it is necessary that the person against whom such allegations are made should come forward with an answer refuting or denying such allegations. For otherwise such allegations remain unrebutted and the Court would in such a case be constrained to accept the allegations so remaining unrebutted and unanswered on the test of probability. It is not for the*

parties to say what is relevant or not. The matter is one for the Court to decide. (Para 116)

116. It is somewhat strange that although definite allegations of mala fides on the part of the respondents particularly the Government for the day at the Centre were made with sufficient particulars and though the respondents had ample time to file their affidavits in reply, none of the respondents except Respondent 2, the Lt. Governor of Delhi and Respondent 5, Land & Development Officer has chosen to deny the allegations. The counter-affidavit of Respondent 2 purporting to be on behalf of all the respondents is that the allegations made by the petitioners in paras 11, 12 and 13 are not "relevant" to the matter in issue. In C.S. Rowjee v. A.P. State Road Transport Corporation [AIR 1964 SC 962 : (1964) 6 SCR 330] the Court in a matter arising out of the Motor Vehicles Act, 1939 where certain allegations against the Minister went uncontroverted, had occasion to administer a word of caution. Where mala fides are alleged, it is necessary that the person against whom such allegations are made should come forward with an answer refuting or denying such allegations. For otherwise such allegations remain unrebutted and the Court would in such a case be constrained to accept the allegations so remaining unrebutted and unanswered on the test of probability. That precisely



is the position in the present case, in the absence of any counter-affidavit by any of the respondents. *One should have thought that the Minister for Works & Housing should have sworn an affidavit accepting or denying the allegations made by the petitioners. At our instance, M.M. Mukherjee, Secretary, Ministry of Works & Housing has filed a supplementary affidavit. He avers that the impugned notice dated March 10, 1980 of re-entry upon forfeiture of lease issued by the Engineer Officer, Land & Development Office was on the basis of press reports i.e. reports of the press conference held by the Lt. Governor. Again, there is no attempt on the part of the Union of India, Ministry of Works & Housing to deny the allegations of mala fides on the part of the Government and its functionaries in issuing the impugned orders. On the contrary, he avers that Respondent 1 "adopts the counter-affidavit filed by Respondent 2". It is not for the parties to say what is relevant or not. The matter is one for the Court to decide. There is nothing before us from which we can say that the allegations in paras 11, 12 and 13 of the petition made by the petitioners are not well-founded. Mala Fides on the part of the Government in power or its functionaries would be sufficient to invalidate the impugned notices. Fraud on power vitiates the impugned orders if they were not exercised bona fide for the purpose for which the power was conferred."*



8.2. In fact, it was expected from the State Authorities that they should have proactively come forward with the recommendation regarding Natural Immunity. And since it has developed in majority of the people, they should have taken steps to stop the misappropriation of thousands of crores of public money and to prosecute the corrupt officials involved in such unethical practices. But Respondent No.1 and Respondent No.10 Chief Minister of Maharashtra failed to perform their duty in a judicious manner.

8.3. That, Hon'ble Supreme Court in the case of **State of Odisha Vs. Pratima Mohanty 2021 SCC OnLine SC 1222,** has ruled about the act of omission of the public servant makes them liable for prosecution. it is as under;

> "***20.*** *It is further observed after referring to the decision of this Court in the case of Common Cause, A Registered Society (supra) that if a public servant abuses his office whether by his act of omission or commission, and the consequence of that is injury to an individual or loss of public property, an action may be maintained against such public servant. It is further observed that no public servant can arrogate to himself powers in a manner which is arbitrary. In this regard we wish to recall the observations of this Court as under:*
>
> > *"The concept of public accountability and performance of functions takes in its ambit, proper and timely action in accordance with law. Public duty and public obligation both are essentials of good administration whether by the State or its*

NOTARY M.M. PABALE Mumbai Maharashtra Regd. No. 15220 Expiry Dt. 30-10-2024 GOVT. OF INDIA

instrumentalities." [See Delhi Airtech Services (P) Ltd. v. State of U.P., (2011) 9 SCC 354]

"The higher the public office held by a person the greater is the demand for rectitude on his part." [See Charanjit Lamba v. Army Southern Command, (2010) 11 SCC 314]

"The holder of every public office holds a trust for public good and therefore his actions should all be above board." [See Padma v. Hiralal Motilal Desarda, (2002) 7 SCC 564]

"Every holder of a public office by virtue of which he acts on behalf of the State or public body is ultimately accountable to the people in whom the sovereignty vests. As such, all powers so vested in him are meant to be exercised for public good and promoting the public interest. This is equally true of all actions even in the field of contract. Thus, every holder of a public office is a trustee whose highest duty is to the people of the country and, therefore, every act of the holder of a public office, irrespective of the label classifying that act, is in discharge of public duty meant ultimately for public good." [See Shrilekha Vidyarthi (Kumari) v. State of U.P., (1991) 1 SCC 212]

"Public authorities should realise that in an era of transparency, previous practices of unwarranted secrecy have no longer a place. Accountability and prevention of corruption is possible only through

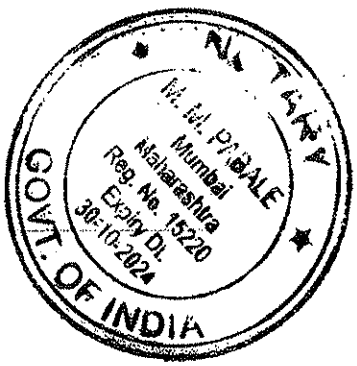


transparency." [See ICAI v. Shaunak H. Satya, (2011) 8 SCC 781]"

9. Reasons given by Respondent No.1 to defend their act of discrimination between vaccinated &unvaccinated in the affidavit dated 15.12.2021 and 21.12.2021 are incorrect, wrong, irrational, illogical and improper. The falsity of reply is proved from their own documents. Such decisions are called as 'Fraud on Power' and are vitiated as per law laid down by the Full Bench of Hon'ble Supreme Court

9.1. That the Respondent No. 1 in his affidavit dated **21.12.2021** has summarized and supported their reasoning in para 4 at Page No. 67, 68 and Para 16 as under;

> *"4... I say that allowing unvaccinated persons to mix with the people, by using the Public Transport will only endanger and will invite the explosive transmission of the corona virus, and its subsequent variants and the Government of Maharashtra, as parens patriae cannot afford to take that risk.*
>
> *I further say that a non-vaccinated person is more at risk than a vaccinated person and therefore it would not be permissible for the non-vaccinated person to endanger others lives.*
>
> *16. I say since if a person has two vaccination doses then the immunity level of the person is protected, so as to protect that person and in fact protect others also from that person, so far as the danger of the corona infection is concerned.*



It is principally, for this reason that the State, has taken the decision not to allow, the persons who have not taken the both doses to travel, by the Public Transport."

9.2. The said submission of Respondent No.1 are falsified from their own documents more particularly from another affidavit dated **15.12.2021** Respondent No. 1 has annexed and relied upon the FAQ's prepared by the State Government of Uttar Pradesh in collaboration with WHO, UNICEF, UNDP, National Health Mission. **[Page No. 954 of the reply affidavit dated 15.12.2021].**

The question and Answers at Point No. 23 & 24 at Page No. 960 reads thus;

"23. Do I need to use the mask/ other COVID-19 appropriate precautions after receiving the vaccine?

*Yes, **it is absolutely necessary that everyone who has received the COVID-19 vaccine should continue to follow the COVID-19 appropriate behaviour** i.e., mask, do gaj ki doori and hand sanitization **to protect** themselves and **those around from spreading the infection.***

24. How long will I remain protected after vaccination?

Longevity of the immune response in vaccinated individuals is yet to be determined. Hence, continuing the use of masks, handwashing, physical distancing,

and other COVID-19 appropriate behaviours is strongly recommended"

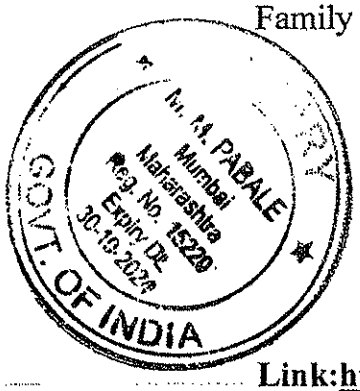
[emphasis supplied]

21. Is it mandatory to take the vaccine?

Vaccination for COVID-19 is voluntary. However, it is advisable to receive the complete schedule of COVID-19 vaccine for protecting oneself against this disease and to limit the spread of this disease to the close contacts including family members, friends, relatives, and co-workers.

9.3. This shows that the vaccinated persons also have to take precautions to protect others from spreading infection. It proves that taking vaccine is completely voluntary and no authority can force anyone to take vaccine. This falsifies the stand taken in affidavit dated **21.12.2021** more particularly in **Para 16** of the Affidavit. Furthermore, if the stand of state as stated in para 16 is correct and if vaccinated people are protected then why they are asking the vaccinated people to wear masks and to follow the covid appropriate behavior.

9.4. That, the recent precaution issued by The Department of Health And Family Welfare Services Govt Of Karnataka Which clearly reads thus;



"Even fully vaccinated persons can be infected and transmit the virus to others

Keep yourself and other safe from COVID-19 follow COVID Appropriate Behaviour at all times."

Link:https://www.facebook.com/185880198557402/posts/1259025457909532/?sfnsn=wiwspwa

(A copy precaution issued by The Department of Health And Family Welfare Services Govt of Karnataka is marked and annexed herewith **Exhibit "RA-3") (Page No. 269)**

9.5. In a recent statement on 30th December 2021 the ICMR Chief made a statement which falsify the stand taken by the Respondent No.1

Briefing media persons, DG, ICMR said, "All COVID vaccines, whether they are from India, Israel, US, Europe, UK or China, are primarily disease-modifying. They do not prevent infection. "Use of masks before and after vaccination is a must and mass gatherings should be avoided.

Link: https://www.aninews.in/news/national/general-news/covid-vaccines-are-disease-modifying-dont-prevent-infection-icmr20211230172454/

9.6. That, from the research data published by the State Government of Kerala it is clear that, the vaccinated people are also super spreader of the infection.

That, the '**Technical Paper**' of the Department of Health and Family Welfare, Government of Kerala titled '**VACCINE BREAKTHROUGH SARS-CoV-2 INFECTIONS** reads thus;

In the said paper at **Page No. 12** the Chapter reads thus;

> ***"Network analysis of a vaccine breakthrough infection cluster to understand transmission dynamics.***
>
> *This network analysis clearly shows that persons with vaccine breakthrough infections can spread infection to others thereby highlighting the importance of masking, physical distancing and hand hygiene even for fully vaccinated persons."*



9.7. Even otherwise as per Respondent No. 1 own submission the longevity of vaccine is not known till date. The recent data shows that the AstraZenca (Covishield) vaccine protection (if any) wane after three months. The news about Lancet study is at following link

https://www.businesstoday.in/coronavirus/story/astrazeneca-covid-vaccine-protection-wanes-after-three-months-lancet-study-316348-2021-12-21

Hence, this is also a ground to prove that, the person who have been vaccinated up to October 2021 have no protection at all and he is also in the category of unvaccinated.

Hence, there is no sense and logic in giving permission to vaccinated and putting restrictions on unvaccinated only.

9.8. Needless to mention here that, the bare words in reply affidavit without being supported by the substantial data and by ignoring their own data without any reasoning is a sufficient ground to infer malafides on the part of Respondent No.1 Sh. Debashish Chakraborty.

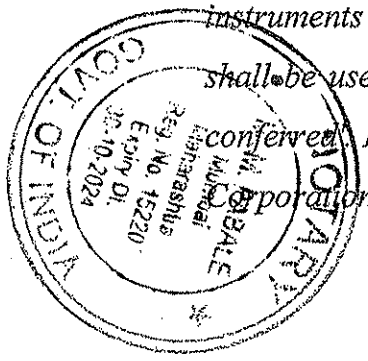
9.9. Full Bench of Hon'ble Supreme Court in the case of **Vijay Shekhar Vs. Union of India (2004) 4 SCC 666,** has ruled that, if the public authority passes any orders by ignoring material on record and considering extraneous materials then it is a case of **'Fraud on Power'.** Such order is vitiated and liable to be quashed.

It is ruled as under;

> *"9. This Court in Express Newspapers Pvt. Ltd. & Ors. v. Union of India & Ors. (AIR 1986 SC 872) at para 118 has held thus :*



*"**Fraud on power voids the order if it is not exercised bona fide for the end design.** There is a distinction between exercise of power in good faith and misuse in bad faith. The former arises **when an authority misuses its power in breach of law, say, by taking into account bona fide, and with best of intentions, some extraneous matters or by ignoring relevant matters. That would render the impugned act or order ultra vires. It would be a case of fraud on powers.** The misuse in bad faith arises when the power is exercised for an improper motive, say, to satisfy a private or personal grudge or for wreaking vengeance of a Minister as in S. Pratap Singh v. State of Punjab, (1964) 4 SCR 733 : (AIR 1964 SC 733). A power is exercised maliciously if its repository is motivated by personal animosity towards those who are directly affected by its exercise. Use of a power for an 'alien' purpose other than the one for which the power is conferred is mala fide use of that power. Same is the position when an order is made for a purpose other than that which finds place in the order.The ulterior or alien purpose clearly speaks of the misuse of the power and it was observed as early as in 1904 by Lord Lindley in General Assembly of Free Church of Scotland v. Overtown, 1904 AC 515, 'that there is a condition implied in this as well as in other instruments which create powers, namely, that the power shall be used bona fide for the purpose for which they are conferred.' It was said by Warrington, C.J. in Short v. Poole Corporation, (1926) 1 Ch 66 that :*



"No public body can be regarded as having statutory authority to act in bad faith or from corrupt motives, and any action purporting to be of that body, but proved to be committed in bad faith or from corrupt motives, would certainly be held to be inoperative."

In Lazarus Estates Ltd. V. Beasley, (1956) 2 QB 702 at Pp. 712-13 Lord Denning, LJ. said :

"No judgment of a Court, no order of Minister, can be allowed to stand if it has been obtained by fraud. Fraud unravels everything."

(emphasis supplied)

See also, in Lazarus case at p.722 per Lord Parker, C.J. :

"'Fraud' vitiates all transactions known to the law of however high a degree of solemnity."

All these three English decisions have been cited with approval by this Court in Pratap Singh's case."

10. *Similar is the view taken by this Court in the case of* ***Ram Chandra Singh v. Savitri Devi and Ors. (2003) 8 SCC 319*** *wherein this Court speaking through one of us (Sinha, J.) held thus :*

"Fraud as is well known vitiates every solemn act. Fraud and justice never dwell together. Fraud is a conduct either by letter or words, which induces the other person or authority to take a definite determinative stand as a response to the conduct of the former either by word or letter. ***It is***

M. M. PABALE
Mumbai
Maharashtra
Reg. No. 15220
Expiry Dt.
30-10-2024
GOVT. OF INDIA

also well settled that misrepresentation itself amounts to fraud. Indeed, innocent misrepresentation may also give reason to claim relief against fraud. *A fraudulent misrepresentation is called deceit and consists in leading a man into damage by willfully or recklessly causing him to believe and act on falsehood. It is a fraud in law if a party makes representations which he knows to be false, and injury ensues therefrom although the motive from which the representations proceeded may not have been bad. An act of fraud on court is always viewed seriously. A collusion or conspiracy with a view to deprive the rights of others in relation to a property would render the transaction void ab initio. Fraud and deception are synonymous. Although in a given case a deception may not amount to fraud, fraud is anathema to all equitable principles and any affair tainted with fraud cannot be perpetuated or saved by the application of any equitable doctrine including res judicata."*

11. Thus, it is clear a fraudulent act even in judicial proceedings cannot be allowed to stand."

9.10. Recently, in the case of **Harshit Agarwal v. Union of India, (2021) 2 SCC 710,** It is ruled as under;



*"10. **Judicial review of administrative action is permissible on grounds of illegality, irrationality and procedural impropriety**. An administrative decision is flawed if it is illegal. A decision is illegal if it pursues an objective other than that for which the power to make the decision was conferred [De Smith's Judicial Review, (6th Edn., p. 225)]. **There is no unfettered discretion in public law** [Food*

Corpn. of India v. Kamdhenu Cattle Feed Industries, (1993) 1 SCC 71] . Discretion conferred on an authority has to be necessarily exercised only for the purpose provided in a statute. The discretion exercised by the decision maker is subject to judicial scrutiny if a purpose other than a specified purpose is pursued. ***If the authority pursues unauthorised purposes, its decision is rendered illegal. If irrelevant considerations are taken into account for reaching the decision or relevant considerations have been ignored, the decision stands vitiated as the decision maker has misdirected himself in law.*** *It is useful to refer to R. v. Vestry of St. Pancras [R. v. Vestry of St. Pancras, (1890) LR 24 QBD 371 (CA)] in which it was held: (QBD pp. 375-76)*

"... If people who have to exercise a public duty by exercising their discretion take into account matters which the courts consider not to be proper for the guidance of their discretion, then in the eye of the law they have not exercised their discretion."

10. Other false and misleading submissions on the part of Respondent No.1:-

10.1. That, the another rationale put forth by the Respondent No. 1 in para 6 of Affidavit dated **21.12.2021** is that the number of hospitalization is more amongst unvaccinated.

10.2. From the reply affidavit dated **15.12.2021** the main arguments of the Respondent No.1 can be summarized are as follows:

a) Vaccination reduced rates of hospitalization of Covid-19 patients

ADVT. M. M. PASALE Mumbai Maharashtra Reg. No. 15220 Expiry Dt. 28-10-2024 GOVT. OF INDIA

b) Suggests that there is some evidence that vaccination will make it less likely that we will pass the virus on to others

10.3. The abovesaid submission is not only false and misleading but also illogical & irrelevant for the purpose of discrimination.

10.4. That, except the bare words no evidence is given by the Respondent No.1 to support their stand.

10.5 Furthermore, the falsity of this narrative is ex-facie proved from the data already given in the Addl. Affidavit. Said data makes it clear that, the hospitalization and deaths are higher amongst vaccinated.

(i) **On 18th December, 2021 the infection and hospitalization of Covid-19 patient in Maharashtra specifically for Omicron was 100% from vaccinated people. But this fact was deliberately and conveniently suppressed by the Respondent No. 1 in his affidavit dated 21.12.2021**

Link :-.

https://timesofindia.indiatimes.com/city/mumbai/mumbai-8-more-omicron-cases-found-in-state-6-in-rural-pune-2-in-mmr/articleshow/88348393.cms

(A copy of article published in Times of India titled as "8 more Omicron cases found in Maharashtra: 6 in rural Pune, 2 in MMR" dated 18th December, 2021 is marked and annexed herewith **Exhibit "RA-4")** **(Page No. 270)**

(ii) That, the news dated 21st December,2021 published in Times of India also falsifies the narratives of the State. The news expose that

ADVT. OF INDIA
S. M. PAGALE
Mumbai
Maharashtra
Reg. No. 15220
Expiry Dt.
30-10-2024

the 81% of Omicron patients in Maharashtra are from fully vaccinated category.

https://timesofindia.indiatimes.com/city/mumbai/mumbai-8-more-omicron-cases-found-in-state-6-in-rural-pune-2-in-mmr/articleshow/88348393.cms

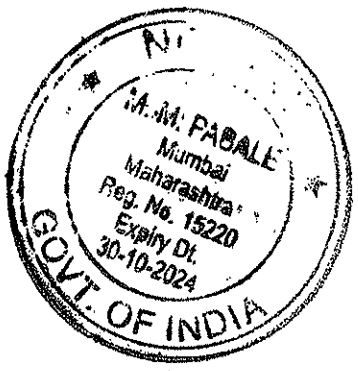
(iv) More than half of hospitalised Covid-19 cases among vaccinated in Bengaluru
https://www.deccanherald.com/state/top-karnataka-stories/more-than-half-of-hospitalised-covid-19-cases-among-vaccinated-in-bengaluru-1015918.html

(v) Over 50% new COVID-19 cases and deaths in Kerala from vaccinated section.

https://www.onmanorama.com/news/kerala/2021/10/12/kerala-covid-cases-deaths-among-vaccinated.html

(vi) Out of 34 Omicron cases treated at Delhi hospital, 33 were fully vaccinated.

Link : https://indianexpress.com/article/cities/delhi/out-of-34-omicron-cases-at-delhi-hospital-33-are-fully-vaccinated-7686188/



(vii) Assam: 80% Covid-19 infections among vaccinated in Guwahati

https://timesofindia.indiatimes.com/city/guwahati/assam-80-covid-19-infections-among-vaccinated-in-guwahati/articleshow/86791235.cms

(viii) Nearly 80% (91 out of 114) Covid-19 cases reported from Sept 1 till Oct 23 in Lucknow were of breakthrough infections,

according to data accessed by TOI from the office of Chief Medical Officers.

http://timesofindia.indiatimes.com/articleshow/87277252.cms?utm_source=contentofinterest&utm_medium=text&utm_campaign=cppst

(ix) Gurgaon : Over half of Covid Cases in October were breakthrough infections

https://timesofindia.indiatimes.com/city/gurgaon/over-half-of-covid-cases-in-oct-were-breakthrough-infections/articleshow/87746000.cms

(x) "A majority of gravely ill patients in Israel are double vaccinated. A majority of deaths over 50 in England are also double vaccinated.

Link: https://www.science.org/content/article/grim-warning-israel-vaccination-blunts-does-not-defeat-delta

https://cdn.nexusnewsfeed.com/images/2021/8/new-severe-covid-19-patients-thumb-1631973102161.png

https://cdn.nexusnewsfeed.com/images/2021/8/covid-19-delta-variant-hospital-admission-and-death-in-england-1631973123881.png

https://cdn.nexusnewsfeed.com/images/2021/8/covid-19-delta-variant-hospital-admission-and-death-in-england-1631973123881.png

(xi) Whistleblower: FDA and CDC Ignore Damning Report that **over 90% of a Hospital's Admissions were Vaccinated for Covid-19** and No One Was Reporting This to VAERS.

A concerned Physician Assistant from America, Deborah Conrad, convinced her hospital to carefully track the Covid-19 vaccination status of every patient admitted to her hospital. The result is shocking.

As Ms. Conrad has detailed, her hospital serves a community in which less than 50% of the individuals were vaccinated for Covid-19 but yet, during the same time period, **approximately 90% of the individuals admitted to her hospital were documented to have received this vaccine.**

One would think that after an association was identified by a healthcare professional, our health authorities would at least review this finding, right? Sadly, when Ms. Conrad reached out to health authorities herself, she was ignored. My firm then sent a letter to the CDC and FDA on July 19, 2021 on Ms. Conrad's behalf (see letter below), yet neither agency has responded. Even worse, when doctors came to Ms. Conrad for assistance with filing VAERS report for their patients, the hospital prohibited her from filing these reports.

https://aaronsiri.substack.com/p/whistleblower-fda-and-cdc-ignore-3e2

NOTARY M. M. PABALE Mumbai Maharashtra Reg. No. 15220 Expiry DL 30-10-2024 GOVT. OF INDIA

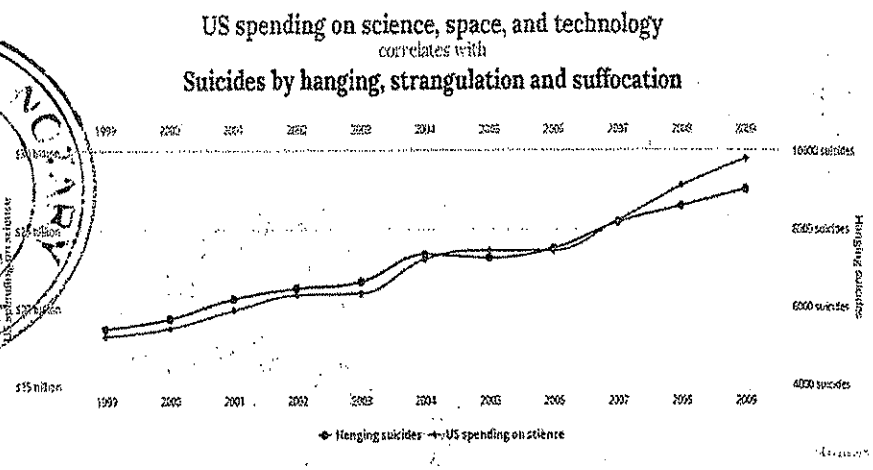
10.6. Furthermore, the dishonesty of Respondent No.1 can also be seen from the very fact that, to support his first point, the Respondent No.1 has attached a graph on page 953 where the numbers show that the rates of

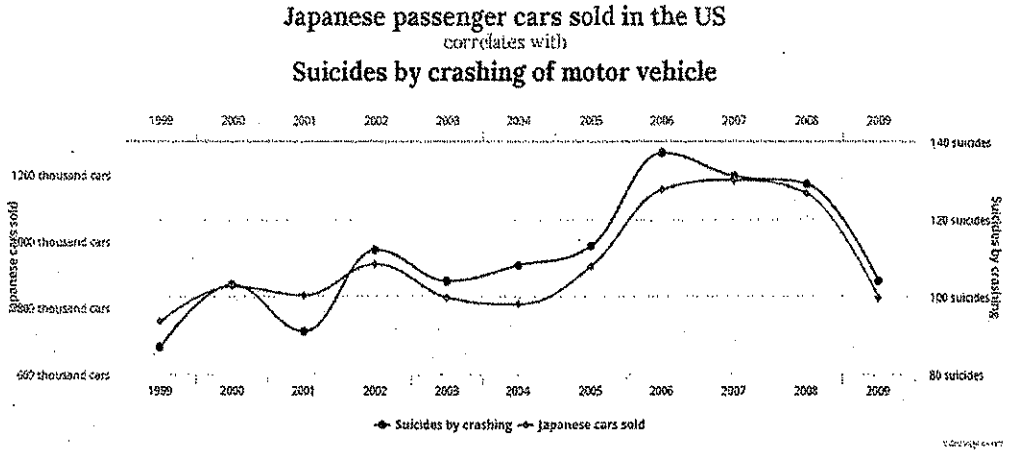
hospitalization have come down as the vaccination rate has increased. This does not prove that the vaccination has reduced the hospitalizations as the hospitalization rate typically peaks at a certain time during the year according to the season, and then declines on its own. This phenomenon could be observed **in the year 2020** as well, **where after the first wave, infections, Covid hospitalizations and deaths declined on their own without any vaccine being developed.**

10.7. In the year 2020 after first wave when hospitalization & death declined, many Indian experts gave statements trying to hypothesize why these phenomena took place, and mentioned many factors like herd immunity, Indians having better immunity, seasonality effect, etc. But now the Respondent No. 1 dishonestly wants to give the said credit to vaccines.

In order to make their case that it is vaccines which reduced the hospitalization, the respondent should have attached segregated data pointing out how many vaccinated, unvaccinated and with natural immunity patients are admitted in the hospitals. What is the percentage of persons with natural immunity Etc. But Respondent No.1 in order to misled the court made such baseless and false submissions wants to give credit to vaccines.

10.8. In fact, **such correlations are known as spurious correlation**. For example:





10.9. Hence, no reliance can be placed on such submissions. In fact such submissions are contempt of Court.

10.10 That, the Petitioner have attached counter data in the petition and in Additional Affidavit which shows that in Bangalore and Kerala, it is the vaccinated who are taking up more than 50% of the hospital beds. The same phenomena can also be observed in UK , USA & Israel, which is also referenced in our petition.

10.11. Petitioner have also attached peer reviewed scientific studies, which show that Ivermectin, Omega3 fatty acids, Vitamin D, Black seeds, Nutritional and oxidative therapies, & Arginine have also been proven to reduce covid-19 infections, hospitalizations and deaths. So even for the sake of arguments it is considered that the vaccines are effective in reducing hospitalizations, they are by no means the only tool. And that cannot be a ground to discriminate between vaccinated and unvaccinated.

10.12. In the reply dated 15.12.2021 the respondent mentions on page 951 that there is some evidence that the vaccines would reduce the chance of the virus spreading, but have not attached any evidence of the same. In contrast to that, Petitioner have attached plenty of documented evidence to show that the vaccines do not reduce the chance of infection/ transmission.

NOTARY
M. M. PARALE
Mumbai
Maharashtra
Reg. No. 15220
Expiry Dt.
30-10-2024
GOVT. OF INDIA

A1

10.13. Petitioner have attached 8 scientific studies which shows that the viral load of a vaccinated person is same or more than the viral load of an unvaccinated person.

10.14. Petitioner have also attached studies which show that vaccinated people are 13 times more likely to spread the virus compared to those naturally immune according to one study, and 27 times more likely in another study.

10.15. Petitioner have also attached data from Assam, India, which shows that 80% of their total Covid cases have occurred in the vaccinated, and a **global study done on 67 countries which shows that the countries with the most number of vaccines administered also had the highest cases**.

10.16. The reply given by the respondent No.1 is silent about the actual percentage of hospitalization amongst vaccinated and non vaccinated. Such a casual approach is time and again criticized by Hon'ble Supreme Court and in many cases such officers and persons are prosecuted and punished by the Hon'ble Supreme Court & this Hon'ble Court in following Cases:

i) Afzal Vs. State of Haryana **AIR 1996 SC 2326,**

ii) Kapol Co.op Bank Ltd. Vs. State of Maharashtra **2004 SCC OnLine 695,**

iii) Murad abdul Mulani Vs. Salma Babu Shaikh **2015 ALL SCR 2874**

iv) Mohd. Zahid Vs. GOVT. Of NCT of Delhi **1998 CRI.L.J 2908**

v) The Secretary, Hailkandi Bar Association Vs. State of Assam **AIR 1996 SC 1925**

vi) State Vs. Mangesh Chavan **2020 SCC Online Bom 67**

11. Health Ministry of Central Government said, the longevity of the immune response in vaccinated individuals is yet to be determined.

Therefore, any contrary claim by the State Government is fallacious.

11.1. That in a reply dated **20.09.2021** the Ministry of Health & Family Welfare have answered the query as under;

> *"**Question-1** Detailed information on approved vaccines to prevent corona outbreaks. As well as detailed information about their time period.*
>
> ***Answer:-** 1. Longevity of the immune response in vaccinated individuals is yet to be determined. Hence, continuing the use of masks, hand washing, physical distancing and other COVID-19 appropriate behaviours is strongly recommended"*

(A copy of **RTI** reply dated **20.09.2021** given by the Ministry of Health & Family Welfare is marked and annexed herewith **Exhibit "RA- 5") (Page No. 272)**

11.2. Hence, the paper claim by Respondent No.1 which is unsubstantiated and is of no use.

12. Subsequent order dated 27.12.2021 is so impractical that the Respondent No.1 Chief Secretary himself is not following it.

12.1. That, the Respondent No.1 Chief Secretary in his affidavit dated 21.12.2021 has relied upon the new order/SOP dated 27.11.2021. As per the said order only the person having taken the two doses of vaccine are allowed to enter and work the public office.

Mr. Vn. FABALE
Mumbai
Maharashtra
Reg. No. 15228
Expiry Dt.
30-10-2024
GOVT. OF INDIA

12.2. But as per the news published in Times of India on 4th December, 2021 it is clear that the Respondent No.1 i.e. Chief Secretary Shri. Debashish Chakrabarty himself took his first vaccine dose on 2rd December, 2021.

Link: https://timesofindia.indiatimes.com/city/mumbai/10-months-on-chief-secretary-of-maharashtra-takes-his-first-shot/articleshow/88080789.cms

(A copy of the news published in Times of India titled as **"10 months on, Chief Secretary of Maharashtra takes his first shot"** on 4th December, 2021, is marked and annexed herewith **Exhibit "RA-6") (Page No. 275)**

12.3. The question now arises as to how Respondent No.1 Shri. Debashish Chakrabarty was allowed to attend his office against their own rules. And how before his second dose he has affirmed the reply affidavit from the Government office of Chief Secretary.

12.4. That, the Respondent No.1 & its officials themselves are not able to follow such draconian rules but they are expecting common man to follow it and putting fines upon them.

12.5. Needless to mention here that, in a wedding ceremony of daughter of MP Shri Sanjay Raut, all officers of Respondent No. 1 and all guests were without mask and have not followed the Covid Appropriate Behavior (CAB) as mentioned in order dated **27.11.2021,** but no action is taken against them.

A detailed complaint is filed by Shri. Amber Koiri, Member of National Steering Committee of Awaken India Moment.

NOTARY
Adv. M. PADALE
Mumbai
Maharashtra
Reg. No. 15220
Expiry Dt.
31.10.2024
GOVT. OF INDIA

(A copy of complaint against Shri Sanjay Raut by Shri Amber Koiri **dated** 2nd December,2021, is marked and annexed herewith **Exhibit "RA-7") (Page No. 277)**

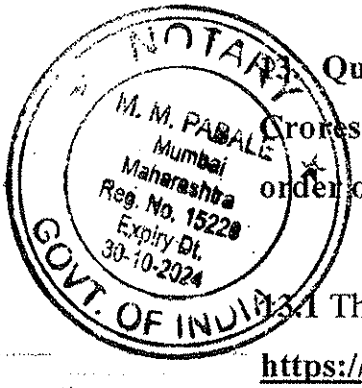
Despite the detailed written complaint, with sound proofs of video recording, no action is taken. The reason has to be answered by the Respondent No.1.

12.6. This shows that there is actually no threat and the said order is useless. But the state wants to harass the common man and extort money.

12.7. Full Bench of Hon'ble Supreme Court in **Nandini Sathpathy's Case (1978) 2 SCC 424** case has ruled that ***'you cannot become law unto yourself, expecting others to obey the law'***.

12.8. In **Raghbir (Ranbir) Vs State of Haryana AIR 1980 SC 1087**, the Supreme Court has observed as under;

> *"We conclude with the disconcerting note sounded by Abraham Lincoln: "**If you once forfeit the confidence of your fellow citizens you can never regain their respect and esteem. It is true that you can fool all the people some of the time, and some of the people all the time, but you cannot fool all the people all the time**."*



13. Question is regarding violation of fundamental rights of the Crores of citizen and it cannot be curtailed by passing an arbitrary order on the basis of incomplete data without any scientific proofs.

13.1 That, the people who skipped the second dose are around **92 lakh (https://timesofindia.indiatimes.com/city/mumbai/maharashtra-**

second-vax-dose-critical-for-devpt-of-antibodies-says-expert/articleshow/87898107.cms) **and the people** who have not taken even a single dose are around 1 Crores 50 Lacs. The number of people who have taken the first dose are 7 crore 60 lakh, and the number of people who have taken both doses are 4 crore 30 lakh. (https://www.hindustantimes.com/cities/mumbai-news/15-million-yet-to-get-a-jab-in-state-101638901754007.html)

13.2. Hence, **on the basis of incomplete data without any scientific proofs, the fundamental rights of the crores of citizen cannot be curtailed.** Such cavalier and casual approach need to be sternly dealt with.

13.3. Even at country level around 11 Crores Citizen have refused to take second dose of the vaccines.(https://www.indiatoday.in/india/story/11-crore-skipped-covid-vaccine-second-dose-govt-data-1870239-2021-10-27)

13.4. Around 21 Crore Indians (15 percent of the population) have not taken a single dose. (https://timesofindia.indiatimes.com/india/over-50-of-adult-population-in-india-now-fully-vaccinated/articleshow/88111521.cms)

14. Proofs of suppression of data by state regarding vaccine deaths and side effects which proves the concerns expressed by Hon'ble Justice Dr. D.Y. Chandrachud that court cannot rely only on state to determine truth in the cases related with Covid-19:-

1194

14.1. In the UK 25 million doses of Covishield were administered and 1138 deaths post vaccination were reported. In India, 740 million doses were administered and only 850 deaths were reported. How is this possible? The answer to that is given by Justice Shri. D.Y. Chandrachud, in a statement where he asked citizens and public intellectuals to bring out the right data, as the state has a tendency to suppress data.

14.2. That, in an interview dated **29 August, 2021** Hon'ble Justice D.Y. Chandrachud had said that the state is in habit of suppressing the information and data regarding Covid-19 pandemic and it is the duty of the intellectual citizen to expose their lies.

The excerpts of said speech are as under;

> ***"Supreme Court Judge Hon'ble Justice Dr. D. Y. Chandrachud on 29th August 2021 said that the State officer can spread lies, but citizens must be vigilant. Public intellectuals have a duty to expose lies of the state.*** *Emphasizing the need for truth in a democracy, he said the state can indulge in falsehood and it was the duty of citizens to strengthen public institutions and question the state to determine the truth.* ***In the context of the Covid-19 pandemic, we see that there is an increasing trend of countries across the world trying to manipulate data. Hence, one cannot only rely on the state to determine the truth"***

Link:

https://www.newindianexpress.com/thesundaystandard/2021/aug/29/state-can-spread-lies-but-citizens-must-be-vigilantsupreme-court-justice-dy-chandrachud-2351171.html

NOTARY ... GOVT. OF INDIA

14.3. The dishonesty of the State authorities is ex-facie clear and can be easily seen from following data. The National AEFI committee has acknowledged that only 4 deaths have occurred from the vaccine. However, the reply received from a small district in Kerala (Mallapuram) district medical office has acknowledged that 11 people died only in Mallapuram due to side effects of vaccine till **25.09.2021.**

(A copy of the RTI reply received from a small district in Kerala **(Mallapuram)** district medical office has acknowledged that 11 people died only in Mallapuram due to side effects of vaccine till **25.09.2021** marked and annexed herewith **Exhibit "RA-8") (Page No. 280)**

If based on the deaths occurred due to vaccination, proportionate algorithm is applied or fair and transparent enquiry is done then the figure of entire country will range in lacs of deaths due to vaccines.

14.4. The National AEFI data states that, only **954 Deaths** have occurred post vaccination. However, as per records collected by Awaken India Movement from the cases reported in media shows that more than 10,800 deaths have occurred post vaccination. The other deaths which are not reported in media is much higher and the number will go in lacs.

Because many heart attacks occurred due to vaccines after a period of months of vaccination or quite long time after vaccination are neither reported nor counted by the AEFI Committee. This exposes the lack of fairness on the part of the state authorities.

Link for reported cases of 10800 deaths is as under;

Link:

https://drive.google.com/file/d/1uikc1a6_KDzUx7HNLrfwaI1NJRt0D_YP/view?usp=sharing

14.5. Needless to mention that as per rules AEFI committee is bound to take cognizance if news reports even if it is not reported to them directly.

AEFI Surveillance and Response Operational Guidelines – 2015 on page 25 under para "4.2 Channels for reporting AEFI" and sub para "4.2.2 Immediate serious AEFI notification (by the first person who identifies the event)" mentions the following:

"In India, depending on the type of AEFI, the place where the event occurs, its severity and the confidence of the beneficiary in the care provider, serious AEFI are first brought to the notice of the health system by the patient directly health-care worker who administered the vaccine care provider treating the case supervising immunization staff pharmacy dispensing the vaccine (usually in the private sector)- **local media** - ADR monitoring centres

It is therefore important that each potential reporter be aware of the process and procedure adopted for reporting serious and severe AEFI.

Immediately after the identification/notification of a serious/ severe AEFI, a two-step process is initiated:

Step 1: reporting serious/severe AEFI to the appropriate authority

Step 2: district-level investigation of selected reported AEFI.

All serious/severe AEFI are to be immediately notified by the first person who identifies the event. This person should notify the case to the nearest government PHC/CHC and/or the DIO by the

quickest means of communication (telephone, messenger, etc.) All persons involved in reporting AEFI should be aware of the timeline and channels of reporting. All notified AEFI should be documented on a case reporting form (CRF) (see Annex l) and submitted to the next level as soon as possible."

1. Furthermore, on page 80 under "AEFI committees and monitoring of surveillance",para "9.2 Terms of reference for AEFI committees at various levels" and sub para "9.2.1 District AEFI committee", it is mentioned:

   "Terms of reference (TOR) of the district AEFI committee - Analyse programme information, media reports and other sources of information on serious AEFI and ensure AEFI reporting and investigation are of the highest standards

2. In lieu of the above guidelines and the repeated intimation of such media reports of Death following Covid vaccination, it is expected of the concerned authorities that all such reports are taken up for Investigation by the various AEFI Committees.

3. As can be seen from the repeated communication done by Awaken Indian Movement to the highest authorities, it is imperative that these AEFIs are registered and duly investigated at the earliest. **Source** : https://www.itsu.org.in/wp-content/downloads/AEFI-Surveillance-and-Response-Operational-Guidelines-2015_compressed%20(1).pdf

15. Defense taken by the state (Respondent No.1) on the basis of false and incorrect data does not pass the Scrutiny of Article 14 and

intelligent differentia as laid down in the case of Madan Mili Vs. UOI 2021 SCC OnLine Gau 1503.

15.1. That, the **Respondent No. 1,** in his affidavit dated **21.12.2021** in **para 19** had given the false, incorrect submission that there are only two classes of the people one who have taken the two doses of Vaccines and other who have not taken the two doses of Vaccines..

The actual categories are:

i) Those who have taken the vaccines.

ii) Those who have not taken the vaccines but have taken the certificates of two doses of vaccines in connivance with authorities and doctors. Many FIR are registered and police found that the racket is spread over many states. The figure may range in crores.

Link:

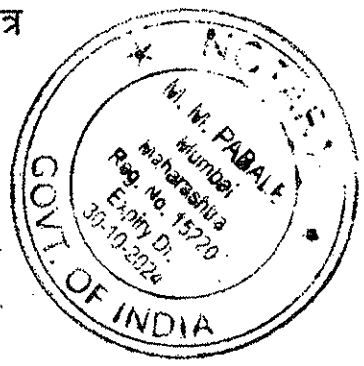
a) Maharashtra: Thane's vaccine certificate scam trail leads to other states, say police

https://timesofindia.indiatimes.com/city/thane/maharashtra-thanes-fake-vaccine-certificate-scam-linked-with-other-states-say-police/articleshow/88185258.cms

b) Four arrested in Aurangabad for issuing bogus corona vaccination certificate.

http://www.uniindia.com/four-arrested-in-aurangabad-for-issuing-bogus-corona-vaccination-certificates/west/news/2593705.html

c) लस न घेता दोन हजारांत प्रमाणपत्र



http://epaper.saamana.com/ArticlePage/APpage.php?edn=Mumbai&articleid=SAMANA_MUM_20211224_2_5&artwidth=180.28333333333333px

iii) **Safest and protected Persons** with Natural immunity developed due to previous infection.

iv) **Safest and protected persons** having developed with antibodies even without getting symptomatic infection but only due to their body coming in contact with the **SARS- CO-V2** virus.

(v) Persons who have taken Covishield vaccines before **October, 2021,** whose protection waned as per the scientific data published in Lancet.

Link: https://www.businesstoday.in/coronavirus/story/astrazeneca-covid-vaccine-protection-wanes-after-three-months-lancet-study-316348-2021-12-21

(vi) The citizens below 18 years of age.

(vii) The person who are in the prohibited category of taking vaccines and having medical certificates from a registered medical practitioner.

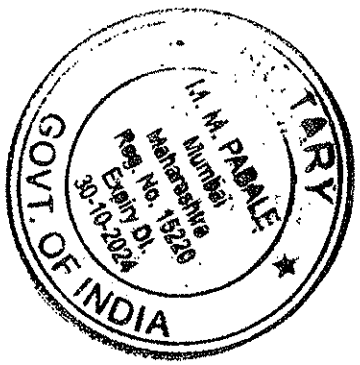
15.2. Hence, the submission made by the Respondent No. 1 regarding classification between vaccinated and unvaccinated is false, misleading, incorrect, twisted and based on suppression and dishonest concealment of facts. Therefore, the decision based on such flawed classification it does not pass the security of the Article 14 of the Constitution of India.

GOVT. OF INDIA NOTARY M. M. PABALE Mumbai Maharashtra Reg. No. 15220 Expiry Dt. 30-10-2024

1200

15.3. Hon'ble High Court in **Madan Milli Vs. UOI 2021 SCC OnLine Gau 1503,** regarding Covid-19 vaccines given the **criteria for making classification and rules of intelligent differentia**. It is ruled as under;

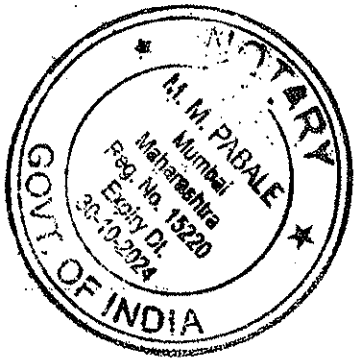
> *12. The right granted under Article 19 (1) (d) of the Constitution of India to move freely throughout the territory of India, however, is not absolute and the State may impose a reasonable restrictions on the exercise of the rights under Article 19 (1) (d) of the Constitution of India either in the interest of the general public or for the protection of the interest of the Schedule Tribe.* ***While putting any restrictions, as above, such restrictions, however, must be a reasonable one conforming to the requirement of Article 14 of the Constitution of India as well.*** *Article 14 of the Constitution of India guarantees to every persons the right not to be denied equality before the law or the equal protection of laws. "Equality before the law" means that amongst equals the law should be equal and should be equally administered and that like should be treated alike.* ***Classification of persons into groups for different treatment of such groups is permissible if there is a reasonable basis for such difference.*** *Article 14 of the Constitution of India forbids class legislation, but does not forbid classification or differentiation which rests upon reasonable grounds of distinction.* ***The power of making classification, however, is not without limit. A classification to be valid must be reasonable. It***



must always rest upon some real and substantial distinction bearing reasonable and just needs in respect of which the classification is made. *In order to pass the test of permissible classification, 2 (two) conditions must be fulfilled, namely,* ***(i) the classification must be founded on an intelligible differentiation which distinguishes persons or things that are grouped together from others left out of the group; and (ii) the differentia must have a rational relation to the object sought to be achieved by such classification.***

14. Thus, if the sole object of issuing the Order dated 30.06.2021, by the Chief Secretary cum Chairperson-State Executive Committee, Government of Arunachal Pradesh, vide Memo No. SEOC/DRR&DM/01/2011-12, is for containment of the Covid-19 pandemic and its further spread in the State of Arunachal Pradesh, the classification sought to be made between vaccinated and unvaccinated persons for Covid-19 virus for the purpose of issuing temporary permits for developmental works in both public and private sector, vide Clause 11 thereof, prima facie, appears to be a classification not founded on intelligible differentia nor it is found to have a rational relation/nexus to the object sought to be achieved by such classification, namely, containment and further spread of Covid-19 pandemic.

13. In the instant case, the classification sought to be made between the vaccinated and unvaccinated persons for Covid-19 by Clause 11 of the Order dated 30.06.2021 for the purpose of issuing a temporary permit for developmental works in both public and private sector in the State of Arunachal Pradesh is undoubtedly to contain Covid-19 pandemic and its further spread in the State of Arunachal Pradesh. There is no evidence available either in the record or in the public domain that Covid-19 vaccinated persons cannot be infected with Covid-19 virus, or he/she cannot be a carrier of a Covid-19 virus and consequently, a spreader of Covid-19 virus. In so far as the spread of Covid-19 Virus to others is concerned, the Covid-19 vaccinated and unvaccinated person or persons are the same. Both can equally be a potential spreader if they are infected with Covid-19 Virus in them. This aspect of the matter came up for consideration by this Court in WP(C)/37/2020 (In Re Dinthar Incident Aizawl v. State of Mizoram Aizawl; in which case, this Court vide Order dated 02.07.2021, in paragraph 14 thereof, had observed as follows -



"14. It has been brought to our notice that even persons who have been vaccinated can still be infected with the covid virus, which would in turn imply that vaccinated persons who are covid positive, can also spread the said virus to others. It

is not the case of the State respondents that vaccinated persons cannot be infected with the covid virus or are incapable of spreading the virus. Thus, even a vaccinated infected covid person can be a super-spreader. If vaccinated and un-vaccinated persons can be infected by the covid virus and if they can both be spreaders of the virus, the restriction placed only upon the un-vaccinated persons, debarring them from earning their livelihood or leaving their houses to obtain essential items is unjustified, grossly unreasonable and arbitrary. As such, the submission made by the learned Additional Advocate General that the restrictions made against the un-vaccinated persons vis-à-vis the vaccinated persons is reasonable does not hold any water. As the vaccinated and un-vaccinated persons would have to follow the covid proper behavior protocols as per the SOP, there is no justification for discrimination."

15.4. In **Erusian Equipment & Chemicals Ltd. v. State of West Bengal and Anr. ([1975] 2 SCR 674),** the Supreme Court observed that where Government activity involves public element, the "citizen has a right to gain equal treatment", and **when "the State acts to the prejudice of a person, it has to be supported by legality."** Functioning of "democratic form of Government demands equality and absence of arbitrariness and discrimination."

Every action of the executive Government must be informed by reasons and should be free from arbitrariness. That is the very essence of rule of law and its bare minimum requirement.

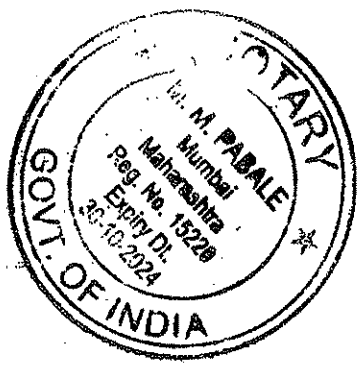
The decision taken in an arbitrary manner contradicts the principle of legitimate expectation and the plea of legitimate expectation relates to procedural fairness in decision making and forms a part of the rule of non-arbitrariness as denial of administrative fairness is Constitutional anathema.

The rule of law inhibits arbitrary action and such action is liable to be invalidated. **Every action of the State or its instrumentalities should not only be fair, legitimate and above-board but should be without any affection or aversion. It should neither be suggestive of discrimination nor even apparently give an Impression of bias, favouritism and nepotism**.

Procedural fairness is an implied mandatory requirement to protect arbitrary action where Statute confers wide power coupled with wide discretion on the authority. If procedure adopted by an authority offends the fundamental fairness or established ethos or shocks the conscience, the order stands vitiated. The decision-making process remains bad.

Official arbitrariness is more subversive of doctrine of equality than the statutory discrimination. In spite of statutory discrimination, one knows where he stands but; the wand of official arbitrariness can be waved in all directions indiscriminately.

15.5. Similarly, in **S.G. Jaisinghani v. Union of India and Ors. ([1967] 65 ITR 34 (SC)), the Constitution Bench of the Apex Court observed as under:**



"In the context it is important to emphasize that absence of arbitrary power is the first essence of the rule of law, upon which our whole Constitutional System is based. In a system governed by rule of law, discretion, when conferred upon Executive Authorities, must be confined within the clearly defined limits. Rule of law, from this point of view, means that the decision should be made by the application of known principle and rules and h general such, decision should be predictable and the citizen should know where he is, if a decision is taken without any principle or without any rule, it is unpredictable and such a decision is" antithesis to the decision taken in accordance with the rule of law."

Even in a situation where an authority is vested with a discretionary power, such power can be exercised by adopting that mode which best serves the interest and even if the Statute is silent as to how the discretion should be exercised, then too the authority cannot act whimsically or arbitrarily and its action should be guided by reasonableness and fairness because the legislature never intend that its authorities could abuse the laws or use it unfairly. Any action which results in unfairness and arbitrariness results in violation of Article 14 of the Constitution. It has also been emphasized that an authority cannot assume to itself an absolute power to adopt any procedure and

1206

the discretion must always be exercised according to law.

15.6. In **Dr. Binapani Dei (supra),** the Hon'ble Apex Court held as under:

> ***"It is one of the fundamental rules of our constitutional set up that every citizen is protected against the exercise of arbitrary authority by the State or its officers If there is power to decide and determine to the prejudice of a person, duty to act judicially is implicit in the exercise of such power. If the essentials of justice be ignored and an order to the prejudice of a person is made, the order is a nullity."***

15.7. Each action of such authorities must pass the test of reasonableness and whenever action taken is found to be lacking bona fide and made in colorable exercise of the power, the Court should not hesitate to strike down such unfair and unjust proceedings. **Vide Hansraj H. Jain v. State of Maharashtra and Ors [(1993) 3 SCC 634].**

15.8. In fact, the order of the State or State instrumentality would stand vitiated if it lacks bona fides as it would only be a case of colourable exercise of power. In **State of Punjab and Anr. v. Gurdial Singh and Ors.[(1980) 1 SCR 1071]** the Hon'ble Apex Court has dealt with the issue of **legal malice which is, just different from the concept of personal bias**. The Court observed as under:

> ***"When the custodian of power is influenced in its exercise by considerations outside those for promotion of which the***

NOTARY M. M. PABALE Mumbai Maharashtra Reg. No. 15220 Expiry Dt. 30-10-2024 GOVT. OF INDIA

power is vested the Court calls it a colourable exercise and is undeceived by illusion.... If considerations, foreign to the scope of the power or extraneous to the statute, enter the verdict or impels the action mala fides or fraud on power vitiates the...official act."

15.9. In **Delhi Transport Corporation v. D.T.C. Mazdoor Congress and Ors.[(1991) I LLJ 395 SC] and Dwarka Dass and Ors. v. State of Haryana (2003 CriLJ 414)** the Supreme Court observed that "discretion when conferred upon the executive authorities, must be confined within definite limits. The rule of law from this point of view means that decision should be made by the application by known-principles and rules and in general, such decision should be predictable and the citizen should know where he is.

15.10. The scope of discretionary power of an authority has been dealt with by the Supreme Court in **Bangalore Medical Trust v. B.S. Muddappa and Ors [(1991) 3 SCR 102]** and it has been observed that, even where statutes are silent and only power is conferred to act in one or the other manner, the Authority cannot act whimsically or arbitrarily. It should be guided by reasonableness and fairness. The legislature never intends its authorities to abuse the law or use it unfairly.

It is ruled as under;

Even where statutes are silent and only power is conferred to act in one or the other manner, the Authority cannot act whimsically or arbitrarily. It should be guided by reasonableness and fairness. The legislature never intends its authorities to abuse the law or use it unfairly.

GOVT. OF INDIA NOTARY M. M. PARALE Mumbai Regd. No. 15270 Expiry On 30.10.2024

"Discretion is an effective tool in administration. But wrong notions about it results in ill-conceived consequences. In law it provides an option to the authority concerned to adopt one or the other alternative. But ***a better, proper and legal exercise of discretion is one where the authority examines the fact, is aware of law and then decides objectively and rationally what serves the interest better. When a statute either provides guidance or rules or regulations are framed for exercise of discretion then the action should be in accordance with it. Even where statutes are silent and only power is conferred to act in one or the other manner, the Authority cannot act whimsically or arbitrarily. It should be guided by reasonableness and fairness. The legislature never intends its authorities to abuse the law or use it unfairly.****"*

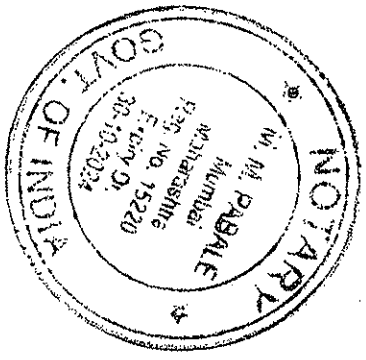
15.11. In **Union of India v. Kuldeep Singh (AIR 2004 SC 827),** the Supreme Court again observed:

"When anything is left to any person, judge or Magistrate to be done according to his discretion, the law intends it must be done with sound discretion, and according to law. *(See Tomlin's Law Dictionary.) In its ordinary meaning, the word "discretion" signifies unrestrained exercise of choice or will; freedom to act according to one's own judgment; unrestrained exercise of will; the liberty or power of acting without control other than one's own judgment. But, when*

NOTARY
M. M. PABALE
Mumbai
Maharashtra
Reg. No. 15228
Expiry Dt. 30-10-2024
GOVT. OF INDIA

applied to public functionaries, it means a power or right conferred upon them by law, of acting officially in certain circumstances according to the dictates of their own judgment and conscience, uncontrolled by the judgment or conscience of others. Discretion is to discern between right and wrong; and therefore, whoever hath power to act at discretion, is bound by the rule of reason and law."

Discretion, in general, is the discernment of what is right and proper. It denotes knowledge and prudence, the discernment which enables a person to judge critically of what is correct and proper united with caution; nice soundness of judgment; a science or understanding to discern between falsity and truth, between wrong and right, between shadow and substance, between equity and colourable glosses and pretences, and not to do according to the will and private affections of persons. When It is said that something is to be done within the discretion of the authorities, that something is to be done according to the rules of reason and justice, not according to private opinion; according to law and not humour. It is to be not arbitrary, vague, and fanciful, but legal and regular. And it must be exercised within the limit, to which an honest man, competent to the discharge of his office ought to confine himself (per Lord Halsbury, L.C., in Sharp v. Wakefield). Also see S.G. Jaisinghani v. Union of India { [1967] 65 ITR 34 (SC) }.



1210

15.12. In **Suman Gupta v. State of J.&K., (1983) 4 SCC 339 : AIR 1983 SC 1235,** the Supreme Court also considered the scope of discretionary powers and observed:—

> *".....We think it beyond dispute that the exercise of all administrative power vested in public authority must be structured within a system of controls informed by both relevance and reason - relevance in relation to the object which it seeks to serve, and reason in regard to the manner in which it attempts to do so. Wherever the exercise of such power affects individual rights, there can be no greater assurance protecting its valid exercise than its governance by these twin tests. A stream of case law radiating from the now well known decision in this Court in Maneka Gandhi v. Union of India has laid down in clear terms that Article 14 of the Constitution is violated by powers and procedures which in themselves result in unfairness and arbitrariness. It must be remembered that our entire constitutional system is founded in the rule of law, and in any system so designed it is impossible to conceive of legitimate power which is arbitrary in character and travels beyond the bounds of reason....."*
>
> *(Emphasis supplied)*

NOTARY ... M. PARALE Mumbai Maharashtra Reg. No. 15220 Expiry Dt. 30-10-2024 GOVT. OF INDIA

15.13. Hence, the impugned order passed by the Respondent No.1 and subsequent order dated **27.11.2021** is neither logical nor legal. It is arbitrary, illegal and unconstitutional, therefore liable to be quashed.

16. As per Hon'ble Supreme Court judgment, when public servant files false affidavit with suppression of material and relevant facts then such public servant should be punished under section 2 (c) & 12 of Contempt of Court Act,1971 and also under section 191,192,193,199,200,471,474,120(b), 34 etc of IPC as per section 340 of Cr.P.C.

16.1. That, both the reply affidavits filed by Shri. Debashish Chakrabarty and Dr. Sadhana Tayade are false and misleading. It hides more that what it tells. The affidavits are drafted with dishonest, twisting, concealment and suppression of the material facts.

This was done with ulterior motive to misled the Court and to get the dismissed of petition.

16.2. That, in the affidavit dated **15.12.2021** the Respondent No. 1 through Dr. Sadhana Tayade had taken a defence in **para 5** that **'there are some evidence'.**

"5. I say that, the vaccination is important which could save the life. COVID-19 vaccines provide strong protection against serious illness hospitalization and death. There is also some evidence that being vaccinate will make it less likely that you will pass the virus on to others, which means your decision to get vaccine also protects those around you."

16.3. This was not based on any evidence and not answering the question raised by the Petitioner that whether only vaccinated person are safe for allowing them to use facility. And whether unvaccinated and more

particularly those who are having developed natural immunity due to previous infection are not safe.

Secondly, if vaccinated can spread infection and they are asked to wear masks to protect others then on the same condition unvaccinated can also be permitted and there can be no discrimination as ruled in **Madan Mili Vs. UOI 2021 SCC OnLine Gau 1503**.

16.4. Furthermore, when the Petitioner pointed out the contrary evidence and also this Hon'ble Court also not satisfied with the logic and technical objection and passed a specific order asking the specific affidavit from Chief Secretary, then having perceived adverse atmosphere, the Respondent No. 1 changed its stand and fabricated further false evidence in his affidavit dated **21.12.2021** and come with another theory that, vaccination reduces hospitalization and it will help in oxygen emergency.

16.5. The falsity of the narrative as mentioned in the affidavit dated **15.12.2021** & **21.12.2021** is ex-facie proved from the evidence of sterling nature and undisputed by the Respondent No. 1.

16.6. That, Hon'ble Supreme Court time and now made it clear that, the filing of false affidavit by anyone and more particularly by the Government officials should be viewed seriously. And such people should be prosecuted for perjury and contempt. This is necessary to protect the pure stream of justice being polluted at the hands of dishonest litigants and Government officials, who are having scant regards for the courts of law and justice delivery system.

16.7. The suppression, concealment and twisting of material fact is also treated as the act of filing false affidavit.

16.8. Hon'ble Supreme Court in the case of **ABCD v. Union of India (2020) 2 SCC 52** had ruled that anyone who takes recourse to fraud, deflects the course of judicial proceedings; or if anything is done with oblique motive, the same interferes with the administration of justice. Such persons are required to be properly dealt with, not only to punish them for the wrong done, but also to deter others from indulging in similar acts which shake the faith of people in the system of administration of justice.

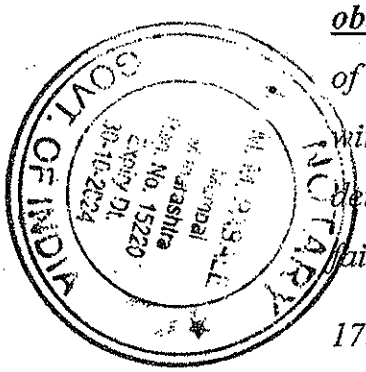
An applicant who does not come with candid facts and "clean breast" cannot hold a writ of the court with "soiled hands". Suppression or concealment of material facts is not an advocacy. It is a jugglery, manipulation, maneuvering or misrepresentation, which has no place in equitable and prerogative jurisdiction.

A person who makes an attempt to deceive the court, interferes with the administration of justice and can be held guilty of contempt of court.

A notice was issued in suo motu exercise of power of Supreme Court

It is ruled as under;

> *"2. Anyone who takes recourse to fraud, deflects the course of judicial proceedings; or if anything is done with oblique motive, the same interferes with the administration of justice. Such persons are required to be properly dealt with, not only to punish them for the wrong done, but also to deter others from indulging in similar acts which shake the faith of people in the system of administration of justice.*
>
> *17. In K.D. Sharma v. SAIL [K.D. Sharma v. SAIL, (2008) 12 SCC 481] it was observed : (SCC p. 493, para 39)*



"39. If the primary object as highlighted in Kensington Income Tax Commrs. [R. v. General Commissioners for Purposes of Income Tax Acts For District of Kensington, ex p Princess Edmond De Polignac, (1917) 1 KB 486 : 86 LJKB 257 : 116 LT 136 (CA)] is kept in mind, an applicant who does not come with candid facts and "clean breast" cannot hold a writ of the court with "soiled hands". Suppression or concealment of material facts is not an advocacy. It is a jugglery, manipulation, manoeuvring or misrepresentation, which has no place in equitable and prerogative jurisdiction. If the applicant does not disclose all the material facts fairly and truly but states them in a distorted manner and misleads the court, the court has inherent power in order to protect itself and to prevent an abuse of its process to discharge the rule nisi and refuse to proceed further with the examination of the case on merits. If the court does not reject the petition on that ground, the court would be failing in its duty. In fact, such an applicant requires to be dealt with for contempt of court for abusing the process of the court.".

19.In the circumstances a notice is required to be issued to the petitioner in suo motu exercise of power of this Court "why action in contempt be not initiated against her and why appropriate direction be not passed under Section 195(1)(a)(i) of the Code". The Registry is directed to register the matter as suo motu proceedings and send a copy

SECRETARY
GOVT. OF INDIA
M. M. PABALE
Mumbai
Maharashtra
Reg. No. 15220
Entry Dt.
30-10-2024

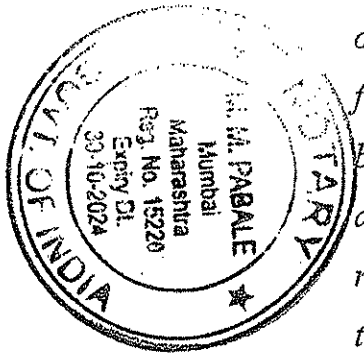
of this order to the petitioner, who is directed to appear in-person before this Court on 14-1-2020. .

16.....In Chandra Shashi v. Anil Kumar Verma [Chandra Shashi v. Anil Kumar Verma, (1995) 1 SCC 421 : 1995 SCC (Cri) 239] that a person who makes an attempt to deceive the court, interferes with the administration of justice and can be held guilty of contempt of court. In that case a husband who had filed a fabricated document to oppose the prayer of his wife seeking transfer of matrimonial proceedings was found guilty of contempt of court and sentenced to two weeks' imprisonment.."

16.9. In **Sarvepalli Radhakrishnan University Vs. UOI (2019) 14 SCC 761**, it is ruled as under;

13. In R. Karuppan, Advocate, In re [R. Karuppan, Advocate, In re, (2001) 5 SCC 289 : 2001 SCC (Cri) 876] , this Court observed as under : (SCC p. 293, para 13)

"13. Courts are entrusted with the powers of dispensation and adjudication of justice of the rival claims of the parties besides determining the criminal liability of the offenders for offences committed against the society. The courts are further expected to do justice quickly and impartially not being biased by any extraneous considerations. Justice-dispensation system would be wrecked if statutory restrictions are not imposed upon the litigants, who attempt to mislead the court by filing and relying upon false evidence particularly in cases, the adjudication of which is dependent upon the statement of facts. If the result of the proceedings is to be respected, these issues before the courts must be



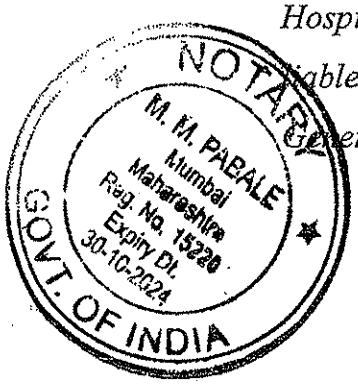
resolved to the extent possible in accordance with the truth. The purity of proceedings of the court cannot be permitted to be sullied by a party on frivolous, vexatious or insufficient grounds or relying upon false evidence inspired by extraneous considerations or revengeful desire to harass or spite his opponent. Sanctity of the affidavits has to be preserved and protected discouraging the filing of irresponsible statements, without any regard to accuracy."

14. *In Mohan Singh v. Amar Singh [Mohan Singh v. Amar Singh, (1998) 6 SCC 686] , it was observed by this Court : (SCC p. 704, para 36)*

"36. ...Tampering with the record of judicial proceedings and filing of false affidavit in a court of law has the tendency of causing obstruction in the due course of justice. It undermines and obstructs free flow of the unsoiled stream of justice and aims at striking a blow at the rule of law. The stream of justice has to be kept clear and pure and no one can be permitted to take liberties with it by soiling its purity."

20. *For the aforementioned reasons, we pass the following order:*

20.1. *Mr S.S. Kushwaha, Dean of RKDF Medical College Hospital and Research Centre i.e. Petitioner 2 herein is liable for prosecution under Section 193 IPC. The Secretary General of this Court is directed to depute an officer to*



initiate the prosecution in a competent court having jurisdiction at Delhi.

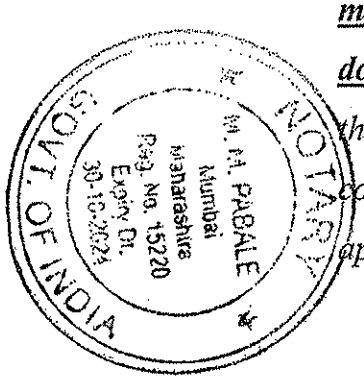
20.2. *The College is barred from making admissions for the first year MBBS course for the next two years i.e. 2018-19 and 2019-2020.*

20.3. *A penalty of Rs five crores is imposed on the College for playing fraud on this Court. The amount may be paid to the account of the Supreme Court Legal Services Committee.*

20.4. *The students are entitled to receive the refund of fee paid by them for admission to the College for the academic year 2017-2019. In addition, the College is directed to pay a compensation of Rs one lakh to the said students."*

16.10. In **Afzal Vs. State (1996) 7 SCC 397,** it is ruled as under;

A] ***I.P.C. 193*** *– Prosecution of S.P. and other Police personnel – I.O. during enquiry illegally detained a minor boy and warned that he could be released only when his father surrender before Police - Petition filed before Supreme Court –* ***Report is called form S.P. – False and misleading report submitted by S.P. – Supreme Court being doubtful of report called the report from C.B.I****. – It proved the malafides of S.P. – S.P. is guilty u.s. 193 of I.P.C. and convicted for 1 years rigrous imprisonment – Supreme Court appreciated the work done by the C.B.I.*



*B] **Contempt of Court** – S.P. first filed a false fabricated counter affidavit to get favourable order from Court – After his falsity disclosed then perceiving adverse atmosphere he again fabricated further false evidence to misled the Court – S.P. Not making can did admissions nor tendering unqualified apology – He is guilty of committing contempt of Judicial process – Sentenced to rigrour imprisonment for 6 month – Police Officers Randhir Singh (ASI), Ishwar Sigh (SI) and M.S. Alhawat (superintendent of police) convicted – DGP is directed to take the convicts in to custody forthwith and send them to central Jail – And submit the compliance report to the Registry within one week*

16.11. In the case of **New Delhi Municipal Council *vs.* M/s. Prominent Hotels Limited 2015 SCC OnLine Del 11910**, it is ruled as under;

*"**25.6.** In the recent case of Subrata Roy Sahara v. Union of India, (2014) 8 SCC 470, J.S. Khehar, J. observed that the Indian judicial system is grossly afflicted with frivolous litigation. Relevant portion of the said judgment is as under:*

"188. The number of similar litigants, as the parties in this group of cases, is on the increase. They derive their strength from abuse of the legal process. Counsel are available, if the litigant is willing to pay their fee. Their percentage is slightly higher at the lower levels of the judicial hierarchy, and almost non-existent at the level of the Supreme Court. One wonders what is it that a Judge should be made of, to deal with such litigants who have nothing to lose. What is the level of merit, grit and composure required to stand up to the pressures of today's litigants? What is it that is needed to

NOTARY M. M. PABALE Mumbai Maharashtra Regd. No. 15220 Expiry Dt. 30-10-2024 GOVT. OF INDIA

bear the affront, scorn and ridicule hurled at officers presiding over courts? Surely one would need superhumans to handle the emerging pressures on the judicial system. The resultant duress is gruelling. One would hope for support for officers presiding over courts from the legal fraternity, as also, from the superior judiciary up to the highest level. Then and only then, will it be possible to maintain equilibrium essential to deal with complicated disputations which arise for determination all the time irrespective of the level and the stature of the court concerned. And also, to deal with such litigants.

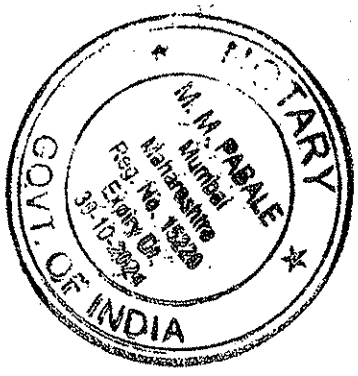
191. The Indian judicial system is grossly afflicted, with frivolous litigation. Ways and means need to be evolved, to deter litigants from their compulsive obsession, towards senseless and ill-considered claims. One needs to keep in mind, that in the process of litigation, there is an innocent sufferer on the other side, of every irresponsible and senseless claim. He suffers long drawn anxious periods of nervousness and restlessness, whilst the litigation is pending, without any fault on his part. He pays for the litigation, from out of his savings (or out of his borrowings), worrying that the other side may trick him into defeat, for no fault of his. He spends invaluable time briefing counsel and preparing them for his claim. Time which he should have spent at work, or with his family, is lost, for no fault of his. Should a litigant not be compensated for, what he has lost, for no fault?...

NOTARY
M. M. PABALE
Mumbai
Maharashtra
Reg. No. 15220
Expiry Dt.
30-10-2024
GOVT. OF INDIA

1220

193. This abuse of the judicial process is not limited to any particular class of litigants. The State and its agencies litigate endlessly upto the highest Court, just because of the lack of responsibility, to take decisions. So much so, that we have started to entertain the impression, that all administrative and executive decision making, are being left to Courts, just for that reason. In private litigation as well, the concerned litigant would continue to approach the higher Court, despite the fact that he had lost in every Court hitherto before. The effort is not to discourage a litigant, in whose perception, his cause is fair and legitimate. The effort is only to introduce consequences, if the litigant's perception was incorrect, and if his cause is found to be, not fair and legitimate, he must pay for the same. In the present setting of the adjudicatory process, a litigant, no matter how irresponsible he is, suffers no consequences. Every litigant, therefore likes to take a chance, even when counsel's advice is otherwise.

*194. **Does the concerned litigant realize, that the litigant on the other side has had to defend himself, from Court to Court, and has had to incur expenses towards such defence? And there are some litigants who continue to pursue senseless and ill-considered claims, to somehow or the other, defeat the process of law**. ...*



25.7. In Satyender Singh v. Gulab Singh, 2012 (129) DRJ 128, the Division Bench of this Court following Dalip Singh v. State of U.P. (supra) observed that the Courts are flooded with litigation with false and incoherent pleas and tainted evidence

led by the parties due to which the judicial system in the country is choked and such litigants are consuming Courts' time for a wrong cause. The observations of this Court are as under : -

"2. As rightly observed by the Supreme Court, Satya is a basic value of life which was required to be followed by everybody and is recognized since many centuries. ***In spite of caution, courts are continued to be flooded with litigation with false and incoherent pleas and tainted evidence led by the parties. The judicial system in the country is choked and such litigants are consuming courts' time for a wrong cause. Efforts are made by the parties to steal a march over their rivals by resorting to false and incoherent statements made before the Court.*** *Indeed, it is a nightmare faced by a Trier of Facts; required to stitch a garment, when confronted with a fabric where the weft, shuttling back and forth across the warp in weaving, is nothing but lies. As the threads of the weft fall, the yarn of the warp also collapses; and there is no fabric left."*

26. ***Imposition of Costs***

26.5. *In Padmawati v. Harijan Sewak Sangh, 154 (2008) DLT 411, this Court imposed cost of Rs. 15.1 lakhs and noted as under:*

"6. The case at hand shows that frivolous defences and frivolous litigation is a calculated venture involving no risks situation. ***You have only to engage professionals to prolong the litigation so as to deprive the rights of a person and enjoy the fruits of illegalities. I consider that in such cases where Court finds that using the Courts as a tool, a litigant***

NOTARY
Mr. M. PABALE
Mumbai
Maharashtra
Reg. No. 15220
Expiry Dt.
31-10-2024
GOVT. OF INDIA

1222

has perpetuated illegalities or has perpetuated an illegal possession, the Court must impose costs on such litigants which should be equal to the benefits derived by the litigant and harm and deprivation suffered by the rightful person so as to check the frivolous litigation and prevent the people from reaping a rich harvest of illegal acts through the Courts. One of the aim of every judicial system has to be to discourage unjust enrichment using Courts as a tool. The costs imposed by the Courts must in all cases should be the real costs equal to deprivation suffered by the rightful person.

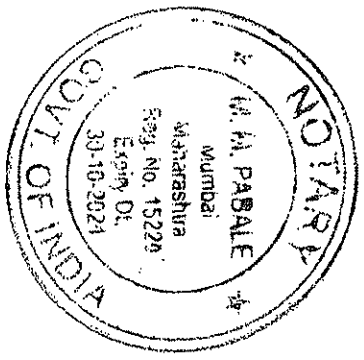
7. ... The petitioners are, therefore, liable to pay costs which is equivalent to the average market rent of 292 months to the Respondent No. 1 and which comes to Rs. 14,60,000/- apart from litigation expenses and Counsel's fee throughout which is assessed at Rs. 50,000/-. The petition is hereby dismissed with costs of Rs. 15,10,000/- to be recovered from the petitioners jointly and severally. If any amount has been paid towards user charges, the same shall be adjustable.

9. Before parting with this case, I consider it necessary to pen down that ***one of the reasons for over-flowing of court dockets is the frivolous litigation in which the Courts are engaged by the litigants and which is dragged as long as possible. Even if these litigants ultimately loose the lis, they become the real victors and have the last laugh. This class of people who perpetuate illegal acts by obtaining stays and injunctions from the Courts must be made to pay the sufferer not only the entire illegal gains made by them as***

GOVT. OF INDIA
Mr. M. PABALE
Mumbai
Maharashtra
Reg. No. 15220
Expiry Dt. 30-10-2024

costs to the person deprived of his right and also must be burdened with exemplary costs. Faith of people in judiciary can only be sustained if the persons on the right side of the law do not feel that even if they keep fighting for justice in the Court and ultimately win, they would turn out to be a fool since winning a case after 20 or 30 years would make wrong doer as real gainer, who had reaped the benefits for all those years. Thus, it becomes the duty of the Courts to see that such wrong doers are discouraged at every step and even if they succeed in prolonging the litigation due to their money power, ultimately they must suffer the costs of all these years long litigation. Despite settled legal positions, the obvious wrong doers, use one after another tier of judicial review mechanism as a gamble, knowing fully well that dice is always loaded in their favour, since even if they lose, the time gained is the real gain. This situation must be redeemed by the Courts."

26.1. *In Ramrameshwari Devi v. Nirmala Devi, (2011) 8 SCC 249, the Supreme Court has held that the Courts have to take into consideration pragmatic realities and have to be realistic in imposing the costs. The relevant paragraphs of the said judgment are reproduced hereunder : -*



"43. .....We are clearly of the view that unless we ensure that wrongdoers are denied profit or undue benefit from the frivolous litigation, it would be difficult to control frivolous and uncalled for litigations. In order to curb uncalled for and frivolous litigation, the courts have to ensure that there is no incentive or motive for uncalled for litigation. It is a

matter of common experience that court's otherwise scarce and valuable time is consumed or more appropriately wasted in a large number of uncalled for cases.

52. The main question which arises for our consideration is whether the prevailing delay in civil litigation can be curbed? In our considered opinion the existing system can be drastically changed or improved if the following steps are taken by the trial courts while dealing with the civil trials.

C. Imposition of actual, realistic or proper costs and or ordering prosecution would go a long way in controlling the tendency of introducing false pleadings and forged and fabricated documents by the litigants. Imposition of heavy costs would also control unnecessary adjournments by the parties. In appropriate cases the courts may consider ordering prosecution otherwise it may not be possible to maintain purity and sanctity of judicial proceedings.

54. While imposing costs we have to take into consideration pragmatic realities and be realistic what the Defendants or the Respondents had to actually incur in contesting the litigation before different courts. We have to also broadly take into consideration the prevalent fee structure of the lawyers and other miscellaneous expenses which have to be incurred towards drafting and filing of the counter affidavit, miscellaneous charges towards typing, photocopying, court fee etc.

NOTARY
M. M. PABALE
Mumbai
Maharashtra
Reg. No. 15229
Expiry Dt.
30-10-2024
GOVT. OF INDIA

55. The other factor which should not be forgotten while imposing costs is for how long the Defendants or

Respondents were compelled to contest and defend the litigation in various courts. The Appellants in the instant case have harassed the Respondents to the hilt for four decades in a totally frivolous and dishonest litigation in various courts. The Appellants have also wasted judicial time of the various courts for the last 40 years.

56. On consideration of totality of the facts and circumstances of this case, we do not find any infirmity in the well reasoned impugned order/judgment. These appeals are consequently dismissed with costs, which we quantify as Rs. 2,00,000/- (Rupees Two Lakhs only). We are imposing the costs not out of anguish but by following the fundamental principle that wrongdoers should not get benefit out of frivolous litigation."

26.2. *In Maria Margarida Sequeria Fernandes v. Erasmo Jack de Sequeria (2012) 5 SCC 370, the Supreme Court held that heavy costs and prosecution should be ordered in cases of false claims and defences as under : -*

"85. This Court in a recent judgment in Ramrameshwari Devi (supra) aptly observed at page 266 that unless wrongdoers are denied profit from frivolous litigation, it would be difficult to prevent it. In order to curb uncalled for and frivolous litigation, the Courts have to ensure that there is no incentive or motive for uncalled for litigation. It is a matter of common experience that Court's otherwise scarce time is consumed or more appropriately, wasted in a large number of uncalled for cases. In this very judgment, the Court provided that this problem can be solved or at least be

NOTARY GOVT. OF INDIA N. M. PARALE Mumbai Maharashtra Reg. No. 15220 Expiry Dt. 30.9.2023

minimized if exemplary cost is imposed for instituting frivolous litigation. The Court observed at pages 267-268 that imposition of actual, realistic or proper costs and/or ordering prosecution in appropriate cases would go a long way in controlling the tendency of introducing false pleadings and forged and fabricated documents by the litigants. Imposition of heavy costs would also control unnecessary adjournments by the parties. ***In appropriate cases, the Courts may consider ordering prosecution otherwise it may not be possible to maintain purity and sanctity of judicial proceedings****."*

16.12. SUPPRESSION AMOUNTS TO FILING OF FALSE AFFIDAVIT: -

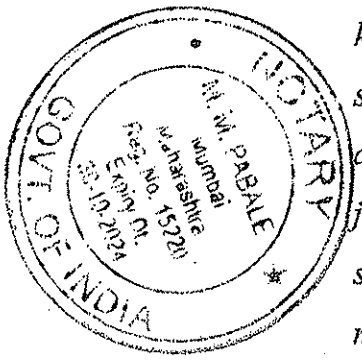
15.12.1. In **Samson Arthur Vs. Quinn Logistic 2015 SCC OnLine Hyd 403**, it is ruled as under;

*"**52.** If the aforesaid submissions of Sri. S. Niranjan Reddy, Learned Counsel, were to merit acceptance, it would then mean that relevant facts have been deliberately suppressed from the Company Court. If a wrong or misleading statement is deliberately and willfully made by a party to a litigation with a view to obtain a favourable order, it would prejudice or interfere with the due course of the judicial proceeding. (Naraindas v. The Government of Madhya Pradesh; Afzal v. State of Haryana; Sri. V. Satyanarayana Rao v. State of A.P; S.R. Ramaraj v. Special Court, Bombay; V. Satyanarayana Rao6). "Suppressio veri", i.e., the suppression of relevant and*

NOTARY M. M. PABALE Mumbai Maharashtra Reg. No. 15220 Expiry Dt. 30-10-2024 GOVT. OF INDIA

material facts is as bad as Suggestio falsi i.e., a false representation deliberately made. Both are intended to dilute- one by inaction and the other by action. "Suppressio veri Suggestion falsi"-suppression of the truth is equivalent to the suggestion of what is false. (Black's Law Dictionary with pronounciations-Sixth edition). A false statement willfully and deliberately made, and a suppression of a relevant and material fact, interfere with the due course of justice and obstruct the administration of justice. (V. Satyanarayana Rao6).

***64.** There is no justification in the request, made on behalf of the appellants, that the offences be compounded. The public have an interest, an abiding and a real interest, and a vital stake in the effective and orderly administration of justice. Unless justice is so administered, there is the peril of all rights and liberties perishing. The Court has the duty of protecting the interest of the public in the due administration of justice. (Advocate General State of Bihar v. Madhya Pradesh Khair Industries; V. Satyanarayana Rao6). In order to sustain and maintain the sanctity and solemnity of proceedings in law courts it is necessary that parties should not make false or, knowingly, inaccurate statements or misrepresentation and/or should not conceal material facts with a design to gain some advantage or benefit at the hands of the Court where truth and justice are the solemn pursuits. If any party attempts to pollute such a place by recourse to misrepresentation, and conceals material facts, he does so at his own risk. Such a party must be ready to take the consequences that follow. There is a compelling need to take a serious view in such matters to ensure*



purity in the administration of justice. (Vijay Syal v. State of Punjab). As a petition containing misleading and inaccurate statements, if filed to achieve an ulterior purpose, amounts to an abuse of the process of the court, the litigant should not be dealt with lightly. A litigant is bound to make full and true disclosure of facts. (Manohar Lal v. Ugrasen; Tilokchand and Motichand v. H.B. Munshi). Whenever the court comes to the conclusion that its process is being abused, it would be justified in refusing to proceed further. This rule has been evolved out of the need for courts to deter a litigant from abusing its process by deceit. (Manohar Lal16; State of Haryana v. Karnal Distillery Co. Ltd.; Sabia Khan v. State of U.P.; Abdul Rahman v. Prasony Bai; S.J.S. Business Enterprises (P) Ltd. v. State of Bihar and Oswal Fats & Oils Ltd. v. Commr. (Admn.)). It is the duty of the High Court to ensure that its judicial process is not abused, and its order does not become an instrument or aid to overreach the adversary. (M.V. Venkataramana Bhat v. Returning Officer and Tahsildar). Every person invoking the jurisdiction of the Court must state the truth, be it in the pleadings, affidavits or evidence. The pleadings must set-forth sufficient factual details which inspire confidence and credibility. (A. Shanmugam v. Ariya Kshatriya Rajakula Vamsathu Madalaya Nand Havana Paripalanai Sangam Represented by its President). It is the duty of the Court, once false averment of facts are discovered, to take appropriate steps to ensure that no one derives any benefit or advantage by abusing the legal process. Fraudulent and dishonest litigants must be discouraged. (A. Shanmugam24). It is the bounden obligation of the Court to neutralize any unjust

NOTARY M. M. PABALE Mumbai Maharashtra Reg. No. 15220 Expiry Dt. 30-10-2024 GOVT. OF INDIA

and/or undeserved benefit or advantage obtained by abusing the judicial process. (A. Shanmugam24).

65. *Dishonesty should not be permitted to bear fruit and confer benefit to the person who has made a misrepresentation. (District Collector and Chairman, Vizianagaram Social Welfare Residential School Society, Vizianagaram v. M. Tripura Sundari Devi; Union of India v. M. Bhaskaran; Vice Chairman, Kendriya Vidyalaya Sangathan v. Girdharilal Yadav; State of Maharashtra v. Ravi Prakash Babulalsing Parmar; Himadri Chemicals Industries Ltd. v. Coal Tar Refining Company; Mohammed Ibrahim v. State of Bihar; and Meghmala v. G. Narasimha Reddy). A person, whose case is based on falsehood, can be summarily thrown out at any stage of the litigation. (S.P. Chengalvaraya Naidu (Dead) by LRs. v. Jagannath (Dead) by LRs.). Grave allegations are levelled against the appellants herein of having deliberately and consciously made false statements on oath, of having suppressed material facts, and to have misled the Company Court into passing an order appointing a provisional liquidator and, thereafter, into passing an order of winding up. These allegations, if true, would mean that the process of the Court has been abused. It is therefore expedient, in the interest of justice, that the matter is enquired into and action is taken by lodging a complaint before the Magistrate. Compounding offences, where litigants are alleged to have abused the process of Court, may not be justified. We find no merit in the submission of Sri. S. Ravi, Learned Senior Counsel, that the*

NOTARY
M. M. PASALE
Mumbai
Maharashtra
Reg. No. 15220
Expiry Dt.
30-10-2024
GOVT. OF INDIA

offences, alleged to have been committed by the appellants, should be compounded.

69. Viewed from any angle the order of the Learned Company Judge, in directing the Registrar (Judicial) to depute an officer, not below the rank of Assistant Registrar, to file a complaint under Section 340(1) Cr.P.C. read with Sections 191, 193 and 209 IPC against the appellants herein before a Magistrate of competent jurisdiction at Hyderabad, is in accordance with law and does not necessitate interference. We reiterate that the Magistrate, on receipt of the complaint, shall consider the same in accordance with law uninfluenced by any observations made either in this order or in the order under appeal. Both the appeals fail and are, accordingly, dismissed. The miscellaneous petitions pending, if any, shall also stand dismissed. No costs."

17. The rules made by the Respondent No.1 state authority are not with the approval of National Platform for Disaster Risk Reduction (NPDRR) as mandates in sub. rule (3).

17.1. That vide **Notice No. 47-31/2021 DM -III**, dated **05.07.2017**, sub **rule (3)** it is clarified that, the National Platform For Disaster Risk Reduction shall be the authority which will decide the extent and manner in which the Disaster Management Policy has been implemented by the Central & State Government.

Rule 3 reads thus;

3. The functions of the NPDRR shall be

(i) To review the progress made in the field of disaster management from time to time.

(ii) To appraise the extent and manner in which the Disaster Management Policy has been implemented by the Central and State Governments, and other concerned agencies, and to give appropriate advice in the matter.

(iii) To advise regarding coordination between the Central and State Governments/UT Administrations, State Governments, local Governments and civil society organizations for development of Disaster Risk Reduction.

(iv) To advise suo-motu or on a reference made by the Central Government or any State Government or a Union Territory Administration on any question pertaining to disaster management.

(v) To review the Disaster Management Policy."

17.2. The order dated **27.11.2021** or any order passed by the Respondent No. 1 nowhere mentions that they are acting as per the above rules and are acting as per the advice given by the NPDRR and therefore all the order are illegal and null & void.

18. The impugned order are vitiated as said orders/rules/regulations are not placed before the House of State Legislature nor it is approved by the both the House as mandated under section 78(3) of Disaster Management Act, 2005

18.1. Section 78 of the Disaster Management Act, 2005 reads thus;

"78. Power of State Government to make rules.— (1) The State Government may, by notification in the Official Gazette, make rules to carry out the provisions of this Act.

.....

1232

84

(3) Every rule made by the State Government under this Act shall be laid, as soon as may be after it is made, before each House of the State Legislature where it consists of two Houses, or where such Legislature consists of one House before that House."

19. Executive order cannot become the law. The liberty of citizen cannot be curtailed on the basis of orders passed by the authority. There is a need of creating a law by the legislation as per Article 19(6) of the Constitution of India as explained by the Hon'ble High Court in Re Dinthar Incident Vs. State of Mizoram and Others 2021 SCC OnLine Gau 1313.

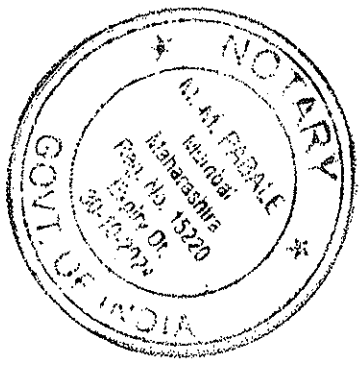
19.1 In **Re Dinthar Incident Vs. State of Mizoram and Others 2021 SCC OnLine Gau 1313,** it is ruled as under;

"17. With regard to the contention of the learned Additional Advocate General that the State Government can make restrictions curtailing the Fundamental Rights of the citizens under the Disaster Management Act, 2005 (hereinafter referred to as the "Act"), by way of the SOP, the same in our considered view is clearly not sustainable, as the said clauses in the SOP which are in issue in the present case cannot be said to be reasonable restrictions made in terms of Article 19(6). A restriction cannot be arbitrary or of a nature that goes beyond the requirement of the interest of the general public. Though no general pattern or a fixed principle can be laid down so as to be universal in application, as conditions may vary from case to case, keeping in view the prevailing conditions and surroundings

NOTARY
M. M. PABALE
Mumbai
Maharashtra
Reg. No. 15220
Expiry Dt.
30-10-2024
GOVT. OF INDIA

circumstances, the requirement of Article 19(6) of the Constitution is that the restriction has to be made in the form of a law and not by way of an executive instruction. The preamble of the Act clearly states that it is an Act to provide an effective management of the disasters and for matters connected therewith or incidental thereto. There is nothing discernible in the Act, to show that the said Act has been made for imposing any restriction on the exercise of the rights conferred by Article 19 of the Constitution. Further, the SOP dated 29.06.2021 is only an executive instructions allegedly made under Section 22(2)(h) & Section 24(1) of the Act and not a law. The provisions of Sections 22 & 24 only provides for the functions and powers of the State Executive Committee in the event of threatening disaster situation or disaster. It does not give any power to the State Executive Committee to issue executive instructions discriminating persons with regard to their right to liberty, livelihood and life and violating the fundamental rights of the citizens, which is protected by the Constitution.

19. *In view of the reasons stated above, we hold that the restrictions placed upon un-vaccinated individuals vis-à-vis vaccinated individuals in terms of Clause 5(2), 6(1), 6(5), Serial No. 31 & 42 of Annexure-3 of the SOP dated 29.06.2021 are arbitrary and not in consonance with the provisions of Article 14, 19 & 21 of the Constitution. The said impugned clauses are interfered with, to the extent that the allowances available and given to vaccinated persons in the above clauses shall also be made equally applicable to*



1234

un-vaccinated persons. The State respondents are accordingly directed to issue a corrigendum of the SOP dated 29.06.2021 at the earliest incorporating the above directions.

***20.** The Order dated 29.06.2021 issued by the Chief Secretary Mizoram with the enclosed SOP dated 29.06.2021, the letter dated 01.07.2021 issued by the Under Secretary to the Government of Mizoram, Disaster Management & Rehabilitation Department and the Notice dated 01.07.2021 issued by the Deputy Commissioner, Aizawl are made a part of the record and marked as Annexure-X, Y & Z respectively."*

20. Disaster Management Act, 2005, National & International Law applicable in India and our Constitution does not permit any discrimination between vaccinated and un-vaccinated.

20.1. The affidavit given on behalf of the Union of India before Supreme Court & Bombay High Court and also answer given by the Minister in Lok Sabha makes it clear that, any such discrimination is not permissible and no benefits and service can be attached to the vaccination status of a person.

20.2. That, recently on 28th November, 2021 in a Counter Affidavit is filed before Hon'ble Supreme Court by Dr. P.B.N. Prasad, working as **Joint Drugs Controller (India), Central Drugs Standard Control Organization,** Directorate General of Health Services, **Ministry of Health and Family Welfare, Government of India,** it is once again reiterated that vaccination is not linked to any benefits or services. The relevant paragraph reads as under;

M. M. PADALE
Mumbai
Maharashtra
Reg. No. 15220
Expiry Dt.
30-10-2024
GOVT. OF INDIA

> *"64. In so far as the Petitioner's submissions regarding Covid 19 vaccine being mandatory, **as per the Operational Guidelines document, COVID-19 vaccination is voluntary.** However, it is emphasised and encouraged that all individuals take vaccination for public health and in his/ her interest as well as public interest since in case of pandemic, an individual's ill health has a direct effect on the society. **Covid-19 vaccination is also not linked to any benefits or services.** Therefore, any submissions made by the Petitioner to the contrary, in so far as the Answering Respondents are concerned, is denied."*

20.3. That, in affidavit dated **8.10.2021** by Shri. Satyendra Singh, Under Secretary Health Ministry of India before Hon'ble Bombay high Court in **Writ Petition No. 1820 of 2021**, it is made clear that the COVID-19 vaccination is completely voluntary for all citizens of India and Ministry of Health and Family Welfare, Government of India has not formulated or suggested any policies for discrimination between citizens of India on the basis of their vaccination status. The relevant paras of the affidavit read as under;

> *"9. That, it is further humbly submitted that the directions and guidelines released by Government of India and Ministry of Health and family Welfare, do not entail compulsory or forcible vaccination against COVID-19 disease implying that **COVID-19 vaccination is completely voluntary for all citizens of India. Ministry of Health and Family Welfare, Government of India has not formulated or suggested any policies for discrimination between citizens of India on the basis of their vaccination status.***

NOTARY M. M. PABALE Mumbai Maharashtra Reg. No. 15220 Expiry Dt. 31-10-2024 GOVT. OF INDIA

10. That, it is duly advised, advertised and communicated by MoHFW through various print and social media platforms that all citizens should get vaccinated, but this in no way implies that any person can be forced to be vaccinated against her / his wishes.

11. That, as per the existing guidelines, there is no provisions for forcing any citizen to book appointment for Covid Vaccination on Co-WIN or visiting Covid Vaccination Centre for vaccination if a person above the age of 18 years visits a Covid Vaccination Centre by her / his choice for vaccination and asks for the same, it implies that she / he is voluntarily coming to the center to get the benefit of Covid Vaccination."

20.4. The reply given under RTI reply Central Government's dated **01.03.2021** which is at Pg No. 953 Para No.3.2 of Additional Affidavit is also sufficient to make clear the stand of Central Government.]

That in the reply under RTI **01.03.2021** given by the Health Ministry makes it abundantly clear that the various facilities such as train travels, salary etc. cannot be connected with the vaccination status of a person.

The Central Government's reply dated **01.03.2021** to an application under RTI is as under;

"RTI reply by Government of India's Health Ministry on 1.03.2021 to Shri. Anurag Sinha

प्रश्न १: कोरोना वैक्सीन लेना स्वैच्छिक है या अनिवार्य, जबरदस्ती?

NOTARY
M. M. PABALE
Mumbai
Maharashtra
Reg. No. 15220
Expiry Dt.
30-10-2024
GOVT. OF INDIA

उत्तर : *कोरोना वैक्सीन लेना स्वैच्छिक है।*

प्रश्न २ : क्या वैक्सीन नहीं लेने पर सारी सरकारी सुविधाए बंद कर दी जायगी, सरकारी योजना पेंशन ?

उत्तर *: आवेदन में लिखी बातें निराधार है। किसी भी सरकारी सुविधा, नागरिकता, नौकरी इत्यादि से वैक्सीन का कोई सम्बन्ध नहीं है।*

प्रश्न ३ : क्या वैक्सीन नहीं लेने पर नौकरी नहीं मिलेगा, ट्रेन, बस, मेट्रो में चढ़ने नहीं मिलेगी?

उत्तर *:आवेदन में लिखी बातें निराधार है। किसी भी सरकारी सुविधा, नागरिकता, नौकरी इत्यादि से वैक्सीन का कोई सम्बन्ध नहीं है।*

प्रश्न ४: यदि कोई IAS, IPS स्वास्थ्य या पुलिस कर्मचारी नागरिक को धमकी दे की वैक्सीन ले नही तो ये कर देगे तो नागरिक क्या कर सकती क्या कोर्ट जा सकते हैं?

उत्तर *: आवेदन में लिखी बातें निराधार है। किसी भी सरकारी सुविधा, नागरिकता, नौकरी इत्यादि से वैक्सीन का कोई सम्बन्ध नहीं है।*

प्रश्न ५: क्या वैक्सीन नहीं लेने पर स्कूलों, कॉलेज, विश्वविद्यालय, गैस कनेक्शन, पानी, बिजली कनेक्शन, राशन आदि के लिए क्या वैक्सीन नहीं मिलेगे ?

उत्तर *: आवेदन में लिखी बातें निराधार है। किसी भी सरकारी सुविधा, नागरिकता, नौकरी इत्यादि से वैक्सीन का कोई सम्बन्ध नहीं है।*

NOTARY
M. M. PARIKH
Mumbai
Maharashtra
Reg. No. 15220
Expiry Dt. 30-10-2024
GOVT. OF INDIA

प्रश्न ६ : क्या वैक्सीन नही लेने पर नौकरी से निकला जा सकता है वेतन रोका जा सकत है, निजी और सरकारी विभाग दोनों मे?

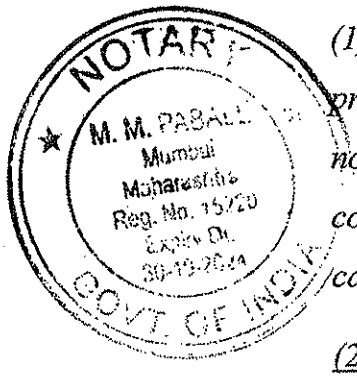
उत्तर : आवेदन में लिखी बातें निराधार है। किसी भी सरकारी सुविधा, नागरिकता, नौकरी इत्यादि से वैक्सीन का कोई सम्बन्ध नहीं है।"

20.5. That, as per **Section 76** of the Disaster Management Ac, 2005 the National Authority under Disaster Management Act has to take decision as per approvals of the Central Government. Therefore, stand taken by the Central Government is the stand of the National Authority under Disaster Management Act, 2005.

Section 76 of the Disaster Management Ac, 2005 reads thus;

76. Power to make regulations.—

(1) The National Institute of Disaster Management, with the previous approval of the Central Government may, by notification in the Official Gazette, make regulations consistent with this Act and the rules made thereunder to carry out the purposes of this Act. —



(1) The National Institute of Disaster Management, with the previous approval of the Central Government may, by notification in the Official Gazette, make regulations consistent with this Act and the rules made thereunder to carry out the purposes of this Act."

(2) In particular, and without prejudice to the generality of the foregoing power, such regulations may provide for all or any of the following matters, namely:—

(a) powers and functions to be exercised and discharged by the governing body;

(b) procedure to be followed by the governing body in exercise of the powers and discharge of its functions;

(c) any other matter for which under this Act provision may be made by the regulations.

20.6. That, as per **Section 38(i) & 39(a)** of the Disaster Management Act, the State authority has to act in line with the policy decision of the National Authority.

"38 State Government to take measures. —

*(i) Subject to the provisions of this Act, **each State Government shall take all measures specified in the guidelines laid down by the National Authority** and such further measures as it deems necessary or expedient, for the purpose of disaster management.*

39 Responsibilities of departments of the State Government. —It shall be the responsibility of every department of the Government of a State to—

*(a) take measures necessary for prevention of disasters, mitigation, preparedness and capacity-building **in accordance with the guidelines laid down by the National Authority and the State Authority;"***

20.7. That, the ex-officio Chairman of National Authority is Hon'ble Prime Minister of India **(Respondent No.9)** and therefore, there is no question of any different stand by the National Authority than that of the central government.

20.8. That, the power of National Authority under Disaster Management Act, 2005 is explained in following sections of the Act.

6 Powers and functions of National Authority. —

(1) Subject to the provisions of this Act, the National Authority shall have the responsibility for laying down the policies, plans and guidelines for disaster management for ensuring timely and effective response to disaster.

(2) Without prejudice to generality of the provisions contained in sub-section (1), the National Authority may—

(a) lay down policies on disaster management;

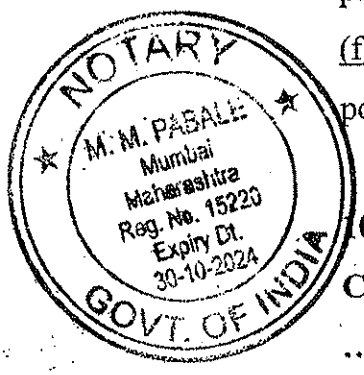
(b) approve the National Plan;

(c) approve plans prepared by the Ministries or Departments of the Government of India in accordance with the National Plan;

(d) lay down guidelines to be followed by the State Authorities in drawing up the State Plan;

(e) lay down guidelines to be followed by the different Ministries or Departments of the Government of India for the purpose of integrating the measures for prevention of disaster or the mitigation of its effects in their development plans and projects;

(f) coordinate the enforcement and implementation of the policy and plan for disaster management;



10 Powers and functions of National Executive Committee. —

.....

(e) provide necessary technical assistance to the State Governments and the State Authorities for preparing their disaster management plans in accordance with the guidelines laid down by the National Authority;

.....

(l) lay down guidelines for, or give directions to, the concerned Ministries or Departments of the Government of India, the State Governments and the State Authorities regarding measures to be taken by them in response to any threatening disaster situation or disaster;

.....

(o) provide necessary technical assistance or give advice to the State Authorities and District Authorities for carrying out their functions under this Act;

.....

20.9. Hence, it is crystal clear that, the state authorities cannot frame any policies against the National Authority. And National Authority has to work as per the policy of the Central Government.

20.10. Therefore, the impugned orders by the state authorities which are not in Conformity with the National Authority are itself illegal & vitiated.

20.11. That, recently i.e. on **1st December, 2021** the Central Government has given notice to state Government has given notice to state Government for keeping their rules uniform and in line with the Central Government the letter dated 1st December, 2021 sent by Rajesh Bhushan to Dr. Pradeep Vyas, Additional Secretary, Government of Maharashtra reads thus;

"This is with reference to the Govt. Of Maharashtra Order No. ***DMU/2020/CR.92/DisM1*** *dated 30th Nov. 2020, vide which the following restrictions have been imposed:*

> i. *Mandatory RTPCR testing of all international travellers at the Mumbai airport, irrespective of country of origin ii. Mandatory 14-day home quarantine for all international passengers, despite being tested RTPCR Negative upon arrival iii. Mandatory RTPCR test for passengers planning to undertake connecting flights after disembarking at Mumbai and further travel subject to a negative RTPCR result iv. Requirement of negative RTPCR test 48 hours prior to date of journey, for domestic passengers travelling from other States to Maharashtra*

2. This is in divergence with the SOPs & Guidelines issued by Ministry of Health & Family Welfare, Govt. of India. I would, therefore, urge you to align the Orders issued by the State with the Guidelines issued by the Ministry of Health & Family Welfare, Govt. Of India, so that uniform implementation of the guidelines may be ensured across all States/UTs. I would also advise that such modified orders of the State Government are given wide publicity to obviate any inconvenience to travelers."

NOTARY M. M. PABALE Mumbai Maharashtra Reg. No. 15220 Expiry Dt. 30-10-2024 GOVT. OF INDIA

(A copy of Central Government letter dated **1st December, 2021** sent by Mr. Rajesh Bhushan to Dr. Pradeep Vyas, Additional Secretary,

Government of Maharashtra marked and annexed herewith **Exhibit "RA-9") (Page No. 281)**

20.12. International Law Applicable in India: -

20.12.1. That Article 11 of the **Universal Declaration on Bioethics & Human Rights, 2005** also prohibits any discrimination.

Said Article reads thus;

*"**Article 11** – Non-discrimination and non-stigmatization No individual or group should be discriminated against or stigmatized on any grounds, in violation of human dignity, human rights and fundamental freedoms.*

***Article 8** – Respect for human vulnerability and personal integrity In applying and advancing scientific knowledge, medical practice and associated technologies, human vulnerability should be taken into account. Individuals and groups of special vulnerability should be protected and the personal integrity of such individuals respected."*

20.12.2. That **Article 7** of the International Covenant on Civil & Political Rights reads thus;

Article 7

No one shall be subjected to torture or to cruel, inhuman or degrading treatment or punishment. **In particular, no one shall be subjected without his free consent to medical or scientific experimentation.**

20.12.3. That, as per information given by the government of India in there reply date **9th June 2021** it is clear that the vaccines are

experimental and given permission under emergency situation for restricted use.

In RTI Application No. **CDSCO/R/X/21/00010** dated **9th June 2021** information given by Government of India reads thus;

> ***Question:***
> *Please provide copy, scientific proof, or evidence of covid-19 Vaccine is safe and effective.*
> ***Answer:***
> *Further, it is mentioned that as per the provisions of New Drugs and Clinical Trials Rules, 2019 and considering COVID pandemic, CDSCO in consultation with Subject Expert Committee (SEC) has approved three COVID-19 vaccines* ***for restricted use in emergency situation and the clinical trials are still ongoing for conclusion of results of complete safety, immunogenicity and efficacy.***

20.12.4. That Article 253 & 256 of Constitution of India reads thus;

> ***"Article 253 in The Constitution Of India***
>
> ***253.*** *Legislation for giving effect to international agreements Notwithstanding anything in the foregoing provisions of this Chapter, Parliament has power to make any law for the whole or any part of the territory of India for implementing any treaty, agreement or convention with any other country or countries or any decision made at any international conference, association or other body.*

NOTARY M. M. PABALE Mumbai Maharashtra Reg. No. 15220 Expiry Dt. 30-10-2024 GOVT. OF INDIA

20.12.5. Hon'ble Supreme Court in the case of **Gramophone Co. of India Ltd. v. Birendra Bahadur Pandey, (1984) 2 SCC 534,** a three judge bench of this Hon'ble Court held:

> *5. There can be no question that nations must march with the international community and the municipal law must respect rules of international law even as nations respect international opinion. The comity of nations requires that rules of international law may be accommodated in the municipal law even without express legislative sanction provided they do not run into conflict with Acts of Parliament. But when they do run into such conflict, the sovereignty and the integrity of the Republic and the supremacy of the constituted legislatures in making the laws may not be subjected to external rules except to the extent legitimately accepted by the constituted legislatures themselves. The doctrine of incorporation also recognises the position that the rules of international law are incorporated into national law and considered to be part of the national law, unless they are in conflict with an Act of Parliament. Comity of nations or no, municipal law must prevail in case of conflict. National courts cannot say yes if Parliament has said no to a principle of international law. National courts will endorse international law but not if it conflicts with national law. National courts being organs of the national State and not organs of international law must perforce apply national law if international law conflicts with it. But the courts are*



under an obligation within legitimate limits, to so interpret the municipal statute as to avoid confrontation with the comity of nations or the well established principles of international law. But if conflict is inevitable, the latter must yield.

6. The proposition has been well stated by Latham, C.J., in Politics v. Commonwealth [70 Comm LR 60]:

> ***"Every statute is to be interpreted and applied, as far as its language admits, as not to be inconsistent with the comity of nations or with the established rules of international law. It must be held that legislation otherwise within the power of the Commonwealth Parliament does not become invalid because it conflicts with a rule of international law, though every effort should be made to construe Commonwealth statutes so as to avoid breaches of international law and of international comity. The question, therefore, is not a question of the power of the Commonwealth Parliament to legislate in breach of international law, but is a question whether in fact it has done so."***

M. M. PABALE
Mumbai
Maharashtra
Reg. No. 15220
Expiry Dt.
30-10-2024
GOVT. OF INDIA

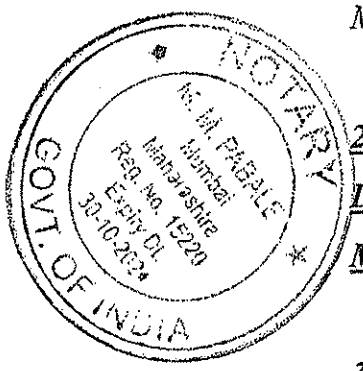
21. False & incorrect objection about non-joinder of parties:-

21.1. On the previous date i.e., on **15.12.2021** the Counsel for State of Maharashtra i.e. Respondent No.1 mislead the court that, the state Disaster Management authority is not made the party. The order passed by this Hon'ble Court reads as under;

"2. Mr. Anturkar, learned senior advocate is in the midst of his arguments. According to him, neither does the petitioners have locus standi to present writ petitions invoking the writ jurisdiction of this Court in public interest nor has the cause of action been spelt out therein. It is also urged by him that circulars/ notifications issued by the State Disaster Management Authority and the State Executive Committee, constituted in terms of the provisions of the Disaster Management Act, 2005, are under challenge ***in both the writ petitions without such Authority and/or Committee being impleaded as respondents in the writ petitions."***

21.2. The list of Respondents as mentioned in the petition are as under;

1. The State of Maharashtra
Through Chief Secreatary
The Government of Maharashtra
Mantralaya, Mumbai – 4000 23.



2. Under Secretary
Disaster Management Unit,
Mantralaya, Mumbai - 4000 23.

3. Shri. Iqbal Chahal
Municipal Commissioner,
M.C.G.M. Annex Building,
Mahapalika Marg No. 1,
Fort, Mumbai – 4000 01.

4. Shri. Shrirang Gholap
Under Secretary
Disaster Management Unit,
Government of Maharashtra.

5. Shri. Sitaram Kunte
Chief Secretary, Maharashtra State.

21.3. This proves that the counsel for Respondent No. 1 made false & misleading submission before the Court.

22. Reliance on the judgement passed by the Gujarat High Court is in Contempt of Hon'ble Supreme Court judgement in Pradip J. Mehta v. Commissioner of Income-tax, Ahmedabad (2008)14 SCC 283 & Dwarikesh Sugar Industries Ltd. v. Prem Heavy Engineering Works (P) Ltd., (1997) 6 SCC 450.

22.1. That, the Respondent No.1 in his affidavit dated **21.12.2021** in **para 31** relied on the judgement dated **17.12.2021** passed in the case of **Nishant Prajapati Vs. Union of India in writ number 142 of 2021.**

22.2. Said judgement not a precedent and also illegal and per incuriam as it is passed in utter disregard and defince of the law laid down by Hon'ble Supreme Court in the case of:

i) Pradip J. Mehta v. Commissioner of Income-tax, Ahmedabad (2008)14 SCC 283 .

ii) Dwarikesh Sugar Industries Ltd. v. Prem Heavy Engineering Works (P) Ltd., (1997) 6 SCC 450.

NOTARY M. M. PABALE Mumbai Maharashtra Reg. No. 15220 Expiry Dt. 30-10-2024 GOVT. OF INDIA

22.3. That, the said judgement is bad in law and also based on incorrect facts and therefore is a nullity.

22.4. That, in the said judgement, the Ld. Gujarat High Court did not appreciated the ratio laid down in **Registrar General, High Court of Meghalaya Vs. State of Meghalaya 2021 SCC OnLine Megh 130, Re: Dinthar Incident Vs. State of Mizoram and Others 2021 SCC OnLine Gau 1313.**

Secondly, the Ld. Bench even did not referred the landmark judgment of Hon'ble Supreme Court in the case of **Common Cause Vs. Union of India (2018) 5 SCC 1.**

22.5. Hence, the finding of the judgment passed by the Ld. Bench of Gujrat High Court are against the law laid down in **Pradip J. Mehta v. Commissioner of Income-Tax, Ahmedabad (2008)14 SCC 283,** where it is ruled as under;

> ***"Precedent - View taken by other High Court should be referred and appreciated***
>
> *23. Although, the judgments referred to above were cited at the Bar in the High Court, which were taken note of by the learned Judges of the Bench of the High Court,* ***but without either recording its agreement or dissent, it answered the two questions referred to it in favour of the Revenue****. Judicial decorum, propriety and discipline required that the High Court should, especially in the event of its contra view or dissent, have discussed the aforesaid judgments of the different High Courts and recorded its own reasons for its contra view. We quite see the fact that the*

NOTARY GOVT. OF INDIA

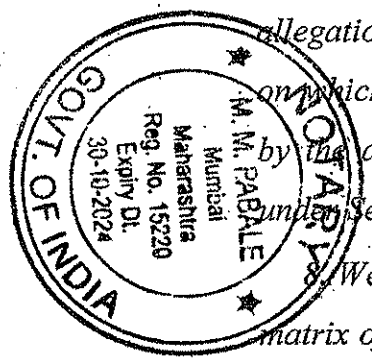
1250

judgments given by a High Court are not binding on the other High Court(s), but all the same, they have persuasive value. Another High Court would be within its right to differ with the view taken by the other High Courts but, in all fairness, ***the High Court should record its dissent with reasons therefor.*** *The judgment of the other High Courts, though not binding, have persuasive value which should be taken note of and dissented from by recording its own reasons.*

22.6. Similar view is taken by the Hon'ble Supreme Court in a recent judgement in the case of **Lajpat v. State of U.P., (2019) 2 SCC 432** where it is ruled as under;

"7. On perusal of the impugned order, we find that ***the Single Judge has only quoted the principles of law laid down by this Court in several decisions*** *relating to powers of the High Court to interfere in the cases filed under Section 482 of the Code from para 2 to the concluding paragraph* ***but has failed to even refer to the facts of the case with a view to appreciate the factual controversy****, such as, what is the nature of the complaint/FIR filed against the appellants, the allegations on which it is filed, who filed it, the grounds on which the complaint/FIR/proceedings are challenged by the appellants, why such grounds are not made out under Section 482 of the Code, etc.*

8. We are, therefore, at a loss to know the factual matrix of the case much less to appreciate except to read



the legal principles laid down by this Court in several decisions.

9. *In our view, the Single Judge ought to have first set out the brief facts of the case with a view to understand the factual matrix of the case and then examined the challenge made to the proceedings in the light of the principles of law laid down by this Court and then recorded his finding as to on what basis and reasons, a case is made out for any interference or not.*

10. *In our view, this is the least that is required in every order to support the conclusion reached for disposal of the case. It enables the higher court to examine the question as to whether the reasoning given by the court below is factually and legally sustainable.*



11. *We find that the aforementioned exercise was not done by the High Court while passing the impugned order [Lajpat v. State of U.P., 2018 SCC OnLine All 3421] and hence interference is called for.*

12. *We, therefore, find ourselves unable to concur with such disposal of the application by the High Court and feel inclined to set aside the impugned order [Lajpat v. State of U.P., 2018 SCC OnLine All 3421] and remand the case to the High Court (Single Judge) with a request to decide the application afresh on merits in accordance with law keeping in view the aforementioned observations after issuing notice to Respondents 1 and 2."*

22.7. Further in the case of **Niharika infrastructure Vs State of Maharashtra 2021 SCC OnLine SC 315** and in **Rajbir Singh Dalal (Dr.) v. Chaudhari Devi Lal University, (2008) 9 SCC 284,** Hon'ble Supreme Court had made it clear that, such judgement cannot be called as precedents **when there is no intelligent reason are given.**

22.8. In **Neeharika Infrastructure Pvt. Ltd. Vs. State of Maharashtra 2021 SCC OnLine SC 315,** it is ruled as under;

> *"76. While considering the importance of the reasons to be given during the decision-making process, in the case of Kranti Associates (P) Ltd. v. Masood Ahmed, (2010) 9 SCC 496, in paragraph 47, this Court has summarised as under:*
>
> *"47. Summarising the above discussion, this Court holds:*
>
> ....
>
> ***(l) Reasons in support of decisions must be cogent, clear and succinct. A pretence of reasons or "rubber-stamp reasons" is not to be equated with a valid decision-making process.***
>
> ....
>
> ***(n)** Since the requirement to record reasons emanates from the broad doctrine of fairness in decision-making, the said requirement is now virtually a component of human rights and was considered part of Strasbourg Jurisprudence. See Ruiz Torija v. Spain [(1994) 19 EHRR 553] EHRR, at 562 para 29 and Anya v. University of Oxford [2001 EWCA Civ 405], wherein the Court referred to Article 6 of the European Convention of Human Rights which requires"*

22.9. Hon'ble Supreme Court in the case of **Rajbir Singh Dalal (Dr.) v. Chaudhari Devi Lal University, (2008) 9 SCC 284** it is ruled as under;

> *"34. The decision of a court is a precedent if it lays down some principle of law supported by reasons. Mere casual observations or directions without laying down any principle of law and without giving reasons does not amount to a precedent.*
>
> *35. In State of Punjab v. Baldev Singh [(1999) 6 SCC 172 : 1999 SCC (Cri) 1080] a Constitution Bench of this Court observed (vide SCC para 43) that a decision is an authority for what it decides (i.e. the principle of law it lays down), and not that everything said therein constitutes a precedent.*
>
> *41. In view of the above, we are of the opinion that the decision of this Court in Bhanu Prasad Panda (Dr.) case [(2001) 8 SCC 532 : 2002 SCC (L&S) 14] cannot be read as a Euclid's formula or treated as a precedent, since it has not given any reason for holding that Political Science and Public Administration are distinct and separate subjects, and since the aforesaid decision was given on a concession."*

22.10. That, in the order dated **17.12.2021** following incorrect observations are made.

> *"10. We take this opportunity of making a fervent appeal to all the citizens of the State of Gujarat to get themselves vaccinated, if not yet till this date. It is very essential to get vaccinated with two doses as prescribed to protect themselves from the threat of Covid-19, more particularly*

the new variant, namely, Omicron. It's time for people to take the third dose of booster."

22.11. That, above observations are not only incorrect and without jurisdiction but also have serious impact on the health of the citizen.

22.12. That, the Government data and more particularly the recent data makes it clear that the vaccine is no protection from Covid – 19. The person getting vaccines can get infection, can spread infection and can die with Covid - 19. The recent data also proved that the vaccine failed against omicron and the person getting booster doses are also infected with omicron.

(i) VACCINE FAILED AGAINST OMICRON

82.5% Omicron patients in Maharashtra are fully vaccinated.

One is having booster dose.

TNN | Dec 18, 2021,04.37 AM IST

Publisher:- TIMES OF INDIA

MUMBAI: Eight new cases of the Omicron variant were detected in the state on Friday, taking the tally in Maharashtra to 40.Six were from Pune, and one each from Mumbai and Kalyan-Dombivli. All of them had been fully vaccinated, and one had even got a booster, said health authorities. Of the total 40 infected, 33 were vaccinated.

Link:-

https://timesofindia.indiatimes.com/city/mumbai/mumbai-8-more-omicron-cases-found-in-state-6-in-rural-pune-2-in-mmr/articleshow/88348393.cms

22.13. The Ld. Bench also ignored the Natural Immunity which is the major factor in protecting the person. Therefore, the order based on incorrect facts is nullity and cannot be treated as a precedent.

22.14. That it is settled law that the order based on incorrect facts is nullity and in view of section 44 of the Evidence Act its validity can be challenged where it is relied. **(Union of India Vs Ramesh Gandhi (2012) 1 SCC 476, A.V. PapayyaSastry Vs. Govt of A.P. and others, (2007) 4 SCC 221, State Vs Walchand 1996 Cri.L.J. 1102)**

23. Unauthorized access of personal data of the Petitioner is an offence on the part of the Respondent No.1. Unlawful and irrelevant objection raised in contempt of the order dated 15.12.2021 passed by this Hon'ble Court.

23.1. That, the Respondent No.1 in **Para 4** of the reply affidavit dated **21.12.2021** have mentioned that the petitioner is fully vaccinated and therefore he cannot challenge the unlawful mandates.

23.2. At the outset it is submitted that the Respondent No.1. have unlawfully accessed the private data of the Petitioner without his permission. This is also an offence under Information & Technology Act and other provisions which protect the personal privacy and medical privacy of the citizen.

23.3. Section 72 of the information technology Act 2000, reads as under;

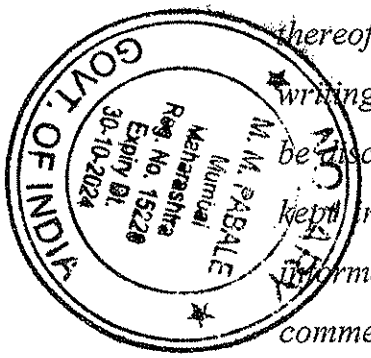
> *"72. Penalty for Breach of confidentiality and privacy.–Save as otherwise provided in this Act or any other law for the time being in force, if any person who, in pursuance of any of the powers conferred under this Act, rules or regulations made thereunder, has secured access to any electronic record, book, register, correspondence, information,*



document or other material without the consent of the person concerned discloses such electronic record, book, register, correspondence, information, document or other material to any other person shall be punished with imprisonment for a term which may extend to two years, or with fine which may extend to one lakh rupees, or with both."

23.4. Section 11 of the Right to information Act 2005, reads as under;

"11. (1) Where a Central Public Information Officer or a State Public Information Officer, as the case may be, intends to disclose ***any information or record, or part thereof*** *on a request made under this Act, which relates to or has been supplied by a third party* ***and has been treated as confidential by that third party****, the Central Public Information Officer or State Public Information Officer, as the case may be, shall, within five days from the receipt of the request, give a written notice to such third party of the request and of the fact that the Central Public Information Officer or State Public Information Officer, as the case may be, intends to disclose the information or record, or part thereof, and invite the third party to make a submission in writing or orally, regarding whether the information should be disclosed, and such submission of the third party shall be kept in view while taking a decision about disclosure of information: Provided that except in the case of trade or commercial secrets protected by law, disclosure may be allowed if the public interest in disclosure outweighs in*



importance any possible harm or injury to the interests of such third party.

(2) Where a notice is served by the Central Public Information Officer or State Public Information Officer, as the case may be, under sub-section (1) to a third party in respect of any information or record or part thereof, the third party shall, within ten days from the date of receipt of such notice, be given the opportunity to make representation against the proposed disclosure.

(3) Notwithstanding anything contained in section 7, the Central Public Information Officer or State Public Information Officer, as the case may be, shall, within forty days after receipt of the request under section 6, if the third party has been given an opportunity to make representation under sub-section (2), make a decision as to whether or not to disclose the information or record or part thereof and give in writing the notice of his decision to the third party."

23.5. Furthermore, the reason for petitioner being compelled to take vaccine is attributable to Respondent No.1 only. That, the petition was filed on **24.09.2021** and due to restriction on entry to Local Train, malls, offices and other places, the Petitioner was compelled to take Vaccines taken thereafter, as immediate stay was not granted to the said mandates.

23.6. There are crores of such cases. A recent news article also proves it.

Link: https://indianexpress.com/article/cities/mumbai/maharashtra-lakh-people-took-jab-no-vaccine-no-entry-order-beed-7646251/



(A copy of article published titled as **"Maharashtra: Over 1.6 lakh people took jab after 'No vaccine, no entry' order in Beed"** dated 28 November, 2021 marked and annexed herewith **Exhibit "RA-10") (Page No. 282)**

23.7. Hence, the vaccination was not wilful but forceful. In fact, petitioner is suffering with serious health problems due to vaccination and for that he is going to file a separate writ asking compensation to him to be paid by Respondent No 1.

23.8. Hon'ble High Court in **Registrar General, High Court of Meghalaya Vs. State of Meghalaya 2021 SCC OnLine Megh 130**, it is ruled as under;

> "……
>
> ***Thus, by use of force or through deception if an unwilling capable adult is made to have the flu vaccine would be considered both a crime and tort or civil wrong, as was ruled in Airedale NHS Trust v Bland reported at 1993 AC 789 = (1993) 2 WLR 316 = (1993) 1 All ER 821, around thirty years (30) ago. Thus, coercive element of vaccination has, since the early phases of the initiation of vaccination as a preventive measure against several diseases, have been time and again not only discouraged but also consistently ruled against by the Courts for over more than a century.***
>
> *In this context, around one hundred and seven (107) years ago, in Schloendroff v Society of New York Hospitals reported at (1914) 211 NY 125 = 105 NE 92; 1914 NY Justice Cardozo ruled that „every human being of adult*

years and sound mind has a right to determine what shall be done with their body".

This finds mention in decisions of the European Commission and Court of Human Rights [X vs. Netherlands of 1978 (decision rendered on 4th December, 1978); X vs. Austria of 1979 (decision rendered on 13th December, 1979)] which has become truer in the present times across the world than ever before. Compulsorily administration of a vaccine without hampering one"s right to life and liberty based on informed choice and informed consent is one thing. However, if any compulsory vaccination drive is coercive by its very nature and spirit, it assumes a different proportion and character.

However, vaccination by force or being made mandatory by adopting coercive methods, vitiates the very fundamental purpose of the welfare attached to it."

23.9. That, Hon'ble Supreme Court in the case of **Noida Entrepreneurs Association Vs. NOIDA and Ors. (2011) 6 SCC 508,** had ruled that, whenever a thing is prohibited, it is prohibited whether done directly or indirectly. Hence indirect mandates of the vaccine is not permissible. It is ruled as under;

*"**25.** It is a settled proposition of law that whatever is prohibited by law to be done, cannot legally be affected by an indirect and circuitous contrivance on the principle of quando aliquid prohibetur, prohibetur at omne per quod devenitur ad illud, which **means "whenever a thing is***

prohibited, it is prohibited whether done directly or indirectly". *(See Swantraj v. State of Maharashtra [(1975) 3 SCC 322 : 1974 SCC (Cri) 930 : AIR 1974 SC 517] , CCE v. Acer India Ltd. [(2004) 8 SCC 173] and Sant Lal Gupta v. Modern Coop. Group Housing Society Ltd. [(2010) 13 SCC 336 : (2010) 4 SCC (Civ) 904 : JT (2010) 11 SC 273])*

26. *In Jagir Singh v. Ranbir Singh [(1979) 1 SCC 560 : 1979 SCC (Cri) 348 : AIR 1979 SC 381] this Court has observed that an authority cannot be permitted to evade a law by "shift or contrivance". While deciding the said case, the Court placed reliance on the judgment in Fox v. Bishop of Chester [(1824) 2 B&C 635 : 107 ER 520] , wherein it has been observed as under: (Jagir Singh case [(1979) 1 SCC 560 : 1979 SCC (Cri) 348 : AIR 1979 SC 381] , SCC p. 565, para 5)*

> *"5. ... 'To carry out effectually the object of a statute, it must be so construed as to defeat all attempts to do, or avoid doing, in an indirect or circuitous manner that which it has prohibited or enjoined.' [**Ed.**: As observed in Maxwell on the Interpretation of Statutes, 11th Edn., p. 109. See SCC p. 565, para 5 of Jagir Singh case, (1979) 1 SCC 560.]"*

23.10. ~~That~~, as per **Article 51(A)** of the Constitution of India it is constitutional duty of the Petitioner to raise voice against any malafide acts of the state authority which is causing loss of life, liberty and money of the citizen.

23.11. That, Hon'ble Supreme Court in **Manohar Lal vs Vinesh Anand, (2001) 5 SCC 407** has ruled that the criminal law can be set in motion by any person. The status of a person either being vaccinated or unvaccinated has no relation with the right to seek justice and to challenge the unlawful orders.

> *"Before adverting to the matter in issue and the rival contentions advanced one redeeming feature ought to be noticed here pertain to Criminal jurisprudence: **To pursue an offender in the event of commission of an offence, is to sub-serve a social need Society cannot afford to have a criminal escape his liability, since that would bring about a state of social pollution, which is neither desired nor warranted and this is irrespective of the concept of locus the doctrine of locus-standi is totally foreign to criminal jurisprudence. This observation of ours however obtains support from the decision of this Court in AR Antulay v. Ramdas Sriniwas Nayak & Anr. : 1984 (2) SCC 500**."*

23.12. Even otherwise, this Hon'ble Court has already made it clear in its order dated **15.12.2021** that the issue is in larger public interest & the Court will take suo-moto cognizance even if there is any technical objection about the maintainability of the petition.

Hence, the act of raising such objection again in reply affidavit dated **21.12.2021** is in Contempt of the order dated **15.12.2021**

24. Act of Respondent No. 1 Chief Secretary is not protected by the element of good faith but actuated with legal malice and in bad faith:

24.1. Section 52 of the IPC reads thus;

"Good faith.—Nothing is said to be done or believed in "good faith" which is done or believed without due care and attention."

24.2. In **Express Newspapers (P) Ltd. v. Union of India, (1986) 1 SCC 133** it is ruled as under;

*"**119.** Fraud on power voids the order if it is not exercised bona fide for the end design. There is a distinction between exercise of power in good faith and misuse in bad faith. The former arises when an authority misuses its power in breach of law, say, by taking into account bona fide, and with best of intentions, some extraneous matters or by ignoring relevant matters. That would render the impugned act or order ultra vires. It would be a case of fraud on powers. The misuse in bad faith arises when the power is exercised for an improper motive, say, to satisfy a private or personal grudge or for wreaking vengeance of a Minister as in S. Pratap Singh v. State of Punjab [AIR 1964 SC 72 : (1964) 4 SCR 733] . A power is exercised maliciously if its repository is motivated by personal animosity towards those who are directly affected by its exercise. Use of a power for an "alien" purpose other than the one for which the power is conferred is mala fide use of that power. Same is the position when an order is made for a purpose other than that which finds place in the order. The ulterior or alien purpose clearly speaks of the misuse of the power and it was observed as early as in 1904 by Lord Lindley in General Assembly of Free Church of Scotland v. Overtown [LR 1904 AC 515] "that there is a condition implied in this as well as*

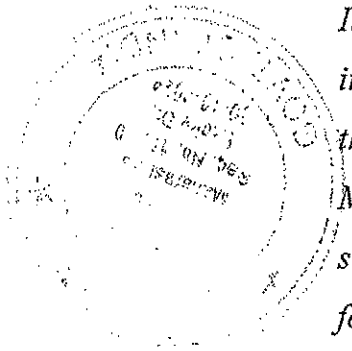
in other instruments which create powers, namely, that the powers shall be used bona fide for the purpose for which they are conferred". It was said by Warrington, C.J. in Short v. Poole Corpn. [LR 1926 ChD 66] that:

"No public body can be regarded as having statutory authority to act in bad faith or from corrupt motives, and any action purporting to be of that body, but proved to be committed in bad faith or from corrupt motives, would certainly be held to be inoperative."

In Lazarus Estates Ltd. v. Beasley [(1956) 1 QB 702, 712-13] Lord Denning, L.J. said:

> *"No judgment of a court, no order of a Minister, can be allowed to stand if it has been obtained by fraud. Fraud unravels everything."*

24.3. In **Noor Mohamed @ Mohd. Shah R. Patel & Ors. Vs. Nadirshah Ismailshah Patel & Anr., 2004 ALL MR (CRI.) 42 ,** it was held that;



It has to be kept in mind that nothing can be said to be done in good faith which is not done with due care and caution. If these ingredients are indicated by the complaint, the Magistrate is obliged to take the cognizance of the complaint so presented before him unless there are the other grounds for acting otherwise which has to be justified by reasons recorded in writing.

24.4. In **Brijendra Singh v. State of U.P. and Ors., AIR 1981 SC 636,** this Court while dealing with the issue held:

"..The expression has several shades of meanings. In the popular sense, the phrase 'in good faith' simply means

"honestly, without fraud, collusion, or deceit; really, actually, without pretence and without intent to assist or act in furtherance of a fraudulent or otherwise unlawful scheme". (See Words and Phrases, Permanent Edition, Vol. 18A, page 91). Although the meaning of "good faith" may vary in the context of different statutes, subjects and situations, honest intent free from taint of fraud or fraudulent design, is a constant element of its connotation. Even so, the quality and quantity of the honesty requisite for constituting 'good faith' is conditioned by the context and object of the statute in which this term is employed. It is a cardinal canon of construction that an expression which has no uniform, precisely fixed meaning, takes its colour, light and content from the context."



45. For the aforesaid qualities attached to a duty one can attempt to decipher it from a private act which can be secret or mysterious. An authorised act or duty is official and is in connection with authority. Thus, it cannot afford to be something hidden or non-transparent unless such a duty is protected under some law like the Official Secrets Act."

24.5. <u>Legal Malice</u>:

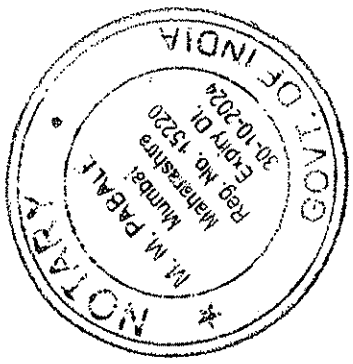
24.5.1. In **<u>Selvi J. Jayalalithaa Vs. State (2014) 2 SCC 401</u>,** it is ruled as under;

"26. <u>In Ravi Yashwant Bhoir v. District Collector, Raigad & Ors.</u>, AIR 2012 SC 1339, while dealing with the issue, this Court held:

*"37..... Legal malice" or "malice in law" means something done without lawful excuse. It is a deliberate act in disregard to the rights of others. It is an act which is taken with an oblique or indirect object. It is an act done wrongfully and wilfully without reasonable or probable cause, and not necessarily an act done from ill-feeling and spite. Mala fide exercise of power does not imply any moral turpitude. It means exercise of statutory power for "purposes foreign to those for which it is in law intended." It means conscious violation of the law to the prejudice of another, a depraved inclination on the part of the authority to disregard the rights of others, where intent is manifested by its injurious acts. Passing an order for unauthorized purpose constitutes malice in law." **(See also: Kalabharati Advertising v. Hemant Vimalnath Narichania & Ors., AIR 2010 SC 3745).''***

24.5.2. In the case of **Kalabharati advertising Vs. Hemant Vimalnath Narichania & Ors. (2010) 9 SCC 437**, it is ruled as under;

25. The State is under obligation to act fairly without ill will or malice— in fact or in law. "Legal malice" or "malice in law" means something done without lawful excuse. It is an act done wrongfully and wilfully without reasonable or probable cause, and not necessarily an act done from ill feeling and spite. It is a deliberate act in disregard to the rights of others. Where malice is attributed to the State, it can never be a case of personal ill will or spite on the part of



the State. It is an act which is taken with an oblique or indirect object. It means exercise of statutory power for "purposes foreign to those for which it is in law intended". It means conscious violation of the law to the prejudice of another, a depraved inclination on the part of the authority to disregard the rights of others, which intent is manifested by its injurious acts. (Vide ADM, Jabalpur v. Shivakant Shukla [(1976) 2 SCC 521 : AIR 1976 SC 1207] , S.R. Venkataraman v. Union of India [(1979) 2 SCC 491 : 1979 SCC (L&S) 216 : AIR 1979 SC 49] , State of A.P. v. Goverdhanlal Pitti [(2003) 4 SCC 739 : AIR 2003 SC 1941] , BPL Ltd. v. S.P. Gururaja [(2003) 8 SCC 567] and W.B. SEB v. Dilip Kumar Ray [(2007) 14 SCC 568 : (2009) 1 SCC (L&S) 860] .)

***26.** Passing an order for an unauthorised purpose constitutes malice in law. (Vide Punjab SEB Ltd. v. Zora Singh [(2005) 6 SCC 776] and Union of India v. V. Ramakrishnan [(2005) 8 SCC 394 : 2005 SCC (L&S) 1150] .)*

24.5.3. In the case of **West Bengal State Electricity Board Vs, Dilip Kumar Ray (2007) 14 SCC 568**; it is ruled as under;

" Malice in fact.—'Malice in fact' means express malice. Malice in fact or actual malice, relates to the actual state or condition of the mind of the person who did the act.

Malice in fact is where the malice is not established by legal presumption or proof of certain facts, but is to be found from the evidence in the case.

Malice in fact implies a desire or intention to injure, while malice in law is not necessarily inconsistent with an honest purpose.

Malice in law —'Malice in law' means implied malice.

'Malice in law' simply means a depraved inclination on the part of a person to disregard the rights of others, which intent is manifested by his injurious acts.

19. *"[Malice in law.] Malice in law is, however, quite different. Viscount Haldane described it as follows in Shearer v. Shields [1914 AC 808 : 83 LJPC 216 : 111 LT 297 (HL)] :*

'A person who inflicts an injury upon another person in contravention of the law is not allowed to say that he did so with an innocent mind; he is taken to know the law, and he must act within the law. He may, therefore, be guilty of malice in law, although, so far the state of his mind is concerned, he acts ignorantly, and in that sense innocently.'

Thus malice in its legal sense means malice such as may be assumed from the doing of a wrongful act intentionally but without just cause or excuse, or for want of reasonable or probable cause." (See S.R. Venkataraman v. Union of India [(1979) 2 SCC 491 : 1979 SCC (L&S) 216 : AIR 1979 SC 49] , SCC p. 494, para 5.)

20. *"21. [Malice per common law.] Malice in common law or acceptance means ill will against a person, but in the legal sense it means a wrongful act done intentionally without just cause or excuse." (See Chairman and MD, BPL*

1268

Ltd. v. S.P. Gururaja[(2003) 8 SCC 567 : JT 2003 Supp (2) SC 515] , SCC p. 580, para 21.)"

25. Omission to prevent illegality makes the Respondent No.1 Chief Secretary liable for action under section 218,201,202 etc. of IPC.

25.1. The subordinate officers of Respondent No.1 are bringing such mandates by stopping the salary of the employees. Not allowing people to get the Petrol, Rations, Cooking Gas Cylenders etc.,. The concerned officials and more particularly the District Collector of Aurangabad are indulged in such activities. But Respondent No. 1 is not only keeping silence but also promoting their acts which itself makes them liable for the prosecution for act of omission or for an act of abetment.

25.2. Hon'ble Supreme court in the case of **State of Odisha Vs. Partima Mohanty 2021 SCC OnLine SC 1222**, the public servant more particularly from the office of Health Ministry if failed to take action as expected then he/she will be liable for prosecution. Under section **218, 201, 202, 120(B), 34, 109 etc. of Indian Penal Code.** It is ruled that;

"20. It is further observed after referring to the decision of this Court in the case of Common Cause, A Registered Society (supra) that ***if a public servant abuses his office whether by his act of omission or commission, and the consequence of that is injury to an individual or loss of public property, an action may be maintained against such public servant.*** *It is further observed that no public servant can arrogate to himself powers in a manner which is arbitrary. In this regard we wish to recall the observations of this Court as under:*

"The concept of public accountability and performance of functions takes in its ambit, proper and timely action in accordance with law. Public duty and public obligation both are essentials of good administration whether by the State or its instrumentalities." [See Delhi Airtech Services (P) Ltd. v. State of U.P., (2011) 9 SCC 354]

"The higher the public office held by a person the greater is the demand for rectitude on his part."[See Charanjit Lamba v. Army Southern Command, (2010) 11 SCC 314]

"The holder of every public office holds a trust for public good and therefore his actions should all be above board." [See Padma v. Hiralal Motilal Desarda, (2002) 7 SCC 564]

"Every holder of a public office by virtue of which he acts on behalf of the State or public body is ultimately accountable to the people in whom the sovereignty vests. As such, all powers so vested in him are meant to be exercised for public good and promoting the public interest. This is equally true of all actions even in the field of contract. Thus, every holder of a public office is a trustee whose highest duty is to the people of the country and, therefore, every act of the holder of a public office, irrespective of the label classifying that act, is in discharge of public duty meant ultimately for public good." [See Shrilekha Vidyarthi (Kumari) v. State of U.P., (1991) 1 SCC 212]

1270

"Public authorities should realise that in an era of transparency, previous practices of unwarranted secrecy have no longer a place. Accountability and prevention of corruption is possible only through transparency." [See ICAI v. Shaunak H. Satya, (2011) 8 SCC 781]"

25.3. In **Regina vs. Dytham [1979] Q.B. 722**, it is ruled as under:

" Failure of Duties - Law Enforcement-Misconduct of officer of justice-Constable witnessing assault wilfully omitting to preserve peace or protect victim or arrest assailants - Wilful neglect without reasonable excuse of justification- Guilty Police officer sentenced to fine of £ 150 or three months imprisonment. He was also directed to pay £ 150 towards legal aid cost of his defence.

Ninthly, the only authority against the appellant's eighth submission is Reg. v. Wyat, 1 Salk. 380, which is distinguishable and need not be followed. Since the Act of 1964 provides a code of conduct, it is unnecessary to go back to ancient authority. A constable is not to be distinguished from any other public servant.

So also in Reg. v. Wyat (1705) 1 Salk. 380 it was held that "where an officer" (in that case a constable) "neglects a duty incumbent on him, either by common law or statute, he is for his default indictable." Counsel for the appellant contended that this was too

wide a statement of principle since it omitted any reference to corruption or fraud; but in Stephen's Digest of the Criminal Law , 9th ed. (1950), p. 114, art. 145 are to be found these words:

"Every public officer commits a misdemeanour who wilfully neglects to perform any duty which he is bound either by common law or by statute to perform provided that the discharge of such duty is not attended with greater danger than a man of ordinary firmness and activity may be expected to encounter."

In the present case it was not suggested that the appellant could not have summoned or sought assistance to help the victim or to arrest his assailants. The charge as framed left this answer open to him. Not surprisingly he did not seek to avail himself of it, for the facts spoke strongly against any such answer. The allegation made was not of mere non-feasance but of deliberate failure and wilful neglect.

This involves an element of culpability which is not restricted to corruption or dishonesty but which must be of such a degree that the misconduct impugned is calculated to injure the public interest so as to call for condemnation and punishment. Whether such a situation is revealed by the evidence is a matter that a jury has to decide. It puts no heavier burden upon them than when in more familiar contexts they are called upon to consider whether driving is dangerous

or a publication is obscene or a place of public resort is a disorderly house: see Reg. v. Quinn [1962] 2 Q.B. 245.

The judge's ruling was correct. The appeal is dismissed.

2. In Mr. Colin Adesokan vs. Sainsbury Supermarkets Ltd [2017] EWCA Civ 22, it is ruled as under ;

"25. However, I have come to the view that this was a conclusion open to the judge in the particular circumstances of this case. In my view the critical feature justifying this conclusion is that the appellant, as Regional Manager, was responsible for ensuring the successful implementation of the TP in his region. He was not the person who would carry out the exercise – that would have been the responsibility of Mr Briner - but once it became known to him that the integrity of the process was being undermined or at least was at risk of being undermined as a result of the email, it was his duty to ensure that this was remedied. Given the critical role which TP played in the culture of Sainsbury's, he had to correct the message sent by Mr Briner in the email, or at least take steps to ensure that this was done. The step he did take, requiring Mr Briner to clarify the situation, was not enough, or at least it was plainly insufficient once he knew that this order had been ignored and thereafter he did nothing further about it.



Section 218, 201,202 of IPC reads thus;

218. Public servant framing incorrect record or writing with intent to save person from punishment or property from forfeiture.—*Whoever, being a public servant, and being as such public servant, charged with the preparation of any record or other writing, frames that record or writing in a manner which he knows to be incorrect, with intent to cause, or knowing it to be likely that he will thereby cause, loss or injury to the public or to any person, or with intent thereby to save, or knowing it to be likely that he will thereby save, any person from legal punishment, or with intent to save, or knowing that he is likely thereby to save, any property from forfeiture or other charge to which it is liable by law, shall be punished with imprisonment of either description for a term which may extend to three years, or with fine, or with both.*

201. Causing disappearance of evidence of offence, or giving false information to screen offender.— *Whoever, knowing or having reason to believe that an offence has been committed, causes any evidence of the commission of that offence to disappear, with the intention of screening the offender from legal punishment, or with that intention gives any information respecting the offence which he knows or believes to be false; if a capital offence.—shall, if the offence which he knows or believes to have been*

committed is punishable with death, be punished with imprisonment of either description for a term which may extend to seven years, and shall also be liable to fine; if punishable with imprisonment for life.—and if the offence is punishable with 1[imprisonment for life], or with imprisonment which may extend to ten years, shall be punished with imprisonment of either description for a term which may extend to three years, and shall also be liable to fine; if punishable with less than ten years' imprisonment.—and if the offence is punishable with imprisonment for any term not extending to ten years, shall be punished with imprisonment of the description provided for the offence, for a term which may extend to one-fourth part of the longest term of the imprisonment provided for the offence, or with fine, or with both. Illustration A, knowing that B has murdered Z, assists B to hide the body with the intention of screening B from punishment. A is liable to imprisonment of either description for seven years, and also to fine.

202. Intentional omission to give information of offence by person bound to inform.—*Whoever, knowing or having reason to believe that an offence has been committed, intentionally omits to give any information respecting that offence which he is legally bound to give, shall be punished with imprisonment of either description for a term which may extend to six months, or with fine, or with both.*

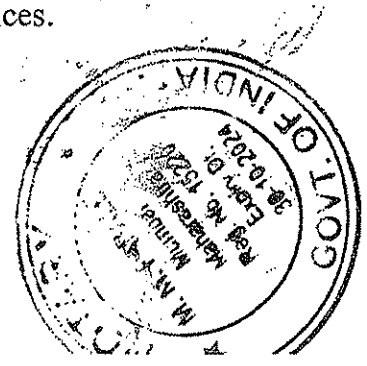
26. The doubt created by the State i.e. Respondent No. 01, regarding possible shortage of oxygen is not only irrelevant for defending discrimination but also a dishonest statement because said problem which may be faced in future can only be because of wrong mandates of the State. Because the shortage of oxygen in the body is mainly due to the mask mandate as proven in the research which is explained in the earlier paragraphs.

26.1. Malafides of State action are ex-facie proved from the very fact that they themselves are making such unscientific mask mandates and asking the public to wear mask whole time and putting heavy fines on poor people those who don't wear mask. Out of such extortion techniques around 83 Crores rupees are collected officially by the BMC and the unaccounted figure may go in Hundreds of Crores as exposed by the Mid-Day in their sting operation.

Link: https://www.mid-day.com/mumbai/mumbai-news/article/bmcs-pro-mask-drive-is-just-an-extortion-racket-23205778

(A copy of news published in Mid-Day titled as **"BMC's pro-mask drive is just an extortion racket"** dated 20th December,2021 marked and annexed herewith **Exhibit "RA-11") (Page No. 284)**

26.2. Because of such unscientific mandates there is a decrease in the level of oxygen in that person's body. Then taking undue advantage of that situation, State authority are creating panic and then suggesting for imposing lockdown. This is done for the ulterior purposes and to give the wrongful profits to the vaccine companies and also to the companies who are earning through their online services.



1276

27. As per Supreme Court judgment in Common Cause Vs. Union of India (2018) 5 SCC 1, the state authority cannot put questions to any citizen regarding his decision to refuse to take vaccines. Therefore, the program 'Ghar Gahr Dastak' or any such attempts to collect information or put pressures are contemptuous.

27.1. That, Supreme Court in **Common Cause Vs. Union of India (2018) 5 SCC 1**, it is ruled as under;

> *"517. The entitlement of each individual to a dignified existence necessitates constitutional recognition of the principle that an individual possessed of a free and competent mental state is entitled to decide whether or not to accept medical treatment. The right of such an individual to refuse medical treatment is unconditional.* ***Neither the law nor the Constitution compel an individual who is competent and able to take decisions, to disclose the reasons for refusing medical treatment nor is such a refusal subject to the supervisory control of an outside entity;***
>
> *202.9. Right to life and liberty as envisaged under Article 21 of the Constitution is meaningless unless it encompasses within its sphere individual dignity. With the passage of time,* ***this Court has expanded the spectrum of Article 21 to include within it the right to live with dignity as component of right to life and liberty.***
>
> *306. In addition to personal autonomy, other facets of human dignity, namely, "self-expression" and "right*



to determine" also support the argument that ***it is the choice of the patient to receive or not to receive treatment."***

27.2. Hence, the state authorities are not permitted to use any mandatory methods putting questions to the citizen as to why they don't want to take vaccine.

27.3. Similar law is laid down in;

i. **Montgomery's case [2015] UKSC 11**

ii. **Registrar General Vs. State of Meghalaya 2021 SCC OnLine Megh 130**

iii. **Airdale NHS Trust Vs. Bland (1993) 1 All ER 821**

iv. **Osbert Khaling Vs State of Manipur 2021 SCC OnLine Mani 234**

28. Order dated 27.11.2021 relied by Respondent No.1 is more aggravated form of the unlawful Act. It is also contempt of court as per law laid down by the Full Bench in the case of S. Abdul Karim (1976) 1 SCC 975 which mandates for keeping equanimity till matter is subjudice.

28.1. That, the Respondent No.1 in his affidavit dated **21.12.2021** relied on the order dated **27.11.2021** which were brought after filing of the present petition.

28.2. That when the matter was subjudice before this Hon'ble Court then the Respondent No.1 were expected to maintain equanimity as even Respondent No.1 himself was not vaccinated.

28.3. In **S. Abdul Karim Vs. M. K. Prakash and others (1976) 1 SCC 975** it is ruled as under;

"31..... It is true that the Magistrate was aware that 'Ps' criminal revision petition against his interim order, dated 28-4-1969, was then ***pending in the High Court. In such a situation, the prudent course for him was to postpone the making of any final order in regard to the delivery of this timber till the final disposal of the revision petition by the High Court.*** *It would also have been proper for him to issue notice to 'P' and give an opportunity of being heard before making any order. That would have been the ideal.*

32. ***In the absence of any mens rea, the Magistrate had, at the most, committed only a technical contempt of the High Court.*** *In such a case, as was pointed out by this Court in Debabrata Bandopadhyay case, penal action was not called for."*

28.4. That, this Hon'ble High Court in the case of **Kishore Rajput Vs. Preeti Rajput 2007(3) Bom CR.279,** had laid down the same ratio. It is ruled as under;

"Normally, when this Court is ceased of the matter, it is expected of the subordinate courts to stay their hands away. It is difficult to understand as to what was an alarming urgency to proceed further and dismiss the petition when the ***learned Judge of the Family Court was very well aware that the order dated 15th September 2006 was challenged before this Court by the present petitioner. No doubt, that the learned Family Court is right in observing that there was no stay by this Court.*** *But as a matter of propriety and when the learned Judge was very much*

aware about pendency of the petition before this Court, the learned Judge ought to have stayed his hands away and waited till further orders to be passed by this Court. In that view of the matter, I am inclined to allow the petition. ***(Para 7)"***

28.5. But Respondent No 1 not only continued with their illegality but acted in more brazen manner and passed the order dated **27.11.2021.** This shows their collous criminal mindset to overreach the law.

28.6. The said order dated **27.11.2021** is mainly regarding complete restrictions on unvaccinated and advocating the strict mask mandates to all including vaccinated.

28.7. Said order is illegal, illogical and arbitrary for following reasons:

28.8. Said order is not tabled before legislature as mandated under **section 78(3)** of the **Disaster Management Act, 2005.**

28.9. Regarding discrimination of unvaccinated already detailed submission are given.

28.10. The illegality, unscientific and arbitrary approach of state authority regarding mask mandates, is proved from the information given by the Central Government;

28.10.1. That, as per the policy of Central Government wearing of mask is not mandatory. It is further made clear that the healthy people should not wear the mask.

28.10.2. In RTI reply dated **27th May, 2021 to Mr. Sourav Bysack Being RTI Application No. F. No. Z.28016/133/2021-DM CELL** it is made clear that mask are not mandatory.

*"Use of mask/face cover has been advised to all in various SOPs/Guidelines issued by MoHFW. **However as per these guidelines/SOPs its use has not been explicitly made mandatory."***

(A copy of RTI reply dated **27th May, 2021** to Mr. **Sourav Bysack** Being **RTI Application No. F. No. Z.28016/133/2021-DM CELL** is marked and annexed herewith **Exhibit "RA-12" (Page No. 293)**

28.10.3. In RTI reply dated **19.05.2021 to Shri. Amit Chauhan RTI Application No. INCMR/R/E/21/00355,** it is specifically pointed out as under'

"4. Use of masks by general public

4.1. Persons having no symptoms are not to use mask

Medical masks should not be used by healthy persons who are not having any symptoms because it create a false sense of security that can lead to neglecting other essential measures such as washing of hands.

Further, there is no scientific evidence to show health benefit of using masks for non-sick persons in the community. In fact, erroneous use of masks or continuous use of a disposable mask for longer than 6 hours or repeated use of same mask may actually increase risk of getting an infection. It also incurs unnecessary cost."

(A copy of RTI reply dated **19.05.2021** to **Shri. Amit Chauhan** Being **RTI Application No. F. No. INCMR/R/E/21/00355**is marked and annexed herewith **Exhibit "RA-13" (Page No. 295)**

28.10.4. In reply dated **17.07.2021** the Health Ministry of Central Government, had made it clear that the size of virus is many times smaller than the pore size of the best quality mask.

> ***"1. SARS-CoV-2 virus is round shaped virus with an average size of 70-80 nm.***
>
> ***2. Pore size of standard surgical mask and N95 mask is 0.3 – 10 μm & 0.1 – 0.3 μm respectively."***

(A copy of RTI reply dated **17.07.2021** Being **RTI Application No. F. No. NIOVP/R/E/21/00046** is marked and annexed herewith **Exhibit "RA-14" (Page No. 299)**

28.10.5. That **47 scientific studies** have confirmed that the mask are ineffective and **32 studies** confirm that mask having negative health effects.

Link: https://www.lifesitenews.com/news/47-studies-confirm-inefectiveness-of-masks-for-covid-and-32-more-confirm-their-negative-health-effects/?fbclid=IwAR1ksLTTglmF31y90NjCW3vjUo_CHLG5y2oqN0dfs7ghwcZEwTc1zVBwsz0M

(A copy of article published titled as **"47 studies confirm ineffectiveness of masks for COVID and 32 more confirm their negative health effects"** dated 23rd July, 2021 marked and annexed herewith **Exhibit "RA-15") (Page No. 300)**

28.10.6. The research also proved that the person wearing mask will have problem of deoxygenation.

The Said report reads thus:

1282

"Preliminary report on surgical mask induced deoxygenation during major surgery.

Face mask side effects include lowered oxygen levels.

This study proved that surgeons that wore a mask in surgery for an hour + had significant reductions in blood oxygen saturation.

This is relevant because most of us are being made to wear face masks at work for the whole shift, long journeys on public transport, and when we are in a public places doing shopping etc. and this requires a degree of exertion that is not taken into account.

"Considering our findings, pulse rates of the surgeon's increase and SpO2 decrease after the first hour."



Decreasing oxygen and increasing carbon dioxide in the bloodstream stimulates a compensatory response in the respiratory centers of the brain. These changes in blood gases result in increases in both frequency and depth of breaths. This exposes another risk – if your mask traps some virus you are breathing more hence increasing viral load and exposure."

Link:https://www.sciencedirect.com/science/article/abs/pii/S1130147308702355?via%3Dihub

Study article: https://pubmed.ncbi.nlm.nih.gov/18500410/

28.10.7. The mask mandate issued by the Respondent No.1, unlike vaccine mandate does not have any provision/clause about the person with respiratory problems or having troubles in wearing masks. The order also does not mention as to when mask can be remand. Because central Government has warned to not wear the same mask for more than 5 hours to 8 hours or if it becomes wet.

28.10.8. But then also the **Respondent No. 1**, State of Maharashtra, in their order dated **27.11.2021** and also in their earlier orders made the rules for mandating mask and extorted crores of rupees from common man.

The collection of fine only from area of Bombay Municipal Corporation was around **83 Crores**. So, if we go through the collection across the state then it will be much more. These figures are sufficient to prove the extent of harassment being caused to common man.

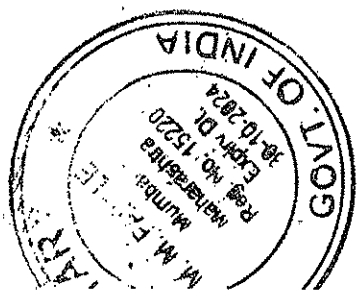
28.10.9. In addition to the illegality the mandate is also arbitrary. The order does not give any reason or reference of any scientific research data to support their stand.

28.10.10. The mask mandate also don't give any reason as to why the healthy person with natural immunity should wear the mask. In fact, as per experts such persons are safest and 13 times more safer than the fully vaccinated people.

Link: https://www.youtube.com/watch?v=6v5VrpgXPm4

28.10.11. The dishonesty, Corruption, and cruelty of the mandates and extortion techniques by the Bombay municipal corporation is exposed by Journalists of Mid-Day

https://www.mid-day.com/mumbai/mumbai-news/article/bmcs-pro-mask-drive-is-just-an-extortion-racket-23205778



(A copy of news published in Mid-Day titled as **"BMC's pro-mask drive is just an extortion racket"** dated 20th December,2021 marked and annexed herewith **Exhibit "RA-11") (Page No. 284)**

28.11. It makes it ex-facie clear that, the Respondent No.1 and its authorities are misusing their power in an arbitrary manner by ignoring their own data and rules framed by the National Authority.

28.12. Because of such unlawful orders all the citizen, police officers and also the public servants are facing health problems.

Here the so-called remedy is worse than the disease.

29. Criminal liability of Respondent No.10 Shri Udhhav Thackery, Chief Minister of Maharashtra and Chairman of State Disaster Management Authority.

29.1. That, all the illegalities and offences committed by the Respondent No.1 Chief Secretary and other officials of State of Maharashtra are under the leadership and directions of Respondent No.10 Shri Udhhav Thackery, Chairman of State Disaster Management Authority and Chief Minister of Maharashtra.

29.2. That, earlier Hon'ble Supreme Court in the case of **State of Maharashtra Vs. Sarangdharsingh Shivdassingh Chavan (2011) 1 SCC 577** have imposed a cost of rupees 10 Lakh for similar misconduct on the part of Chief Minister of Maharashtra. It is observed by the Supreme Court as under;

46. This Court is extremely anguished to see that such an instruction could come from the Chief Minister of a State which is governed under a constitution which resolves to

constitute India into a socialist, secular, democratic republic. The Chief Minister's instructions are so incongruous and anachronistic, being in defiance of all logic and reason, that our conscience is deeply disturbed. We condemn the same in no uncertain terms.

56..... Article 164(3) lays down that the Governor shall before a Minister enters upon his office, administer to him the oath of office and secrecy according to the form set out in the Third Schedule, in terms of which, the Minister is required to take oath that he shall discharge his duties in accordance with the Constitution and the law without fear or favour, affection or ill will.

Some members of the political class who are entrusted with greater responsibilities and who take oath to do their duties in accordance with the Constitution and the law without fear or favour, affection or ill will, have by their acts and omissions demonstrated that they have no respect for a system based on the rule of law.

58. If the Chief Minister was impelled by motives of personal ill will against the road transport operators in the western part of Kurnool and he gave the direction to the Corporation to change the order of the districts as originally planned by them and instead take up Kurnool first in order to prejudicially affect his political opponents, and the Corporation carried out his directions it does not need much argument to show that the resultant scheme framed by the Corporation would also be vitiated by mala

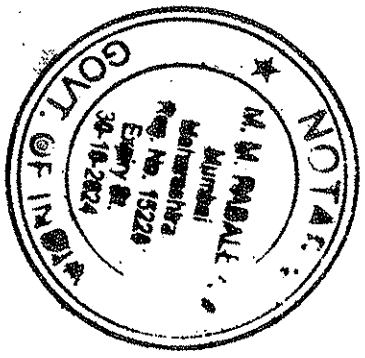
1281

fides notwithstanding the interposition of the semi-autonomous Corporation.

The law does not accord any special treatment to any person in respect of any complaint having been filed against him when it disclose the commission of any cognizable offence. It is a vital component of the rule of law. (Para 31)

39. *The aforesaid action of the Chief Minister is completely contrary to and inconsistent with the constitutional promise of equality and also the Preambular resolve of social and economic justice. As the Chief Minister of the State Mr Deshmukh has taken a solemn oath of allegiance to the Constitution but the directions which he gave are wholly unconstitutional and seek to subvert the constitutional norms of equality and social justice.*

40. *The argument that some of the cases in which complaints were filed against the family of Sananda, were investigated and charge-sheets were filed, is a poor consolation and does not justify the issuing of the wholly unauthorised and unconstitutional instructions to the Collector. It is not known to us in how many cases investigation has been totally scuttled in view of the impugned directions.*



41. *.....**How can the subordinate police officers carry on investigation ignoring such instructions of the Chief Minister? Therefore, the instructions of the Chief Minister have completely subverted the rule of law.***

48. We dismiss this appeal with costs of Rs. 10,00,000 (rupees ten lakhs) to be paid by the appellant in favour of the Maharashtra State Legal Services Authority. This fund shall be earmarked by the Authority to help the cases of poor farmers. Such costs should be paid within a period of six weeks from date.

49....Would like to separately record my views on the crucial issue of Ministerial interference in the functioning of the authorities entrusted with the task of enforcing the laws enacted by the legislature.

55. Under the Constitution, the executive power of the State vests in the Governor and is required to be exercised by him either directly or through officers subordinate to him in accordance with the Constitution [Article 154(1)]. ***Article 163 mandates that there shall be a Council of Ministers with the Chief Minister as the head to aid and advise the Governor in the exercise of his functions, except insofar as he is by or under the Constitution required to exercise his functions or any of them in his discretion.***

57. ***The judgment of the Constitution Bench in C.S. Rowjee v. State of A.P. [AIR 1964 SC 962 : (1964) 6 SCR 330] is an illustration of the misuse of public office by the Chief Minister for political gain.*** *The schemes framed by the Government of Andhra Pradesh under Chapter IV-A of the Motor Vehicles Act, 1939 for nationalisation of motor transport in certain areas of Kurnool District of Andhra Pradesh were challenged by filing writ petitions under*

GOVT. OF INDIA
M. M. PABALE
Mumbai
Maharashtra
Reg. No. 15228
Expiry Dt.
30-10-2024
NOTARY

Article 226 of the Constitution. The High Court repelled the challenge to the validity of the schemes and also negatived the argument that the same were vitiated due to mala fides of the then Chief Minister of the State. This Court allowed the appeals and quashed the scheme and declared that the schemes are invalid and cannot be enforced. While examining the issue of mala fide exercise of power, the Constitution Bench stuck a note of caution by observing that allegations of mala fides and of improper motives on the part of those in power are frequently made and sometimes without any foundation and, therefore, it is the duty of the Court to scrutinise those allegations with care so as to avoid being in any manner influenced by them if they are not well founded.

***58.** The Court in C.S. Rowjee [AIR 1964 SC 962 : (1964) 6 SCR 330] then noted that the scheme was originally framed by the Corporation on the recommendations of the Anantharamakrishnan Committee, but was modified at the asking of the Chief Minister so that his opponents may be prejudicially affected and proceeded to observe: (AIR pp. 972-73, paras 28-30)*

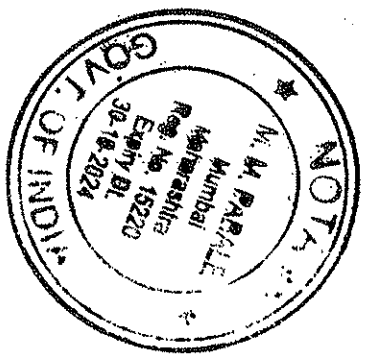
> *"28. ... The first matter which stands out prominently in this connection is the element of time and the sequence of dates. We have already pointed out that the Corporation had as late as March 1962 considered the entire subject and had accepted the recommendation of the Anantharamakrishnan Committee as to the order in which the transport in*

GOVT. OF INDIA NOTARY M. M. PASALE Mumbai Maharashtra Reg. No. 15220 Expiry Dt. 30-10-2024

the several districts should be nationalised and had set these out in their administration report for the three year period 1958 to 1961. It must, therefore, be taken that every factor which the Anantharamakrishnan Committee had considered relevant and material for determining the order of the districts had been independently investigated, examined and concurred in, before those recommendations were approved. It means that up to March-April 1962 a consideration of all the relevant factors had led the Corporation to a conclusion identical with that of the Anantharamakrishnan Committee. The next thing that happened was a conference of the Corporation and its officials with the Chief Minister on 19-4-1962. The proceedings of the conference are not on the record nor is there any evidence as to whether any record was made of what happened at the conference. But we have the statement of the Chief Minister made on the floor of the State Assembly in which he gave an account of what transpired between him and the Corporation and its officials. We have already extracted the relevant portions of that speech from which the following points emerge: (1) that the Chief Minister claimed a right to lay down rules of policy for the guidance of the Corporation and, in fact, the learned Advocate General submitted to us that under the Road Transport Corporation Act, 1950, the Government had a right to give directions as to policy to the



*Corporation; (2) that the policy direction that he gave related to and included the order in which the districts should be taken up for nationalisation; and (3) that applying the criteria that the districts to be nationalised should be contiguous to those in which nationalised services already existed, Kurnool answered this test better than Chittoor and he applying the tests he laid down, therefore suggested that instead of Chittoor, Kurnool should be taken up next. One matter that emerges from this is that it was as a result of policy decision taken by the Chief Minister and the direction given to the Corporation that Kurnool was taken up for nationalisation next after Guntur. It is also to be noticed that if the direction by the Chief Minister, was a policy decision, the Corporation was under the law bound to give effect to it (vide Section 34 of the Road Transport Corporation Act, 1950). We are not here concerned with the question whether a policy decision contemplated by Section 34 of the Road Transport Act could relate to a matter which under Section 68-C of the Act is left to the unfettered discretion and judgment of the Corporation, where that is the State undertaking, or again whether or not the policy decision has to be by a formal government order in writing for what is relevant is whether the materials placed before the Court establish that the Corporation gave effect to it as a direction which they were expected to and did obey. **If the Chief Minister was***



impelled by motives of personal ill will against the road transport operators in the western part of Kurnool and he gave the direction to the Corporation to change the order of the districts as originally planned by them and instead take up Kurnool first in order to prejudicially affect his political opponents, and the Corporation carried out his directions it does not need much argument to show that the resultant scheme framed by the Corporation would also be vitiated by mala fides notwithstanding the interposition of the semi-autonomous Corporation.

60. This Court in Chandrika Jha [(1984) 2 SCC 41] prefaced consideration of the question of interference by the Chief Minister with the statutory functions of the Registrar under Bye-law 29 by making the following observations: (SCC p. 44, para 4)

"4. The case illustrates an unfortunate trend which has now become too common these days in the governance of the country."

*"12...**Under the Cabinet system of Government the Chief Minister occupies a position of pre-eminence and he virtually carries on the governance of the State. The Chief Minister may call for any information which is available to the Minister in charge of any department and may issue necessary directions for carrying on the general administration of the State Government.***

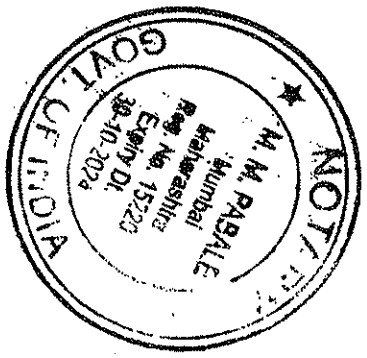
1292

Neither the Chief Minister nor the Minister for Cooperation or Industries had the power to arrogate to himself the statutory functions of the Registrar under Bye-Law 29. The act of the then Chief Minister in extending the term of the Committee of management from time to time was not within his power. Such action was violative of the provisions of the Rules and the bye-laws framed thereunder. The action of the Chief Minister meant the very negation of the beneficial measures contemplated by the Act.

63. This Court in Shivajirao Patil [(1987) 1 SCC 227]

"50...It leaves a great deal of suspicion that tampering was done to please Shri Patil or at his behest. It is true that there is no direct evidence. It is also true that there is no evidence to link him up with tampering. Tampering is established. The relationship is established. The reluctance to face a public enquiry is also apparent. Apparently Shri Patil, though holding a public office does not believe that 'Caesar's wife must be above suspicion'. The facts disclose a sorry state of affairs.

51. This Court cannot be oblivious that there has been a steady decline of public standards or public morals and public morale. It is necessary to cleanse public life in this country along with or even beforecleaning the physical atmosphere. The



pollution in our values and standards in (sic is) an equally grave menace as the pollution of the environment. Where such situations cry out the courts should not and cannot remain mute and dumb."

(emphasis supplied)

*64...11. **The Minister holds public office though he gets constitutional status and performs functions under the Constitution, law or executive policy.** The acts done and duties performed are public acts or duties as the holder of public office. Therefore, he owes certain accountability for the acts done or duties performed. In a democratic society governed by the rule of law, power is conferred on the holder of the public office or the authority concerned by the Constitution by virtue of appointment. The holder of the office, therefore, gets opportunity to abuse or misuse the office. The politician who holds public office must perform public duties with the sense of purpose, and a sense of direction, under rules or sense of priorities. The purpose must be genuine in a free democratic society governed by the rule of law to further socio-economic democracy.*

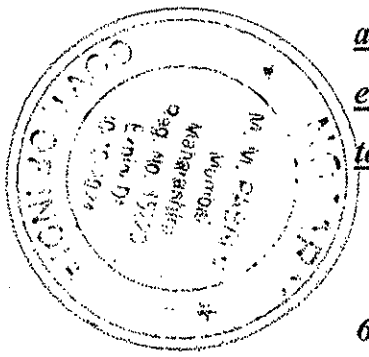
12. ... If the Minister, in fact, is responsible for all the detailed workings of his department, then clearly ministerial responsibility must cover a wider spectrum than mere moral responsibility: for no Minister can

possibly get acquainted with all the detailed decisions involved in the working of his department. ...

14. The so-called public policy cannot be a camouflage for abuse of the power and trust entrusted with a public authority or public servant for the performance of public duties. Misuse implies doing of something improper. The most elementary qualification demanded of a Minister is honesty and incorruptibility. He should not only possess these qualifications but should also appear to possess the same."

(emphasis supplied)

66...No Minister of the Crown can tell him that he must, or must not, keep observation on this place or that; or that he must, or must not, prosecute this man or that one. Nor can any police authority tell him so. The responsibility for law enforcement lies on him. He is answerable to the law and to the law alone."



(emphasis supplied)

68....These are liberties secured by restraints, justice under law, order that provides opportunity, the economy of the good life. From the beginning of human history government has been recognized as the overall holder and regulator of power, maintaining order by limiting all other expressions of power and thereby turning permitted powers into rights. In every age the abuse of power by

governments has led to disasters and uprisings, oppressions and vainglorious wars, and sometimes to experiments in the control of power, seeking to make it responsible, or more responsible, subject in some manner to the will of the people, of the majority or those who represented them."

69. Shri Dilip Kumar Sananda, a Member of the Legislative Assembly approached the Chief Minister for a special treatment. The Chief Minister, without verifying the truthfulness or otherwise of the assertion of Shri Dilip Kumar Sananda that false complaints were being lodged against his family members, issued instructions that complaints against the MLA concerned and his family members should be first placed before the District Anti-Moneylending Committee, which should obtain legal opinion of the District Government Pleader and then only take decision on the same and take appropriate legal action.

70. The camouflage of sophistry used by Shri Vilasrao Deshmukh in the instructions given by him and the affidavit filed before this Court is clearly misleading. The message to the authorities was loud and clear i.e. they were not to take the complaints against Sananda family seriously and not to proceed against them. The District Magistrate, the District Superintendent of Police and officers subordinate to them were bound to comply with the same in their letter and spirit. They could disregard those instructions at their own peril and none of them was expected to do so."

29.3. That, while sentencing Maharashtra Cabinet Minister Shri Swaroop Singh Naik and Chief Secretary Ashok Khot Hon'ble Supreme Court in the case of **T.N. Godavarman Thirumulpad through the Amicus Curiae Vs. Ashok Khot and Ors. 2006(2) ACR 1649 (S.C.),** observed as under;

> ***"The "King is under no man, but under God and the law"- was the reply of the Chief Justice of England, Sir Edward Coke when James-I once declared "Then I am to be under the law. It is treason to affirm it"-so wrote Henry Bracton who was a Judge of the King's Bench. The words of Bracton in his treatise in Latin "quod Rex non debat esse sub homine, sed sub Deo et Lege" (That the King should not be under man, but under God and the law) were quoted time and time again when the Stuart Kings claimed to rule by divine right. We would like to quote and requote those words of Sir Edward Coke even at the threshold. In our democratic polity under the Constitution based on the concept of 'Rule of law' which we have adopted and given to ourselves and which serves as an aorta in the anatomy of our democratic system. THE LAW IS SUPREME. Everyone whether individually or collectively is unquestionably under the supremacy of law. Whoever he may be, however high he is, he is under the law. No matter how powerful he is and how rich he may be.***
>
> *Hence, it is not only the third pillar but also the central pillar of the democratic State. If the judiciary is to perform its duties and functions effectively and remain true to the spirit with which they are sacredly entrusted to it, the dignity*

NOTARY M. M. PABALE Mumbai Maharashtra Reg. No. 15220 Expiry Dt. 30-10-2024 GOVT. OF INDIA

and authority of the Courts have to be respected and protected at all costs.

The case at hand involves two contemnors. Shri Ashok Khot (hereinafter described as 'contemnor No. 1') was the Principal Secretary, Department of Forest, Government of Maharashtra and Shri Swarup Singh Naik (hereinafter described as 'contemnor No. 2') was the Minister, Incharge of Department of Forest at the relevant point of time.

The respondents have acted in brazen defiance of the orders of this Court and their conduct constitutes the contempt by way of (a) wilful disobedience of directions issued by this Court, (b) the manner in which contemnors have conducted themselves clearly tends to lower the authority of this Court and obstructs the administration of justice (c) as their conduct falls both under the definition of Civil contempt, as well as seeing dimensions of the matters, under criminal contempt.

Any country or society professing rule of law as its basic feature or characteristic does not distinguish between high or low, weak or mighty. Only monarchies and even some democracies have adopted the age old principle that the king cannot be sued in his own courts.

With us every official, from Prime Minister down to a constable or a collector of taxes, is under the same responsibility for every act done with legal justification as any other citizen.

This is a case where not only right from the beginning attempt has been made to overreach the orders of this Court but also to draw red-herrings. Still worse is the accepted position of inserting a note in the official file with oblique motives. That makes the situation worse. In this case the contemnors deserve severe punishment. This will set an example for those who have propensity of disregarding the court's orders because of their money power, social status or posts held. Exemplary sentences are called for in respect of both the contemnors. Custodial sentence of one month simple imprisonment in each case would meet the ends of justice. It is to be noted that in Re: Sri Pravakar Behera (Suo Motu C.P. 301/2003 dated 19.12.2003) 2003 (10) SCALE 1126, this Court had imposed costs of Rs. 50,000/- on a D.F.O. on the ground that renewal of license was not impermissible in cases where licenses were issued prior to this Court's order dated 4.3.1997. That was the case of an officer in the lower rung. Considering the high positions held by the contemnors more stringent punishment is called for, and, therefore, we are compressing custodial sentence."

NOTARY
M. M. PABALE
Mumbai
Maharashtra
Reg. No. 15220
Expiry Dt.
GOVT. OF INDIA

29.4. That, the extortions and other offences committed by Mr. Anil Deshmukh Ex Home Minister of Maharashtra working in the Cabinet of Respondent No.1 Shri Uddhav Thackary is already on record and as per the order passed by this Hon'ble Court an FIR is registered. And the said Home Minister Shri Anil Deshmukh and his chief Secretary Shri. Sanjeev Palande are in jail. **[Param Bir Singh v. State of Maharashtra, 2021 SCC OnLine Bom 516]**

29.5. That, frauds and corruption committed by the State Authorities **is ranging in Thousands of Crores in Covid management under the leadership of Respondent No. 10 Shri Udhhav Thackery** as has been exposed by Shri Kirit Somaiya, Former, Minister of Parliamentary.

That, the summary of frauds related with covid-19 pandemic exposed by Bhartiya Janta Party's former M.P. Dr. Kirit Somaiyya are as under:

29.5.1 Fraud of around Rs. 2,100 crores in Covid-19 hospital. The land was sold by the government to a builder for Rs. 62 crores. However, in few hours the MCGM shown its willingness to purchase it for around Rs. 2,100 crores to build covid hospital. After intervention by Dr. Kirit Somaiyya said deal was cancelled.

29.5.2. MCGM invited tender for purchase of 1 Crore vaccine doses. All the 11 tenders were suspicious. Due to intervention by Dr. Kirit Somaiyya said process was cancelled.

29.5.3. The MCGM purchased 72,000 Remdesivir injections for covid treatment at the rate of Rs. 1668 per injection. While, at the same time the same injections were purchased by the Haffkine Institute for Rs. 668 means MCGM paid Rs. 1000 extra per injection for a purchase of 72,000 injection.

(A copy of **"Summary of frauds related with Covid-19 pandemic exposed by Bhartiya Janta Party's former M.P. Dr. Kirit Somaiyya"** marked and annexed herewith **Exhibit "RA-16") (Page No. 329)**

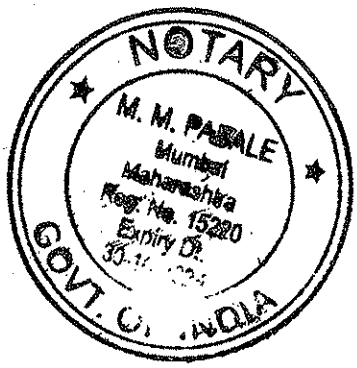
29.6. That, Secretary General of Human Rights Security Council, Shri Rashid Khan Pathan on 13th October,2021 and another activist Shri

1300

Madan Dube on 9th November 2021 have already filed an application cum complaint before Hon'ble Governor of Maharashtra seeking sanction to prosecute Respondent No. 1 Shri Udhhav Thackery and Ors.

The prayers of the said complaint reads thus;

"१) लस कंपन्यांना हजारो कोटींचा गैरफायदा पोहोचवण्यासाठी भारतीय संविधान केंद्र शासनाचे निर्देश व माननीय सर्वोच्च व उच्च न्यायालयाच्या आदेशाची अवमानना करून नागरिकांच्या मूलभूत अधिकारांचे उल्लंघन करणारे व त्यांच्या जिवाला धोका निर्माण करणारे असंवैधानिक व बेकायदेशीर गुन्ह्यात वर नमूद आरोपी व त्यांना सहकार्य करणारे इतर सर्व आरोपी यांच्याविरुद्ध भारतीय दंड विधान च्या कलम 109, 166, 167, 115, 52, 192, 193, 199, 200, 302,505, 304,120 (B), 34 आणी आपत्ति व्यवस्थापन कायदा 2005' चे कलम 51 (b), 55 आदी विविध गुन्ह्यांमध्ये फौजदारी कारवाई करण्याकरिता फौजदारी प्रक्रिया संहिता कलम 197 अंतर्गत परवानगी देण्यात यावी,



२) आरोपींना मुंबई महापालिकेच्या माध्यमाने बिल गेट्स व रॉकरफेलर फाऊंडेशन या संस्थाकडून लस कंपन्यांच्या फायद्याचे प्रकल्प राबविण्यासाठी • मिळणारा निधी व आदित्य ठाकरे यांचे फार्मा मिफियासोबत संबंधाची चौकशी करण्याचे आदेश देण्यात यावे..

३) खोट्या, बनावट व शास्त्रीय आधार नसलेल्या गोष्टींच्या आधारे आरोपींनी राज्यात मास्क व इतर विविध निर्बंध व लॉकडाऊन थोपून नागरिकांच्या रोजगाराचे, वित्त व जिवीत्वाचे अतोनात नुकसान केल्यामुळे आरोपीविरुद्ध कठोर कारवाई करून

आरोपींची मालमत्ता जप्त करून सर्व नागरिकांना नुकसान भरपाई देण्यासंबंधी कारवाईसाठी योग्य आदेश देण्यात यावे;

४) अर्जदाराच्या जीवाचे काही बरेवाईट झाल्यास सदरचा अर्ज हेच अर्जदाराचे मृत्यूपूर्व बयान समजण्यात येवून आरोपींना माझ्या मृत्यूस जबाबदार ठरवून त्यांच्याविरुद्ध हत्येचा कट रचून हत्या घडवून आणल्याची कारवाई करावी. आरोपींना जामीन न देता तुरुंगात ठेवून केस चालविण्यासाठी सीबीआय व इतर अधिकऱ्यांनी न्यायालयात अर्ज देण्याचे निर्देश द्यावेत.

५) अर्जदारास योग्य ते पोलिस संरक्षण पुरविण्याचे आदेश देण्यात यावेत."

29.7. Translation of Prayers of Complaint **dated 13.10.2021** filed by Shri Rashid Khan Pathan reads thus;

"**(1)** The petitioner be granted sanction as per **Section 197 of Cr.P.C.** to prosecute accused and all others who are helping them and involved in the conspiracy under, **Section 109, 166, 167, 115, 52, 192, 193, 199, 200, 302, 505, 304, 120 (B), 34 etc. of IPC** and **section 51 (b), 55 etc. of Disaster Management Act, 2005** for making rules which are violative of fundamental rights of the citizen and against the constitutional mandate, Central Government directives and in contempt of law laid down by the Hon'ble Supreme Court and High Court with ulterior motive and purposes of giving wrongful profit of thousands of crores to vaccine companies;

(2) Direction for investigation about links of Shri Aditya Thackrey with pharma mafia and the amount received by the

accused from Bill Gates & Rockefeller Foundation through MCGM for implementing the projects to give benefits to the vaccine companies;

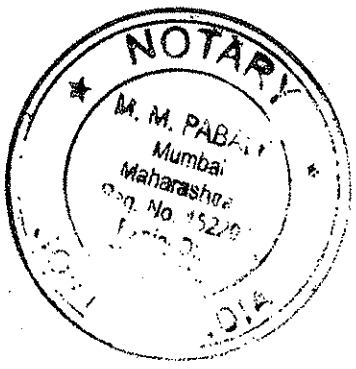
(3) Directions for action against accused for bringing unlawful mask and other mandates and lockdown on the basis of false, fabricated and unscientific grounds and direction for forfeiture/seizure of the property of accused to give compensation to the citizen;

(4) Direction to the effect that if anything happens to the complainant or if complainant is killed or met with unnatural death then this complaint be treated as complainant's dying declaration and the accused be held responsible for his death and the accused be tried under trial without granting bail and keeping them in the jail.

(5) Directions for providing Police protection to the complainant."

29.8. The other co-accused in the said complaint are as under;

1. श्री उद्धव ठाकरे
मुख्यमंत्री महाराष्ट्र राज्य,
मंत्रालय, मुंबई



2. श्री. अजित पवार
उप- मुख्यमंत्री, महाराष्ट्र राज्य,
मंत्रालय, मुंबई

3. श्री राजेश टोपे
आरोग्य मंत्री, महाराष्ट्र राज्य,
मंत्रालय, मुंबई

4. श्री आदित्य ठाकरे
पर्यटन मंत्री, महाराष्ट्र राज्य,
मंत्रालय, मुंबई

5. श्री. सीताराम कुंटे
मुख्यसचिव, महाराष्ट्र राज्य,
मंत्रालय, मुंबई



6. श्री इकबाल चहल
आयुक्त, बृहमुंबई महानगरपालिका, मुंबई

7. श्री सुरेश काकाणी
अतिरिक्त कमिशनर
बृहमुंबई महानगरपालिका, मुंबई

29.9. Worth to mention here that, the application come complaint is filed on **13th October, 2021**. Hence, as per law laid down by the Hon'ble Supreme Court in the case of **Subramaniyan Swamy versus Manmohan Singh & Ors. (2013) 3 SCC 64,** the complainant is likely to get the sanction to prosecute Respondent No. 10 Shri Uddhav Thackeray.

Also Relied on:- Shashikant Prasad Vs. The State through C.B.I. /A.C.B. Lucknow 2013 SCC OnLine 13099.

29.10. Viewed from this angle, it is also clear that the decisions of Respondent No. 1 and Respondent No. 10 Shri Uddhav Thackeray are not in good faith but for extraneous purposes.

30. As per Supreme Court judgment government officials opposing meritorious case on the basis of false and frivolous grounds needs to be saddled with heavy cost.

30.1. Hon'ble Supreme Court in **State of Maharashtra Vs. Sarangdharsingh Chavan (2011) 1 SCC 577**, imposed a cost of **Rs. 10 lakhs** upon State of Maharashtra for arising unlawful rules.

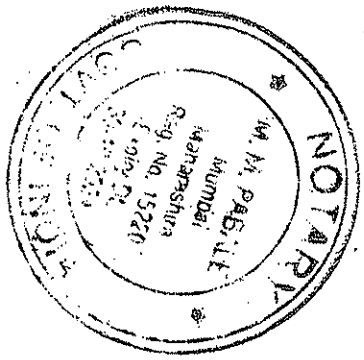
30.2. That, Hon'ble Supreme Court in the case of **Union of India v. Pirthwi Singh, (2018) 16 SCC 363**, ruled as under;

> *"3. ..... The conduct of the Union of India in filing civil appeals/special leave petitions after the issue is concluded by this Court was not appreciated. It was noted that the Union of India must take full responsibility for unnecessarily adding to the burden of the justice delivery system.*
>
> *4. To ensure that the Union of India is far more circumspect, costs of Rs 1,00,000 were imposed and it was observed that the Union of India must shape up its litigation policy. Unfortunately, the Union of India has learnt no lesson and has continued its non-cooperative attitude.*
>
> ***6. The Union of India must appreciate that by pursuing frivolous or infructuous cases, it is adding to the burden of this Court and collaterally harming other litigants by***

NOTARY M. M. PABALE Mumbai Maharashtra Reg. No. 15220 Expiry Dt. 30-10-2024 GOVT. OF INDIA

delaying hearing of their cases through the sheer volume of numbers. If the Union of India cares little for the justice delivery system, it should at least display some concern for litigants, many of whom have to spend a small fortune in litigating in the Supreme Court.

7. On 23-6-2010, the Union of India released the "National Legal Mission to Reduce Average Pendency Time from 15 Years to 3 Years" and this document is called "National Litigation Policy". The vision/mission of the National Litigation Policy is as follows:



"1. The National Litigation Policy is based on the recognition that Government and its various agencies are the predominant litigants in courts and Tribunals in the country. Its aim is to transform Government into an efficient and responsible litigant. This policy is also based on the recognition that it is the responsibility of the Government to protect the rights of citizens, to respect fundamental rights and those in charge of the conduct of government litigation should never forget this basic principle.

"Efficient litigant" means

(i) Focusing on the core issues involved in the litigation and addressing them squarely.

(ii) Managing and conducting litigation in a cohesive, coordinated and time-bound manner.

(iii) Ensuring that good cases are won and bad cases are not needlessly persevered with.

(iv) A litigant who is represented by competent and sensitive legal persons: competent in their skills and sensitive to the facts that Government is not an ordinary litigant and that a litigation does not have to be won at any cost.

"Responsible litigant" means

(i) That litigation will not be resorted to for the sake of litigating.

(ii) That false pleas and technical points will not be taken and shall be discouraged.

(iii) Ensuring that the correct facts and all relevant documents will be placed before the court.

(iv) That nothing will be suppressed from the court and there will be no attempt to mislead any court or tribunal.

2. The Government must cease to be a compulsive litigant. The philosophy that matters should be left to the courts for ultimate decision has to be discarded. The easy approach, "Let the court decide", must be eschewed and condemned.

3. The purpose underlying this Policy is also to reduce government litigation in courts so that valuable court time would be spent in resolving other pending cases so as to achieve the goal in the National Legal Mission to reduce average pendency time from 15 years to 3 years. Litigators on behalf of the Government have to keep in mind the principles incorporated in the National Mission for judicial reforms which includes identifying

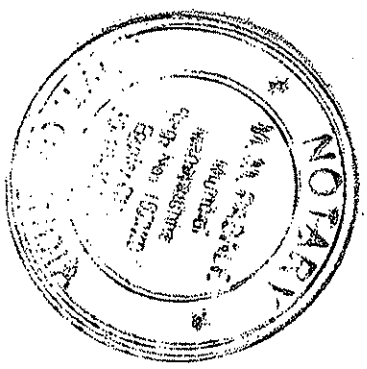
NOTARY
M. M. PABALE
Mumbai
Maharashtra
Reg. No. 15220
Expiry Dt.
30-10-2006
GOVT. OF INDIA

bottlenecks which the Government and its agencies may be concerned with and also removing unnecessary government cases. Prioritisation in litigation has to be achieved with particular emphasis on welfare legislation, social reform, weaker sections and senior citizens and other categories requiring assistance must be given utmost priority."

(emphasis supplied)

None of the pious platitudes in the National Litigation Policy have been followed indicating not only the Union of India's lack of concern for the justice delivery system but scant regard for its own National Litigation Policy.

***8.** The website of the Department of Justice shows that the National Litigation Policy, 2010 is being reviewed and formulation of the National Litigation Policy, 2015 is under consideration. When this will be finalised is anybody's guess. There is also an Action Plan to Reduce Government Litigation which was formulated on 13-6-2017.*



***9.** Nothing has been finalised by the Union of India for the last almost about 8 years and under the garb of ease of doing business, the judiciary is being asked to reform. The boot is really on the other leg.*

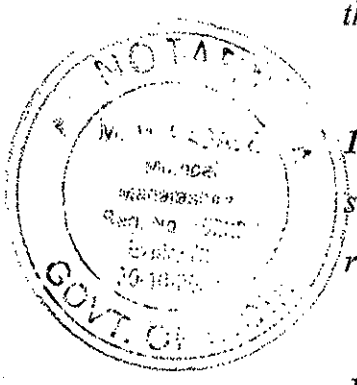
***10.** Interestingly, the Action Plan mentions, among others, two interesting steps to reduce pendency:*

(i) Avoid unnecessary filing of appeals—appeals should not be filed in routine matters—only in cases where there is a substantial policy matter.

(ii) Vexatious litigation should be immediately withdrawn.

These pendency reduction steps (particularly (ii) above) have been conveniently overlooked as far as this appeal is concerned.

11. *To make matters worse, in this appeal, the Union of India has engaged 10 lawyers, including an Additional Solicitor General and a Senior Advocate! This is as per the appearance slip submitted to the Registry of this Court. In other words, the Union of India has created a huge financial liability by engaging so many lawyers for an appeal whose fate can be easily imagined on the basis of existing orders of dismissal in similar cases. Yet the Union of India is increasing its liability and asking the taxpayers to bear an avoidable financial burden for the misadventure. Is any thought being given to this?*



12. *The real question is: when will the Rip Van Winkleism stop and the Union of India wake up to its duties and responsibilities to the justice delivery system?*

13. *To say the least, this is an extremely unfortunate situation of unnecessary and avoidable burdening of this Court through frivolous litigation which calls for yet another*

reminder through the imposition of costs on the Union of India while dismissing this appeal. We hope that someday some sense, if not better sense, will prevail on the Union of India with regard to the formulation of a realistic and meaningful National Litigation Policy and what it calls "ease of doing business", which can, if faithfully implemented benefit litigants across the country.

14. *The appeal is dismissed with costs of Rs 1,00,000 as before to be deposited with the Supreme Court Legal Services Committee within four weeks from today for utilisation for juvenile justice issues. Pending IAs are also disposed of.*

15. *List for compliance after five weeks."*

30.3. That, Hon'ble Supreme Court in the case of **V. Chandrasekaran Vs. Administrative Officer (2012) 12 SCC 133**, imposed a cost of Rs. 25 Lacs. It is ruled as under;

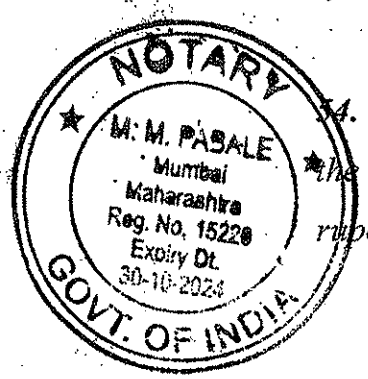
"48. In Maria Margarida Sequeira Fernandes v. Erasmo Jack de Sequeira [(2012) 5 SCC 370: (2012) 3 SCC (Civ) 126] this Court taking note of its earlier judgment in Ramrameshwari Devi v. Nirmala Devi [(2011) 8 SCC 249 : (2011) 3 SCC (Cri) 481 : (2011) 4 SCC (Civ) 1] held: (Maria Margarida case [(2012) 5 SCC 370 : (2012) 3 SCC (Civ) 126] , SCC p. 393, para 81)

"81. False claims and defences are really serious problems with real estate litigation, predominantly because of ever-escalating prices of the real estate. Litigation pertaining to

valuable real estate properties is dragged on by unscrupulous litigants in the hope that the other party will tire out and ultimately would settle with them by paying a huge amount. This happens because of the enormous delay in adjudication of cases in our courts. If pragmatic approach is adopted, then this problem can be minimised to a large extent."

The Court further observed that wrongdoers must be denied profit from their frivolous litigation, and that they should be prevented from introducing and relying upon false pleadings and forged or fabricated documents in the records furnished by them to the court.

53.21. *The State/Board authorities never made an attempt to stop the construction. Nor the Board approached the court to restrain the appellants from encroaching upon its land and from construction of the flats. Connivance of the officers of the Board in the scandal is writ large and does not require any proof. The facts of the case reveal a very sorry state of affairs as to how the public property can be looted with the connivance and collusion of the so-called trustees of the public properties. It reflects on the very bad governance of the State authorities.*



54. *The aforesaid conclusions do not warrant any relief to the appellants. The appeals are dismissed with costs of rupees twenty-five lakhs, which the appellants are directed*

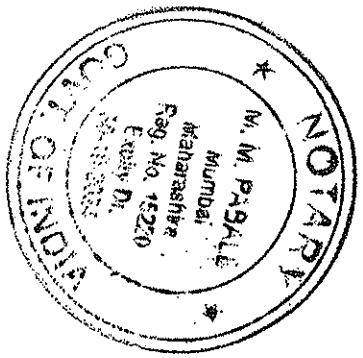
to deposit with the Supreme Court Legal Services Authority within a period of six weeks.

55. In addition thereto, the Chief Secretary of Tamil Nadu is requested to examine the issues involved in the case and find out as to who were the officials of the State or the Board responsible for this loot of the public properties and proceed against them in accordance with law. He is further directed to ensure eviction of the appellants from the public land forthwith."

30.4. That, Full Bench of Hon'ble Supreme Court in the case of **Sarvepalli Radhakrishnan University Vs. UOI (2019) 14 SCC 761**, has imposed a cost of Rs. 5 crores for filing false affidavit. This cost was imposed in addition to the prosecution under section 191, 193 etc. of IPC.

30.5. In **Baduvan Kunhi Vs. K.M. Abdulla and Ors. 2016 SCC OnLine Ker 23602**, it is ruled as under;

*"50. Their Lordships, in that context, have quoted with approval **Dalip Singh v. State of UP (2010) 2 SCC 114**, **Ritesh Tewari v. State of U.P., (2010) 10 SCC 677** and **Amar Singh v. Union of India, (2011) 7 SCC 69**. It pays to mention the pertinent observations in those decisions. In Dalip Singh it is observed that an altogether new creed of litigants, that is, dishonest litigants are the fast emerging breed. Though truth constitutes an integral part of the justice delivery system, the quest for personal gain has become so intense that those involved in litigation do not hesitate to seek shelter of falsehood, misrepresentation and suppression of facts in court proceedings. A litigant who*



attempts to pollute the stream of justice, or who touches the pure fountain of justice with tainted hands, is not entitled to any relief, interim or final.

51. In Ritesh Tewari and Amar Singh, as quoted in V. Chandrasekharan, it is observed that the truth should be the guiding star in the entire judicial process. "Every trial is a voyage of discovery in which truth is the quest". An action at law is not a game of chess; therefore, a litigant cannot prevaricate and take inconsistent positions. It is one of those fundamental principles of jurisprudence that litigants must observe total clarity and candour in their pleadings.

52. In ***Vijay Mallya v. Enforcement Directorate*** **(2015) 8 SCC 799** *the Apex Court speaking J. Chelameswar, J., has invoked Anatole France, who poetically, poignantly observed that "The law in its majestic equality, forbids the rich as well as the poor to sleep under bridges, to beg in the streets and to steal bread." Having found on facts that the appellant abused the process of court, the Apex Court imposed exemplary costs of ten lakh rupees to be paid to the Supreme Court Legal Services Authority.*

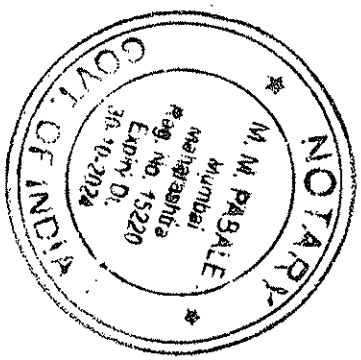
NOTARY
M. M. PABALE
Mumbai
Maharashtra
Reg. No. 15220
Expiry Dt.
30-10-2024
GOVT. OF INDIA

53. In ***Phool Chandra v. State of U.P.(2014) 13 SCC 112****, the Apex Court, per curiam, observed, "It is high time that the courts should come down heavily upon such frivolous litigation, and unless we ensure that the wrongdoers are denied profit or undue benefit from the frivolous litigation, it would be difficult to control frivolous and uncalled for litigation. In order to curb such kind of litigation, the courts have to ensure that there is no incentive*

or motive which can be ensured by imposing exemplary costs upon the parties as well as on the learned counsel who act in an irresponsible manner."

54. In ***Messer Holdings Ltd. v. Shyam Madanmohan Ruia (2016) 11 SCC 484*** *the Apex Court has observed that enormous amount of judicial time of that Court and High Courts (in that case) was spent on litigation that was eminently avoidable and could have been well spent on more deserving cases. All that was in the name of "fight for justice." It has, in that process, quoted with approval* ***Ramrameshwari Devi v. Nirmala Devi (2011) 8 SCC 249*** *to hold that the courts must consider, while imposing costs, pragmatic realities and also the prevalent fee structure of the lawyers and other miscellaneous expenses which have to be incurred towards conducting litigation. The Court deemed it appropriate to impose twenty-five lakh rupees on each of the three parties.*

55. Accordingly, taking a cue from the above, apart from allowing the writ appeal, we impose an exemplary cost of Rs. 1,00,000/- on the first respondent to be payable within one month from today to Kerala State Mediation and Conciliation Centre (KSMCC), High Court of Kerala. If the first respondent fails to pay the costs, the Director, KSMCC, shall require the District Collector to recover as revenue arrears the costs imposed now. For that purpose, the District Collector shall treat the communication from the Director, KSMCC, as a proceeding under Section 69 (2) of



the Revenue Recovery Act and take further steps accordingly.

56. The registry is further directed to send a copy of this judgment to the Bar Council of Kerala. After receiving a copy of the judgment, treating that as a complaint, the Bar Council, shall initiate appropriate disciplinary proceedings under Section 35 of the Advocates Act, 1961, and the Rules made thereunder, agasint Sri. A. K. Abdul Azeez, the advocate.

NOTARY
M. M. PABALE
Mumbai
Maharashtra
Reg. No. 15220
Expiry Dt.
30-10-2024
GOVT. OF INDIA

57. We further direct the registry to place the matter before the jurisdictional Bench to further adjudicate on the issue of contempt."

31. The data relied by the petitioner in support of his submissions to prove the falsity and dishonesty of the Respondent No.1.

SUMMARY OF DATA RELIED BY PETITIONER

SR. NOS.	PARTICULERS	Page Nos.
1.	**[Exhibit – "RA-17"]** Sero-Survey shows Delhi has 97% antibodies, Mumbai over 85%, and India over 67%.	**253**
2.	**[Exhibit – "RA-18"]** Indian studies regarding Natural Immunity & Indian Expert Opinion.	**356**
3.	**[Exhibit – "RA-19"]** 138 papers published in pre-print servers & peer reviewed medical journals confirm natural immunity	**358**

	is equal to or better than vaccine immunity.	
4.	**[Exhibit – "RA-20"]** Studies which show that vaccinated people have just as much, or more viral load than the UN-vaccinated.	447
5.	**[Exhibit – "RA-21"]** Latest Government Data on AEFI in India.	449
6.	**[Exhibit – "RA-22"]** Comparison of deaths and serious adverse events in India and other countries.	452
7.	**[Exhibit – "RA-23"]** Under reporting in VAERS & India.	455
8.	**[Exhibit – "RA-24"]** Letters from Indian Experts opining on the state of AEFI reporting in India.	468
9.	**[Exhibit – "RA-25"]** Covid Deaths in India and Infection Fatality Rate.	475
10.	**[Exhibit – "RA-26"]** Studies & Data which link AstraZeneca (Covishield) to serious adverse events.	477
11.	**[Exhibit – "RA-27"]** Research showing that giving vaccines to person with earlier infection causes serious harm.	483
12.	**[Exhibit – "RA-28"]** Covishield banned/age restricted in 15 countries.	484
13.	**[Exhibit – "RA-29"]** How vaccines don't reduce Covid cases even at a country level.	493
14.	**[Exhibit – "RA-30"]**	496

NOTARY
M. M. PABALE
Mumbai
Maharashtra
Reg. No. 15220
Expiry Dt.
30-10-2024
GOVT. OF INDIA

	Vaccinated people are at higher risk of testing positive, hospitalization & death.	
15.	**[Exhibit – "RA-31"]** Research shows vaccinated people are 13 times more likely to get infected than those who are naturally immune.	**500**
16.	**[Exhibit – "RA-32"]** Evidence that Covid Vaccines compromise Natural Immunity.	**502**
17.	**[Exhibit – "RA-33"]** Ways other than vaccines of reducing Covid infection, hospitalization & death.	**505**
18.	**[Exhibit – "RA-34"]** Maharashtra Govt Order dated 27th November 2021.	**514**
19.	**[Exhibit – "RA-35"]** Cowin API lets anyone know a persons vaccination status using their phone number.	**520**
20.	**[Exhibit – "RA-36"]** National Disaster Management Authorities website contains advisories from Ministry of Home Affairs & Ministry of Health & Family Welfare.	**523**
21.	**[Exhibit – "RA-37"]** Fully Vaccinated people in India testing positive for Omicron, one of them even had a booster.	**524**
22.	**[Exhibit – "RA-38"]** CDC announces 79% of Omicron cases have occurred in the fully vaccinated.	**529**
23.	**[Exhibit – "RA-39"]**	**534**

NOTARY
M. M. PABALE
Mumbai
Maharashtra
Reg. No. 15229
Expiry Dt.
30-10-2024
GOVT. OF INDIA

	Indian experts suggest booster doses not needed to tackle Omicron Variant.	
24.	**[Exhibit – "RA-40"]** How mass vaccination is giving rise to new variants.	**540**
25.	**[Exhibit – "RA-41"]** Possible consequences of using boosters in an Omicron wave.	**544**
26.	**[Exhibit – "RA-42"]** Study suggests T-cell immunity from natural infection will work against Omicron.	**553**
27.	**[Exhibit – "RA-43"]** Natural Immunity 75% effective against Omicron, vaccine only 33%.	**562**
28.	**[Exhibit – "RA-44"]** Examples of Immunity that lasts for decades in other viral respiratory infections like Sars & the 1918 Flu.	**564**
29.	**[Exhibit – "RA-45"]** All trials done to approve Astrazeneca (Covishield) were done in foreign countries.	**565**
30.	**[Exhibit – "RA-46"]** When asked under Indian Evidence Act 1976, ICMR sent foreign studies to support their position on Masks, RT-PCR testing, Lockdowns and social distancing, & said that no studies have been done by them.	**593**
31.	**[Exhibit – "RA-47"]** Japan Health Ministry's Stand Regarding Vaccination.	**597**

NOTARY
M. N. PABALE
Mumbai
Maharashtra
Reg. No. 15220
Expiry Dt.
30-10-2024
GOVT. OF INDIA

32.	**[Exhibit – "RA-48"]** Our Response to Affidavit filed by State Japan Health Ministry's Stand Regarding Vaccination Government.	**604**
33.	**[Exhibit – "RA-49"]** Natural Immunity vs. Vaccine Immunity Comparison table.	**607**

32. Omicron is the blessing as explained by the experts and proved from the scientific data but the Respondent No.1 state & Respondent No.4 Shri Iqbal Chahal is deliberately creating panic and spreading misinformation suppressing the truth in connivance with some media persons to spread fear amongst the public and therefore it is an offence under Section 54, 55 of the Disaster Management Act, 2005 on the part of all the public officials involved.

32.1. That, as per article published in **'Outlook'** on **22.12.2021,** the domain experts have called the Omicron as a blessing. Few experts of the said article are as under;

"Will Omicron End The Pandemic? Top Experts Say Omicron May Act As 'Natural Vaccine' For Covid-19

Source: *Outlook*

Link: *https://www.outlookindia.com/website/story/india-news-with-mild-symptoms-omicron-is-probably-natural-vaccine-top-scientists-doctors/406227*

Author: *Jeevan Prakash Sharma*

Published on: *22 Dec 2021,*

NOTARY M. M. PABALE Mumbai Maharashtra Reg. No. 15220 Expiry Dt. 30-11-2024 GOVT. OF INDIA

Noted immunologist, Gobardhan Das, who is Professor of Molecular Medicine at Jawaharlal Nehru University, said, "I believe Omicron is probably the natural vaccine. Omicron is the version of the Delta variant with additional mutation. If you have seen its symptoms, people are not getting hospitalised. It is casing very mild symptoms."

He adds, "So it suggests that over a period of time, this virus has attenuated itself. This is like our vaccine strategy where we make attenuation in the virus and administer it to people."

Considering its high rate of infectivity, which is five times more than the Delta variant, Prof Das is of the view that Omicron is the better vaccine than any available vaccine.

"The whole virus is going inside the body which has multiple mutations. So the more the body fight against the virus, the better is the immune response. This will produce a better response. It is happening for good as it will produce a better immune response," Prof Das said.

Another noted immunologist Dr. N K Mehra, former dean of AIIMS and honorary emeritus scientist, Indian Council of Medical Research, says, "I fully support this view because as of now it is very mild and it can prove to be a boon in disguise. Two international studies have shown that it grows ten times slower than the Delta variant in the lungs which is a very good sign. We need to see the data for another few

GOVT. OF INDIA NOTARY M. M. PARAL Mumbai, Maharashtra Reg. No. 15220 Expiry Dt. 30-10-2024

weeks to find out if it behaves in a similar way in all the countries."

Dr. Sandeep Budhiraja, Group Medical Director of Max Healthcare & Senior Director, Institute of Internal Medicine seconds with both Prof Das and Dr. Mehra on the basis of the current data.

"The data which is available so far and what we have seen so far from our experience of Omicron is that this is going to work as a live attenuated vaccine. ***Since it is highly infectious and spread very fast but hopefully it is going to cause mild illness for most people, it will act as a booster dose for those who are vaccinated and a vaccine dose for those who are unvaccinated****," Dr. Budhiraja said.*

He says that this is good for poor countries like those in Africa where vaccine uptake is very low and so this virus may act as a natural vaccine and give additional protection to the people.

NOTARY
M. M. PARALE
Mumbai
Maharashtra
Reg. No. 15220
Expiry Dt.
30-10-2024
GOVT. OF INDIA

Dr. Amitav Banerjee, Head, Department of Community Medicine, Dr. DY Patil Medical College Pune, agrees that viruses mutate to adapt themselves so that they can survive and which according to him is Darwin's Law.

"We also call it Nature's Law of adaptation. The new mutant, according to the available data and report, is causing very mild and self-limiting symptoms," Dr. Banerjee added.

Dr. Banerjee is of the view that a deadly virus dies with the person whom it infects but a variant that causes a very mild infection survives and spreads fast. This is so because it is so mild that most of the time people remain asymptomatic and don't even isolate themselves.

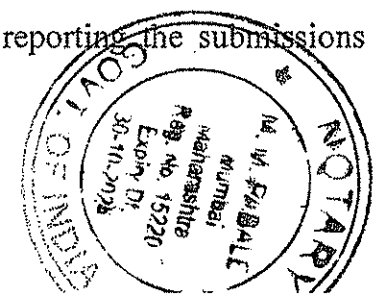
He added, "In this wild goose chase for mutating viruses we may end up chasing a version of the common cold! We should ask whether it is worth the effort? We should weigh the collateral harm which will ensue. To mitigate the impact of mutants, if any, we should resort to focused protection including vaccination of high risk groups while the young & **healthy can lead normal lives."**

(A copy of Article published in **'Outlook'** on **22.12.2021** titled as **"Will Omicron End the Pandemic? Top Experts Say Omicron May Act As 'Natural Vaccine' For Covid-19"** marked and annexed herewith **Exhibit "RA-50") (Page No. 610)**

Similar Article is published in **Daily Lokmat** on 23rd December, 2021.

33. Sponsored, biased, one-sided reporting by some media is contempt of court and also make them co-accused in the conspiracy:

33.1. The one-sided prejudicial reporting by some media persons regarding the present proceeding when it is subjudice, more particularly by the Portal **'Live Law'.** The said portal and few media persons are publishing selective updates of the proceedings. They reported the details of affidavit dated **21.12.2021** filed by the respondent but not reported the details of additional affidavit dated **20.11.2021** filed by the petitioner or not reporting the submissions given by the counsel for petitioner. The



news are being published in a particular direction. They have not published about the detailed arguments and submissions regarding natural immunity and others important aspects. This act of Live Law and few other sponsored media like Marathi Daily Samna, which is owned by wife of Respondent No. 10 Shri Uddhav Thackeray, makes the editorial board, and their reporter and others liable for action under Contempt as per law laid down by this Hon'ble Court in the case **Nilesh Navalakha Vs. Union of India 2020 SCC OnLine Bom 56**. Where it is ruled as under;

> *238. Soon after the 1952 Act was enacted, in Rizwan-ul-Hasan v. State of U.P., reported in AIR 1953 SC 185, the Supreme Court while referring to Anantalal Singha (supra), observed on the different sorts of contempt known to law as follows:*
>
> *"8. *** There are three different sorts of contempt known to law in such matters. One kind of contempt is scandalizing the court itself. There may likewise be a contempt of the court in abusing parties who are concerned in causes in that court. There may also be a contempt of court in prejudicing mankind against persons before the cause is heard. ***"*
>
> *(underlining for emphasis by us)*
>
> *239. Hon'ble K. Subba Rao, J. in his dissenting opinion in Saibal Kumar Gupta (supra) had the occasion to trace the law of contempt while observing as follows:*

NOTARY M. M. PABALE Mumbai Maharashtra Reg. No. 15220 Expiry Dt. 30-10-2024 GOVT. OF INDIA

*"26. *** The Contempt of Courts Act, 1926, has not defined the phrase 'contempt of court'. The judgment of Lord Hardwicke, L.C., in Re Read & Huggonson [(1742) 2 Atk 469], which has always been regarded as the locus classicus on the subject, declared 'Nothing is more incumbent upon courts of justice, than to preserve their proceedings from being misrepresented; nor is there anything of more pernicious consequence, than to prejudice the minds of the public against persons concerned as parties in causes before the cause is finally heard'. The learned Lord Chancellor characterized contempt as of three kinds, namely, scandalizing the court, abusing parties in court, prejudicing mankind against parties and the court before the cause is heard. Adverting to the third category, which is germane to the present case, the Lord Chancellor proceeded to state at p. 471 thus:*

> *'There may also be a contempt of this court, in prejudicing mankind against persons before the cause is heard. There cannot be anything of greater consequence, than to keep the streams of justice clear and pure, that parties may proceed with safety both to themselves and their characters.'*

But to constitute contempt of court, in the words of Lord Russel, C.J., 'the applicant must show that something has been published which either is

GOVT. OF INDIA NOTARY Mr. M. PABALE Mumbai Maharashtra Reg. No. 15220 Expiry Dt. 30.10.2024

clearly intended, or at least is calculated, to prejudice a trial which is pending'. (See The Queen v. Payne, [1896] 1 Q.B. 577). In The Queen v. Gray, [1900] 2 Q.B. 36, the phrase 'contempt of court' is defined' as, inter alia, 'something done calculated to obstruct or interfere with the due course of justice or the lawful process of the courts'. Lord Goddard, C.J., in R. v. Odham's Press Ltd., (1956) 3 All ER 494, after considering the relevant authority on the subject, laid down the following test to ascertain whether there is contempt of court in a given case, at p. 497:

> *'The test is whether the matter complained of is calculated to interfere with the course of justice....'*

NOTARY
M. M. PARALE
Mumbai
Maharashtra
Reg. No. 15220
Expiry Dt.
30-10-2024
GOVT. OF INDIA

Words much to the same effect were used by Parker, C.J., in a recent decision in R. v. Duffy, (1960) 2 All ER 891, when he stated at p. 894 that,

> *'....the question in every case is whether...the article was intended or calculated to prejudice the fair hearing of the proceedings.'*

In Halsbury's Laws of England, 3rd Edn. Vol. 8, it is stated at p. 8, 'It is sufficient if it is clear that the comment tends to prejudice the trial of the action'. Adverting to the third category of contempt

described by Lord Hardwicke, L.C., the learned author says at p. 8 thus:

> *'The effect of such misrepresentations may be not only to deter persons from coming forward to give evidence on one side, but to induce witnesses to give evidence on the other side alone, to prejudice the minds of jurors, or to cause the parties to discontinue or compromise, or to deter other persons with good causes of action from coming to the court.'*

27. The said view has been accepted and followed also in India : see State v. Biswanath Mohapatra, ILR 1955 Cut 305 and Ganesh Shankar Vidyarthi case, AIR 1929 All 81.

29. On the said authorities it is settled law that a person will be guilty of contempt of court if the act done by him is intended or calculated or likely to interfere with the course of justice.

(underlining for emphasis by us)

240. *In P.C. Sen, In re, reported in AIR 1970 SC 1821, the Supreme Court was seized of an appeal carried from an order of the Calcutta High Court by none other than the Chief Minister of West Bengal, whereby he was held guilty of contempt and his conduct was disapproved. On the law of contempt, this is what the Court held:*

NOTARY M. M. PARAB Mumbai Maharashtra Reg. No. 15220 Expiry Dt. 30.10.2024 GOVT. OF INDIA

"8. The law relating to contempt of Court is well settled. Any act done or writing published which is calculated to bring a court or a Judge into contempt, or to lower his authority, or to interfere with the due course of justice or the lawful process of the Court, is a contempt of Court; R.V. Gray [[1900] 2 Q.B. 36]. Contempt by speech or writing may be by scandalising the Court itself, or by abusing parties to actions, or by prejudicing mankind in favour of or against a party before the cause is heard. It is incumbent upon Courts of justice to preserve their proceedings from being misrepresented, for prejudicing the minds of the public against persons concerned as parties in causes before the cause is finally heard has pernicious consequences. Speeches or writings misrepresenting the proceedings of the Court or prejudicing the public for or against a party or involving reflections on parties to a proceeding amount to contempt. To make a speech tending to influence the result of a pending trial, whether civil or criminal is a grave contempt. Comments on pending proceedings, if emanating from the parties or their lawyers, are generally a more serious contempt than those coming from independent sources. The question in all cases of comment on pending proceedings is not whether the publication does interfere, but whether it tends to interfere, with the due course of justice. The question is not

NOTARY
M. M. PABALE
Mumbai
Maharashtra
Reg. No. 15220
Expiry Dt.

so much of the intention of the contemner as whether it is calculated to interfere with the administration of justice. As observed by the Judicial Committee in Devi Prasad Sharma v. King-Emperor, (1942-43) 70 IA 216 at p. 224:

> *"...the test applied by the ... Board which heard the reference was whether the words complained of were in the circumstances calculated to obstruct or interfere with the course of justice and the due administration of the law."*
>
> ***If, therefore, the speech which was broadcast by the Chief Minister was calculated to interfere with the course of justice, it was liable to be declared a contempt of the Court even assuming that he had not intended thereby to interfere with the due course of justice. ***"***
>
> *(underlining for emphasis by us)*

33.2. That, it also requires an investigation through C.B.I to find out that upon whose sponsorship and on whose instances such one sided, prejudicial news are published with dishonest concealment, twisting and suppressing the material facts with ulterior motive to create confusion in the mind of public and to threaten, misguide, mislead and confuse the public and witnesses.

33.3. Needless to mention here that the Acting Editor of Saamna i.e. Shri. Sanjay Raut and Editor Smt. Rashmi Thackeray are not having any

respect for the Courts of Law and in their Editorial dated 8th February, 2021 titled as **'Nyaylaya Wa Chaitanyamurtee'**, it is said that **'there is no doubt in anyone's mind that the judicial system is under the shoes of ruling party'**. Which is the grossest contempt. With the same mindset they are publishing the manipulated and twisted news article in utter disregard and defiance of the law laid down by this Hon'ble Court in **Nilesh Navlekha's case 2021 SCC OnLine Bom 56.**

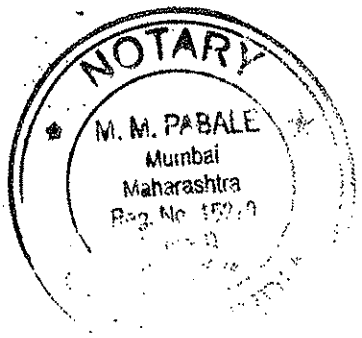
34.3. Needless to mention that already a Delhi Police is investing a case on the complaint given by Sh. Sumbit Patra, Spoke person, BJP regarding the toolkit given to few media for spreading fears and running false narratives about second wave of Covid-19.

The conspiracy can be easily proved from the very fact that all these narratives including urgency of oxygen and its propaganda disappeared from media news channels and newspapers when on **25.05.2021** Police started investigation in the **'Toolkit'** as exposed by Mr. Sambit Patra, Spokesperson of BJP. Police went to the office of the twitter at Delhi and served notice asking information.

Following news article's excerpts are sufficient to explain the issue of **ToolKit**

The Economic Times

Dt. 25.05.2021



On Monday, the Delhi Police's Special Cell sent a notice to Twitter India in connection with the probe into a complaint about the alleged "COVID toolkit", asking it to share information based on which it had classified a related tweet by BJP spokesperson

SambitPatra as "manipulated media", officials had said.

The BJP has accused the Congress of creating a "toolkit" on how to tarnish the image of the country and Prime Minister Narendra Modi over the handling of the COVID-19 pandemic. However, the Congress has denied the allegation and claimed that the BJP is propagating a fake "toolkit" to defame it.

Last week, Twitter labelled as "manipulated media" a tweet by Patra on the alleged "toolkit". Twitter says it "may label Tweets that include media (videos, audio, and images) that have been deceptively altered or fabricated".

Biswal said the Delhi Police is inquiring into a complaint in the toolkit matter.



"It appears that Twitter has some information which is not known to us and on the basis of which they have classified it (Patra's tweet) as such. This information is relevant to the inquiry. The Special Cell, which is conducting the inquiry, wants to find out the truth. Twitter, which has claimed to know the underlying truth, should clarify," he said.

The government had earlier asked Twitter to remove the "manipulated media" tag as the matter is pending before law enforcement agency, and made it clear that the social media platform cannot pass judgment when the issue is under investigation.

BJP leaders, including Patra, have posted numerous tweets to attack the Congress over the purported "toolkit".

Link: **https://economictimes.indiatimes.com/news/politics-and-nation/two-congress-leaders-get-delhi-police-notices-to-join-probe-in-covid-toolkit-case/articleshow/82937577.cms?from=mdr**

33.4. That as per **section 10** of the Indian Evidence Act, 1872 such media persons are liable for prosecution.

33.5. In **Raman Lal Vs. State of Rajasthan 2000 SCC OnLine Raj 226,** has ruled that;

*"**Conspiracy – I.P.C. Sec. 120 (B) –** Apex court made it clear that an inference of conspiracy has to be drawn on the basis of circumstantial evidence only because it becomes difficult to get direct evidence on such issue – The offence can only be proved largely from the inference drawn from acts or illegal ommission committed by them in furtherance of a common design – Once such a conspiracy is proved, act of one conspirator becomes the act of the others – A Co-conspirator who joins subsequently and commits overt acts in furtherance of the conspiracy must also be held liable – Proceeding against accused cannot be quashed."*

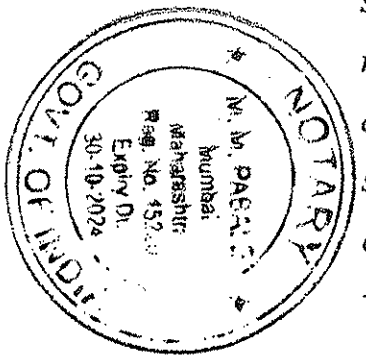
NOTARY M. M. PABALE Mumbai Maharashtra Reg. No. 152 Expiry Dt. 30-10-2024 GOVT. OF INDIA

34. State authority was duty-bound to publish the side effects of vaccines and also to publish that there cannot be any force or mandate for taking vaccine. If anyone is forced to take vaccines then the public should be given a grievance cell to complain as done by the Japan Government. But Respondent No.1 adopted unlawful,

unconstitutional approach thereby putting the citizen at the mercy of correct officials. This Hon'ble Court can direct Respondent No.1 to publish the side effects and readdress grievance cell.

34.1. That, Hon'ble High Court in **Master Haridaan Kumar Vs. Union of India 2019 SCC OnLine Del 11929** it is ruled as under;

> *"14. The contention that indication of the side effects and contraindications in the advertisement would discourage parents or guardians from consenting to the MR campaign and, therefore, the same should be avoided, is unmerited. The entire object of issuing advertisements is to ensure that necessary information is available to all parents/guardians in order that they can take an informed decision. The respondents are not only required to indicate the benefits of the MR vaccine but also indicate the side effects or contraindications so that the parents/guardians can take an informed decision whether the vaccine is to be administered to their wards/children.*
>
> ***15. In view of the above, it is directed as under:***
>
> *(4) MR vaccines will not be administered to those students whose parents/guardians have declined to give their consent. The said vaccination will be administered only to those students whose parents have given their consent either by returning the consent forms or by conforming the same directly to the class teacher/nodal teacher and also to students whose parents/guardians cannot be contacted despite best efforts by the class teacher/nodal teacher and who have otherwise not indicated to the contrary.*



(I) Directorate of Family Welfare shall issue quarter page advisements in various newspapers as indicated by the respondents, namely, The Hindustan Times, The Times of India, *The Hindu, The Pioneer, The Indian Express, Delhi Tribune, Mail Today, The Asian Age, Navbharat Times, Dainik Jagran, Punjab Kesari, Hindustan, Amar Ujala, Navodaya Times, Hamara Samaj, Pratap, Daur-e-Jadeed, Jathedar, Jan Ekta. The advertisements shall also indicate that the vaccination shall be administered with Auto Disable Syringes to the eligible children by Auxiliary Nurse Midwifery.* ***The advertisement shall also clearly indicate the side effects and contraindications as may be finalised by the Department of Preventive Medicine, All India Institute of Medical Sciences."***

NOTARY
M. M. PAWALE
Mumbai
Maharashtra
Reg. No. 15220
Expiry Dt.
30-10-2024
GOVT. OF INDIA

34.1.1. That the WHO has warned the people getting CoviShield (AstraZeneca) vaccines to be careful as it is causing a serious paralytic disease **GBS (Guillain Barre Syndrome).**

Link: https://www.who.int/news/item/26-07-2021-statement-of-the-who-gacvs-covid-19-subcommittee-on-gbs

34.1.2. Needless to mention that, as pointed out in **Para 9.1** of the Additional Affidavit at **Page no. 970**, the AEFI Committee admitted that the death of Dr. Snehal Lunawat was due to side-effects of Covi Shield.

34.1.3. That, in India, there are Lacs of such cases and more than **10,700** vaccine deaths are reported in media. But AEFI committee is not working fairly and properly.

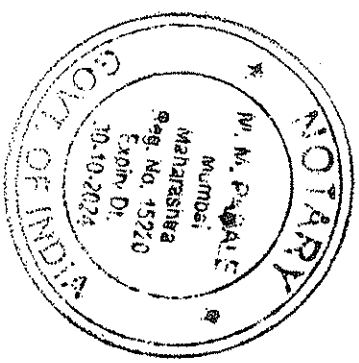
34.1.4. That, as mentioned in **Para 18.2** at **Page No. 1000** the Covi Shield vaccine are banned in 12 European Countries. Only because of 1 death connected to vaccines.

15 Countries around the world have currently banned the use of Covishield. (See page 148 point 12)

34.2. That the provisions of Universal Declaration on Bioethics and Human Rights,2005 also mandate for informed consent.

Relevant Articles reads thus;

> ***"Article 3 – Human dignity and human rights***
>
> *1. Human dignity, human rights and fundamental freedoms are to be fully respected.*
>
> ***2. The interests and welfare of the individual should have priority over the sole interest of science or society.***
>
> *Article 6 – Consent*
>
> ***1. Any preventive, diagnostic and therapeutic medical intervention is only to be carried out with the prior, free and informed consent of the person concerned, based on adequate information. The consent should, where appropriate, be express and may be withdrawn by the person concerned at any time and for any reason without disadvantage or prejudice.***
>
> *2. Scientific research should only be carried out with the prior, free, express and informed consent of the person concerned. The information should be adequate, provided in a comprehensible form and should include modalities for*



withdrawal of consent. Consent may be withdrawn by the person concerned at any time and for any reason without any disadvantage or prejudice. Exceptions to this principle should be made only in accordance with ethical and legal standards adopted by States, consistent with the principles and provisions set out in this Declaration, in particular in Article 27, and international human rights law.

3. In appropriate cases of research carried out on a group of persons or a community, additional agreement of the legal representatives of the group or community concerned may be sought. In no case should a collective community agreement or the consent of a community leader or other authority substitute for an individual's informed consent.

Article 7 – Persons without the capacity to consent

In accordance with domestic law, special protection is to be given to persons who do not have the capacity to consent:

(a) authorization for research and medical practice should be obtained in accordance with the best interest of the person concerned and in accordance with domestic law. However, the person concerned should be involved to the greatest extent possible in the decision-making process of consent, as well as that of withdrawing consent;

(b) research should only be carried out for his or her direct health benefit, subject to the authorization and the protective conditions prescribed by law, and if there is no research alternative of comparable effectiveness with research participants able to consent. Research which does not have

NOTARY M. M. PABALE Mumbai Maharashtra Reg. No. 152[illegible] Expiry On 30-10-202[illegible] GOVT. OF INDIA

potential direct health benefit should only be undertaken by way of exception, with the utmost restraint, exposing the person only to a minimal risk and minimal burden and, if the research is expected to contribute to the health benefit of other persons in the same category, subject to the conditions prescribed by law and compatible with the protection of the individual's human rights. Refusal of such persons to take part in research should be respected.

Article 8 – Respect for human vulnerability and personal integrity

In applying and advancing scientific knowledge, medical practice and associated technologies, human vulnerability should be taken into account. Individuals and groups of special vulnerability should be protected and the personal integrity of such individuals respected.

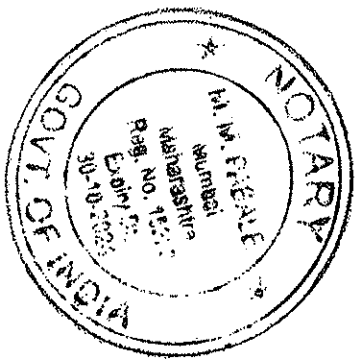
Article 16 – Protecting future generations

The impact of life sciences on future generations, including on their genetic constitution, should be given due regard.

Application of the principles

***Article 18** – Decision-making and addressing bioethical issues*

1. Professionalism, honesty, integrity and transparency in decision-making should be promoted, in particular declarations of all conflicts of interest and appropriate sharing of knowledge. Every endeavour should be made to



use the best available scientific knowledge and methodology in addressing and periodically reviewing bioethical issues.

2. Persons and professionals concerned and society as a whole should be engaged in dialogue on a regular basis.

3. Opportunities for informed pluralistic public debate, seeking the expression of all relevant opinions, should be promoted."

34.3. In **Montgomery Vs. Lanarkshire Health Board [2015] UKSC 11,** it is ruled as under;

"89. Three further points should be made. First, it follows from this approach that the assessment of ***whether a risk is material cannot be reduced to percentages****. The significance of a given risk is likely to reflect a variety of factors besides its magnitude: for example, the nature of the risk, the effect which its occurrence would have upon the life of the patient, the importance to the patient of the benefits sought to be achieved by the treatment, the alternatives available, and the risks involved in those alternatives. The assessment is therefore fact-sensitive, and sensitive also to the characteristics of the patient.*

77. These developments in society are reflected in professional practice. The court has been referred in particular to the guidance given to doctors by the General Medical Council, who participated as interveners in the present appeal. ***One of the documents currently in force (Good Medical Practice (2013)) states, under the heading***

"The duties of a doctor registered with the General Medical Council":

"Work in partnership with patients. Listen to, and respond to, their concerns and preferences. Give patients the information they want or need in a way they can understand. Respect patients' right to reach decisions with you about their treatment and care."

78. Another current document (Consent: patients and doctors making decisions together (2008)) describes a basic model of partnership between doctor and patient:

"The doctor explains the options to the patient, setting out the potential benefits, risks, burdens and side effects of each option, including the option to have no treatment. The doctor may recommend a particular option which they believe to be best for the patient, but they must not put pressure on the patient to accept their advice. The patient weighs up the potential benefits, risks and burdens of the various options as well as any non-clinical issues that are relevant to them. The patient decides whether to accept any of the options and, if so, which one." (para 5)

In relation to risks, in particular, the document advises that the doctor must tell patients if treatment might result in a serious adverse outcome, even if the risk is very small, and should also tell patients about less serious complications if they occur frequently (para 32). The submissions on behalf of the General Medical Council acknowledged, in relation to these documents, that an approach based upon the informed

involvement of patients in their treatment, rather than their being passive and potentially reluctant recipients, can have therapeutic benefits, and is regarded as an integral aspect of professionalism in treatment.

80. *In addition to these developments in society and in medical practice, there have also been developments in the law. Under the stimulus of the Human Rights Act 1998, the courts have become increasingly conscious of the extent to which the common law reflects fundamental values. As Lord Scarman pointed out in Sidaway's case, these include the value of self-determination (see, for example, S (An Infant) v S [1972] AC 24, 43 per Lord Reid; McColl v Strathclyde Regional Council 1983 SC 225, 241; Airedale NHS Trust v Bland [1993] AC 789, 864 per Lord Goff of Chieveley). As well as underlying aspects of the common law, that value also underlies the right to respect for private life protected by article 8 of the European Convention on Human Rights. The resulting duty to involve the patient in decisions relating to her treatment has been recognised in judgments of the European Court of Human Rights, such as Glass v United Kingdom (2004) EHRR 341 and Tysiac v Poland (2007) 45 EHRR 947, as well as in a number of decisions of courts in the United Kingdom. The same value is also reflected more specifically in other international instruments: see, in particular, article 5 of the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine, concluded by the member*

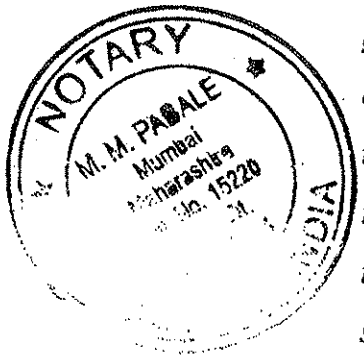
states of the Council of Europe, other states and the European Community at Oviedo on 4 April 1997.

*82. **In the law of negligence, this approach entails a duty on the part of doctors to take reasonable care to ensure that a patient is aware of material risks of injury that are inherent in treatment.** This can be understood, within the traditional framework of negligence, as a duty of care to avoid exposing a person to a risk of injury which she would otherwise have avoided, but it is also the counterpart of the patient's entitlement to decide whether or not to incur that risk. The existence of that entitlement, and the fact that its exercise does not depend exclusively on medical considerations, are important. They point to a fundamental distinction between, on the one hand, the doctor's role when considering possible investigatory or treatment options and, on the other, her role in discussing with the patient any recommended treatment and possible alternatives, and the risks of injury which may be involved.*

83. The former role is an exercise of professional skill and judgment: what risks of injury are involved in an operation, for example, is a matter falling within the expertise of members of the medical profession. But it is a non sequitur to conclude that the question whether a risk of injury, or the availability of an alternative form of treatment, ought to be discussed with the patient is also a matter of purely professional judgment. The doctor's advisory role cannot be regarded as solely an exercise of medical skill without leaving out of account the patient's entitlement to decide on

the risks to her health which she is willing to run (a decision which may be influenced by non-medical considerations). Responsibility for determining the nature and extent of a person's rights rests with the courts, not with the medical professions.

87. *The correct position, in relation to the risks of injury involved in treatment, can now be seen to be substantially that adopted in Sidaway by Lord Scarman, and by Lord Woolf MR in Pearce, subject to the refinement made by the High Court of Australia in Rogers v Whitaker, which we have discussed at paras 77-73.* ***An adult person of sound mind is entitled to decide which, if any, of the available forms of treatment to undergo, and her consent must be obtained before treatment interfering with her bodily integrity is undertaken. The doctor is therefore under a duty to take reasonable care to ensure that the patient is aware of any material risks involved in any recommended treatment, and of any reasonable alternative or variant treatments.*** *The test of materiality is whether, in the circumstances of the particular case, a reasonable person in the patient's position would be likely to attach significance to the risk, or the doctor is or should reasonably be aware that the particular patient would be likely to attach significance to it.*



90. *Secondly, the doctor's advisory role involves dialogue, the aim of which is to ensure that the patient understands the seriousness of her condition, and the anticipated benefits and risks of the proposed treatment and any reasonable*

alternatives, so that she is then in a position to make an informed decision. This role will only be performed effectively if the information provided is comprehensible. ***The doctor's duty is not therefore fulfilled by bombarding the patient with technical information which she cannot reasonably be expected to grasp, let alone by routinely demanding her signature on a consent form.***

116. *As NICE (2011) puts it, "Pregnant women should be offered evidence-based information and support to enable them to make informed decisions about their care and treatment" (para 1.1.1.1). Gone are the days when it was thought that, on becoming pregnant, a woman lost, not only her capacity, but also her right to act as a genuinely autonomous human being."*

34.4. But Respondent No.1 state failed to perform its duty as per law and vaccinated the public by suppressing the data and it is a case of cheating.

34.4.1. That, recently the Health Ministry of Japan has made Following declaration/orders on their website:

"Consent to vaccination

Although we encourage all citizens to receive the COVID-19 vaccination, it is not compulsory or mandatory. Vaccination will be given only with the consent of the person to be vaccinated after the information provided. Please get vaccinated of your own decision, understanding both the effectiveness in preventing infectious diseases and the risk of side effects. No vaccination will be given without consent.

NOTARY M. M. PABALE Mumbai

Please do not force anyone in your workplace or those who around you to be vaccinated, and do not discriminate against those who have not been vaccinated."

34.4.2. Furthermore, the Government of Japan also asked the citizens to make complain to Human Rights Division if there is any discrimination on the basis of vaccination status.

34.4.3. The government made companies of Covid "vaccines" to warn of dangerous and potentially deadly side effects such as myocarditis. In addition, the country is reaffirming its commitment to adverse event reporting requirements to ensure all possible side effects are documented. For more details read the article:
https://rairfoundation.com/alert-japan-places-myocarditis-warning-on-vaccines- requires-informed-consent/

Alert: Japan Places Myocarditis Warning on **'Vaccines' - Requires Informed Consent Amy Mek.**

34.4.3. That the above declaration is mandatory to all countries across the world because of **Universal Declaration on Bioethics & Human Rights, 2005** and also as per law laid down in **Montgomery's case [2015] UKSC 11, Airdale NHS Trust Vs. Bland (1993) 1 All ER 821, Common Cause Vs. Union of India (2018) 5SCC 1, Registrar General Vs. State of Meghalaya 2021 SCC OnLine Megh 130.**

34.4.4. It applies with much more rigour and force in India because neither State nor Central Government is going to grant any compensation to the victim of side effects of vaccines including deaths.

NOTARY M. M. PARALE Mumbai Maharashtra Reg. No. 15220 Expiry Dt. 30-10-2024 T. OF INDIA

34.4.5. Needless to mention here that, in a recent case of vaccine injury the Government of Singapore granted a compensation of **Rs. 1 Crore 78 Las** to the victim as vaccine cause increase in heart beats.

Link:- https://greatgameindia.com/pfizer-heart-attack-compensation/

34.4.6. That, in a case of side effects of vaccines, the United States Government has set up the **'National Vaccine Injury Compensation Program'**. In a case ofside effects of MMR vaccines the court granted a settlement of 101 Million U.S Dollars **(Rupees 7,50,34,31,400 Crores).**

34.4.7. That, in another case related with misrepresentation by pharma companies by suppressing the side effects of medicines. The companies failure to report certain safety data was also taken into consideration. The investigating agency of US at their own investigated and recovered an amount 10.2 Billion U.S. Around 7,57,71,92,40,000 Crore Rupees. The excerpts from the news published on July 2, 2012 in The United State' Department of Justice.

> "*The company's unlawful promotion of certain prescription drugs, its failure to report certain safety data, and its civil liabilityfor alleged false price reporting practices.*
>
> *GSK did not make available data from two other studies in which Paxil also failed to demonstrate efficacy in treating depression in patients under 18. The United States further alleges that GSK sponsored dinner programs, lunch programs, spa programs and similar activities to promote the use of Paxil in children and adolescents. GSK paid a speaker to talk*

NOTARY M. M. PABALE Mumbai Maharashtra Regd. No. 15220

to an audience of doctors and paid for the meal or spa treatment for the doctors who attended.

Between 2001 and 2007, GSK failed to include certain safety dataabout Avandia, a diabetes drug.

The missing information included data regarding certain post- marketing studies, as well as data regarding two studies undertaken in response to European regulators' concerns about the cardiovascular safety of Avandia. Since 2007, the FDA has added two black box warnings to the Avandia label to alert physicians about the potential increased risk of (1) congestive heart failure, and (2) myocardial infarction (heart attack).

GSK has agreed to plead guilty to failing to report data to the FDA and has agreed to pay a criminal fine in the amount of $242,612,800 for its unlawful conduct concerning Avandia.

It also includes allegations that GSK paid kickbacks to health care professionals to induce them to promote and prescribe these drugs as well as the drugs Imitrex, Lotronex, Flovent and Valtrex. The United States alleges that this conduct caused false claims to be submitted to federal health care programs.

GSK has agreed to pay $1.043 billion relating to false cl aims arisingfrom this alleged conduct. The federal sh are of this settlement is$832 million and the state shar e is $210 million."

NOTARY M. M. PAGALE Mumbai Maharashtra Reg. No. 15220 Expiry Dt. 30-10-2021

34.4.8. Constitution Bench of Hon'ble Supreme Court in the case of **Anita Kushwaha Vs. Pushap Sadan (2016) 8 SCC 509,** has ruled that the life of Indian Citizen is not less pricy than the life of people in England or anywhere. But in India the rights are more precious.

It is ruled that;

> *"18... Bose, J. emphasised the importance of the right of any person to apply to the court and demand that he be dealt with according to law. He said: (Prabhakar Kesheo case [Prabhakar Kesheo Tare v. Emperor, AIR 1943 Nag 26 : 1942 SCC OnLine MP 78] , SCC OnLine MP para 1)*
>
> *"1. ... The right is prized in India no less highly than in England, or indeed any other part of the Empire, perhaps even more highly here than elsewhere; and it is zealously guarded by the courts."*

NOTARY
M. M. PABALE
Mumbai
Maharashtra
Reg. No. 15220
Expiry Dt.
30-10-2021
GOVT. OF INDIA

35. The act of respondent no.1 in filling such misleading affidavit and giving it wide publicity so as to incite hatred against the unvaccinated people is also an offence under section 505(2) and 153 (A) etc. of IPC.

36. The insistence of the state authority i.e. Respondent No. 1 by asking the citizens to get immunization only through vaccines is contempt of the Supreme Court Judgment in Dr. AKB Sadbhavan Mission School of Homeo Pharmacy Vs. Secretary (2021) 2 SCC 539, and other law applicable in India.

36.1. Hon'ble Supreme Court in **Dr. AKB Sadbhavan Mission School of Homeo Pharmacy** ***(Supra)***, made it clear that the person can get treatment against Covid-19 either through Homeopathy or

through Allopathy or any medicine and Allopathy cannot claim the 100% cure.

It is ruled as under;

> *"26. The above guidelines make it clear that Homoeopathy has been envisaged by the Ministry as a therapeutic aid.*
>
> *27. The above guidelines refer to Homoeopathic medicines as medicines for prophylaxis, amelioration and mitigation. The guidelines, however, specifically provide that "the prescription has to be given only by institutionally qualified practitioners". The High Court in its impugned judgment [M.S. Vineeth v. Ministry of Ayush, WP (C) No. 9459 of 2020, decided on 21-8-2020 (Ker)] has not fully comprehended the Guidelines dated 6-3-2020 and taking a restricted view of the guidelines and have made observations for taking appropriate actions against Homoeopathic medical practitioners, which cannot be approved. The High Court, however, is right in its observation that no medical practitioner can claim that it can cure Covid-19. There is no such claim in other therapy including allopathy. The High Court is right in observing that no claim for cure can be made in Homoeopathy. Homoeopathy is contemplated to be used in preventing and mitigating Covid-19 as is reflected by the advisory and guidelines issued by the Ministry of Ayush as noticed above.*

NOTARY M. M. PABALE Mumbai Maharashtra Reg. No. 15220 Expiry Dt. GOVT.

25. We, however, make it clear that what is permissible for Homoeopathic medical practitioner in reference to Covid-19 symptomatic and asymptomatic patients is already regulated by the said advisory and guidelines. The Government of India, Ministry of Ayush has also brought on record the guidelines issued subsequent to 6-3-2020 for Homoeopathic medical practitioners for Covid-19, where Homoeopathic approach to Covid-19 has been elaborately dealt with. The said guidelines, which have been issued after 4-4-2020 have been brought on the record as Annexure C by the Ministry of Ayush. The guidelines contained the following under the heading "Homoeopathic approach":

*"**Homoeopathic Approach***

It is advised that before taking up for homoeopathic medicines for prophylaxis, amelioration and mitigation, physician must acquaint himself of above sections.

In case of epidemics or pandemics, first approach is to follow preventive measures and educate people about general measures and to provide such interventions which will keep their immunity enhanced. Homoeopathy therefore recommends issuing of public notice for Genus epidemicus identified by the designated experts for immunity enhancement and practitioners may suggest the same to the people and as per the Advisory issued by Ministry of Ayush.

Second approach is to provide homoeopathic symptomatic mitigation to affected persons. Homoeopathic medicines are also useful in the treatment of communicable diseases like influenza like illness, dengue, acute

NOTARY M. M. PABALE Mumbai Maharashtra Reg. No. 15220 Expiry 31-10-2021 GOVT. OF INDIA

encephalitis syndrome. Several studies are also published which show the immune modulatory potential of homoeopathic medicines in preclinical studies. These medicines can be prescribed in an integrated manner or standalone depending on the severity on a case to case.

Therapeutic Aid

As a system with holistic approach medicine were selected based on the presenting signs and symptoms of each patient. The medicines given here are suggestive based on their use and studies in the past in diseases of similar presentation like Covid-19. Patients of Covid-19 are to be treated with adjuvant Homoeopathic medicines with the permission from local health authorities and Medical Superintendent of the Hospital. Homoeopathic doctors must follow all preventive measures (using PPEs) as are required for dealing with Covid-19 patients.

The remedies according to different stages of disease are given below:

NOTARY M. M. PABALE Mumbai Maharashtra Reg. No. 15228 Expiry Dt. 30-10-2024 GOVT.

Mild Disease *(Symptomatic Amelioration and Mitigation Approach): Medicines like Aconite napellus, Arsenicum album, Bryonia alba, Gelsemium sempervirens, Rhus tox, Eupatorium perfoliatum, Ipecacaucunha, Belladonna, Camphora, may be used depending upon the symptoms similarities.*

Severe disease but not in critical condition:

It is defined by following criteria (Dyspnoea, respiratory frequency ≥ 30/min, blood oxygen saturation (SpO_2) ≤ 93%,

PaO_2/FiO_2 ratio < 300, and/or lung infiltrates > 50% within 24 to 48 hours)/)

- *Suggested medicines are as adjuvant to Standard Management guidelines in the hospital setting only with the approval of authorities and willingness of the patient/guardian.*
- *The prescription is to be given only by institutionally qualified practitioner.*
- *Medicines like Phosphorus, Chelidonium, Veratrum Viride, Iodum, Camphora, Cinchona officinalis, Lycopodium, Ars. iod., Antim ars., Stannum met, Carbo veg., can be prescribed on symptomatic indication.*

Posology

The medicine selected for each patient is tailored to person specific, taking into consideration, his/her mental make-up, physical symptoms, and characteristic particulars, etc. In case of long term illness, besides the abovementioned factors, age, occupation, previous illnesses and life circumstance unique to that individual irrespective of the disease which he/she is suffering from, are also taken into consideration; thus the dictum "Homoeopathy treats the patient but not the disease".

After the appropriate medicine is selected, it is essential to decide the requisite potency, dose and repetition which is imperative for optimum response and faster recovery in each case. Different types of potencies such as decimal or centesimal potencies can be employed for treatment as are required for acute diseases. However, selection of potency of

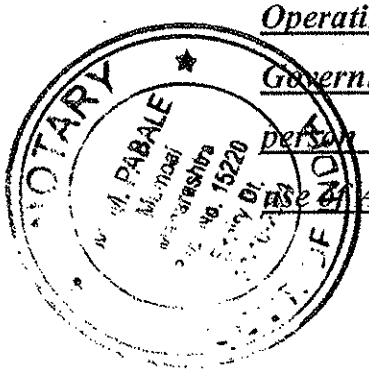
NOTARY M. M. PABALE Mumbai Maharashtra Reg. No. 15220 Expiry Dt. 31-10-2024 GOVT. OF INDIA

the remedy is dependent on various factors like susceptibility of the patient (high or low), type of disease (acute/chronic), seat/nature and intensity of the disease, stage and duration of the disease and also the previous treatment of the disease (24)."

28. We, thus, observe that the directions issued by the High Court in para 14 of the judgment [M.S. Vineeth v. Ministry of Ayush, WP (C) No. 9459 of 2020, decided on 21-8-2020 (Ker)] need to be modified to the extent as indicated above. It goes without saying that Homoeopathic medical practitioners have to follow the advisory dated 6-3-2020 issued by Ayush Ministry as well as guidelines for Homoeopathic medical practitioners for Covid-19 issued by the Government of India, Ministry of Ayush, as noted above. The civil appeal is disposed of accordingly. The interlocutory applications filed seeking permission for impleadment are rejected."

36.2. Similar law is laid down by Hon'ble Karnataka High Court in the matter between **A.Varghese Vs. Union of India 2020 SCC OnLine Kar 2825,** it is ruled as under;

"2. The petition proceeds on the footing that the Standard Operating Procedures / Guidelines prescribed by the State Government as well as the Government of India compel a person suffering from Covid-19 to take treatment only by use of Allopathic drugs.

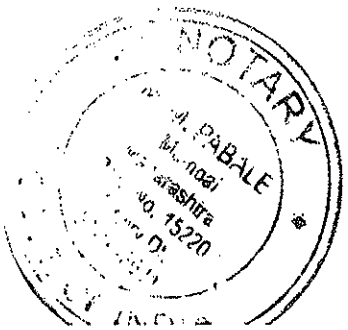


> ***At least from the Standard Operating Procedures, which are placed on record, we do not find anything therein which shows that the Government can compel a patient to take only Allopathic drugs.*** *We cannot go into the question whether Covid-19 can be successfully treated either by Ayurvedic drugs or by Allopathic drugs. It is for the experts in the field of medicine to decide that question."*

36.3. Hence, if doctors give certificate that the patient is immune either because of antibodies or due to having taken alternate treatment such as Ayurvedic, Homeopathy, Naturopathy or any other treatment then there is no question of treating said person differently or discriminating him only because he had not taken the vaccine. Second point is that why a person is required to keep on showing his certificate to everyone.

36.4. Hon'ble Andhra Pradesh High Court in **Ponnekanti Rao Vs. State of Andhra Pradesh 2021 SCC OnLine AP 2171**, made it clear that when the treatment of herbal composition prepared by Mr. Bonigi Anandaiah are found to be safe for the person treated under Covid-19, then State Government should not interfere in his work.

36.5. Petitioner have also attached peer reviewed scientific studies, which show that Ivermectin, Omega3 fatty acids, Vitamin D, Black seeds, Nutritional and oxidative therapies, & Arginine have also been proven to reduce covid-19 infections, hospitalizations and deaths. So even for the sake of arguments it is considered that the vaccines are effective in reducing hospitalizations, they are by no means the only tool. And that cannot be a ground to discriminate between vaccinated and unvaccinated.



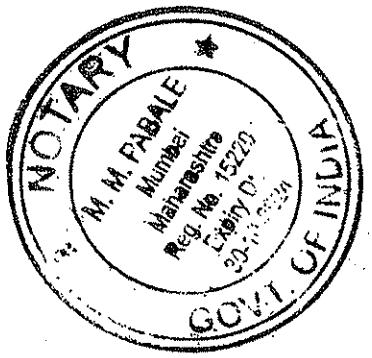
36.6. Under these circumstances the order passed by the Maharashtra Government on **27.11.2021** bringing the rules and running the narratives that only vaccines can treat the people and the person those who are not taking the vaccines are not to be treated as protected is false, frivolous, unlawful, arbitrary, unconstitutional and in contempt of the Hon'ble Supreme Court and High Courts judgments.

37. State cannot bring any prohibitions or lockdown without making arrangements for compensation as mandated under Section 2 of the Epidemic Act, 1897. But Respondent No. 1 maliciously not followed the said provisions.

37.1. That, section 2 of the Epidemic Act, 1897 makes it mandatory to the State authority to make provisions for compensating the citizens for damages/loss caused to the citizens due to such measures.

37.2. Section 2 of the Epidemic Act, 1897 reads thus;

> *"2. Power to take special measures and prescribe regulations as to dangerous epidemic disease.—*
>
> *(1) When at any time the 7[State Government] is satisfied that 7[the State] or any part thereof is visited by, or threatened with, an outbreak of any dangerous epidemic disease, the 8[State Government], if 9[it] thinks that the ordinary provisions of the law for the time being in force are insufficient for the purpose, may take, or require or empower any person to take, such me asures and, by public notice, prescribe such temporary regulations to be observed by the public or by any person or class of persons as 9[it] shall deem necessary to prevent the outbreak of such disease or*



the spread thereof, and may determine in what manner and by whom any expenses incurred (including compensation if any) shall be defrayed.

(2) In particular and without prejudice to the generality of the foregoing provisions, the 7[State Government] may take measures and prescribe regulations for—

(b) the inspection of persons travelling by railway or otherwise, and the segregation, in hospital, temporary accommodation or otherwise, of persons suspected by the inspecting officer of being infected with any such disease."

37.3. That, based on the above provisions, the British Government in the year 1899 paid compensation to the citizens in Pune for losses incurred due to measures of lime wash taken by the British Government.

Compensation by Britishers during pandemic in Pune. Excerpts from news article : -

"<u>How oppressive containment measures during Poona plague led to assassination of British officer</u>

The Indian Express

June 9, 2020

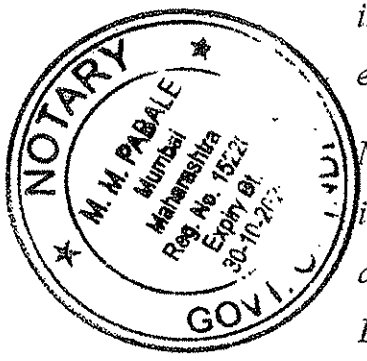
The medical officers were supplied with cash advances and had instructions to pay compensation for any articles belonging to plague patients that may have been destroyed in the process.

NOTARY
M. M. PABALE
Mumbai
Maharashtra
Reg. No. 45220

1354

"It was found at the beginning of the operations that rather too many articles were at times destroyed as rubbish. Orders were accordingly issued on March 26 to Officers commanding limewashing divisions to visit, if possible, all houses to be limewashed and to decide what should be destroyed in each. It was also laid down that when a property of any value to the owners was destroyed by limewashing party, the Officer commanding the division should note the approximate cost of replacing what had been destroyed in order that compensation might afterwards be paid. In practice nothing was destroyed after the first fortnight of the operations except in the presence of an officer," reads the report.

It was at this backdrop that Bal Gangadhar Tilak wrote in Mahratta, his English newspaper: "Plague is more merciful to us than its human prototypes now reigning the city. The tyranny of the Plague Committee and its chosen instruments is yet too brutal to allow respectable people to breathe at ease."



No doubt that the regulations and measures as they were imposed in Pune were the most stringent among all the cities afflicted by the pandemic. In fact, Antony MacDonnel, Lieutenant-Governor of the North-Western Provinces, had observed in a July 1897 communique that "If the plague regulations had been enforced in any city of these provinces in the way in which ...they were...enforced in Poona, there would have been bloodshed here."

THE MURDERS

Blood was indeed shed in Pune too. On June 22, 1897, Chapekar brothers – Damodar (27), Balkrisha (24) and Vasudev (17 or 18) – shot Rand and Lieutenant Charles Ayerst (mistaking him for Rand before he was located in the preceding carriage) while they were returning from Queen Victoria's Jubilee Celebration at Government House in Ganeshkhind (now Pune University). While Ayerst died immediately, Rand succumbed to the injuries on July 3.

After the initial frenzy had abated, and following Rand's murder, the Plague Committee slackened its operations although plague continued to flourish.

Link: https://indianexpress.com/article/research/how-oppressive-containment-measures-during-poona-plague-led-to-assassination-of-british-officer-6450775/

37.4. That similar provisions are there in Section 12 & 13 of the Disaster Management Act, 2005 reads thus;

"12 Guidelines for minimum standards of relief. *—*

The National Authority shall recommend guidelines for the minimum standards of relief to be provided to persons affected by disaster, which shall include,—

(i) the minimum requirements to be provided in the relief camps in relation to shelter, food, drinking water, medical cover and sanitation;

(ii) the special provisions to be made for widows and orphans;

NOTARY M. M. PABALE Mumbai Maharashtra Reg. No. 15220 Expiry Dt. 30-10-2024 GOVT. OF INDIA

(iii) ex gratia assistance on account of loss of life as also assistance on account of damage to houses and for restoration of means of livelihood;

(iv) such other relief as may be necessary.

13. Relief in loan repayment etc. —

The National Authority may, in cases of disasters of severe magnitude, recommend relief in repayment of loans or for grant of fresh loans to the persons affected by disaster on such concessional terms as may be appropriate."

37.5. That, the **Respondent No. 1** only taken the first part of the provisions and brought the draconian mandates of prohibiting unvaccinated people from moving outside their home. But did not provided any amount to such people to compensate them against the said measures. In fact the State authorities are bound to compensate all such people including petitioner who are sufferer of the arbitrary rules made by the State i.e. Respondent No. 1.

37.6. That, many citizens have made written application to the officials of Respondent No. 1 for providing them compensation as per above provision.

(A copy of one such application is marked and annexed herewith **Exhibit "RA-51") (Page No. 614)**

But officials of Respondent No. 1 failed to compensate the citizen. This is sufficient proof of Malafides and arbitrary acts of the Respondent No. 1



38. Respondent No. 1 – State of Maharashtra was duty bound to follow the Constitution Bench judgment in Mineral Development Ltd. Vs. State (1960) 2 SCR 609 and remove the persons from committee, who are directly or indirectly getting funds from the vaccine/pharma companies more particularly from Bill & Melinda Gates Foundation, Rockefeller Foundation, whose aim is to give wrongful profits to the vaccine companies at the cost of killing the people.

38.1. That, there is another ground/reason to doubt the bonafides of the Respondent No. 1 State of Maharashtra, in passing such unlawful, unscientific, illogical & arbitrary mandates.

38.2. That, the 'Toxic Philanthropist' and kingpin of vaccine mafia Mr. Bill Gates through his Bill & Melinda Gates Foundation keep on giving funds, sponsorship and manage Government officials to do work for the welfare of the vaccine companies in the name of charity.

38.3. That, the findings of 72nd Report by Parliamentary Committee are sufficient to prove the entire conspiracy and modus operandi of Bill Gates and other Pharma mafias in killing innocent people for the profit of vaccine companies.

38.4. Mastermind accused **Bill Gates**, who is manufacturing **'CoviShield'** in India in partnership with Serum Institute is habitual offender of Mass Murders by vaccination in conspiracy with Government officials.

38.5. That, the parliamentary committee in its 72nd report gave clear and specific findings about the serious offences of murder of **8 female children** and recommended investigation and prosecution of office bearers of **NGO PATH** related with **Bill & Milinda Gates foundation**

along with official of ICMR and other government officials involved in the conspiracy.

(A copy of Parliamentary Committee's 72nd Report dated 23rd August, 2013 marked and annexed herewith **Exhibit "RA-52") (Page No. 620)**

38.6. The Constitution Bench in **Kalpana Mehta v. Union of India, (2018) 7 SCC 1**, have upheld the evidentiary value of 72nd report by Parliamentary Committee.

38.7. The excerpts of the **Parliamentary Committee's 72nd** report are as under;

> *"7.13. Coming to the instant case, it is established that PATH by carrying out the clinical trials for HPV vaccines in Andhra Pradesh and Gujarat under the pretext of observation/ demonstration* ***project has violated all laws and regulations laid down for clinical trials by the Government. While doing so, its sole aim has been to promote the commercial interests of HPV vaccine manufacturers who would have reaped windfall profits had PATH been successful in getting the HPV vaccine included in the UIP of the Country. This is a serious breach of trust by any entity as the project involved life and safety of girl children and adolescents who were mostly unaware of the implications of vaccination. The violation is also a serious breach of medical ethics. This act of PATH is a clear cut violation of the human rights of these girl children and adolescents.*** *It also deems it an established case of*

NOTARY M. M. PABALE Mumbai Maharashtra Reg. No. 15220 Expiry Dt. 30-10-20.. GOVT. OF INDIA

child abuse. The Committee, therefore, recommends action by the Government against PATH. The Committee also desires that the National Human Rights Commission and National Commission for Protection of Children Rights may take up this matter from the point of view of the violation of human rights and child abuse. The National Commission for Women should also suomotu take cognizance of this case as all the poor and hapless subjects are females.

7.14. The Ministry of Health and Family Welfare should without wasting time report the violations indulged in by PATH to international bodies like WHO and UNICEF so as to ensure that appropriate remedial action is initiated by these agencies worldwide.

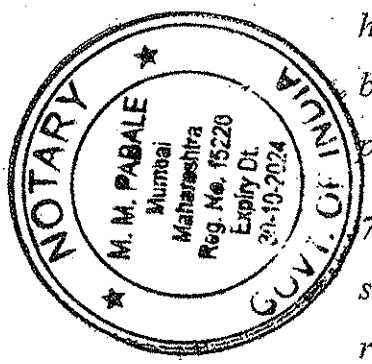
7.15. The Committee also desires that the Ministry of Health and Family Welfare may take up the matter through the Ministry of External Affairs with the US Government so as to ensure that appropriate action is taken against PATH under the laws of its country of origin in case of any violations of laws there.

6.26. The Committee observes that the wrongful use of the NRHM logo for a project implemented by a private, foreign agency as well as the identification of this project with the UIP has adversely affected and damaged the credibility of the programme as well as that of the NRHM. The Committee, therefore,

NOTARY
M. M. PABALE
Mumbai
Maharashtra
Reg. No. 15220
Expiry Dt.
30-10-2024
GOVT. OF INDIA

recommends that ***such practices of diverting public funds for advancing interests of a private agency should never be allowed in future. The Committee strongly recommends that strict action should be taken against those officials responsible for such lapses.***

6.27. Besides, the Committee notes that no information had been provided to Indian authorities about funding of the project except that it was reportedly funded by Bill and Melinda Gates Foundation and that the vaccines had been donated by the manufacturers. The information regarding financial investments of ICMR and State Governments in the project was not provided, though the States clearly provided cold chain and manpower for immunization. The Committee, accordingly, observes that it might have been more prudent if the National Technical Advisory group on Immunization (NTAGI) had been brought into the picture right in the beginning to review and give its views on the study prior to its approval and implementation.



7.11. The Committee is concerned that if PATH can set up an office in India so easily without getting the required mandatory approvals/permissions, then individuals and entities inimical to the interest of the country can do the same. The Committee expresses its concern that paper and shell companies can be easily registered in many jurisdictions and then set up a

place of business in India as "Liaison offices" with no questions being asked. ***It is surprising that security and intelligence agencies did not raise an eyebrow on the way a foreign entity entered India virtually incognito through the backdoor.*** *The Committee desires that such incidents should not be allowed in future. The Government should tighten the rules lest one day foreign citizens, with deep roots in organizations/nations inimical to India, set up offices in the country to engage in anti-national and/or unlawful activities.*

6.29. *Considering the above lapses and irregularities committed by PATH during the course of conducting the trials on hapless tribal children in Andhra Pradesh and Gujarat, the Committee is convinced that the authorities concerned did not exercise due diligence in scrutinizing the publicity material of PATH. Blurring the distinction between the UIP and PATH project due to the involvement of the State Governments in the project and ignoring the financial contribution of ICMR and the State Governments are very serious issues. The Committee, therefore, recommends that the Ministry should investigate into the above acts of omissions and commissions and take necessary action against those who are found responsible for breach of rules and regulations.*

2.5. *The Committee finds the entire matter very intriguing and fishy. The choice of countries and*

NOTARY
M. M. PABALE
Mumbai
Maharashtra
Reg. No. 15220
Expiry Dt.
31-10-2024
GOVT. OF INDIA

population groups; the monopolistic nature, at that point of time, of the product being pushed; the unlimited market potential and opportunities in the universal immunization progammes of the respective countries are all pointers to a well planned scheme to commercially exploit a situation. Had PATH been successful in getting the HPV 4 vaccine included in the universal immunization programme of the concerned countries, ***this would have generated windfall profit for the manufacturer(s) by way of automatic sale, year after year, without any promotional or marketing expenses.*** *It is well known that once introduced into the immunization programme it becomes politically impossible to stop any vaccination. To achieve this end effortlessly without going through the arduous and strictly regulated route of clinical trials, PATH resorted to an element of subterfuge by calling the clinical trials as "Observational Studies" or "Demonstration Project" and various such expressions. Thus,* ***the interest, safety and well being of subjects were completely jeopardized by PATH by using self-determined and self-servicing nomenclature which is not only highly deplorable but a serious breach of law of the land.*** *The Committee is not aware about the strategy followed by PATH in the remaining three countries viz. Uganda, Vietnam and Peru. The Government should take up the matter with the Governments of these countries through diplomatic channels to know*

NOTARY M. M. PABALE Mumbai Maharashtra Reg. No. 15220 Expiry Dt. 30-10-2024 GOVT. OF INDIA

the truth of the matter and take appropriate necessary action, accordingly. The Committee would also like to be apprised of the responses of these countries in the matter.

3.18. *The Committee feels that there was serious dereliction of duty by many of the Institutions and individuals involved. The Committee observes that ICMR representatives, instead of ensuring highest levels of ethical standards in research studies, apparently acted at the behest of the PATH in promoting the interests of manufacturers of the HPV Vaccine. 7 3.19 It was unwise on the part of ICMR to go in the PPP mode with PATH, as such an involvement gives rise to grave Conflict of Interest. The Committee takes a serious view of the role of ICMR in the entire episode and is constrained to observe that ICMR should have been more responsible in the matter. The Committee strongly recommends that the Ministry may review the activities of ICMR functionaries involved in PATH project.*

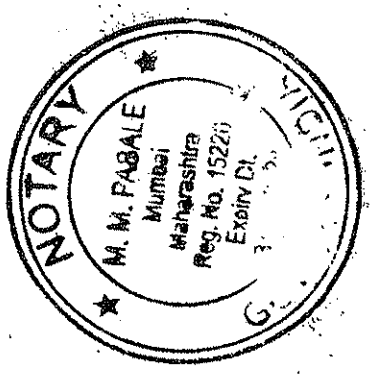
6.10. *The Committee notes that once this matter was taken up by it, the Government appointed an Inquiry Committee on 15 April, 2010 to inquire into 'alleged irregularities in the conduct of the studies using HPV vaccines by PATH in India'. The Committee has noted the serious conflict of interest of members of this Inquiry Committee with the subject matter. The*

NOTARY M. M. PABALE Mumbai Maharashtra Reg. No. 15220 Expiry Dt. 30-10-2013 GOVT. OF INDIA

1364

Committee, therefore, strongly deprecates the Government for appointing a committee to inquire into such a serious matter in such a casual manner even without ascertaining as to whether any of the members of the said Inquiry Committee were having any conflict of interest with the subject matter of inquiry.

6.17. The Committee, accordingly, concludes that most, if not all consent forms, were carelessly filled-up and were incomplete and inaccurate. The full explanation, role, usefulness and pros and cons of vaccination had not been properly communicated to the parents/guardians. The Committee observes that there is a gross violation of the consent and legal requirement of consent which had been substantiated by the experts. The Committee takes a serious view of the violations and strongly recommends ***that on the basis of the above facts, PATH should be made accountable and the Ministry should take appropriate action in the matter including taking legal action against it for breach of various laws of the land and possible violations of laws of the Country of its origin.***



6.29. Considering the above lapses and irregularities committed by PATH during the course of conducting the trials on hapless tribal children in Andhra Pradesh and Gujarat, the Committee is convinced that the authorities concerned did not exercise due

diligence in scrutinizing the publicity material of PATH. Blurring the distinction between the UIP and PATH project due to the involvement of the State Governments in the project and ignoring the financial contribution of ICMR and the State Governments are very serious issues. The Committee, therefore, recommends that the Ministry should investigate into the above acts of omissions and commissions and take necessary action against those who are found responsible for breach of rules and regulations."

38.8. The polio program of enhancing polio doses in children as designed by the Bill Gates has caused a death of thousands of children in Indian and around 4,90,000 children suffered new type of paralysis.

The relevant news article published in The Hindu and Great Game India are as under;

(a) Link:

https://www.thehindu.com/news/cities/Delhi/vaccine-induced-paralysis-calls-for-action-says-study/article24740588.ece

"Vaccine-induced paralysis calls for action, says study

Frequency of pulse polio administration is directly or indirectly related to incidence of non-polio acute flaccid paralysis, say researchers

Over 4.9 lakh persons in India developed paralysis between 2000 and 2017 because of oral polio vaccine (OPV), say leading doctors in two reputed hospitals here.

NOTARY
Mr. M. PABALI
Mumbai
Maharashtra
Reg. No. 15220
Expiry Dt.
30-10-2021
GOVT. OF INDIA

AFP is defined as a sudden onset of paralysis or weakness in any part of the body of a child less than 15 years of age. The surveillance allows nations to detect paralytic poliomyelitis due to wild poliovirus transmission in the population.

"These are all cases of non-polio paralysis, which increased dramatically as polio paralysis was brought down with repeated doses of OPV. This report shows that the rate of paralysis is now coming down where OPV doses have decreased and this is additional proof that paralysis is caused by OPV," says Dr. Puliyel.

For instance, there were an additional 47,500 children with paralysis in 2011, which was over and above the assumed NPAFP rate of 2 per 1 lakh cases and the NPAFP rate started to decrease from 2012, when the number of pulse polio rounds decreased.

"From the results, NPAFP rate shows a decline with reduction in pulse polio doses suggesting that OPV vaccinations are responsible for the paralysis. A total of 6.4 lakh children developed NPAFP from 2000 to 2017, suggesting that there were an additional 4.91 lakh paralysed children above the numbers expected to develop NPAFP," they add.



The report says that "repeated doses of live vaccine virus delivered to the intestine may colonise the gut and alter the viral microbiome of the intestine".

Also, studies from Finland and Turkey suggest that Guillain-Barré Syndrome (GBS) is causatively associated with OPV vaccination campaigns

"While the mechanism involved is speculative, our findings support the hypothesis that the frequency of pulse polio administration is directly or indirectly related to the incidence of NPAFP. Now that India has been polio-free for over six years, we may be able to reduce NPAFP by further reducing pulse polio rounds," the report says."

(b) Link:

https://greatgameindia.com/bill-gates-agenda-in-india-exposed-by-robert-kennedy-jr/

"Bill Gates Activities in India exposed by Robert Kennedy Jr.

Vaccines, for Bill Gates, are a strategic philanthropy that feed his many vaccine-related businesses (including Microsoft's ambition to control a global vaccination ID enterprise) and give him dictatorial control of global health policy.

Promising his share of $450 million of $1.2 billion to eradicate Polio, Gates took control of India's National Technical Advisory Group on Immunization (NTAGI) which mandated up to 50 doses (Table 1) of polio vaccines through overlapping immunization programs to children before the age of five. Indian doctors blame the Gates campaign for a devastating non-polio acute flaccid paralysis

NOTARY
M. M. PABALE
Mumbai
Maharashtra
Reg. No. 15220
Expiry Dt.
30-10-2024
GOVT. OF INDIA

(NPAFP) epidemic that paralyzed 490,000 children beyond expected rates between 2000 and 2017. In 2017, the Indian government dialed back Gates' vaccine regimen and asked Gates and his vaccine policies to leave India. NPAFP rates dropped precipitously."

38.9. That as per law laid down by the Seven Judge Constitution Bench of Hon'ble Supreme Court in the case of **Mineral Development Ltd. Vs. State (1960) 2 SCR 609**, the Minister or any person having conflict of interest or having interest in the outcome of the decision is disqualified to participate the decision-making process.

38.10 Similar law & ratio is laid down in following cases:

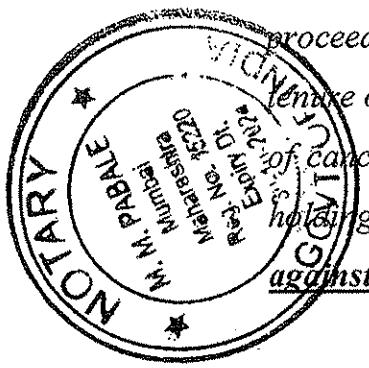
(i) A.K. Kraipak Vs. Union of India (1969) 2 SCC 262

(ii) State of Punjab Vs. Davinder Pal Singh Bhullar (2011) 14 SCC 770

(iii) Suresh Palande Vs. Govt. of Maharashtra 2015 SCC OnLine Bom 6775.

38.11. Seven Judge Constitution bench of Supreme Court in **Mineral Development Ltd. v. State of Bihar AIR 1960 SC 468,** it was held that;

*11... "**It may, therefore, be taken that the allegations of personal bias of the Revenue Minister against the proprietor is not denied. It is also not disputed that** the proceedings against the petitioner were started during the tenure of the said Revenue Minister and that the actual order of cancellation was made by him. We have no hesitation in holding that **the Revenue Minister had personal bias against the proprietor and that he was also acting on the***



belief that the lease was only benami for the said proprietor. *We, therefore, hold that the said Revenue Minister had personal bias within the meaning of the decisions and* ***he should not have taken part in either initiating the enquiry or in cancelling the licence.***

10*...In view of the foregoing principles the first question to be considered is whether in the present case the authority functioning for the State Government — it is admitted that the then Revenue Minister of the State made the impugned order — had personal bias against the petitioner.*

16. *In the result we accept the petition and issue a writ of certiorari against the respondents quashing the order of the Government of Bihar dated September 1, 1955, cancelling miner's licence No. 261-H of 1951 granted in favour of the petitioner. The respondents will pay the costs to the petitioner.*

38.12. Any order or decision which is bad at inception due to consisting of disqualified members vitiates the further decisions and process. Constitution Bench in the case of **A.K. Kraipak v. Union of India (1969) 2 SCC 262** ruled that;

"13. Every organ of the State under our Constitution is regulated and controlled by the rule of law. In a welfare State like ours it is inevitable that the jurisdiction of the administrative bodies is increasing at a rapid rate. ***The concept of rule of law would lose its vitality if the***

NOTARY
M. M. PABALE
Mumbai
Maharashtra
Reg. No. 15220
Expiry Dt.
30-10-2026
GOVT. OF INDIA

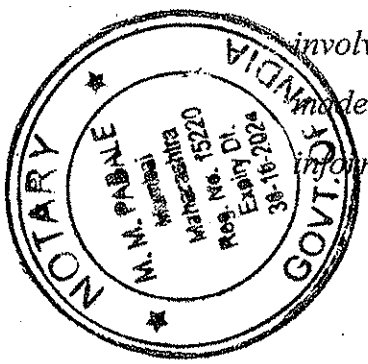
instrumentalities of the State are not charged with the duty of discharging their functions in a fair and just manner. *The requirement of acting judicially in essence is nothing but a requirement to act justly and fairly and not arbitrarily or capriciously.*

18. *In the same case Blain, J., observed thus:*

> *"I would only say that an immigration officer having assumed the jurisdiction granted by those provisions is in a position where it is his duty to exercise that assumed jurisdiction whether it be administrative, executive or quasi-judicial, fairly, by which I mean applying his mind dispassionately to a fair analysis of the particular problem and the information available to him in analysing it. If in any hypothetical case, and in any real case, this court was satisfied that an immigration officer was not so doing, then in my view mandamus would lie."*

19. *In State of Orissa v. Dr Binapani Dei [(1967) 2 SCR 625] Shah, J., speaking for the Court, dealing with an enquiry made as regards the correct age of a government servant, observed thus:*

> *"We think that such an enquiry and decision were contrary to the basic concept of justice and cannot have any value. It is true that the order is administrative in character, but even an administrative order which involves civil consequences as already stated, must be made consistently with the rules of natural justice after informing the first respondent of the case of the State ...."*



The aim of the rules of natural justice is to secure justice or to put it negatively to prevent miscarriage of justice. These rules can operate only in areas not covered by any law validly made. In other words they do not supplant the law of the land but supplement it.

If the purpose of the rules of natural justice is to prevent miscarriage of justice one fails to see why those rules should be made inapplicable to administrative enquiries.

Enquiries which were considered administrative at one time are now being considered as quasi-judicial in character. Arriving at a just decision is the aim of both quasi-judicial enquiries as well as administrative enquiries. An unjust decision in an administrative enquiry may have more far reaching effect than a decision in a quasi-judicial enquiry.

20. *The framework of the law under which the enquiry is held and the constitution of the Tribunal or body of persons appointed for that purpose. Whenever a complaint is made before a court that some principle of natural justice had been contravened the court has to decide whether the observance of that rule was necessary for a just decision on the facts of that case.*

It is unfortunate that Naqishbund was appointed as one of the members of the selection board. It is true that ordinarily the Chief Conservator of Forests in a State should be considered as the most appropriate person to be in the selection board. He must be expected to know his officers thoroughly, their weaknesses as well as their strength. His

NOTARY
M. M. PABALE
Mumbai
Maharashtra
Reg. No. 15220
Expiry Dt.
30-10-2024
GOVT. OF INDIA

opinion as regards their suitability for selection to the All-India Service is entitled to great weight. But then under the circumstances it was improper to have included Naqishbund as a member of the selection board. He was one of the persons to be considered for selection. ***It is against all canons of justice to make a man judge in his own cause.*** *It is true that he did not participate in the deliberations of the committee when his name was considered. But then the very fact that he was a member of the selection board must have had its own impact on the decision of the selection board. Further admittedly he participated in the deliberations of the selection board when the claims of his rivals particularly that of Basu was considered.*

At every stage of his participation in the deliberations of the selection board there was a conflict between his interest and duty. Under those circumstances it is difficult to believe that he could have been impartial. The real question is not whether he was biased.

15. It was in the interest of Naqishbund to keep out his rivals in order to secure his position from further challenge. *Naturally he was also interested in safeguarding his position while preparing the list of selected candidates.*

16. In a group deliberation each member of the group is bound to influence the others, more so, if the member concerned is a person with special knowledge. His bias is likely to operate in a subtle manner. It is no wonder that the other members of the selection board are unaware of the extent to which his opinion influenced their conclusions. We

NOTARY GOVT OF INDIA
M. M. PABALE
Mumbai
Maharashtra
Reg. No. 15220
Expiry Dt.
30-10-2024

are unable to accept the contention that in adjudging the suitability of the candidates the members of the board did not have any mutual discussion. It is not as if the records spoke of themselves. We are unable to believe that the members of selection board functioned like computers.

The horizon of natural justice is constantly expanding. The question how far the principles of natural justice govern administrative enquiries came up for consideration before the Queen's Bench Division In re H.K. (An Infant). [(1967) 2 QB 617 at p. 630] Therein the validity of the action taken by an Immigration Officer came up for consideration. In the course of his judgment Lord Parker C.J. observed thus:

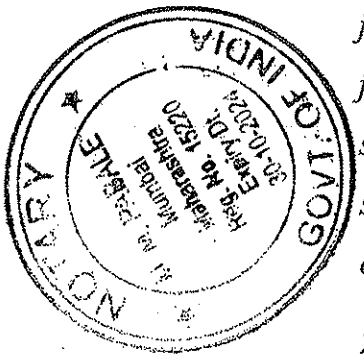
That is not, as I see it, a question of acting or being required to act judicially, but of being required to act fairly. Good administration and an honest or bona fide decision must, as it seems to me, require not merely impartiality, nor merely bringing one's mind to bear on the problem, but acting fairly; and to the limited extent that the circumstances of any particular case allow, and within the legislative framework under which the administrator is working, only to that limited extent do the so-called rules of natural justice apply, which in a case such as this is merely a duty to act fairly.

17. The decisions of the courts do seem to have drawn a strict line in these matters according to whether there is or is not a duty to act judicially or quasi-judicially.

NOTARY
M. M. PABALE
Mumbai
Maharashtra
Reg. No. 15220
Expiry Dt.
30-10-2024
GOVT. OF INDIA

21. Looking at the composition of the board and the nature of the duties entrusted to it we have no doubt that its recommendations should have carried considerable weight with the UPSC. If the decision of the selection board is held to have been vitiated, it is clear to our mind that the final recommendation made by the Commission must also be held to have been vitiated. The recommendations made by the Union Public Service Commission cannot be disassociated from the selections made by the selection board which is the foundation for the recommendations of the Union Public Service Commission.

23. To that extent he was undoubtedly a judge in his own case, a circumstance which is abhorrent to our concept of justice. Now coming to the selection of the officers in the junior scale service, the selections to both the senior scale service as well as junior scale service were made from the same pool. Hence it is not possible to separate the two sets of officers.



24. <u>For the reasons mentioned above these petitions are allowed and the impugned selections set aside. The Union Government and the State Government shall pay the costs of the petitioners.</u>"

38.13. In **<u>Suresh Ramchandra Palande and Ors. Vs. The Government of Maharashtra and Ors. 2016 (2) Mh.L.J.918.</u>** It is ruled that such disqualification rule is applicable to every public servant. It is ruled as under;

"17. At this stage, a reference will have to be also made to the well known decision of the Apex Court in case of J. Mohapatra and Co. v. State of Orissa, (1984) 4 SCC 103. In paragraph 9 of the said decision, the Apex Court has quoted with approval the position of law which has been stated in Halsbury's Laws of England, Fourth Edition, Volume 1, para 68. Paragraph 9 of the said decision of the Apex Court reads thus:

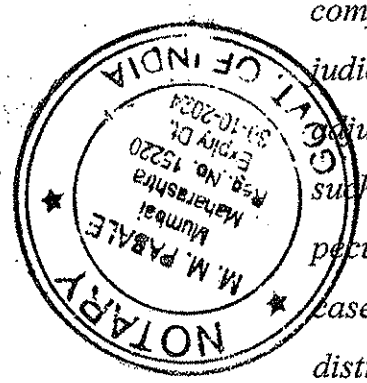
> *"9. It is, however, unnecessary to go further into this controversy for the real question in this appeal is of far greater importance. That is the question of bias on the part of some of the members of the Assessment Sub-Committee. This question has been answered against the appellants and forms the subject-matter of the third and fourth grounds on which the High Court rested its decision. Nemo judex in causa sua, that is, no man shall be a judge in his own cause, is a principle firmly established in law. Justice should not only be done but should manifestly be seen to be done. It is on this principle that the proceedings in Courts of law are open to the public except in those cases where for special reason the law requires or authorizes a hearing in camera.* ***Justice can never be seen to be done if a man acts as a judge in his own cause or is himself interested in its outcome. This principle applies not only to judicial proceedings but also to quasi-iudicial and administrative proceedings****. The position in law has been succinctly stated in Halsbury's Laws of England, Fourth Edition, Volume 1, para 68, as follows:*



Disqualification for financial interest. — ***There is a presumption that any direct financial interest, however small, in the matter in dispute disqualifies a person from adjudicating. Membership of a company, association or other organisation which is financially interested may operate as a bar to adjudicating, as may a bare liability to costs where the decision itself will involve no pecuniary loss.*** *"*

(Emphasis added)

18. Thus, what is held by the Apex Court in the aforesaid decisions is that the presence of direct pecuniary interest irrespective of its extent operates as a complete disqualification to adjudicate a dispute. The complete disqualification operates irrespective of the fact that the pecuniary interest may be very small. In such a case, the issue of waiver of objection regarding bias will not arise at all as the presence of pecuniary bias prevents the Judge from taking up the case in which he has pecuniary interest. Therefore, any direct financial interest operates as a complete bar which prohibits a person exercising even quasi judicial powers from participating in the process of adjudication. Hence, the plea of waiver is not available in such cases. As stated earlier, this is a case where the pecuniary and proximate interest in the subject matter of the case is admitted by Shri Sodal. There is in our view a distinction to be drawn between a personal bias, one that may be waived, and a pecuniary bias which stands on a wholly different footing. In the first place, to be invoked waiver requires that a disclosure be made of the possibly



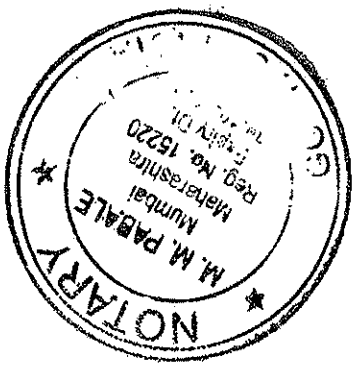
conflicting interest. It is when that interest is made known that a party can waive it. But this can only apply in the case of a personal bias such a relationship or a friendship. A pecuniary bias stands on another footing altogether. On the principles enunciated in Mohapatra's case, a direct, proximate and existing pecuniary bias can never be waived. It is to be noted that in Mohapatra's case, the Apex Court held that the existence of a pecuniary interest was a disqualification and that this disqualification did not depend on the amount of the pecuniary interest. The Apex Court also rejected the invocation of the doctrine of necessity in such a case by holding that nothing prevented the government in that case from reconstituting the committee in question.

24. In the well known decision of the Apex Court in the case of A.K. Kripak v. Union of India, (1969) 2 SCC 262 in paragraph 15, the Apex Court held thus:

> *"15. It is unfortunate that Naquishbund was appointed as one of the members of the selection board. It is true that ordinarily the Chief Conservator of Forests in a State should be considered as the most appropriate person to be in the selection board. He must be expected to know his officers thoroughly, their weaknesses as well as their strength. His opinion as regards their suitability for selection to the All India Service is entitled to great weight. But then under the circumstances it was improper to have included Naquishbund as a member of the selection board. He was one of the persons to be considered for selection. It is against all canons of justice to make a man judge in his own cause. It is true that he*

NOTARY
M. M. PABALE
Mumbai
Maharashtra
Reg. No. 15220
Expiry Dt.
30-10-2024
GOVT. OF INDIA

did not participate in the deliberations of the committee when his name was considered. But then the very fact that he was a member of the selection board must have had its own impact on the decision of the selection board. Further admittedly he participated in the deliberations of the selection board when the claims of his rivals particularly that of Basu was considered he was also party to the preparation of the list of selected candidates in order of preference. At every stage of this participation in the deliberations of the selection board there was a conflict between his interest and duty. Under those circumstances it is difficult to believe that he could have been impartial. The real question is not whether he was biased. It is difficult to prove the state of mind of a person. Therefore what we have to see is whether there is reasonable ground for believing that he was likely to have been biased. We agree with the learned Attorney-General that a mere suspicion of bias is not sufficient. There must be a reasonable likelihood of bias. In deciding the question of bias we have to take into consideration human probabilities and ordinary course of human conduct. It was in the interest of Naqishbund to keep out his rivals in order to secure his position from further challenge. Naturally he was also interested in safeguarding his position while preparing the list of selected candidates."



25. *The Apex Court reiterated that the real question is not whether there was a bias. The test laid down by Apex Court is to see whether there is any reasonable likelihood of bias.*

We may also make an useful reference to the decision of the Apex Court in the case of Ranjit Thakur v. Union of India, (1987) 4 SCC 611 and in particular paragraphs 16 and 17 thereof. Paragraphs 16 and 17 read thus:

> *"16. It is the essence of a judgment that it is made after due observance of the judicial process; that the Court or tribunal passing it observes, at least the minimal requirements of natural justice; is composed of impartial persons acting fairly and without bias and in good faith.* ***A judgment which is the result of bias or want of impartiality is a nullity and the trial 'coram non iudice'****....*
>
> *17. As to the tests of the likelihood of bias what is relevant is the reasonableness of the apprehension in that regard in the mind of the party. The proper approach for the Judge is not to look at his own mind and ask himself, however, honestly, 'Am I biased?'; but to look at the mind of the party before him."*

(Emphasis added)

Coming back to the case in hand, Mr. S.V. Sodal candidly accepted before this Court that his agricultural lands would have been benefited on the implementation of the impugned order dated 26th October, 2015. In fact, he stated that he holds 12 Acres of agricultural land, which will directly benefit from the impugned order dated 26th October, 2015. Therefore, in our view, it was not even necessary for any of the party to the proceedings to raise an objection of personal or pecuniary bias. In fact, Mr. S.V. Sodal should, on his own,

NOTARY M. M. PABALE Mumbai Maharashtra R&O. No. 15220 Expiry Dt. 31-10-2024 GOVT. OF INDIA

have recused himself when the Case No. 5 of 2015 and Case No. 6 of 2015 were placed before the Regulatory Authority.

26. Therefore, there is no option but to hold that the impugned order dated 26th October, 2015 is completely vitiated."

38.14. Even if there is a single member who is partial and interested and there are other members who are impartial then also it vitiates and invalidate their recommendations, suggestions and all actions.

38.16. In **R. Vs. Commissioner of pawing (1941) 1 QB 467**, William J. Observed;

*"I am strongly dispassed to think that **a Court is badly constituted of which an intrested person is a part, whatever may be the number of disintrested peraons. We cannot go into a poll of the Bench."***

38.15. In **A.K. Kraipak Vs. Union of India (1969) 2 SCC 262**, it is ruled as under;

"15. It is unfortunate that Naqishbund was appointed as one of the members of the selection board. It is true that ordinarily the Chief Conservator of Forests in a State should be considered as the most appropriate person to be in the selection board. He must be expected to know his officers thoroughly, their weaknesses as well as their strength. His opinion as regards their suitability for selection to the All-India Service is entitled to great weight. But then under the circumstances it was improper to have included Naqishbund as a member of the selection board. He was one of the persons to be considered for selection. It is against all

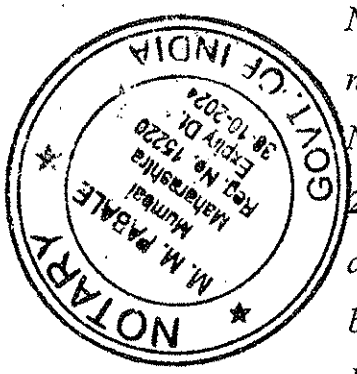
NOTARY M. M. PABALE Mumbai Maharashtra Reg. No. 15220 Expiry Dt. 30-10-2024 GOVT. OF INDIA

canons of justice to make a man judge in his own cause. It is true that he did not participate in the deliberations of the committee when his name was considered. But then the very fact that he was a member of the selection board must have had its own impact on the decision of the selection board. Further admittedly he participated in the deliberations of the selection board when the claims of his rivals particularly that of Basu was considered. He was also party to the preparation of the list of selected candidates in order of preference. At every stage of his participation in the deliberations of the selection board there was a conflict between his interest and duty. Under those circumstances it is difficult to believe that he could have been impartial. The real question is not whether he was biased. It is difficult to prove the state of mind of a person. Therefore what we have to see is whether there is reasonable ground for believing that he was likely to have been biased. We agree with the learned Attorney General that a mere suspicion of bias is not sufficient. There must be a reasonable likelihood of bias. In deciding the question of bias we have to take into consideration human probabilities and ordinary course of human conduct. It was in the interest of Naqishbund to keep out his rivals in order to secure his position from further challenge. Naturally he was also interested in safeguarding his position while preparing the list of selected candidates.

***16.** The members of the selection board other than Naqishbund, each one of them separately, have filed affidavits in this Court swearing that Naqishbund in no manner influenced their decision in making the selections. In*

NOTARY
M. M. PABALE
Mumbai
Maharashtra
Reg. No. 15220
GOVT. OF INDIA

a group deliberation each member of the group is bound to influence the others, more so, if the member concerned is a person with special knowledge. His bias is likely to operate in a subtle manner. It is no wonder that the other members of the selection board are unaware of the extent to which his opinion influenced their conclusions. We are unable to accept the contention that in adjudging the suitability of the candidates the members of the board did not have any mutual discussion. It is not as if the records spoke of themselves. We are unable to believe that the members of selection board functioned like computers. At this stage it may also be noted that at the time the selections were made, the members of the selection board other than Naqishbund were not likely to have known that Basu had appealed against his supersession and that his appeal was pending before the State Government. Therefore there was no occasion for them to distrust the opinion expressed by Naqishbund. Hence the board in making the selections must necessarily have given weight to the opinion expressed by Naqishbund.



21. It was next urged by the learned Attorney General that after all the selection board was only a recommendatory body. Its recommendations had first to be considered by the Home Ministry and thereafter by the UPSC. The final recommendations were made by the UPSC Hence grievances of the petitioners have no real basis. According to him while considering the validity of administrative actions taken, all that we have to see is whether the ultimate decision is just or not. We are unable to agree with the learned Attorney-

General that the recommendations made by the selection board were of little consequence. Looking at the composition of the board and the nature of the duties entrusted to it we have no doubt that its recommendations should have carried considerable weight with the UPSC. If the decision of the selection board is held to have been vitiated, it is clear to our mind that the final recommendation made by the Commission must also be held to have been vitiated. The recommendations made by the Union Public Service Commission cannot be disassociated from the selections made by the selection board which is the foundation for the recommendations of the Union Public Service Commission. In this connection reference may be usefully made to the decision in Regina v. Criminal Injuries Compensation Board Ex parte Lain."

38.16. That, the evidence shows that the member of State Task Force and Municipal Corporation of Greater Mumbai are having some direct or indirect Connection with the pharma companies.

38.16.1. Daksha Shah who holds a lot of influence in making Mumbai's Covid-19 policies is member of Lancet Covid-19 Commission's India Regional Task Force, who's founding donor is the Rockefeller Foundation

(https://covid19commission.org/regional-task-force-india)

38.16.2. Subhash Salunke (Director of IIPH Bhubhaneshwar (Indian Institute of Public Health started by PHFI) and Senior Advisor, PHFI) & Giridhar Babu from PHFI are advising the Maharashtra Govt on Covid 19. Salunke is DGHS for Maharashtra State.

NOTARY M. M. PABALE Mumbai Maharashtra Regd. No. 15720

https://phfi.org/member/dr-subhash-r-salunke-md-dph-dih/
https://phfi.org/member/giridhar-r-babu/

38.16.3. Head of Maharashtra's Task force, Dr Sanjay Oak, was the CEO of a hospital for the first year of his membership in the task force, until he resigned in November 2020.

https://indianexpress.com/article/cities/mumbai/dr-sanjay-oak-resigns-from-post-of-ceo-of-prince-aly-khan-hospital-7066991/

38.16.4. That, the private body Public Health Foundation of India [PHFI] was under radar of Intelligence Bureau.

38.17. That, the frauds committed by PHFI are already exposed and a detailed complaint is filed by Sh. Ambar Koiri before C.B.I

(A copy of Complaint against PHFI dated 18th October, 2021 marked and annexed herewith **Exhibit "RA-53") (Page No. 679)**

38.18. Prosecution of PHFI by Home Ministry and Intelligence Bureau:-

38.18.1. That, PHFI were also prosecuted by the Intelligence Bureau for their frauds of foreign funds.

38.18.2. That, in an order by Home Ministry and as published in an Article in Economic Times published on 21st April 2017, it is clear that, the members of PHFI are misusing the funds for unauthorised purposes :

38.18.3. The seven violations cited by the home ministry against PHFI, which has been receiving a significant chunk of its foreign funding from Bill and Melinda Gates Foundation, include using foreign contributions to

lobby media, parliamentarians and government on tobacco control policy issues, "which is prohibited under FCRA". PHFI, according to the home ministry, has bank accounts with credits of Rs 223 crore more than what it had declared to the home ministry.

38.18.4. Also, it is alleged to have wrongfully declared Rs 43 crore received for anti-tobacco lobbying when foreign funding during 2009-10 and 2012-13 was received seeking permission of the home ministry for the purpose `research' and `establishment of corpus fund'.

38.18.5. Another charge against PHFI includes making remit tances of Rs 22 crore to foreign countries from its FCRA account and Rs 10.75 crore to BBC World Services Trust, UK "for unknown purpose".

38.18.6. The revision order, issued under Section 22 of FCRA, states that PHFI declared only six of its 151 bank accounts to MHA. Of the 151 accounts, 22 are saving or current accounts while 128 are FD accounts. Two bank accounts were used as `transit' accounts for unknown reasons, violating provisions of FCRA and FCRR, 2011, according to the home ministry.

38.18.7. PHFI was also found to be having more than one PAN identity for opening accounts and FDs, in violation of the Income Tax Act, 1961. Besides, the NGO failed to declare foreign receipts of Rs 1.19 crore from GlaxoSmithKline in 2014-

Link: https://economictimes.indiatimes.com/news/politics-and-nation/mha-order-revoking-license-of-phfi-lists-7-undesirable-activities/articleshow/58294627.cms?from=mdr

38.18.8. The Union health ministry is also said to have taken up the matter with Gauba. His predecessor, Rajiv Mehrishi, who was part of the decision to crack down on PHFI, had refused a review after **both the**

Intelligence Bureau and the foreigners division of the home ministry said they had made a watertight case against PHFI. Intelligence Bureau officers said they would not buckle under pressure, for the charges hold ground.

https://www.theweek.in/theweek/current/foreign-bug.html

38.19. That, the PHFI and their dishonest members are influencing the policy of Health developments in such a way that the ultimate benefit will go to the pharma mafia and wrongful loss will be of Govt. of India and 135 Crore citizen. A detailed article exposing the PHFI members and their modus oprandi and their acts of commission and omission to play with the life of Indians to give undeserving benefits to the pharma mafia is published by the petitioner in his article.

Link: India's Covid-19 Task Force & "Experts" Exposed : Conflicts of Interest in Our Public Health System (An exposed by Yohan Tengra.)

Link: https://awakenindiamovement.com/indias-covid-19-task-force-experts-exposed-conflicts-of-interest-in-our-public-health-system/

39. Duty of the Government Pleader.

39.1. In **E.S. Reddi Vs. Chief Secretary, Government of A.P (1987) 3 SCC 258,** it is ruled as under;

A) Duty of Advocates towards Court – Held, he has to act fairly and place all the truth even if it is against his client – he should not withhold the authority or documents which tells against his client – It is a mistake to suppose that he is a mouthpiece of his client to say that he wants – He must disregard

with instruction of his client which conflicts with their duty to the Court.

B) Duty and responsibility of senior counsel - By virtue of the pre-eminence which senior counsel enjoy in the profession, they not only carry greater responsibilities but they also act as a model to the junior members of the profession. A senior counsel more or less occupies a position akin to a Queen's counsel in England next after the Attorney General and the Solicitor General. It is an honor and privilege conferred on advocates of standing and experience by the chief justice and the Judges of this court. They thus become leading counsel and take precedence on all counsel not having that rank- A senior counsel though he cannot draw up pleadings of the party, can nevertheless be engaged "to settle" i.e. to put the pleadings into "proper and satisfactory form" and hence a senior counsel settling pleadings has a more onerous responsibility as otherwise the blame for improper pleadings will be laid at his doors. (Para 10)

"(11) Lord Reid in Rondel v. Worsley has succinctly set out the conflicting nature of the duties a counsel has to perform in his own inimitable manner as follows:

Every counsel has a duty to his client fearlessly to raise every issue, advance every argument, and ask every question, however distasteful, , which he thinks will help his client's case. As an officer of the court

concerned in the administration of justice, he has an overriding duty to the court, to the standards of his profession, and to the public, which may and often does lead to a conflict with his client's wishes or with what the client thinks are his personal interests. Counsel must not mislead the court, he must not lend himself to casting aspersions on the other party or witnesses for which there is no sufficient basis in the information in his possession, he must not withhold authorities or documents which may tell against his clients but which the law or the standards of his profession require him to produce. By so acting he may well incur the displeasure or worse of his client so that if the case is lost, his client would or might seek legal redress if that were open to him.

(12) Again as Lord Denning, M. R. in Rondel v. W would say :



He (the counsel) has time and again to choose between his 265 duty to his client and his duty to the court. This is a conflict often difficult to resolve; and he should not be under pressure to decide it wrongly. . . . When a barrister (or an advocate) puts his first duty to the court, he has nothing to fear. (words in brackets added).

In the words of Lord Dinning:

It is a mistake to suppose that he is the mouthpiece of his client to say what he wants :. . . . He must disregard the most specific instructions of his client, if they conflict with his duty to the court. The code which

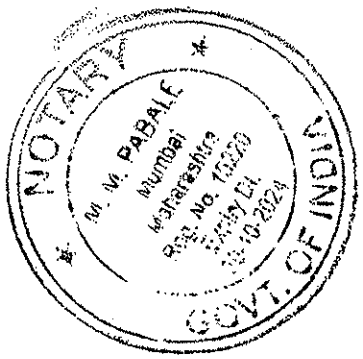
requires a barrister to do all this is not a code of law. It is a code of honor. If he breaks it, he is offending against the rules of the profession and is subject to its discipline."

39.2. In **Hindustan Organic Chemicals Ltd. Vs. ICI India Ltd. 2017 SCC Online Bom 74,** it is read as under;

"DUTY OF ADVOCATES TO NOT TO MISLED THE COURT EVEN ACCIDENTALLY – THEY SHOULD COME BEFORE COURT BY PROPER ONLINE RESEARCH OF CASE LAW BEFORE ADDRESSING THE COURT.

I have found counsel at the Bar citing decisions that are not good law.

The availability of online research databases does not absolve lawyers of their duties as officers of the Court. Those duties include an obligation not to mislead a Court, even accidentally. That in turn casts on each lawyer to carefully check whether a decision sought to be cited is or is not good law. *The performance of that duty may be more onerous with the proliferation of online research tools; but that is a burden that lawyers are required to shoulder, not abandon. Every one of the decisions noted in this order is available in standard online databases. This pattern of slipshod research is inexcusable."*



39.3. In **Heena Nikhil Dharia Vs. Kokilaben Kirtikumar Nayak and Ors. 2016 SCC OnLine Bom 9859**, it is ruled as under;

"DUTY OF ADVOCATE"

AJ The counsel in question was A. S. Oka, now Mr. Justice Oka, and this is what Khanwilkar J was moved to observe in the concluding paragraph of his judgement:

While parting I would like to make a special mention regarding the fairness of Mr. Oka, Advocate. He conducted the matter with a sense of detachment. In his own inimitable style he did the wonderful act of balancing of his duty to his client and as an officer of the Court concerned in the administration of justice. He has fully discharged his overriding duty to the Court to the standards of his profession, and to the public, by not withholding authorities which go against his client. As Lord Denning MR in Randel v W. (1996) 3 All E. R. 657 observed: "Counsel has time and again to choose between his duty to his client and his duty to the Court. This is a conflict often difficult to resolve; and he should not be under pressure to decide it wrongly. Whereas when the Advocate puts his first duty to the Court, he has nothing to fear. But it is a mistake to suppose that he (the Advocate) is the mouthpiece of his client to say what he wants. The Code which obligates the Advocate to disregard the instructions of his client, if they conflict with his duty to the Court, is not a code

of law — it is a code of honour. If he breaks it, he is offending against the rules of the profession and is subject to its discipline.

This view is quoted with approval by the Apex Court in Re. T. V. Choudhary, [1987] 3 SCR 146 (E. S. Reddi v Chief Secretary, Government of AP & Anr.).

The cause before Khanwilkar J may have been lost, but the law gained, and justice was served.

B] Thirteen years ago, Khanwilkar J wrote of a code of honour. That was a time when we did not have the range, width and speed of resources we do today. With the proliferation of online databases and access to past orders on the High Court website, there is no excuse at all for not cross-checking the status of a judgement. I have had no other or greater access in conducting this research; all of it was easily available to counsel at my Bar. Merely because a judgement is found in an online database does not make it a binding precedent without checking whether it has been confirmed or set aside in appeal. Frequently, appellate orders reversing reported decisions of the lower court are not themselves reported. The task of an advocate is perhaps more onerous as a result; but his duty to the court, that duty of fidelity to the law, is not in any lessened. If anything, it is higher now.

C] Judges need the Bar and look to it for a dispassionate guidance through the law's thickets. When we are encouraged instead to lose our way, that need is fatally imperilled. Judges need the Bar and



look to it for a dispassionate guidance through the law's thickets. When we are encouraged instead to lose our way, that need is fatally imperilled."

39.4. That, Hon'ble Supreme Court in the case of **Shiv Kumar Vs. Hukam Chand (1999) 7 SCC 467(F.B) (Vol. 5 Page 786),** ruled as under

"13. The legislature reminds the State that the policy must strictly conform to fairness in the trial of an accused. A Public Prosecutor is not expected to show a thirst to reach the case in the conviction of the accused somehow or the other irrespective of the true facts-involved in the case. The expected attitude of the Public Prosecutor while conducting prosecution must be couched in fairness not only to the court and to the investigating agencies but to the accused as well. ***If an accused is entitled to any legitimate benefit during trial the Public Prosecutor should not scuttle or conceal it On the contrary, it is the duty of the Public Prosecutor to winch it to the fore and make it available to the accused. Even if the defence counsel overlooked it, the Public Prosecutor has the added responsibility to bring it to the notice of the court if it comes this knowledge."***

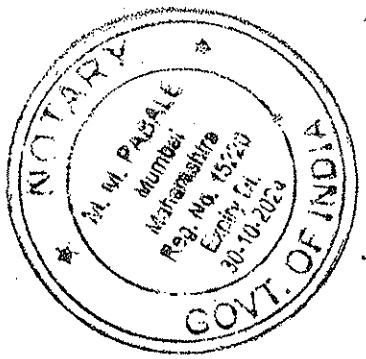
NOTARY GOVT. OF INDIA M. M. PABALE Maharashtra Reg. No. 15220 Expiry Dt. 30-10-2024

39.5. In **Lal Bahadur Gautam Vs. State of UP 2019 SCC OnLine SC 687** it is ruled as under;

10. *Before parting with the order, we are constrained to observe regarding the manner of assistance rendered to us on behalf of the respondent management of the private college. Notwithstanding*

*the easy access to information technology for research today, as compared to the plethora of legal Digests which had to be studied earlier, **reliance was placed upon a judgment based on an expressly repealed Act by the present Act, akin to relying on an overruled judgment. This has only resulted in a waste of judicial time of the Court, coupled with an onerous duty on the judges to do the necessary research. We would not be completely wrong in opining that though it may be negligence also, but the consequences could have been fatal by misleading the Court leading to an erroneous judgment.***

11. Simply, failure in that duty is a wrong against the justice delivery system in the country. Considering that over the years, responsibility and care on this score has shown a decline, and so despite the fact that justice is so important for the Society, it is time that we took note of the problem, and considered such steps to remedy the problem. We reiterate the duty of the parties and their Counsel, at all levels, to double check and verify before making any presentation to the Court. The message must be sent out that everyone has to be responsible and careful in what they present to the Court. Time has come for these issues to be considered so that the citizen's faith in the justice system is not lost. It is also for the Courts at all levels to consider whether a particular



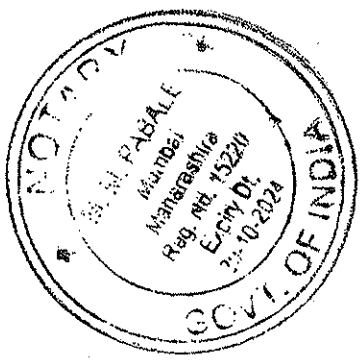
presentation by a party or conduct by a party has occasioned unnecessary waste of court time, and if that be so, pass appropriate orders in that regard. After all court time is to be utilized for justice delivery and in the adversarial system, is not a licence for waste.

12. As a responsible officer of the Court and an important adjunct of the administration of justice, the lawyer undoubtedly owes a duty to the Court as well as to the opposite side. He has to be fair to ensure that justice is done. He demeans himself if he acts merely as a mouthpiece of his client as observed in State of Punjab & Ors. vs. Brijeshwar Singh Chahal & Ors., (2016) 6 SCC 1: "34....relationship between the lawyer and his client is one of trust and confidence. As a responsible officer of the court and an important adjunct of the administration of justice, the lawyer also owes a duty to the court as well as to the opposite side. He has to be fair to ensure that justice is done. He demeans himself if he acts merely as mouthpiece of his client....."



13. The observations with regard to the duty of a counsel and the high degree of fairness and probity required was noticed in D.P. Chadha vs. Triyugi Narain Mishra and others, (2001) 2 SCC 221: "22. A mere error of judgment or expression of a reasonable opinion or taking a stand on a doubtful or debatable issue of law is not a misconduct; the term takes its

colour from the underlying intention. But at the same time misconduct is not necessarily something involving moral turpitude. It is a relative term to be construed by reference to the subjectmatter and the context wherein the term is called upon to be employed. A lawyer in discharging his professional assignment has a duty to his client, a duty to his opponent, a duty to the court, a duty to the society at large and a duty to himself. It needs a high degree of probity and poise to strike a balance and arrive at the place of righteous stand, more so, when there are conflicting claims. While discharging duty to the court, a lawyer should never knowingly be a party to any deception, design or fraud. While placing the law before the court a lawyer is at liberty to put forth a proposition and canvass the same to the best of his wits and ability so as to persuade an exposition which would serve the interest of his client so long as the issue is capable of that resolution by adopting a process of reasoning. However, a point of law well settled or admitting of no controversy must not be dragged into doubt solely with a view to confuse or mislead the Judge and thereby gaining an undue advantage to the client to which he may not be entitled. Such conduct of an advocate becomes worse when a view of the law canvassed by him is not only unsupportable in law but if accepted would damage the interest of the client and confer an illegitimate advantage on the opponent. In such a situation the



wrong of the intention and impropriety of the conduct is more than apparent. Professional misconduct is grave when it consists of betraying the confidence of a client and is gravest when it is a deliberate attempt at misleading the court or an attempt at practicing deception or fraud on the court. The client places his faith and fortune in the hands of the counsel for the purpose of that case; the court places its confidence in the counsel in case after case and day after day. A client dissatisfied with his counsel may change him but the same is not with the court. And so the bondage of trust between the court and the counsel admits of no breaking.

24. It has been a saying as old as the profession itself that the court and counsel are two wheels of the chariot of justice. In the adversarial system, it will be more appropriate to say that while the Judge holds the reigns, the two opponent counsel are the wheels of the chariot. While the direction of the movement is controlled by the Judge holding the reigns, the movement itself is facilitated by the wheels without which the chariot of justice may not move and may even collapse. Mutual confidence in the discharge of duties and cordial relations between Bench and Bar smoothen the movement of the chariot. As responsible officers of the court, as they are called – and rightly, the counsel have an overall obligation of assisting the courts in a just and proper manner in the just and



proper administration of justice. Zeal and enthusiasm are the traits of success in profession but overzealousness and misguided enthusiasm have no place in the personality of a professional.

26. A lawyer must not hesitate in telling the court the correct position of law when it is undisputed and admits of no exception. A view of the law settled by the ruling of a superior court or a binding precedent even if it does not serve the cause of his client, must be brought to the notice of court unhesitatingly. This obligation of a counsel flows from the confidence reposed by the court in the counsel appearing for any of the two sides. A counsel, being an officer of court, shall apprise the Judge with the correct position of law whether for or against either party."

14. That a higher responsibility goes upon a lawyer representing an institution was noticed in State of Rajasthan and another vs. Surendra Mohnot and others, j(2014) 14 SCC 77: "33. As far as the counsel for the State is concerned, it can be decidedly stated that he has a high responsibility. A counsel who represents the State is required to state the facts in a correct and honest manner. He has to discharge his duty with immense responsibility and each of his action has to be sensible. He is expected to have higher standard of conduct. He has a special duty towards the court in rendering assistance. It is because he has access to the public records and is

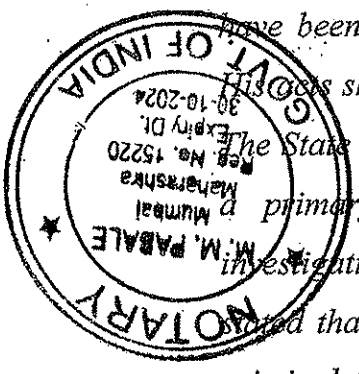
NOTARY W. M. PABALE Mumbai Maharashtra Reg. No. 15220 Expiry Dt. 30-10-2024 GOVT. OF INDIA

also obliged to protect the public interest. That apart, he has a moral responsibility to the court. When these values corrode, one can say "things fall apart". He should always remind himself that an advocate, while not being insensible to ambition and achievement, should feel the sense of ethicality and nobility of the legal profession in his bones.

We hope, that there would be response towards duty; the hallowed and honoured duty."

39.6. In **Deepak Aggarwal Vs. Keshav Kaushik and Ors. (2013) 5 SCC 277** it is ruled as under;

"Public Prosecutor: Role of Public Prosecutor is no different. *He has at all times to ensure that an accused is tried fairly. He should consider the views, legitimate interests and possible concern of witnesses and victims. He is supposed to refuse to use evidence reasonably believed to have been obtained through recourse to unlawful methods. His acts should always serve and protect the public interest. The State being a Prosecutor, the Public Prosecutor carries a primary position. He is not a mouthpiece of the investigating agency. In Chapter II of the BCI Rules, it is stated that an advocate appearing for the prosecution of a criminal trial shall so conduct the prosecution that it does not lead to conviction of the innocent; he should scrupulously avoid suppression of material capable of establishing the innocence of the accused."*



39.7. But the Government Pleader & Senior Counsel representing the Respondent No.1 State of Maharashtra have not performed their duty towards the Court. They drafted and submitted the faulty affidavit having false & misleading submissions with suppression of relevant data from the Court.

40. <u>SUMMARY OF SUBMISSION:</u>

40.1. The impugned notification dated **10.08.2021** and the subsequent notifications including recent notification dated **27.11.2021** which made classification between the vaccinated and unvaccinated people is not based on any scientific evidence or any logical reasoning admissible under law.

40.2. The notifications are against the policy decisions of Central Government. The Central Government in their affidavits filed before Hon'ble Supreme Court and in their reply under RTI and in the answer by Minister before Lok Sabha made it clear that there cannot be any discrimination on the basis of vaccination status of a person and no benefits or services can be denied to a person who has not taken the vaccines,

40.3. As per section 38 (a) 39 (1) of the Disaster Management Act, 2005, the state Government cannot frame any policies against the policy framed by the National Authority. And as per section 76 the National Authority has to decide the policy as per approvals of the Central Government. Therefore, the notification and order passed by Respondent No.1 which are against the policies of the Central Government are illegal.

40.4. The data given by the Respondent No. 1 itself makes it clear that the vaccinated people are neither protected from Covid-19 infection nor other people are safe from the spread of infection by the vaccinated people. The

1500

vaccinated people are also asked to follow the Covid Appropriate Behavior (CAB).

40.5. The another reasoning given by the Respondent No. 1 is about reduction in hospitalization, is not based on any data showing the number and percentage of hospitalization of Covid patients amongst vaccinated and unvaccinated. Even otherwise said submission are proven to be false from the data given by the petitioner.

The data available in the public domain and relied by the petitioner is not disputed by the Respondent No. 1 therefore, prima facie it has to be accepted as true in allowing the petition as per law laid down by the Full Bench of the Supreme Court in the case of **Express Newspapers Pvt. Ltd. Vs. UOI (1986) 1 SCC 133**, **Manohar Lal Sharma Vs. UOI 2021 SCC OnLine SC 985**.

40.6. Even otherwise hypothetical the fear of future hospitalization cannot be ground to discriminate the people and stop them from doing their daily work.

40.7. As per reply given by the Union of India and the scientific research available, the sting operation carried out by the main stream media news paper Mid-Day, makes it clear that the mask mandates are unscientific and providing no protection to healthy people but causing harm to the body and decreasing the oxygen level in them.

The mask mandates are brought by the State (Respondent No. 1) to extort money from common people and the state authorities themselves are not following these rules as exposed from the wedding of daughter of Member of Parliament Shri Sanjay Raut.

40.8. The reasoning given by the state for discrimination has no logic nor having any link with their orders.

Hence said order does not pass the scrutiny of the Article **14, 19** and **21** of the Constitution of India as laid down by Hon'ble Supreme Court and High Court and therefore has to be declared as ultra-virus and need to be quashed forthwith.

40.9. State Authority (Respondent No. 1) acted in violation of **section 2** of Epidemic Diseases Act,1897 and **section 12 and 13** of Disaster Management Act, 2005 while passing orders to prohibit movements of unvaccinated people but not providing them compensation of the losses incurred by them.

40.10. Several applications for granting compensation are not even replied by the Government. This shows the double standard of the Government.

40.11. The state before this Hon'ble Court instead of being fair and transparent in the matter concerning crores of citizens, have acted in bad faith and is contesting the petition like adversial litigation. The dishonesty is writ large as can be seen from the very fact that despite the court's order that the matter is serious and concerning fundamental rights of the citizen, the State Authority did not file the proper reply nor placed the correct and complete data before the Court.

State's action is in Contempt of the Supreme Court & High Court guidelines in **Manohar Lal Sharma Vs. UOI 2021 SCC OnLine SC 985**, **Express Newspapers Pvt. Ltd. Vs. UOI (1986) 1 SCC 133**, **Seethalakshmi Vs. State of Tamil Nadu 1989 SCC OnLine Mad 272**, **Amardeepsingh Thakur Vs. Deputy Inspector General 2020 SCC OnLine Bom 6621**.

40.12. The reply affidavit is false & misleading and prepared with suppression, twisting and dishonest concealment of facts.

NOTARY M. M. PABALE Mumbai Maharashtra Reg. No. 15220 Expiry Dt. 30-10-2024 GOVT. OF INDIA

40.13. No reasoning is given by the state authorities to the specific ground taken by the Petitioner that as to why, the safest person, who had previous infection of Covid-19 and those have developed antibodies are being forced to take vaccines which is giving no benefit to them but causing harm to their bodies and causing loss to the tune of thousands of crores of public money. As per their own survey, there are more than 85% Citizen having developed antibodies.

40.13.1. Hence, the decision taken and order passed by the Respondent No.1 by ignoring this crucial data vitiates the order and lead to only one conclusion that the authorities passed the order by practising **'Fraud on Power'** as per law laid down in **Vijay Shekhar Vs. UOI (2004) 4 SCC 666** & **Harshit Agarwal Vs. UOI (2021) 2 SCC 710**.

40.13.2. This is a sufficient ground to draw an inference of malafides of the state authority and to order investigation through C.B.I. as ruled by Hon'ble Supreme Court in the case of **Noida Entrepreneurs Association Vs. Noida (2011) 6 SCC 508.**

40.14. The Respondent No. 1 Chief Secretary Shri. Debashish Chakrabarty has not taken two doses but then too he is attending the Government office and has affirmed the **affidavit from his office.** This make it clear that the rules are not followed by the state authority itself. Which further means that the state officials are aware that non-compliance to their illogical, unscientific and unlawful rules will cause no threat to themselves or to the public.

Hence their opposition to the petition is unjustified and actuated with malice, ill-will, ulterior motive and malafide intention.

40.15. Government Pleaders and Senior Counsel representing the State of Maharashtra were duty bound to prepare draft and place full facts and

documentary evidence before the Court even if they are against their clients. And to make lawful submissions and should not place reliance on twisted and suppressed data and per-incuriam, irrelevant judgments, as per law laid down by the Hon'ble Supreme Court and this Hon'ble Court in **Shiv Kumar Vs. Hukam Chand (1999) 7 SCC 467(F.B), E. S. Reddi Vs. Chief Secretary, Government of A.P (1987) 3 SCC 258, Lal Bahadur Gautam Vs. State (2019) 6 SCC 441, Heena Nikhil Dharia Vs. Kokilaben Kirtikumar Nayak and Ors. 2016 SCC OnLine Bom 9859, State of Orissa Vs. Nalinikanta Muduli (2004) 7 SCC 19.**

40.15.1. But Government Pleader and Sr. Counsel did not perform their duty as per law laid down by the Hon'ble Supreme Court and this Hon'ble Court.

40.15.2. In fact, they took technical objection on incorrect facts.

40.16. The impugned orders passed by the State authorities and Respondent No. 1 are only executive orders. They are not placed before both the Houses of State Legislature as mandated under **Section 78 (3) of the Disaster Management Act, 2005.**

40.16.1. As per Article 19, 21 of the Constitution of India the curtailment of fundamental rights cannot be on the basis of executive orders but should be by a law enacted by the Parliament. Such orders need to be quashed. **[Re. Dinthar Incident Vs. State of Mizoram 2021 SCC OnLine Gau 1313].**

40.17. The impugned orders are against the policy decisions of National Authority under Disaster Management Act, 2005 and the Central Government and it is in violation of **Section 38(a) & 39(1) of the Act** and therefore it is ultra-vires, null,void & vitiated.

As per **Section 76 of the Disaster Management Act, 2005** the regulations should be made with the prior approval of the Central Government. Hence, the impugned notifications and orders are unlawful and made in breach of the guidelines by the Central Government.

40.17.1. It is an offence under **Section 166, 188, 341, 342, 220, 409, 120(B), 34 etc. of IPC** on the part of Respondent No. 1 Chief Secretary and others who are directly and indirectly involved in the conspiracy.

40.18. The impugned notifications are also illegal as they are passed without taking approval from the **National Platform for Disaster Risk Reduction (NPDRR).** Therefore, impugned notifications are illegal for violation of **Rule 3 of Notification No. 47-31/2012-DM-111** dated **05.07.2017.**

40.19. The data shows that hospitalization, infection amongst vaccinated is higher than the unvaccinated.

40.20. State did not perform their duty of publishing fatal side effects of vaccines and are forcing the people to take vaccines. The informed consent of the citizens is obtained either by deception or by force, which is contempt of law laid down in **Common Cause Vs. Union of India (2018) 5 SCC 1, Montgomery' s Case [2015] UKSC 11** etc. It is violation of **Universal Declaration on Bioethics and Human Rights, 2005.**

40.21. The petitioner was compelled to take vaccine and therefore State is bound to compensate all victim citizen and the petitioner in view of law laid down in **Registrar General Vs. State of Meghalaya 2021 SCC OnLine Megh 130.**

40.22. Respondent No 10 Shri Uddhav Thackery by his act of commission and omission is liable to be prosecuted alongwith the Respondent No.1 Shri Debashish Chakraborty & Ors. as per section 120(B), 34,109 of IPC.

40.23. The media persons involved in the conspiracy committed contempt of judgment in the case of **Nilesh Navalakha Vs. UOI 2021 SCC OnLine Bom 56** by publishing one sided news with ulterior motive to misled and confuse the public and witnesses and thereby to prejudice the cause.

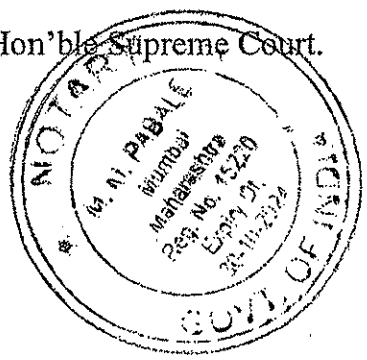
40.23. The media persons and more particularly the editorial board of Marathi Daily Samna, which is owned by wife of Respondent No.10 and web portal Live Law are also liable to be prosecuted in view provisions of the section 10 of Evidence Act and section 120 (B) & 34 of IPC.

41. CONCLUDING PARAGRAPH

41.1. From the material available on record and legal position settled by Hon'ble Supreme Court and High Court including this Hon'ble Court, it is clear that the notifications and orders passed by the Respondent No. 1 are against the law and the policy decided by the Central Government.

The impugned orders are not based on sound materials or logics but actuated by the ulterior purposes.

41.2. The mandates are unlawful, unconstitutional and violative of **Article 14, 19 & 21 of the Constitution of India** and therefore liable to quashed and set aside with a cost of Rs. 5 Crores as per law laid down by the Hon'ble Supreme Court.



41.3. The petitioner and the citizens needs to be compensated as per **Section 2 of Epidemic Act, 1897** by the State, for the losses incurred by each citizen due to unlawful mandates of the State.

41.4. The Respondent No. 1 has not only passed the unlawful orders but also made false and misleading submissions on affidavit before this Hon'ble Court with ulterior purposes. Therefore they are liable to be prosecuted and punished under **Section 52, 191, 192, 193, 199, 200, 201, 202, 218, 471, 474 r/w 120(B), 34, 109 etc. of IPC** and hence appropriate direction is required to be given to the Registrar of the High Court to file complaint as per procedure laid down under Section 340 of the Cr. P.C. OR an enquiry through C.B.I. can be ordered as done in **Sarvepalli Radhakrishnan Vs. Union of India (2019) 14 SCC 761, Afzal and Ors. Vs. State of Haryana and Ors. (1996) 7 SCC 397, ABCD Vs. Union of India (2020) 2 SCC 52.**

41.5. Respondent No. 1 Shri. Debashish Chakraborty & Dr. Sadhna Tayde are also liable for action and punishment under **Section 2(c) & 12 of the Contempt of Court Act, 1971 r/w Article 215 of the Constitution of India** for filing false affidavit before this Hon'ble Court, as per law laid down by Hon'ble Supreme Court in the case of **ABCD Vs. Union of India (2020) 2 SCC 52.**

41.6. That the act of Respondent No. 1 & its authorities in deliberately not following the scientific data and suggestions by the experts like Dr. Sanjay Rai of AIIMS New Delhi, regarding not vaccinating the persons with antibodies due to natural immunity is ex-facie having an impact of wastage & misappropriation thousands of crores of public money with giving wrongful profit to vaccine companies and wrongful loss to common man. Therefore the Respondent No. 1 Shri. Debashish

Chakraborty, Respondent No. 10 Shri. Uddhav Thackrey and all others involved in the conspiracy, who directly or indirectly supported the unlawful acts and helped in facilitation of the crime needs to be prosecuted under **Section 52, 409, 120(B), 109 & 34 etc. of IPC** and for any other offences by which they are responsible for death or side effects caused to innocent persons.

41.7. Since the **Order/SOP/Notifications** issued by the Respondent No. 1 Debashish Chakraborty & others were against the law and policy decisions of the National Authority, therefore all the responsible officers are liable to be prosecuted under **Section 51(b), 55 of the Disaster Management Act, 2005 r/w Section 52, 166, 188, 120(B), 34, 109, 341, 342, 220 etc. of IPC.**

41.8. Since Respondent No. 10 Shri Uddhav Thackrey, Chairman of State Disaster Management Authority, and Chief Minister of Maharastra is accused and complicit to the offence, therefore the investigation has to be done the C.B.I. as per law laid down in **Dr. Jaishri Laxmanrao Patil Vs. State of Maharashtra 2021 SCC OnLine Bom 516.**

41.9. Appropriate action is required under section 2(b), (c) and 12 of Contempt of Court's Act, 1971 against the editorial board of Dainik Samna, web portal Live Law and other media persons involved in spreading one-sided, twisted and bias news about the present case or any other similar issues with ulterior motive to create prejudice amongst the public, witnesses and litigants.

41.10. Directions to all media persons to act as per law laid down in **Nilesh Navalakha Vs. UOI 2021 SCC OnLine Bom 56** and to publish the news regarding this case or covid-19 treatment in a fair and transparent manner by quoting the views of both the sides and not to

1408

spread fear but to remove fear and to help in creating a healthy atmosphere.

Hence, submitted with utmost respect.

Date: 31.12.2021

Place: Mumbai

Deponent

VERIFICATION

I, **Yohan Tengra**, Petitioner, residing at **Building No. 21, 1st Floor, Flat No. 3, Old Khareghat Colony, Hughes Rd, Mumbai – 400007** the abovenamed do hereby solemnly declare that what is stated in the foregoing paragraphs is true to my knowledge and based on information I believe to be true.

Solemnly declared at Mumbai)

Dated 31 DEC 2021 Day of December, 2021)

ID / Aadhar / PAN / PO... 473163644125

Identified by Me, Before Me Seen Org. / POA / Board Resol.....

BEFORE ME

MANISH M. PABALE
B.Sc. LL.M.
ADVOCATE & NOTARY (GOVT. OF INDIA)
104, Natwar Chambers,
94 Nagindas Master Road,
Fort, Mumbai - 400 001.

Advocate for Petitioner

NOTED & REGISTERED

Page No. 90/24 Sr. No. 622

Date 31 DEC 2021

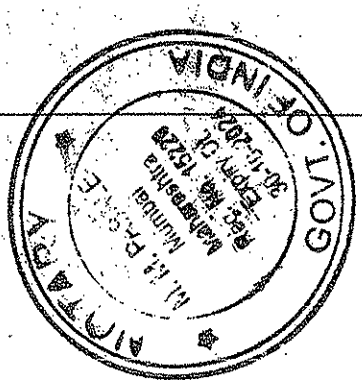
1409

EXHIBIT "RA-1" ~~261~~

World Health Organization

Coronavirus disease (COVID-19): Herd immunity, lockdowns and COVID-19

31 December 2020 | Q&A



Updated 31 December 2020

What is 'herd immunity'?

'Herd immunity', also known as 'population immunity', is the indirect protection from an infectious disease that happens when a population is immune either through vaccination or immunity developed through previous infection. WHO supports achieving 'herd immunity' through vaccination, not by allowing a disease to spread through any segment of the population, as this would result in unnecessary cases and deaths.

Herd immunity against COVID-19 should be achieved by protecting people through vaccination, not by exposing them to the pathogen that causes the disease. *Read the Director-General's 12 October media briefing speech for more detail.*

Vaccines train our immune systems to create proteins that fight disease, known as 'antibodies', just as would happen when we are exposed to a disease but – crucially – vaccines work without making us sick. Vaccinated people are protected from getting the disease in question and passing on the pathogen, breaking any chains of transmission. *Visit our webpage on COVID-19 and vaccines for more detail.*

1410

262

To safely achieve herd immunity against COVID-19, a substantial proportion of a population would need to be vaccinated, lowering the overall amount of virus able to spread in the whole population. One of the aims with working towards herd immunity is to keep vulnerable groups who cannot get vaccinated (e.g. due to health conditions like allergic reactions to the vaccine) safe and protected from the disease. *Read our Q&A on vaccines and immunization for more information.*

The percentage of people who need to be immune in order to achieve herd immunity varies with each disease. For example, herd immunity against measles requires about 95% of a population to be vaccinated. The remaining 5% will be protected by the fact that measles will not spread among those who are vaccinated. For polio, the threshold is about 80%. The proportion of the population that must be vaccinated against COVID-19 to begin inducing herd immunity is not known. This is an important area of research and will likely vary according to the community, the vaccine, the populations prioritized for vaccination, and other factors.

Achieving herd immunity with safe and effective vaccines makes diseases rarer and saves lives.

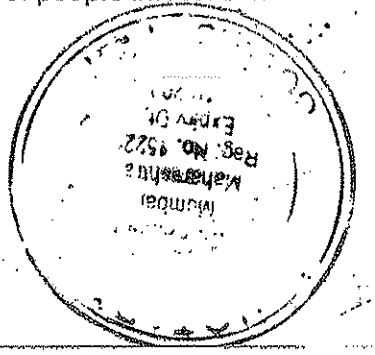
Find out more about the science behind herd immunity by watching or reading this interview with WHO's Chief Scientist, Dr Soumya Swaminathan.

What is WHO's position on 'herd immunity' as a way of fighting COVID-19?

Attempts to reach 'herd immunity' through exposing people to a virus are scientifically problematic and unethical. Letting COVID-19 spread through populations, of any age or health status will lead to unnecessary infections, suffering and death.

The vast majority of people in most countries remain susceptible to this virus. Seroprevalence surveys suggest that in most countries, less than 10% of the population have been infected with COVID-19.

We are still learning about immunity to COVID-19. Most people who are infected with COVID-19 develop an immune response within the first few weeks, but we don't know how strong or lasting that immune response is, or how it differs for different people. There have also been reports of people infected with COVID-19 for a second time.



Until we better understand COVID-19 immunity, it will not be possible to know how much of a population is immune and how long that immunity last for, let alone make future predictions. These challenges should preclude any plans that try to increase immunity within a population by allowing people to get infected.

Although older people and those with underlying conditions are most at risk of severe disease and death, they are not the only ones at risk.

Finally, while most infected people get mild or moderate forms of COVID-19 and some experience no disease, many become seriously ill and must be admitted into hospital. We are only beginning to understand the long-term health impacts among people who have had COVID-19, including what is being described as 'Long COVID.' WHO is working with clinicians and patient groups to better understand the long term effects of COVID-19.

Read the Director-General's opening remarks at the 12 October COVID-19 briefing for a summary of WHO's position.

What do we know about immunity from COVID-19?

Most people who are infected with COVID-19 develop an immune response within the first few weeks after infection.

Research is still ongoing into how strong that protection is and how long it lasts. WHO is also looking into whether the strength and length of immune response depends on the type of infection a person has: without symptoms ('asymptomatic'), mild or severe. Even people without symptoms seem to develop an immune response.

Globally, data from seroprevalence studies suggests that less 10% of those studied have been infected, meaning that the vast majority of the world's population remains susceptible to this virus.

For other coronaviruses – such as the common cold, SARS-CoV-1 and Middle East Respiratory Syndrome (MERS) – immunity declines over time, as is the case with other diseases. While people infected with the SARS-CoV-2 virus develop antibodies and immunity, we do not yet know how long it lasts.

Watch this conversation with Dr Mike Ryan and Dr Maria Van Kerkhove for more information on immunity.

1412

~~264~~

What is WHO's position on 'lockdowns' as a way of fighting COVID-19?

Large scale physical distancing measures and movement restrictions, often referred to as 'lockdowns', can slow COVID-19 transmission by limiting contact between people.

However, these measures can have a profound negative impact on individuals, communities, and societies by bringing social and economic life to a near stop. Such measures disproportionately affect disadvantaged groups, including people in poverty, migrants, internally displaced people and refugees, who most often live in overcrowded and under resourced settings, and depend on daily labour for subsistence.

WHO recognizes that at certain points, some countries have had no choice but to issue stay-at-home orders and other measures, to buy time.

Governments must make the most of the extra time granted by 'lockdown' measures by doing all they can to build their capacities to detect, isolate, test and care for all cases; trace and quarantine all contacts; engage, empower and enable populations to drive the societal response and more.

WHO is hopeful that countries will use targeted interventions where and when needed, based on the local situation.

العربية | 中文 | Français | Русский | Español

WHO TEAM WHO Headquarters (HQ)

Related



1413

~~265~~

WHO's Science in 5 on COVID-19 - Herd Immunity - 28 August 2020



Subscribe to the WHO newsletter →



1414

266

EXHIBIT "RA-2"

Over 85% Mumbai population has Covid-19 antibodies: Latest BMC sero survey

Source: The Indian Express

Link: https://indianexpress.com/article/cities/mumbai/over-85-mumbai-population-has-covid-19-antibodies-latest-bmc-sero-survey-7515921/

Author: Sanjana Bhalerao

Published on: September 18, 2021

The latest survey, which covered 8,674 people, found a sero positivity rate of 87.02 per cent in slums, and 86.22 per cent in non-slum areas.

The fifth sero survey conducted by the Brihanmumbai Municipal Corporation (BMC) in Mumbai in August 2021 shows that 86.64 per cent of the 8,674 people surveyed have antibodies against Covid-19. This is significantly higher than the third sero-surveillance conducted in March this year, which found 36.3 per cent of those surveyed had antibodies against Covid-19.

The latest survey, which covered 8,674 people, found a sero positivity rate of 87.02 per cent in slums, and 86.22 per cent in non-slum areas. This is the first time that there is a meagre difference in the sero positivity of the slum and non-slum population in the city.

The last sero survey, conducted in March this year, had found a sero positivity of 41.6 per cent in slums and 28.5 per cent in non-slum areas. "Overall, the sero-

prevalence in slum and non-slum areas in the city of Greater Mumbai is much higher as compared to the last serosurvey," stated the civic body in its statement.

BMC has conducted three sero-surveillance studies for Covid-19 and one sero-surveillance study for the paediatric population previously. The latest sero-surveillance was conducted between August 12 and September 8 this year.

This sero-surveillance also included the vaccinated population. The BMC had expected antibodies per centre to rise in this survey owing to the mass immunisation programme. The survey found sero-prevalence amongst partially and fully vaccinated participants is 90.26 per cent, while sero-prevalence amongst those who have not taken Covid-19 vaccine is 79.86 per cent.

"The results are in line with what we had expected. We also wanted to include the vaccinated population in the survey," the deputy executive health officer in BMC, Dr Daksha Shah said. "The sero prevalence is at 86.64 per cent, it does not indicate protective levels of IgG antibodies. As we know, the antibodies level starts declining after a month of the infection. Therefore, the citizens mustn't be complacent and we recommended them to continue to strictly follow the 'Covid-Appropriate Behaviour."

"Sero-prevalence was significantly higher in study subjects who received either first or both doses of COVID-19 vaccine as compared to their unvaccinated counterparts. it is essential to strengthening the ongoing COVID-19 vaccination program." stated the civic body in a statement released on Friday.

The rise in antibodies in the non-slum population in this survey is indicative of recent infection trends. In the first wave, slums were worst affected. However, in the second wave, the data by the BMC had shown that out of 87,000 active cases in

April this year, 90 per cent were concentrated in high rise buildings while slums account for just 10 per cent.

In July 2020, the results of the first serosurvey showed seroprevalence stood at 16 per cent in non-slums. In August, a second survey, however, showed that sero prevalence rose marginally to 18 per cent for non-slums. In March this year, seroprevalence in non-slum areas was 28.5 per cent.

Antibodies are formed within a week to three weeks of infection, but their levels start declining after a few months of the infection. The first sero survey last July showed 57 per cent population in slums had antibodies. This reduced to 45 per cent in the second survey in August 2020, and 41.6 per cent this March.

The survey was conducted by the BMC health department, The Lokmanya Tilak Municipal General Hospital and Medical College, Sion Hospital with support from A.T.E. Chandra Foundation and IDFC Institute.

BMC stated that the study was cross-sectional and included participants above 18 years of age, from all 24 wards of the city. Study participants were selected by systematic random sampling and those visiting municipal dispensaries and general practitioners' clinics in slum and non-slum areas respectively.

Out of the total samples, 20 per cent were health care workers. Sero-prevalence in health care workers is 87.14 per cent. The marginal difference was found in the gender-wise sero-prevalence with females showing 88.29 per cent sero-prevalence as compared to males at 85.07 per cent.

Civic officials said based on the survey, they plan to accelerate vaccination programmes to increase antibody levels in the population.

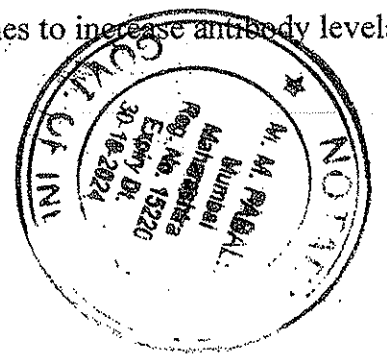
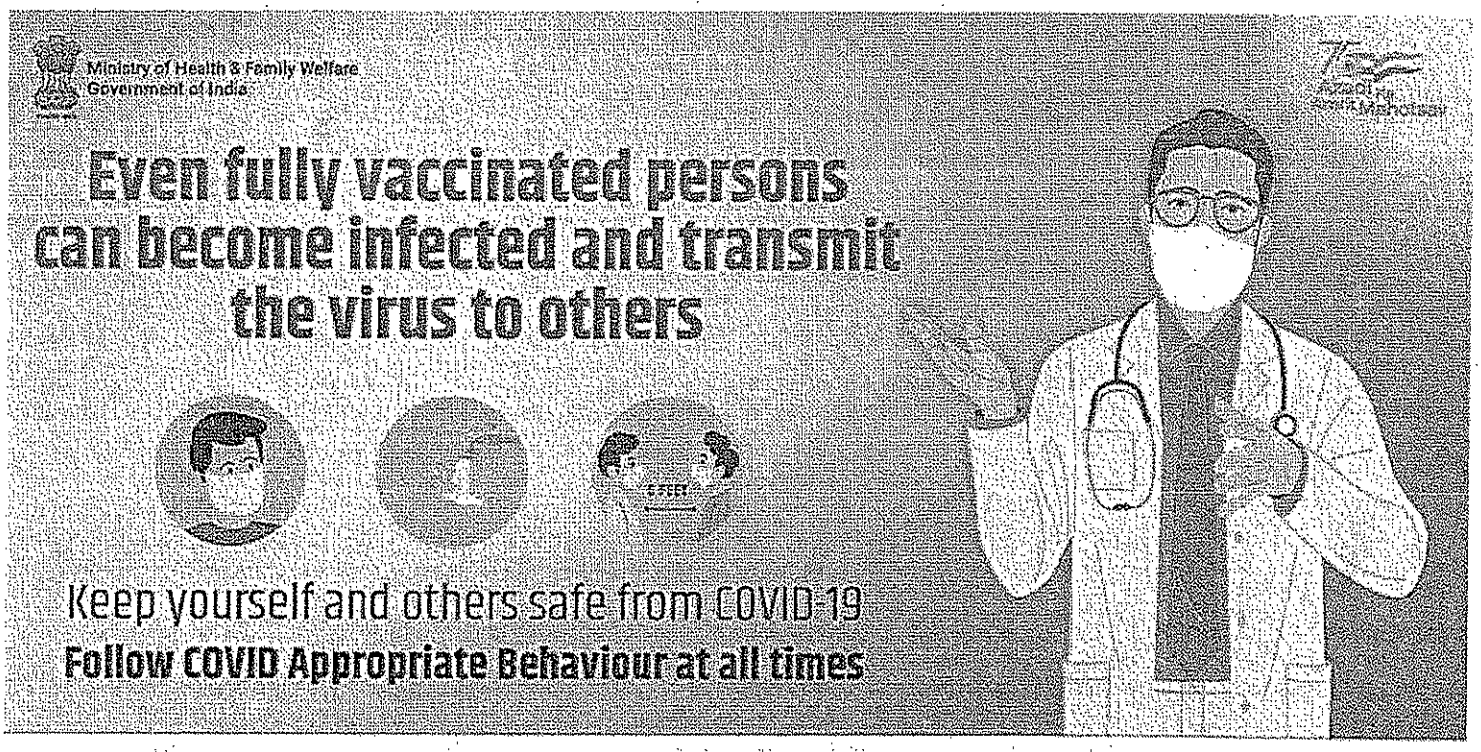


EXHIBIT "RA-3"



NOTARY
GOVT. OF INDIA
Mr. M. PABALE
Mumbai
Maharashtra
Reg. No. 15220
Expiry Dt.
30-10-2024

1418

270

EXHIBIT "RA-4"

8 more Omicron cases found in Maharashtra: 6 in rural Pune, 2 in MMR

Source: The Times of India

Link: https://timesofindia.indiatimes.com/city/mumbai/mumbai-8-more-omicron-cases-found-in-state-6-in-rural-pune-2-in-mmr/articleshow/88348393.cms

Author: Pradeep Gupta

Published on: Dec 18, 2021

Mumbai: Eight new cases of the Omicron variant were detected in the state on Friday, taking the tally in Maharashtra to 40. Six were from Pune, and one each from Mumbai and Kalyan-Dombivli. All of them had been fully vaccinated, and one had even got a booster, said health authorities.

The 29-year-old from Mumbai was vaccinated with three doses of the Pfizer vaccine, confirmed civil authorities. He returned from Newark, US, on December 9. He tested positive at the airport, and his samples were sent for genome sequencing. The National Institute of Virology, Pune, confirmed the presence of Omicron on Friday. A civic official said he has been hospitalized, but has no symptoms. Two of his high risk contacts have tested negative, The city's count has gone up to 14, of whom 13 have been discharged.

All six cases in Pune were from rural areas. Four had a history of travel to Dubai while two others were their contacts. The person found with Omicron in Kalyan-Dombivli had travelled to Nigeria.

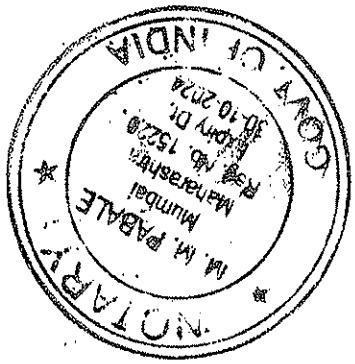


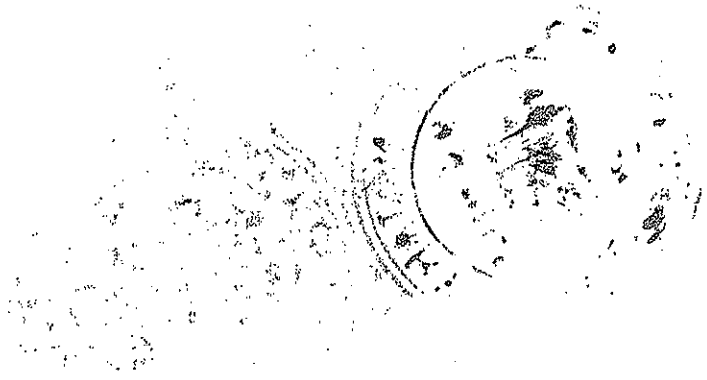
The health department said all those infected were men between 29 and 45 years. Seven patients were asymptomatic, and one had mild symptoms. Only two out of eight were in hospital. Of the total 40 infected, 33 were vaccinated. Five of the infected were minors. Around 25 of them have already been discharged. Dr. Pradeep Awate, state surveillance officer. Said more than 50% didn't have any symptoms at all.

A 45-year-old man, his wife and two children had returned to Dombivli on November 23. They tested positive on December 3 and their samples were sent for genome sequencing the same day. Both husband and wife had taken two doses of vaccines and did not have any symptoms. Interestingly, only the man had been infected with Omicron. He was discharged on Friday.

Kalyan-Dombivli has had two Omicron patients so far. The health department had tested 24 close and 62 low-risk contacts of the Kalyan-Dombivli patients, and four were found positive. None of them had symptoms.

Of the 40 cases in Maharashtra, Mumbai has reported 14, Pimpri Chinchwad 10, Pune (rural) six, Pune city, KalyanDombivli, Osmanabad have reported two cases each, while Latur, Buldhana, Nagpur and Vasai Virar have one case each. Officials said more than 525 samples of people with international travel history have been sent for sequencing.





272

EXHIBIT "RA-5"

Online RTI Request Form Details

RTI Request Details :-

RTI Request Registration number	MOHFW/R/E/21/05560
Public Authority	Department of Health & Family Welfare

Personal Details of RTI Applicant:-

Name	Sagar ugale
Gender	Male
Address	1, V I sawant road, amboli, andheri west , Mumbai, Mumbai
Pincode	400058
Country	India
State	Details not provided
Status	Urban
Educational Status	Literate
Phone Number	Details not provided
Mobile Number	+91-9930386607
Email-ID	rtisagarugale[at]gmail[dot]com

Request Details :-

Citizenship	Indian
Is the Requester Below Poverty Line ?	No

(Description of Information sought (upto 500 characters)

Description of Information Sought
Sub Regarding approved vaccinations in the context of corona. 1) Detailed information on approved vaccines to prevent corona outbreaks. As well as detailed information about their time period. 2) Information about vaccines that have been found to have side effects. Also information about the measures taken and the action taken to stop the supply of vaccines accordingly. 3) Vaccination-wise information on side effects found in individuals who have completed various vaccinations. 4) Information regarding Vaccine which are black listed and was earlier pre-approved. Note: As the required information is related to the life and liberty of the citizen, it should be provided within 48 hours under Section 7 (1) of the Right to Information Act, 2005.

Concerned CPIO	saroop Singh
Supporting document *(only pdf upto 1 MB)*	Supporting document not provided

Print Close

GOVT. OF INDIA NOTARY M. M. PARALE

Select Language: English

Public Authorities Available

RTI Online

Version 2.0

An Initiative of Department of Personnel & Training, Government of India

Online RTI Status Form

Note:Fields marked with * are Mandatory.

Enter Registration Number	MOHFW/R/E/21/05560
Name	Sagar ugale
Date of filing	03/09/2021
Public Authority	Department of Health & Family Welfare
Status	REQUEST DISPOSED OF
Date of action	20/09/2021

Reply :- Your RTI application has been received from RTI Cell, MoHFW/other CPIO and it is seen that sent to other CPIO(s) also. As far as this Office/CPIO i.e. COVID-19 Vaccine Administration Cell (CVAC)/Undersigned CPIO is concerned, it is informed that

1. Longevity of the immune response in vaccinated individuals is yet to be determined. Hence, continuing the use of masks, hand washing, physical distancing and other COVID-19 appropriate behaviors is strongly recommended.

2. (First part) You may visit Ministry of Health & Family Welfare's website www.mohfw.gov.in and see in " Latest updates" FAQs on COVID-19 Vaccines and Vaccination Program (dated 01.09.2021) or refer link https://www.mohfw.gov.in/pdf/FAQsCOVID19vaccinesvaccinationprogramWebsiteupload.pdf

2. (2nd part) Covid Vaccine is being supplied to State/UTs. "The Revised Guidelines for Implementation of National COVID Vaccination Program" came in effect from 21st June 2021, under which Government of India procures 75% of monthly vaccine production and provided to the States/UTs free of cost and private hospitals can procure upto 25% of monthly vaccine production directly from the manufactures.

3. Such information is not maintained. However, For COVID-19 Adverse Events Following Immunization (AEFI)] data/statistics, you may visit CoWIN portal (https://www.cowin.gov.in) or (refer link https://dashboard.cowin.gov.in) then click on Dashboard" for state wise, district wise data, Vaccination centre wise by Selecting STATE and DISTRICT.

4. Related to CDSCO.

As far as COVID-19 Vaccine Administration is concerned, it is kind to inform that since the crux of the information/guidelines/Standard Operating Procedure (SoP) etc has being communicated to the States/UTs and also explained by the experts on various media forums (both print and electronic), therefore, the issue of imminent impact on life and liberty of Indian citizen does not arise.

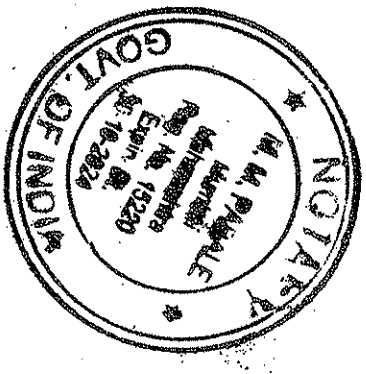
In case, you want to go for an appeal in connection with the information provided, you may appeal to the Shri Elangbam Robert Singh, Director & First Appellate Authority, Ministry of Health & Family Welfare, Nirman Bhawan, New Delhi within 30 days from the date of receipt of this reply.

GOVT. OF INDIA NOTARY M. M. PARALE Mumbai Maharashtra Reg. No. 15220 Expiry Dt. 30-10-2024

Your RTI application has been forwarded to multiple Public Authory(s)	Click here to view details
CPIO Details :-	Satyendra Singh Phone: 011-23062959 singh[dot]satyendra80[at]gov[dot]in
First Appellate Authority Details :-	Elangbam Robert Singh Phone: 23062495 robert[dot]elangbam[at]gov[dot]in
Nodal Officer Details :-	
Telephone Number	011-23061831
Email id	r[dot]attri54[at]nic[dot]in

Print RTI Application | Print Status | Go Back

Copyright © 2013. All rights reserved. Designed, Developed and Hosted by National Informatics Centre, New Delhi



1423
~~275~~

EXHIBIT "RA-6"

10 months on, Chief Secretary of Maharashtra takes his first shot

Source: The Times of India

Link: https://timesofindia.indiatimes.com/city/mumbai/10-months-on-chief-secretary-of-maharashtra-takes-his-first-shot/articleshow/88080789.cms

Author: Malathy Iyer & Bhavika Jain

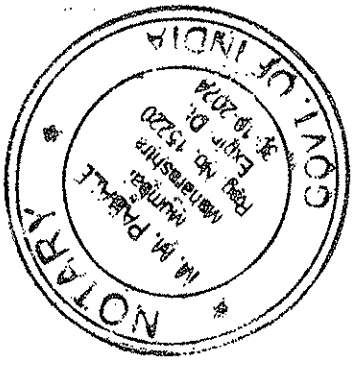
Published on: Dec 4, 2021

MUMBAI: Almost 10 months after Covid vaccination for frontline staff started, Maharashtra's senior-most bureaucrat, acting chief secretary Debashish Chakrabarty, 59, took his first shot on Thursday at JJ Hospital in Byculla.

"He took a Covaxin shot on Thursday," confirmed a senior doctor at the hospital. Chakrabarty took charge after Sitaram Kunte retired three days back.

A doctor who did not want to be identified said when the vaccination drive began, politicians, bureaucrats and doctors took the first shot to build public confidence in the vaccine. There is no record of how many senior officials are yet to be vaccinated, but those who have not taken the vaccine yet or have delayed it have mostly done so due to health reasons.

When contacted, Chakrabarty told TOI that vaccination is a matter of individual choice. "I can take the vaccine anytime," he said. "These are matters of individual choice or there could be other issues with health also. There is nothing like coercion in this," he said.



1424
276

Till he took the Covaxin shot on Thursday, Chakrabarty was one of the 1.6 crore adults in Maharashtra who had not taken even one shot since the Covid vaccination drive began on January 16. At present, 45% of the state's 91.4 million adult population is fully vaccinated.

For the chief secretary, his immunisation status is important because vaccination is a requirement to attend the assembly's winter session scheduled for later this month. Parliamentary affairs minister Anil Parab has said that due to the Omicron threat the administration had decided to only allow fully vaccinated individuals along with an RT-PCR negative report to enter the Vidhan Bhavan premises.

Most government offices in the state have a 'fully vaccinated' requirement for entry into the premises. A few days back, the state administration said that only fully vaccinated individuals could travel by public transport or enter public places.



AIM Awaken India Movement
awakenindiamovement.com
www.awakenindiamovement.com
mail2aim@protonmail.ch

EXHIBIT "RA-7" Date: 02.12.2021 ~~277~~

प्रति,

1. **श्री. सुरेश काकाणी**
   अति. आयुक्त, मुंबई
   महापालिका, मुंबई.

2. **श्री. इकबाल चहल**
   अति. आयुक्त, मुंबई
   महापालिका, मुंबई.

3. **श्री. प्रदीप व्यास**
   अति मुख्य सचिव, महा. राज्य, मंत्रालय, मुंबई.

4. **देबाशिष चक्रवर्ती**
   मुख्य सचिव, महा. राज्य, मंत्रालय, मुंबई.

विषयः i) खासदार संजय राऊत, महापौर किशोरी पेडणेकर व इतर यांनी त्यांच्या मुलीच्या लग्नात शासनाच्या दिनांक 27 नोव्हेंबर, 2021 रोजीच्या नियमावलीचे पालन न करता विना मास्क तसेच सोशल डिस्टंसिंगच्या नियमाचे उल्लंघन केल्याचे सोबतच्या व्हिडिओत व फोटोमध्ये दिसत असल्यामुळे त्यांच्याकडून नियमाप्रमांणे **50,000 रुपये** दंड वसूल करून

1426
278



त्यांच्याविरुद्ध **भादवि 166, 188, 269, 120(B), 34** आणि **आपत्ती व्यवस्थापन कायदा चे कलम 51(b), 55** आदी कलमाअंतर्गत गुन्हा नोंद करून पुढील कारवाई करणेबाबत.

किंवा

ii) नियम चुकीचे असल्याचे मान्य करून ते नियम त्वरित परत घेणेबाबत.

महोदय,

1) महाराष्ट्र शासनाचे मुख्य सचिव यांनी दिनांक 27 नोव्हेंबर, 2021 रोजीच्या आदेशानुसार महाराष्ट्रात सर्वांसाठी मास्क व सोशल डिस्टसींगचे कठोर निर्बंध लादले आहेत.

2) त्या आधारावर तुमचे काही अधिकारी हे सामान्य नागरिकांकडून दंड वसूल करीत आहेत.

3) दिनांक **29.11.2021** रोजी शिवसेनेचे खासदार संजय राऊत यांनी त्यांच्या मुलीच्या लग्नात वरील सर्व निर्बंधाचे उल्लंघन केल्याचे स्पष्ट दिसून येते.

Link:- https://youtu.be/3aMpOrhR7Cc

4) त्या कार्यक्रमात अनेक जिल्हाधिकारी, वरिष्ठ अधिकारी, मंत्री, महापौर हे उपस्थित होते. त्या सर्वांनी वरील नियमांचे उल्लंघन केले आहे.

5) आरोपींविरुद्ध कारवाई करणे हे आपले कर्तव्य असून आपण आरोपींना वाचविण्याचा प्रयत्न केल्यास आपणाविरुद्ध **भादवि 218, 202, 201** आदी कलमांअंतर्गत कारवाई होऊ शकते याची नोंद घ्यावी.

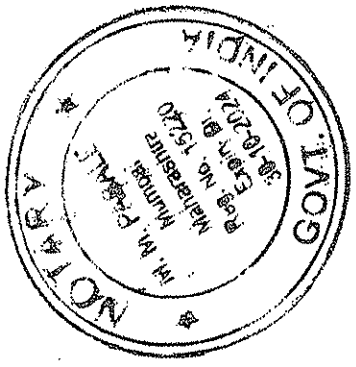
6) तरी आपणास विनंती की,

1427
279

i) खासदार संजय राऊत, महापौर किशोरी पेडणेकर व इतर यांनी त्यांच्या मुलीच्या लग्नात शासनाच्या दिनांक 29 नोव्हेंबर, 2021 रोजीच्या नियमावलीचे पालन न करता विना मास्क तसेच सोशल डिस्टंसिंगच्या नियमाचे उल्लंघन केल्याचे सोबतच्या व्हिडिओत व फोटोमध्ये दिसत असल्यामुळे त्यांच्याकडून नियमाप्रमांणे **50,000 रुपये** दंड वसूल करून त्यांच्याविरुद्ध **भादवि 166, 188, 269, 120(B), 34** आणि **आपत्ती व्यवस्थापन कायदा चे कलम 51(b), 55** आदी कलमाअंतर्गत गुन्हा नोंद करून पुढील कारवाई करण्यात यावे.

किंवा

ii) नियम चुकीचे असल्याचे मान्य करून ते नियम त्वरित परत घेण्यात यावे.



आपला नम्र

श्री. अंबर कोईरी

मेम्बर नॅशनल स्टीरींग कमीटी

अवेकन इंडिया मुव्हमेन्ट

1428

280

EXHIBIT "RA-8"

No. B3/16986/2021

District Medical Office (Health)
Malappuram, Dated: 27/11/2021

From

The Public Information Officer
C&D Section
District Medical Office of Health
Malappuram.

To

Sir,

Sub:- RTI Act 2005 – Reply furnishing of – reg.

Ref:- 1) Your RTI application dated 27.09.2021 received in this office on 05.11.2021 from DHS

2) No. PH1/72345/2021 DHS dated 27/10/2021

.....

As per the reference above, the reply of your questions 5, 6, 7, 8, 12 and 13 are given below.

5. 18256 people tested positive for COVID-19 in Malappuram District even after taking two doses of vaccine till 25.09.2021.

6. 55564 people tested positive for COVID-19 in Malappuram District after taking single dose of vaccine till 25.09.2021.

7. 44 people deceased due to COVID-19 in Malappuram District after taking two doses of vaccines till 25.09.2021.

8. 364 people deceases due to COVID-19 in Malappuram District after taking single dose of vaccine till 25.09.2021.

12. 1024 people deceased in Malappuram District due to COVID-19 since the date of vaccination started till 25.09.2021.

13. 11 people deceased in Malappuram District due to the side effect of vaccination against COVID-19 till 25.09.2021.

Yours faithfully,

Baburaj P
Public Information Officer
C&D Section
District Medical Office (Health) Malappuram

If you are not satisfied with the above reply, you may file appeal petition to the Appellate Authority in the following address:

Appellate Authority
District Medical Officer(Health)
Malappuram - 676505

S.N - 30.11.2021

EXHIBIT "RA-9"

1429

~~281~~

NATION SEALTH MISSION
राष्ट्रीय स्वास्थ्य मिशन

Very
AZOdi 63
Amrit Mahotsav

सत्यमेव जयते

भारत सरकार
स्वास्थ्य एवं परिवार कल्याण विभाग
स्वास्थ्य एवं परिवार कल्याण मंत्रालय

Government of India
Department of Health and Family Welfare
Ministry of Health and Family Welfare

राजेश भूषण, आईएएस
सचिव

RAJESH BHUSHAN, IAS
SECRETARY

D.O. No.01/S(HFW)/Omicron/Maha/2021
01 December, 2021

Dear Sir,

This is with reference to the Govt. Of Maharashtra Order No. DMU/2020/CR.92/DisM-1 dated 30th Nov. 2020, vide which the following restrictions have been imposed:

i. Mandatory RTPCR testing of all international travellers at the Mumbai airport, irrespective of country of origin
ii. Mandatory 14-day home quarantine for all international passengers, despite being tested RTPCR Negative upon arrival
iii. Mandatory RTPCR test for passengers planning to undertake connecting flights after disembarking at Mumbai and further travel subject to a negative RTPCR result
iv. Requirement of negative RTPCR test 48 hours prior to date of journey, for domestic passengers travelling from other States to Maharashtra

2. This is in divergence with the SoPs & Guidelines issued by Ministry of Health & Family Welfare, Govt. of India. I would, therefore, urge you to align the Orders issued by the State with the Guidelines issued by the Ministry of Health & Family Welfare, Govt. Of India, so that uniform implementation of the guidelines may be ensured across all States/UTs. I would also advise that such modified orders of the State Government are given wide publicity to obviate any inconvenience to travellers.

Warm Regards.

Yours sincerely

(Rajesh Bhushan)

Dr. Pradeep Kumar Vyas
Additional Chief Secretary
Department of Health & Family Welfare
Government of Maharashtra
Mumbai
Email : psec.pubhealth@maharashtra.gov.in

NOTARY GOVT. OF INDIA

Room No. 156, A-Wing, Nirman Bhawan, New Delhi-110 011
Tele : (O)011-23061863, 23063221, Fax:01123061252, E-mail : secyhfw@nic.in

1430

282

EXHIBIT "RA-10"

Maharashtra: Over 1.6 lakh people took jab after 'No vaccine, no entry' order in Beed

The order for 'No vaccine no entry' was issued on November 21 by District Collector Radhabinod Sharma as Beed with just 55 per cent first dose coverage was behind the state average of 74 per cent.

Source Name: The Indian Express

Link: https://indianexpress.com/article/cities/mumbai/maharashtra-lakh-people-took-jab-no-vaccine-no-entry-order-beed-7646251/

Published on: November 28, 2021

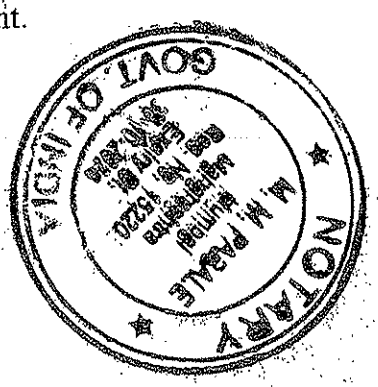
Author Name : Jayprakash S Naidu

A week after the District Collector of Beed started a 'No vaccine, no entry' policy, over 40,000 more people took the first dose of the Covid-19 vaccine than the previous week.

As per the orders, all government departments, private organisations, companies, traders, hawkers, vendors, educational institutions including private classes and all religious places must ensure their employees or visitors have received at least one dose of the vaccine, failing which they should not be allowed to enter the workplace or any government office.

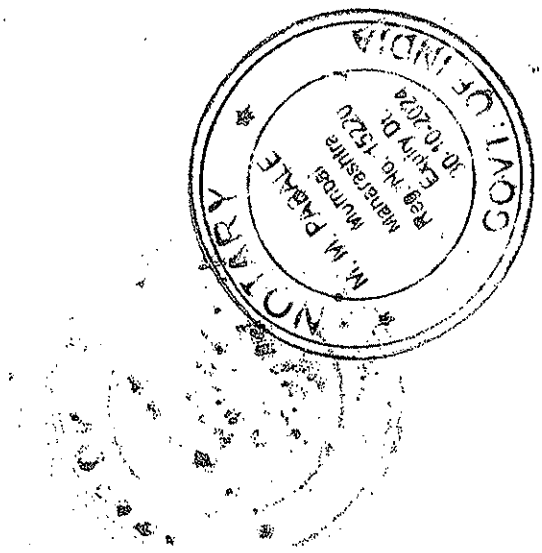
According to the district health department, a total of 1,14,035 (1.14 lakh) people got the first dose of vaccination between November 15 and November 21.

The order for 'No vaccine no entry' was issued on November 21 by District Collector Radhabinod Sharma as Beed with just 55 per cent first dose coverage was behind the state average of 74 per cent.



District authorities were told to ensure that everyone using public transport and even travelling by private vehicles had taken at least one dose. The order asked the district RTO not to accept applications for learning licence or fitness tests from a person who had not received even a single dose.

In the week following the orders from November 22 till November 28, the number of those vaccinated rose to 1,61,815 (1.61 lakh) people. Confirming the development, Dr Rauf Shaikh, Beed district's health officer, told The Indian Express, "The number of people vaccinated shot up after the orders issued by the collector. Our efforts will continue to ensure everyone is vaccinated and a third wave of the pandemic can be avoided."



1432

284

EXHIBIT "RA-11"

BMC's pro-mask drive is just an extortion racket

Source: mid-day

Link: https://www.mid-day.com/mumbai/mumbai-news/article/bmcs-pro-mask-drive-is-just-an-extortion-racket-23205778

Author: Shirish Vaktania

Published on: 20 December, 2021

Apart from threatening people by pretending to be the cops, they abuse passengers in order to make them pay hefty fines

Implementation of BMC's rule on wearing masks has been a major point of contention between the clean-up marshals and citizens. People have been complaining of the high-handedness of marshals who threaten abuse and extort money from them. mid-day decided to see what really happens on the ground and our reporter got himself employed as a marshal through an agency. He was hired within a few days without the mandatory police verification.

The marshals behave no less than thugs and extort money from passengers. Most of the time they do not even provide receipts to those reluctant to pay fines, and pocket whatever profits they make. They make an exception though, by not charging political party workers, cops and government officials. The reporter was deployed at Hans Bhugra Marg Road (which connects WEH and Kalina, Santacruz East).

The agency that recruited the reporter, Tiger Guards Private Limited, has its office at Hanuman Tekdi in Santacruz East. It has employed 50 to 60 clean-up

marshals, and each of them has a target to collect fines from 25 people (Rs 200 each) in a day, which comes to around Rs 5,000.

However, each marshal collects approximately Rs 10,000 a day by extorting money from people, who are unaware of the rates and the rules, and more than 60 per cent of what they get are pocketed by them.

Day 1 MEETING SUPERVISOR

December 8

On the first day, the reporter approached the supervisor of marshals, Mitesh Vitkar, deployed at the Santacruz-Kalina junction on WEH.

Reporter: I need a job as a clean-up marshal who collects fine from people for not wearing masks.

Vitkar: This work contract will end in February.

Reporter: I will work till then. How do I get paid?

Vitkar: The salary depends on each fine collected. You will get Rs 40 for each fine or chalan.

Reporter: What are the timings?

Vitkar — It depends on you, complete your target and go home.

Rep[illegible]ter: What is the target?

Vi[illegible] minimum of 10 fines per day. For 10 fines you will get Rs 400. If you manage to collect fines from 25 people, you will get Rs 1,000. Call me tomorrow, I will fix an interview.

Meanwhile, Vitkar stopped a private vehicle and forced the people sitting inside to pay fines. As per BMC's rules, those travelling in private vehicles are allowed to not wear masks. When the reporter told him the same, Vitkar said, "Sabko rules nahi pata (not everyone knows the rules."

mid-day noticed that the BMC marshals were taking advantage of the fact that many people were not aware of the rules. The reporter tried to contact Vitkar many a times between December 9 and 13, but he finally fixed the interview on December 14 with Contractor Sudhir Choudhary at his office in Hanuman Tekdi, Santacruz East.



Day 2 INTERVIEW WITH CONTRACTOR
December 14

Reporter: I have come for the job of a BMC marshal.
Sudhir Choudhary: Where do you stay?
Reporter: I stay in Khar East.
Choudhary: Have you got your aadhaar card, electricity bill and two photos?
Reporter: I will get them tomorrow.
Choudhary: You have to pay Rs 1,000 for the uniform, which will come in about two to three days. The money is non-refundable.
Reporter: Can I join from today?
Choudhary: We will train you for two days and then you can decide whether to take up the job.
Reporter: I will do it, sir. Will join training from tomorrow.

Day 3&4 ON-FIELD TRAINING
December 15 & 16

When the reporter met Choudhary at his office, he instructed him to take training under marshal Bhagwan Patankar at the Kalina junction. The reporter accompanied Patankar as he collected fines.

Patankar took the reporter to the spot and said that he should stop vehicles by standing right in front of them, so that they don't escape without paying fines. The reporter was introduced to several other marshals — Ganesh Gupta, Vishal

Sawant and Afzal Khan. They usually function in groups and if any motorist refuses to pay fines, they argue and threaten the person. mid-day noticed that the gang makes about Rs 3,000 profit per day, which they call the 'personal cut'.

Patankar used dummy cell phones to threaten the passengers. He pretended to click pictures and forced passengers to cough up fines. They would even threaten citizens by saying that they would call the cops, who would make them pay a fine of Rs 1,200.

Patankar stopped a public vehicle in which two people were wearing their masks around their chins.

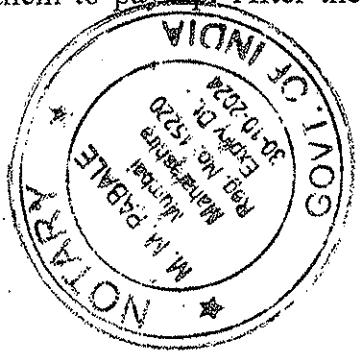
Patankar: Aap dono ne mask nahi pehena hai thik se. Mask nose ke upar properly wear karna hai (you both are not wearing your masks properly, it should be above your nose).
Passengers: We are wearing our masks properly. We will not pay fines.
Patankar: Car side mein le lo, mai police ko call karke bula leta hu. Wo dekh lenge baad mai and aapko Rs 1,200 per head fine bharna parega (I will call the cops and they will make you pay Rs 1,200 fine per head).
Passenger: Police ko kyun bula rahe ho (why are you calling the police?)
Patankar: Ek kam karo, Rs 200 fine bhar do aur jao (pay Rs 200 fine and go).

The passengers gave Rs 200 but were not given a receipt.

Marshal abuses women

Marshal Patankar caught two women passengers who were not wearing masks. He even pretended to click their pictures and threatened to call the cops. Patankar took their car to the side and forced them to pay up. After they left from the spot, he started abusing them.

Marshal misguides woman



Patankar: No mask fine is Rs 500

Passenger: Kyun (why)?

Patankar: Mask nahi pehena hai (you are not wearing a mask).

Passenger: Jaane do yaar (let it go).

Patankar: Kya karna hai bolo? Rs 500 bharna parega. Ek kam karo Rs 300 bhar do aur jao (You have to pay Rs 500, but you can pay Rs 300 and go).

Passenger: Thik hai (okay).

The woman gave Rs 300 to Patankar, who did not give her a receipt.

Reporter: Why did you tell her that the fine amount is Rs 500?

Patankar: I could make out that she did not know about it. Study the people properly and you will get more money.

Marshal Ganesh Gupta

Gupta stopped a public vehicle in which two people were wearing their masks around their chins. Gupta pretended to click their pictures and asked for a Rs 400 fine.

Gupta: Aapka mask nose ke niche hai. Rs 400 fine bharna padenga (your masks are below the nose, will have to pay fine.)

Passengers: We will not pay fine.

Gupta: Ek kam karo, ek ka fine Rs 200 bhar do (pay a fine of Rs 200 for one person.)

Passenger: We will not pay fine.

Gupta: Ek kam karo, Rs 100 fine bhar do and jao, but receipt nahi milenga (pay Rs 100 fine and go, but you won't get receipt.)

Passengers pay Rs 100, which Gupta keeps in his pocket.

Gupta stopped a mini-tempo and told them that they have to pay Rs 400 fine for two people not wearing masks

Tempo driver: Hum log garib hai jaane do (we are poor people, please let us go).

Gupta: Ek jan ka fine Rs 200 bharo aur jao (pay a fine of Rs 200 for one person and go).

Tempo driver: Jaane do please (please let us go).

Gupta: Ek kam karo, police chowky mai chalo waha bharna Rs 1,200 ek jan ka (let's go to the police chowky and you will have to pay a fine of Rs 1,200 each).

Finally the tempo dri[illegible] ave Rs 50 and Gupta put it in his pocket.

Afzal Khan starts work as early at 8 am and fines more than 30-40 people. He earns over Rs 3,000 by extorting people. In one such instance, Khan stopped a public vehicle and threatened a passenger to pay fine.

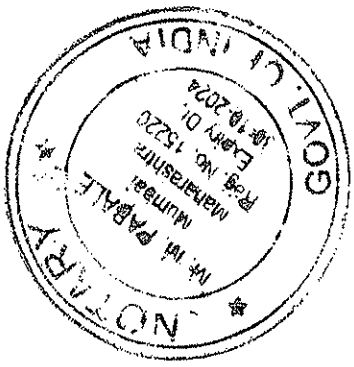
Khan: Mask nahi pehena hai, fine bharo aur jaa. Tujhe jaane nahi dunga fine bhare bina (you have not worn the mask properly, will not let you go without paying a fine).

Passenger: Fine nahi bharenge (will not pay fine).

Khan manhandled the passenger and threatened him by saying that he won't let him.

P[illegible] Rs 100 sirf dunga (will only pay Rs 100)

Khan took the money and did not give a receipt.



Marshals hit a jackpot

Tourist buses are like a jackpot for the marshals as they can extort a lot of money from the passengers. A tempo carrying 15 members of a family was returning from a tour and going towards the airport when three marshals

stopped the vehicle. All of them entered the tempo and took a video of the passengers. None of them were wearing masks. A group of senior citizens got off the vehicle and a heated argument started between them and the marshals over paying fines.

Senior citizens: We are from a single family and have been travelling together for the past couple of days. We are headed to the airport and don't want to miss our flight.

Marshals: I agree you all are from one family but this vehicle is a public one. We will call the police and take the vehicle to the police station.

Senior citizens: We all are fully vaccinated, please leave us.

Marshals: Now the police will take action.

During the conversation one of the marshals pretended to call the cops and tell them that passengers were fighting with them over fines.

Senior citizens: Don't give wrong information to the cops. Let us speak to them.

Marshals: Wait for sometime, the cops will come and take all of you to the Vakola police station.

Meanwhile, two young passengers got off the vehicle and took Marshal [illegible]al Sawant to the side. They then gave him Rs 1,000, but the marshal di[illegible]t provide any receipt. The marshals then divided the money among themselve[illegible]n three equal parts.

Politicians, govt employees let off

BMC marshal Sawant caught a passenger in a public vehicle with his mask below his nose, but he eventually let him go without taking a fine.

Passenger: I am a personal assistant of an MLA. My mask is on my face. I was talking on the phone because of which I pulled it below my nose. I have to reach somewhere for urgent work. I will give you a number where you can talk to the person concerned.

MNS worker

BMC marshal Khan spotted a passenger who was not wearing his mask properly and immediately stopped the car. The person who was driving the car came out and started shouting. He even mentioned that he was from the MNS party. "Phone pe m[illegible] photo le raha hai. Samjha do isko. Mental hospital mai admit karo isko. Kiska photo le raha hai wo bhi nahi pata. Ek phone karenga to tum sab BMC marshals ka khel khatam ho jayega (do you even know whose picture you are clicking? Send him to a mental hospital. I'll make one call and all that you guys are doing will come to an end)," he said. When the marshal realised that the passenger was a party worker, he let him go.

Day 5

December 17

The reporter paid Rs 1,000 and collected the uniform from the Tiger Guard's office. However, he was not given any receipt for the same. He was also asked to train for another day.

Day 6

December 18

At 10 am the reporter went to the agency's office and collected the uniform. Then he worked for two hours. However, during that time the reporter only requested people to wear masks properly. He had also been given a fine receipt book of serial number 2653651 to 2653701.

1440

292

Note: The mid-day reporter didn't fine anyone. Instead, he just requested people to wear their masks. Later, he went to the agency's office and met Sudhir Choudhary. He then submitted the receipt book at 1 pm and told him that he had to leave for some urgent work. The receipt book was not used.



1991

File No.Z.28016/133/2021-DMCell

293

EXHIBIT "RA-12"

F. No. Z.28016/133/2021-DM Cell
Government of India
Ministry of Health & Family Welfare
(DM Cell)

Nirman Bhavan, New Delhi.
Dated the 27th May 2021.

To

Sourav Bysack
Saradapally Mathurdingi, Mrigalal,
Tantipara Haspu, Dankuni, Pin:712311
bysack.sourav@gmail.com

Subject: Request for information under RTI Act 2005.

With reference to your online RTI application bearing registration no. MOHFW/R/E/21/01528dated 15/04/2021 for providing information on the above-mentioned subject. The point wise reply is as under:-

S No.	Question	Answer
1.	Is face Masks are mandatory for everyone.	Use of mask/face cover has been advised to all in various SOPs/Guidelines issued by MoHFW. However as per these guidelines/SOPs its use has not been explicitly made mandatory.
2.	what are the side effects of face mask.	No such information is available in records of DM Cell, MoHFW
3.	how long use of face mask is safe.	Mask has to be worn for a maximum of 8 hours of use or earlier if it becomes wet or visibly soiled.
4.	if a person feel very uncomfortable while using face mask then what he/she should do.	No such information is available in records of DM Cell, MoHFW.
5.	Is face masks lower the oxygen saturation level in blood.	As per MoHFW's Guidelines on Preventive Measures to Contain Spread of COVID-19 in Yoga Institutes & Gymnasiums issued on 1st March 2021 (available at: https://www.mohfw.gov.in/pdf/GuidelinesonPreventiveMeasurestoContainSpreadofCOVID19inYogaInstitutes&Gymnasiums.pdf), use of mask (in particular N-95 masks) during exercise may cause difficulty in breathing. No further information is available in records of DM Cell, MoHFW.
6.	Is government of India conducted any trial/study on using face mask and face mask side effects .	No such information is available in records of DM Cell, MoHFW.
7.	what type of mask is	No such information is available in records of DM Cell, MoHFW.

1452

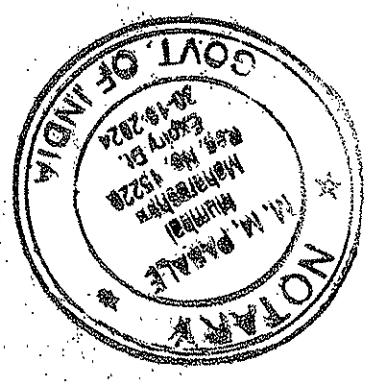
294

	effective and why with scientific evidence	

If you are not satisfied with the above reply, you can prefer an appeal to Appellate Authority i.e. Shri. Govind Jaiswal, Director PH, Ministry of Health & Family Welfare, Room No. 205 "D", Nirman Bhavan, New Delhi, as per the provision of RTI Act, 2005.

Yours sincerely

(Dr.Yogesh)
CPIO&CMO (EMR)
Tel. No. 011- 23060777



1553

EXHIBIT "RA-13"

~~295~~

English

Phubli Authorites Available

RTI Online

Jeis

सत्यमेव जयते

mi Reors

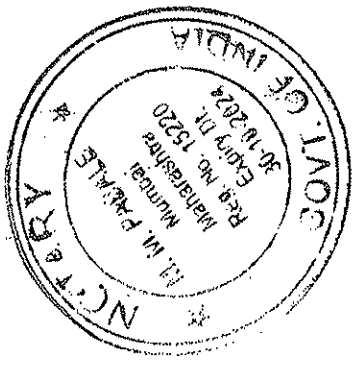
AStaltis View History User Maria FAO

FinalStatus of INCMR/R/E/21/00355

Applicant Name	Amit Chouhan
Date of receipt	19/05/2021
Reqest Filed With	Indian Council of Medical Research
Text of Application	1. What are the side effects of using Face Mask 2. If a person feel uncomfortable while using face mask what he should do 3.is oxygen saturation level fall in blood for using face mask 4.Is face mask are mandatory for everyone 5.was government of India asses the side effects long term use of face mask. 6.Is government of India have any evidence/proof/trial regarding use of face mask and virus protection.
Request document (if any)	document not provided
Status	RTIREQUEST APPLICATION RETURNED TO APPLICANT as on 19/05/2021
Date of Action	19/05/2021
Remarks	Remarks : For face mask related issues, please visit link https://www.mohfw.gov.in/pdf/Useofmaskbypublic.pdf and https://www.mohfw.gov.in/pdf/Poster4GHFGA.pdf Regards

Print

mEI Naronai Porai of Indial Compaint Secend AwEal to CiC! EA
Copyright 7013. All rights reserved. Designed, Developed and Hosted by NationaB Informatics Centre, New Delhi



NOTARY
M. M. PAWALE
Mumbai
Maharashtra
Reg. No. 15220
Expiry Dt.
30-10-2024
GOVT. OF INDIA

1495

296

Ministry of Health and Family Welfare
Directorate General of Health Services
[Emergency Medical Relief]

Novel Cororнavirus Disease (COVID-19)

Guidelines on use of masks by public

1. Introduction

A new disease named novel coronavirus (COVID-19) emerged in early December 2019 in China and has now spread to over 90 countries. As on 9th March 2020, India has reported 42 cases mostly among those who had travelled from affected countries. It causes a minor illness in majority of patients with symptoms of fever and or cough. A small proportion of such persons may progress to severe disease with difficulty in breathing.

It is spread by an infected person with COVID coughing and the droplets from his cough infecting others in close vicinity (less than 1 metre).

Any such new disease invariably related to cough leads to suggestions from various quarters, especially in social media, to use mask by general public to prevent the disease.

2. Purpose of this document

The purpose of this document is to give correct evidence based information to general public on use of mask.

3. Medical masks

Medical masks of different size and shapes are available in the market. The common ones are flat pleated masks of woven fabric which covers the nose and mouth and affixed behind the head with straps/ elastic fasteners. There are also conical or duck bill shaped masks with valves (or without valves) that fit in the contour of face over the nose and mouth, but are costlier.

4. Use of masks by general public

4.1. Persons having no symptoms are not to use mask

Medical masks should not be used by healthy persons who are not having any symptoms because it create a false sense of security that can lead to neglecting other essential measures such as washing of hands.

Further, there is no scientific evidence to show health benefit of using masks for non-sick persons in the community. In fact erroneous use of masks or continuous use of a disposable mask for longer than 6 hours or repeated use of same mask may actually increase risk of getting an infection. It also incurs unnecessary cost.

In such situation, more effective steps are:

i. Wash hands frequently with soap and water for 40 seconds. An alcohol based hand sanitizer with 70% alcohol must be used for 20 seconds. If hands are dirty or soiled, do not use alcohol based hand sanitizer, but wash hands preferably with soap and water.

ii. While coughing or sneezing cover nose and mouth with handkerchief, paper tissue. If handkerchief or tissue paper is not available cough into the flexed elbow. Dispose of tissue immediately after use and wash hands.

iii. Refrain from touching face, mouth, nose and eyes.

iv. Stay at least a metre away from those coughing or sneezing.

v. Monitor your body temperature.

4.2. When and who should use medical masks (apart from health care worker).

4.2.1. When a person develops cough or fever.

Use of medical three layer masks when ill, will prevent your infection from spreading to others. However you also need to wash your hands frequently to avoid spreading infection to others.

4.2.2. While visiting a healthcare facility.

4.2.3. When you are caring for an ill person.

4.2.4. Close family contacts of such suspect/confirmed cases undergoing home care should also use Triple layer medical mask.

4.3. Duration for which a medical mask will remain effective

A medical mask, if properly worn, will be effective for 8 hours. If it gets wet in between, it needs to be changed immediately.

4.4. Correct procedure of wearing triple layer mask

While wearing a medical mask, the steps given below needs to be followed. If you do not follow them, you may get infected from the mask itself. These steps are:

- Unfold the pleats; make sure that they are facing down.
- Place over nose, mouth and chin.
- Fit flexible nose piece (a metallic strip that can easily be located) over nose bridge.

1456

- Secure with tie strings (upper string to be tied on top of head above the ears – lower string at the back of the neck.)
- Ensure there are no gaps on either side of the mask, adjust to fit.
- While in use, avoid touching the mask.
- Do not let the mask hanging from the neck.
- Change the mask after six hours or as soon as they become wet.
- Disposable masks are never to be reused and should be disposed off.
- While removing the mask great care must be taken not to touch the potentially contaminated outer surface of the mask
- To remove mask first untie the string below and then the string above and handle the mask using the upper strings.

4.5. Disposal of used masks

Used mask should be considered as potentially infected. Masks used by patients / care givers/ close contacts during home care should be disinfected using ordinary bleach solution (5%) or sodium hypochlorite solution (1%) and then disposed of either by burning or deep burial.

1997

Select Language: English

Public Authorities Available 299

EXHIBIT "RA-14"

RTI Online

Version 2.0

An Initiative of Department of Personnel & Training, Government of India

Home Submit Request Submit First Appeal View Status View History User Manual FAQ

Final Status of NIOVP/R/E/21/00046

Applicant Name	Amit Chouhan
Date of receipt	17/07/2021
Request Filed With	ICMR-National Institute of Virology (NIV), Pune
Text of Application	Please provide following information 1. Size of SARS-CoV-2 virus 2.Pore size of standard surgical mask and N95 mask
Request document *(if any)*	document not provided
Status	RTI REQUEST APPLICATION RETURNED TO APPLICANT as on 29/07/2021
Date of Action	29/07/2021
Remarks	Remarks :- 1. SARS-CoV-2 virus is round shaped virus with an average size of 70-80 nm. 2. Pore size of standard surgical mask and N95 mask is 0.3 – 10 µm & 0.1 – 0.3 µm respectively.
Print	

Home | National Portal of India | Complaint & Second Appeal to CIC | FAQ

Copyright © 2013. All rights reserved. Designed, Developed and Hosted by National Informatics Centre, New Delhi



1458

300

EXHIBIT "RA-15"

47 studies confirm ineffectiveness of masks for COVID and 32 more confirm their negative health effects

Source: LifeSite

Link: https://www.lifesitenews.com/news/47-studies-confirm-inefectiveness-of-masks-for-covid-and-32-more-confirm-their-negative-health-effects/?fbclid=IwAR1ksLTTglmF31y90NjCW3wiUo_CHLG5v2oqN0df7ghwcZEwTc1zVBwsz0M

Published on: Fri Jul 23, 2021

July 23, 2021 (LifeSiteNews) – Prior to facemask mandates as an alleged preventive for Covid infection and transmission, such masks were infrequently worn in hospitals and other medical facilities. They were only used in operating theatres or for visiting seriously ill patients in order to prevent infection from spit or droplets into open wounds or to partially protect visitors from acquiring and transmitting pathogens more dangerous than Covid. Many doctors and nurses have told LifeSite that for decades, if not longer, staff wearing medical masks were an uncommon sight in health care facilities other than as mentioned.

No studies were needed to justify this practice since most understood viruses were far too small to be stopped by the wearing of most masks, other than sophisticated ones designed for that task and which were too costly and complicated for the general public to properly wear and keep changing or cleaning. It was also

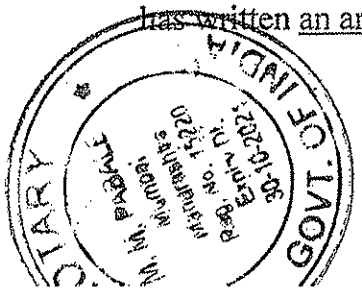
understood that long mask wearing was unhealthy for wearers for common sense and basic science reasons.

There has been an international flood of lies about mask wearing in order to justify the bizarre and disturbing situation we have today of almost everyone wearing masks in many regions, inside and outside healthcare facilities, in schools with children of all ages, during sports events, in churches, in grocery stores and all commercial facilities, while driving and walking, and long after peak infection has passed.

It has also continued long after it was discovered that Covid was not nearly as dangerous as we were led to believe, that many of the mitigation policies caused serious damage of all kinds, including many deaths, and long after prevention and treatment protocols were discovered and used with great success, and the very best ones often criminally suppressed by government and health authorities.

The unnecessary and greatly exaggerated fear during the first few months of this pandemic, which would never have been labeled a pandemic until the WHO unilaterally changed the pandemic definition to include much less dangerous pathogens, has been manipulated to continue to this day, unlike past experiences with similar virus outbreaks. There have been numerous lies fed to the public by the WHO, national and regional government leaders and health bureaucrats and the media and many other institutions – all certainly for the purpose of maintaining fear until the large majority of the public has been injected with the poorly tested, unnecessary and dangerous Covid vaccines for which we have no evidence of their long-term safety.

President Joe Biden has been consistently presenting numerous, outrageous lies to justify his extreme Covid and vaccine policies and Paul Elias Alexander, Ph.D, has written an article published on LifeSite today that summarizes all of the most



prominent and damaging lies that have generated continuing fear and caused a large percentage of Americans and citizens of other nations to accept the Covid vaccines in order to allegedly be able to return to a normal life. Included in Alexander's list are the lies related to mask mandates.

An acquaintance of Paul Alexander has written the list below of 47 studies confirming that masks are useless in preventing Covid infection and transmission and a second list further down of 32 studies confirming the negative health effects caused by frequent mask wearing, especially for young children. This has been a growing, serious concern in recent months as the dangerous health and emotional effects, especially on children, who are at almost zero risk of Covid harm, are becoming more pronounced and deeply worrisome.

VARIOUS FACE MASK STUDIES PROVE THEIR INEFFECTIVENESS

1. Surgical mask / cloth face mask studies

Community and Close Contact Exposures Associated with COVID-19 Among Symptomatic Adults ≥18 Years in 11 Outpatient Health Care Facilities — United States, July 2020

The US Centre for Disease Control performed a study which showed that 85 percent of those who contracted Covid-19 during July 2020 were mask wearers. Just 3.9 percent of the study participants never wore a mask. Original: https://www.cdc.gov/mmwr/volumes/69/wr/pdfs/mm6936a5-H.pdf Erratum.
correction: https://www.cdc.gov/mmwr/volumes/69/wr/mm6938a7.htm?s_cid=mm6938a7_w https://www.theblaze.com/op-ed/horowitz-cdc-study-covid-masks



2. Facial protection for healthcare workers during pandemics: a scoping review

This study used 5462 peer-reviewed articles and 41 grey literature records.

"Conclusion: The COVID-19 pandemic has led to critical shortages of medical-grade PPE. Alternative forms of facial protection offer inferior protection. More robust evidence is required on different types of medical-grade facial protection. As research on COVID-19 advances, investigators should continue to examine the impact on alternatives of medical-grade facial protection" So how is your cloth and surgical mask working again if EVEN medical grade alternatives are failing ?

Study Article: https://pubmed.ncbi.nlm.nih.gov/32371574/

3. Physical interventions to interrupt or reduce the spread of respiratory viruses

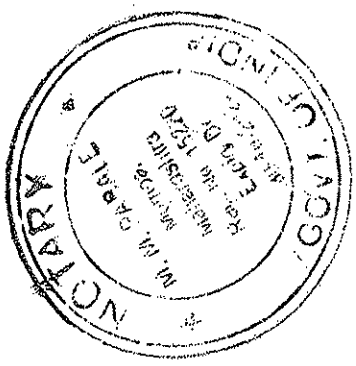
"There is moderate certainty evidence that wearing a mask probably makes little or no difference to the outcome of laboratory-confirmed influenza compared to not wearing a mask"

Study article: https://pubmed.ncbi.nlm.nih.gov/33215698/

4. Disposable surgical face mask for preventing surgical wound infection in clean surgery

"We included three trials, involving a total of 2106 participants. There was no statistically significant difference in infection rates between the masked and unmasked group in any of the trials"

Study article: https://pubmed.ncbi.nlm.nih.gov/27115326/



5. Disposable surgical face mask: a systematic review

Two randomized controlled trials were included involving a total of 1453 patients. In a small trial there was a trend towards masks being associated with fewer infections, whereas in a large trial there was no difference in infection rates between the masked and unmasked group.

Study article: https://pubmed.ncbi.nlm.nih.gov/16295987/

6. Evaluating the efficacy of cloth facemasks in reducing particulate matter exposure

"Our results suggest that cloth masks are only marginally beneficial in protecting individuals from particles<2.5 μm"

Study article: https://pubmed.ncbi.nlm.nih.gov/27531371/

7. Face seal leakage of half masks and surgical masks

"The filtration efficiency of the filter materials was good, over 95% for particles above 5 micron in diameter but great variation existed for smaller particles.

Coronavirus is 0.125 microns. therefore these masks wouldn't protect you from the virus"

Study article: https://pubmed.ncbi.nlm.nih.gov/4014006/

8. Comparison of the Filter Efficiency of Medical Nonwoven Fabrics against Three Different Microbe Aerosols

"The filter efficiencies against influenza virus particles were the lowest"

"We conclude that the filter efficiency test using the phi-X174 phage aerosol may overestimate the protective performance of nonwoven fabrics with filter structure

compared to that against real pathogens such as the influenza virus" Study article: https://pubmed.ncbi.nlm.nih.gov/29910210/

9. Aerosol penetration through surgical masks

"Although surgical mask media may be adequate to remove bacteria exhaled or expelled by health care workers, they may not be sufficient to remove the submicrometer-size aerosols containing pathogens "

Study article: https://pubmed.ncbi.nlm.nih.gov/1524265/

10. Particle removal from air by face masks made from Sterilization Wraps: Effectiveness and Reusability

"We found that 60 GSM face mask had particle capture efficiency of 94% for total particles greater than 0.3 microns"

How big is the virus again? 0.125 microns.

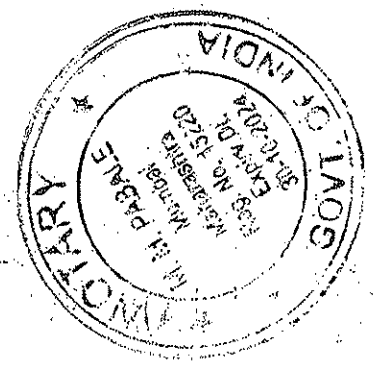
Study article: https://pubmed.ncbi.nlm.nih.gov/33052962/

11. A New Method for Testing Filtration Efficiency of Mask Materials Under Sneeze-like Pressure

This study states that "alternatives" like silk and gauze etc could possibly be good options in the pandemic. It's done on starch particles.

Does not state how big they are either, but they can still get through the material and my research points out that starch particles are "big", much bigger than most viruses.

Study article: https://pubmed.ncbi.nlm.nih.gov/32503823/



12. Protecting staff against airborne viral particles: in vivo efficiency of laser masks

"The laser mask provided significantly less protection than the FFP2 respirator (P=0.02), and only marginally more protection than the surgical mask. The continued use of laser masks for respiratory protection is questionable. Taping masks to the face only provided a small improvement in protection"

Study article: https://pubmed.ncbi.nlm.nih.gov/16920222/

13. Quantitative Method for Comparative Assessment of Particle Removal Efficiency of Fabric Masks as Alternatives to Standard Surgical Masks for PPE

"Worn as designed, both commercial surgical masks and cloth masks had widely varying effectiveness (53 – 75 percent and 28 – 91 percent particle removal efficiency, respectively)". Different brand, different results and only when they applied "nylon layers" did the "efficiency" improve. Synthetic fibres do not breathe, so this will inevitably effect your breathing.

Study article: https://pubmed.ncbi.nlm.nih.gov/32838296/

14. The efficacy of standard surgical face masks: an investigation using "tracer particles"

"Since the microspheres were not identified on the exterior of these face masks, they must have escaped around the mask edges and found their way into the wound". Human albumin cells, aka aborted fetal tissue, is much larger than the virus and still escaped the mask.

Study article: https://pubmed.ncbi.nlm.nih.gov/7379387/

15. Testing the efficacy of homemade masks: would they protect in an influenza pandemic?

"Our findings suggest that a homemade mask should only be considered as a last resort to prevent droplet transmission from infected individuals" so why has the government suggested you make your own when they are not effective ?

Study article: https://pubmed.ncbi.nlm.nih.gov/24229526/

16. Using half-facepiece respirators for H1N1

"Increasing the filtration level of a particle respirator does not increase the respirator's ability to reduce a user's exposure to contaminants"

https://pubmed.ncbi.nlm.nih.gov/19927872/

17. Why Masks Don't Work Against COVID-19

The site is full of studies proving masks dont work for coronavirus or the flu.

Article: https://www.citizensforfreespeech.org/why_masks_don_t_work_against_covid_19?fbclid=IwAR0Qviyvt6BObOg_aMij03Cj0fgTcm_gm5jhXcMkO8GcH3Kur-bwib0o8rf8

18. Masks Don't Work: A Review of Science Relevant to COVID-19 Social Policy

This is full of studies proving mask protection is negligible for coronavirus, flu etc.

Article: https://www.rcreader.com/commentary/masks-dont-work-covid-a-review-of-science-relevant-to-covide-19-social-

1456

308

policy?fbclid=IwAR0Qviyvt6BObOgaMij03Cj0fgTcm_gm5jhXcMkO8GcH3Kur-bwib0o8rf8

19. Face masks to prevent transmission of influenza virus: a systematic review

There is less data to support the use of face masks or respirators to prevent becoming infected.

Study article: https://pubmed.ncbi.nlm.nih.gov/20092668/

20. "Exercise with facemask; Are we handling a devil's sword?" – A physiological hypothesis

No evidence to suggest that wearing a mask during exercise offers any benefit from the droplet transfer from the virus.

"Exercising with facemasks may reduce available Oxygen and increase air trapping preventing substantial carbon dioxide exchange. The hypercapnic hypoxia may potentially increase acidic environment,cardiac overload, anaerobic metabolism and renal overload, which may substantially aggravate the underlying pathology of established chronic diseases"

Study article: https://pubmed.ncbi.nlm.nih.gov/32590322/

21. Use of face masks by non-scrubbed operating room staff: a randomized controlled trial

Surgical site infection rates did not increase when non-scrubbed personnel did not wear face masks.
2010 Study article: https://pubmed.ncbi.nlm.nih.gov/20575920/

22. Surgical face masks in modern operating rooms – a costly and unnecessary ritual?

When the wearing of face masks by non-scrubbed staff working in an operating room with forced ventilation seems to be unnecessary.

Study article: https://pubmed.ncbi.nlm.nih.gov/1680906/

23. Masks: a ward investigation and review of the literature

Wearing multi layer operating room masks for every visit had no effect on nose and throat carriage rates.

Study article: https://pubmed.ncbi.nlm.nih.gov/2873176/

24. Aerosol penetration and leakage characteristics of masks used in the health care industry

The protection provided by surgical masks may be insufficient in environments containing potentially hazardous submirconometer-sized aerosols.

"Conclusion: We conclude that the protection provided by surgical masks may be insufficient in environments containing potentially hazardous submicrometer-sized aerosols"

Study article: https://pubmed.ncbi.nlm.nih.gov/8239046/

25. Masks for prevention of viral respiratory infections among health care workers and the public: PEER umbrella systematic review

Meta analysis review that says there is limited evidence to suggest that the use of masks may reduce the risk of spreading viral respiratory infections.

Study article: https://pubmed.ncbi.nlm.nih.gov/32675098/

26. Modeling of the Transmission of Coronaviruses, Measles Virus, Influenza Virus, *Mycobacterium tuberculosis*, and *Legionella pneumophila* in Dental Clinics

Evidence to suggest that transmission probability is strongly driven by indoor air quality, followed by patient effectiveness and the least by respiratory protection via mask use.

So this could explain "second waves" and has nothing to do with hand shaking, or not wearing a mask.

Study article: https://pubmed.ncbi.nlm.nih.gov/32614681/

27. Nonpharmaceutical Measures for Pandemic Influenza in Nonhealthcare Settings-Personal Protective and Environmental Measures

The use of face masks, either by infected or non infected peresons, does not have a significant effect on influenza transmission.

SO MASKS DON'T PROTECT YOU FROM ME, AND VICE VERSA.

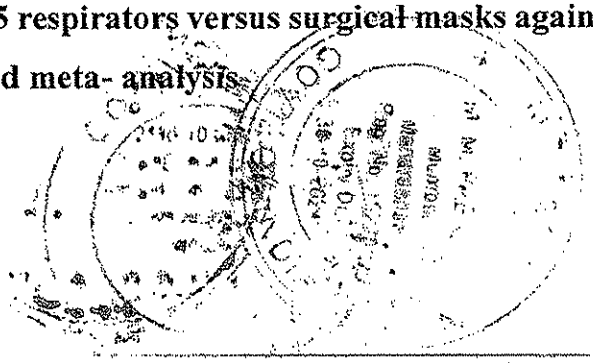
Study article: https://pubmed.ncbi.nlm.nih.gov/32027586/

28. Effectiveness of personal protective measures in reducing pandemic influenza transmission: A systematic review and meta-analysis

Meta analyses suggest that regular hand hygiene provided a significant protective effect over face masks and their insignificant protection.

Study article: https://pubmed.ncbi.nlm.nih.gov/28487207/

29. Effectiveness of N95 respirators versus surgical masks against influenza: A systematic review and meta- analysis



Use of n95 respirators compared to surgical masks is not associated with a lower risk of laboratory confirmed influenza.

Study article: https://pubmed.ncbi.nlm.nih.gov/32167245/

30. Adolescents' face mask usage and contact transmission in novel Coronavirus

Face mask surfaces can become contamination sources. People are storing them in their pockets, bags, putting them on tables, people are reusing them etc. This is why this study is relevant:

Study article: https://pubmed.ncbi.nlm.nih.gov/32582579/

31. Visualizing the effectiveness of face masks in obstructing respiratory jets

Loosely folded face masks and "bandana style" face coverings provide minimum stopping capability for the smallest aerosolized droplets.

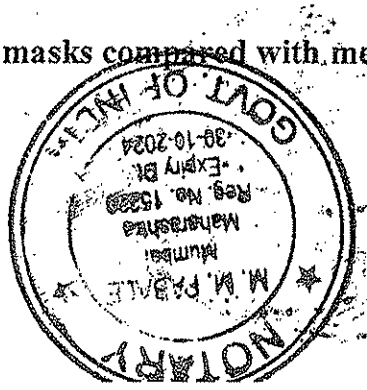
This applies to anyone who folds or shoves a mask into their pockets or bag. It also applies to cloth and homemade cloth masks:
Study article: https://pubmed.ncbi.nlm.nih.gov/32624649/

32. Use of surgical face masks to reduce the incidence of the common cold among health care workers in Japan: a randomized controlled trial

Face mask use in healthcare workers has not been demonstrated to provide benefit in terms of colds symptoms or getting colds.

Study article: https://pubmed.ncbi.nlm.nih.gov/19216002/

33. A cluster randomised trial of cloth masks compared with medical masks in healthcare workers



Penetration of cloth masks by influenza particles was almost 97 percent and medical masks 44 percent. so cloth masks are essentially useless, and "medical grade" masks don't provide adequate protection.

Study article: https://pubmed.ncbi.nlm.nih.gov/25903751/

34. Simple respiratory protection–evaluation of the filtration performance of cloth masks and common fabric materials against 20-1000 nm size particles

Cloth masks and other fabric materials tested in the study had 40-90 percent instantaneous penetration levels against polydisperse NaCl aerosols.

"Results obtained in the study show that common fabric materials may provide marginal protection against nanoparticles, including those in the size ranges of virus-containing particles in exhaled breath"

Study article: https://pubmed.ncbi.nlm.nih.gov/20584862/

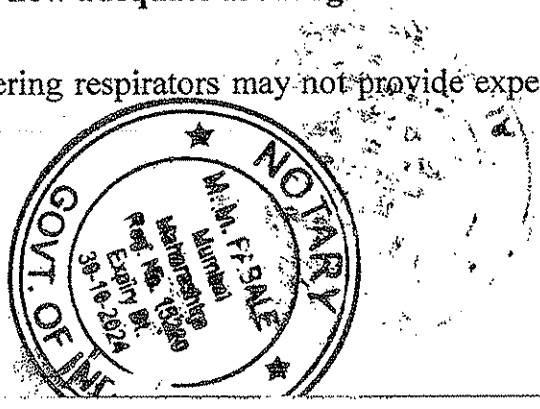
35. Respiratory performance offered by N95 respirators and surgical masks: human subject evaluation with NaCl aerosol representing bacterial and viral particle size range

"The study indicates that N95 filtering facepiece respirators may not achieve the expected protection level against bacteria and viruses"

Study article: https://pubmed.ncbi.nlm.nih.gov/18326870/

36. Do N95 respirators provide 95% protection level against airborne viruses, and how adequate are surgical masks?

The n95 filtering respirators may not provide expected protection level against small virons



Study article: https://pubmed.ncbi.nlm.nih.gov/16490606/

37. Do Surgical Masks Stop the Coronavirus?

Study article: https://slate.com/news-and-politics/2020/01/coronavirus-surgical-masks-china.html

38. Effectiveness of personal protective measures in reducing pandemic influenza transmission: A systematic review and meta-analysis

This study states that an N95, depending on the brand, can range from 0.1-0.3 microns. however, most people cannot buy an N95 with a micron smaller than 0.3 micron because they are expensive and not readily available on the public market.

"N95 respirators made by different companies were found to have different filtration efficiencies for the most penetrating particle size (0.1 to 0.3 micron)"

"Above the most penetrating particle size the filtration efficiency increases with size; it reaches approximately 99.5% or higher at about 0.75 micron"

"Meta-analyses suggest that regular hand hygiene provided a significant protective effect (OR=0.62; 95% CI 0.52-0.73; I2=0%), and facemask use provided a non-significant protective effect (OR=0.53; 95% CI 0.16-1.71; I2=48%) against 2009 pandemic influenza infection"

Study article: https://pubmed.ncbi.nlm.nih.gov/28487207/

39. Effectiveness of N95 respirators versus surgical masks against influenza: A systematic review and meta- analysis

"The use of N95 respirators compared with surgical masks is not associated with a lower risk of laboratory-confirmed influenza. It suggests that N95 respirators

should not be recommended for the general public or non high-risk medical staff who are not in close contact with influenza patients or suspected patients"

N95 masks did show a positive effect for BACTERIA but not viruses.

Study article: https://pubmed.ncbi.nlm.nih.gov/32167245/

40. Adolescents' face mask usage and contact transmission in novel Coronavirus

This study used dye to show if masks were contaminated. "As a result, masks surface becomes a contamination source. In the contact experiment, ten adults were requested to put on and off a surgical mask while doing a word processing task. The extended contamination areas were recorded and identified by image analysis"

Study article: https://pubmed.ncbi.nlm.nih.gov/32582579/

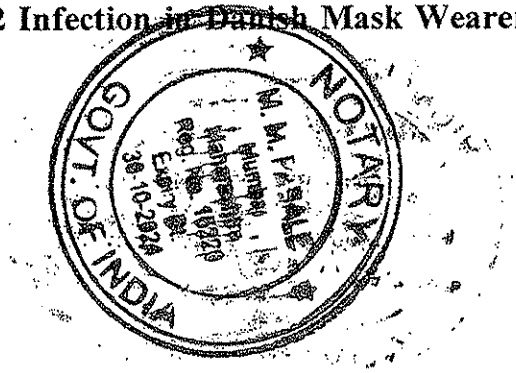
41. Use of surgical face masks to reduce the incidence of the common cold among health care workers in Japan: a randomized controlled trial

"Of the 8 symptoms recorded daily, subjects in the mask group were significantly more likely to experience headache during the study period"

"Face mask use in health care workers has not been demonstrated to provide benefit in terms of cold symptoms or getting colds"

Study article: https://pubmed.ncbi.nlm.nih.gov/19216002/

42. Effectiveness of Adding a Mask Recommendation to Other Public Health Measures to Prevent SARS CoV-2 Infection in Danish Mask Wearers : A Randomized Controlled Trial



"The recommendation to wear surgical masks to supplement other public health measures did not reduce the SARS-CoV-2 infection rate among wearers by more than 50 percent in a community with modest infection rates, some degree of social distancing, and uncommon general mask use"

Study article: https://pubmed.ncbi.nlm.nih.gov/33205991/

43. A cluster randomised trial of cloth masks compared with medical masks in healthcare workers

"An analysis of mask use showed ILI (RR=6.64, 95 percent CI 1.45 to 28.65) and laboratory-confirmed virus (RR=1.72, 95 percent CI 1.01 to 2.94) were significantly higher in the cloth masks group compared with the medical masks group. Penetration of cloth masks by particles was almost 97 percent and medical masks 44 percent"

Study article: https://pubmed.ncbi.nlm.nih.gov/25903751/

44. Respiratory performance offered by N95 respirators and surgical masks: human subject evaluation with NaCl aerosol representing bacterial and viral particle size range

"The study indicates that N95 filtering facepiece respirators may not achieve the expected protection level against bacteria and viruses. An exhalation valve on the N95 respirator does not affect the respiratory protection"

Study article: https://pubmed.ncbi.nlm.nih.gov/18326870/

45. Performance of N95 respirators: filtration efficiency for airborne microbial and inert particles

Coronavirus is 0.125 micron, as you can read in this study, it states that most N95 masks can only filter particles as small as 0.75 microns. This is too big to trap this virus. that is a fact.

And even with an efficiency of 95 percent (depending on brand, so filtration may be lower) IF the virus can be trapped... it's still missing 5 percent and maybe more based on an N95 that has 0.1 microns .

Study article: https://pubmed.ncbi.nlm.nih.gov/9487666/

CORONAVIRUSES ARE 0.125 MICRON. SO THE BEST N95 ON THE MARKET WOULD DO NOTHING .

46. A Novel Coronavirus from Patients with Pneumonia in China, 2019

A chinese study that proves that an airborne coronavirus particle (0.125 micron) can pass directly through an n95 mask

Study article: https://pubmed.ncbi.nlm.nih.gov/31978945/

47. Airborne coronavirus particle (<0.125 micron) will pass directly through a N95 face mask.

Study article: https://www.greenmedinfo.com/article/airborne-coronavirus-particle

SIZE OF THE CORONAVIRUS: Size can vary but all are smaller than 0.3 micron .

"Human coronaviruses measure between 0.1 and 0.2 microns, which is one to two times below the cutoff" This "cut off" is referring to the size an N95 mask can trap. Most of us, are not using MEDICAL or regular N95s.

FACE MASK SIDE EFFECTS AND HEALTH IMPLICATIONS

1. Preliminary report on surgical mask induced deoxygenation during major surgery

Face mask side effects include lowered oxygen levels.

This study proved that surgeons that wore a mask in surgery for an hour + had significant reductions in blood oxygen saturation.

This is relevant because most of us are being made to wear face masks at work for the whole shift, long journeys on public transport, and when we are in a public places doing shopping etc. and this requires a degree of exertion that is not taken into account.

"Considering our findings, pulse rates of the surgeon's increase and SpO2 decrease after the first hour."

Decreasing oxygen and increasing carbon dioxide in the bloodstream stimulates a compensatory response in the respiratory centers of the brain. These changes in blood gases result in increases in both frequency and depth of breaths. This exposes another risk – if your mask traps some virus you are breathing more hence increasing viral load and exposure.

https://www.sciencedirect.com/science/article/abs/pii/S1130147308702355?via%3Dihub

Study article: https://pubmed.ncbi.nlm.nih.gov/18500410/

2. Impact of structural features on dynamic breathing resistance of healthcare face mask

Face mask side effects include impeded breathing.

Ask people if they have issues breathing in these masks. anecdotal or not, as everyone is different.

"The results showed that each evaluation index was significantly different ($P < 0.05$) among different test

masks"

Study article: https://pubmed.ncbi.nlm.nih.gov/31280156/

3. Respiratory consequences of N95-type Mask usage in pregnant healthcare workers-a controlled clinical study

The benefits of using N95 mask to prevent serious emerging infectious diseases should be weighed against potential respiratory consequences associated with extended N95 respirator usage.

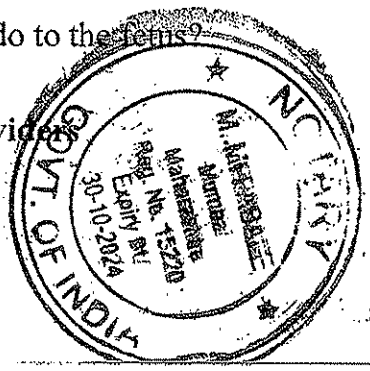
"Study article: https://pubmed.ncbi.nlm.nih.gov/26579222

"It is known that the N95 mask, if worn for hours, can reduce blood oxygenation as much as 20 percent, which can lead to a loss of consciousness, as happened to the hapless fellow driving aroundalone in his car wearing an N95 mask, causing him to pass out, crash his car and sustain injuries. I am sure that we have several cases of elderly individuals or any person with poor lung function passing out, hitting their head. This, of course, can lead to death"

"CONCLUSIONS: Breathing through N95 mask materials have been shown to impede gaseous exchange and impose an additional workload on the metabolic system of pregnant healthcare workers,and this needs to be taken into consideration in guidelines for respirator use"

Yet we force pregnant women to use them…? What could this do to the fetus?

4. Headaches and the N95 face-mask amongst healthcare providers



Face mask side effects include headaches.

These headaches can force you to use added or unnecessary medications like painkillers that carry their own side effects. The theory as to why masks can trigger headaches is the RESTRICTION OF OXYGEN.

What are the long-term health effects on Health Care Workers with headaches arising from impeded breathing?

Here are several sources and studies that back up this claim:
Study article: https://pubmed.ncbi.nlm.nih.gov/16441251/

Headaches Associated With Personal Protective Equipment – A Cross-Sectional Study Among Frontline Healthcare Workers During COVID-19
Study article: https://pubmed.ncbi.nlm.nih.gov/32232837/

How to Avoid Migraine Triggers While Wearing Your Mask
https://www.withcove.com/learn/migraine-triggers-mask

5. Use of surgical face masks to reduce the incidence of the common cold among health care workers in Japan: a randomized controlled trial

"Of the 8 symptoms recorded daily, subjects in the mask group were significantly more likely to experience headaches during the study period"

"Face mask use in health care workers has not been demonstrated to provide benefit in terms of cold symptoms or getting colds"

Study article: https://pubmed.ncbi.nlm.nih.gov/19216002/

6. Your Health Your Responsibility

NOTARY GOVT. OF INDIA M. M. PARIKH Mumbai Maharashtra Reg. No. 15220 Expiry On 30.10.2024

This video shows that even reading a book with a mask on decreases blood oxygen levels to your brain. what implications does this have for developing children forced to wear masks at school etc? https://youtu.be/ul5E5BUrII4

7. Physiological impact of the N95 filtering facepiece respirator on healthcare workers

"CONCLUSIONS: In healthy healthcare workers, FFR did not impose any important physiological burden during 1 hour of use, at realistic clinical work rates, but the FFR dead-space carbon dioxide andoxygen levels were significantly above and below, respectively, the ambient workplace standards, and elevated P(CO2) is a possibility"

Remember in "healthy healthcare workers" even their carbon dioxide levels rose. Most of the wider public have at least one health problem. Even healthy people were shown to have elevated CO2 levelsabove the healthy guidelines. Study article: https://pubmed.ncbi.nlm.nih.gov/20420727/

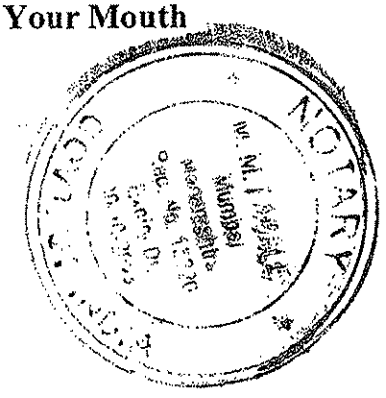
8. The adverse skin reactions of health care workers using personal protective equipment for COVID-19

Face mask side effects include adverse skin reactions

The adverse skin reactions of health care workers using personal protective equipment for COVID-19
Study article: https://pubmed.ncbi.nlm.nih.gov/32541493/

9. Your Mask May Be Causing Candida Growth in Your Mouth

Face mask side effects include yeast infections



https://www.everydayhealth.com/coronavirus/your-mask-may-be-causing-candida-growth-in-your-mouth/

10. 'Mask mouth' is a seriously stinky side effect of wearing masks

Face mask side effects include dental issues.

"We're seeing inflammation in people's gums that have been healthy forever, and cavities in people who have never had them before," says Dr. Rob Ramondi, a dentist and co-founder of One ManhattanDental. "About 50 percent of our patients are being impacted by this, [so] we decided to name it 'mask mouth' — after 'meth mouth.' "

"While mask mouth isn't quite as obvious, if left untreated, the results could be equally harmful.

Gum disease — or periodontal disease — will eventually lead to strokes and an increased risk of heart attacks,"

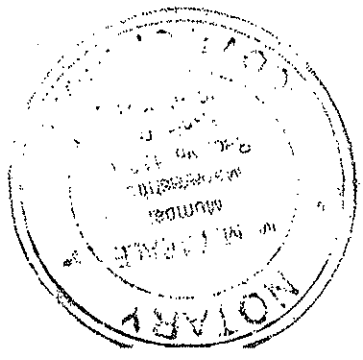
says Dr. Marc Sclafani, another co-founder of One Manhattan Dental" https://nypost.com/2020/08/05/mask-mouth-is-a-seriously-stinky-side-effect-of-wearing-masks/

11. All That Mask-Wearing Could Be Giving You (Gasp!) Mouth Fungus—Here's How to Deal With it

https://www.wellandgood.com/mouth-sores-from-wearing-masks/

12. 'Maskne' Is a Real Thing—Here's How to Stop Face Mask Breakouts

Face mask side effects include acne



https://www.health.com/condition/skin-conditions/maskne-mask-acne-mechanica

13. Improper use of medical masks can cause infections Face mask side effects include mould and infections

Masks can cause bacterial and fungal infections around the mouth,and in the mouth and lungs EVEN if you wash the cloth mask. Mould colonies were found in masks in as little as one day.

https://www.aa.com.tr/en/health/improper-use-of-medical-masks-can-cause-infections-/1766676

14. Mould Colonization in Your Sinuses Could Be Holding You Back From Making a Full Recovery <

Information on mould and how it can affect your health. https://moldfreeliving.com/2019/01/26/could-mold-colonization-in-your-sinuses/

15. An investigation into the efficiency of disposable face masks

What are the dangers of bacterial and fungal growths on a used and loaded mask?

This study tested all kinds of disposable masks and proved they cause you to breathe back in your own crap. Study article: https://pubmed.ncbi.nlm.nih.gov/7440756/

16. Can the Elastic of Surgical Face Masks Stimulate Ear Protrusion in Children?

Disfiguration in children. Can masks stimulate ear protrusion in children?



This is due to masks that are too tightly fitted.

Tight masks can also cause tension headaches. Is this healthy for children long term?
Study article: https://pubmed.ncbi.nlm.nih.gov/32556449/

17. When You Wear A Face Mask Every Day, This Is What Happens To Your Lungs

Mask use can trigger allergies due to the mask collecting particles that stay on you for long periods of time. https://www.thelist.com/214073/when-you-wear-a-face-mask-every-day-this-is-what-happens-to-your-lungs/

18. The physiological impact of wearing an N95 mask during hemodialysis as a precaution against SARS in patients with end-stage renal disease

The physiological impact of wearing an N95 mask during hemodialysis as a precaution against SARS in patients with end-stage renal disease.

And yet, we make sick people wear them. Even people without breathing issues, have lowered oxygen rates.
Study article: https://pubmed.ncbi.nlm.nih.gov/15340662/

19. Other Face Mask Side Effects and Health Implications to Consider

There is a great potential for harm that may arise from public policies forcing mask use on the wider population.

The following unanswered questions arise unanswered:

- Can masks shed fibers or micro plastics that we can breathe in?

- Do these masks excrete chemical substances that are harmful when inhaled?
- Can masks excrete chemicals or fumes when heated, either with bodyheat sunlight or other sources of heat?
- Clothing dye can cause reactions, so how do we know that the manufacturing process of these masks do not pose a risk to us? Because, in reality, we do not buy our masks from medical companiesor facilities who operate in sterile environments.

20. [Gaps in asepsis due to surgical caps, face masks, external surfaces of infusion bottles and sterile wrappers of disposable articles]

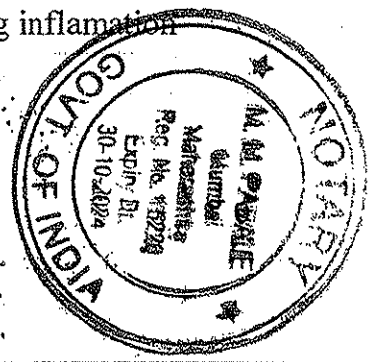
"It is obvious that the surfaces of the boxes of sterile packed disposable instruments and infusion bottles are not sterile. The disposable surgical masks and surgical caps used for sterile clothing are delivered by the producers not sterile, either." AND THIS IS HOSPITAL EQUIPMENT. Study article: https://pubmed.ncbi.nlm.nih.gov/6099666/

21. Mask Production Video

This is a "factory" that produces alot of masks. Does this look a sterile environment to you? This is what the majority of us are getting when we purchase online or in stores that sell them in bulk. Do you wantthat on your face? https://youtu.be/8gyO9TSlC0Q

22. Allergies and the Immune System

Can pathogen-laden droplets interact with environmental dust and aerosols captured on the mask? Can this elicit a greater reaction to viruses? For example, if you have a dust allergy your mask is collecting this thus causing inflamation to the wearer and lowering his or her immune system.



"This can cause wheezing, itching, runny nose, watery or itchy eyes, and other symptoms" would that not

facilitate spread and infection rate of viruses?

https://www.hopkinsmedicine.org/health/conditions-and-diseases/allergies-and-the-immune-system

23. Virus interactions with bacteria: Partners in the infectious dance

Bacteria and viruses can interact an increase infection suseptability: https://journals.plos.org/plospathogens/article?id=10.1371/journal.ppat.1008234

24. When viruses and bacteria unite!

https://blogs.scientificamerican.com/lab-rat/when-viruses-and-bacteria-unite/

25. An empirical and theoretical investigation into the psychological effects of wearing a mask

Face mask side effects include altered behaviour

Are there negative social consequences to a masked society? This study implies that, yes, masks do cause people to adopt altered behaviours based on mask use.
https://strathprints.strath.ac.uk/43402/

26. Mask mandates may affect a child's emotional, intellectual development

Face mask side effects stagnate a child's natural intellectual development. It is well known that children find it hard to recognise faces up until a certain age. Mask use will further interfere with this. Is this healthy for a developing child?

https://www.wishtv.com/news/mask-mandates-may-affect-a-childs-emotional-intellectual-development/

27. Disabled People and Masks Contributing Toward Mental Health Issues

Face mask side effects and mental health

What about disabled people? Deaf /people hard of hearing rely on mouth reading. What are the implications for them? What about people who suffer cognitive and behavioural disorders like autism? This could cause them HUGE distress. Not just from wearing a mask, but seeing others in masks (because let's face it – IT'S NOT NORMAL BEHAVIOUR).

Can masks cause anxiety, or make other mental health disorders worse?

Since masks CAN impede breathing, this can cause fainting and other bodily reaction that would otherwise be avoided if masks were not used. Here is a search engine link to prove that it is very common: https://duckduckgo.com/?q=mask+anxiety&ia=web

28. Maine study looks into long-term psychological effects of wearing face masks coronavirus, COVID-19 pandemic

This is a study on the psychological effects of masks.

https://www.msn.com/en-us/health/wellness/umaine-study-looks-into-long-term-psychological-effects-of- wearing-face-masks-coronavirus-covid-19-pandemic/ar-BB13EfiU

29. Masks: Have You Been Captured by This Psyop?

Are there negative psychological consequences to wearing a mask, as a fear-based behavioral modification? This can easily trigger fear as a mask is reminding

you there's a virus. The use of mask can also cause you to engage in risky behaviours due to a "false sense of security" because you feel protected.

https://kellybroganmd.com/masks-have-you-been-captured-by-this-psyop/

30. Masking the Truth – Face Masks, Empathy and Dis-inhibition

https://podtail.com/fi/podcast/conspiracy-theoryology/masking-the-truth-face-masks-empathy-and-dis-inhib/

31. Covid-19 face masks: A potential source of microplastic fibers in the environment

What are the environmental consequences of mask manufacturing and disposal?

Proof of increased littering due to increased mask use. a quick engine search will tell you, people are dumping them EVERYWHERE – into our rivers, into greenland areas etc. Plastics like nylon leach chemicals are going into our environment.

https://pubmed.ncbi.nlm.nih.gov/32563114/

32. Why Masks Don't Work Against COVID-19

Can used and loaded masks become vectors of enhanced transmission for both the wearer and other people? (The evidence from studies suggest yes). Masks become useless after about 20 minutes due to the moisture in your breath. This moisture can become the droplets that viruses travel on. Can this not facilitate transmission?

Can masks become collectors and retainers of pathogens that otherwise, could be avoided when breathing without a mask? (The evidence suggests yes).

Can large droplets trapped via a mask become atomized or aerosolized into breathable components? Even down to the virion size. (The evidence suggests yes).

https://www.citizensforfreespeech.org/why_masks_don_t_work_against_covid_19

LifeSiteNews has produced an extensive COVID-19 vaccines resources page. View it here.



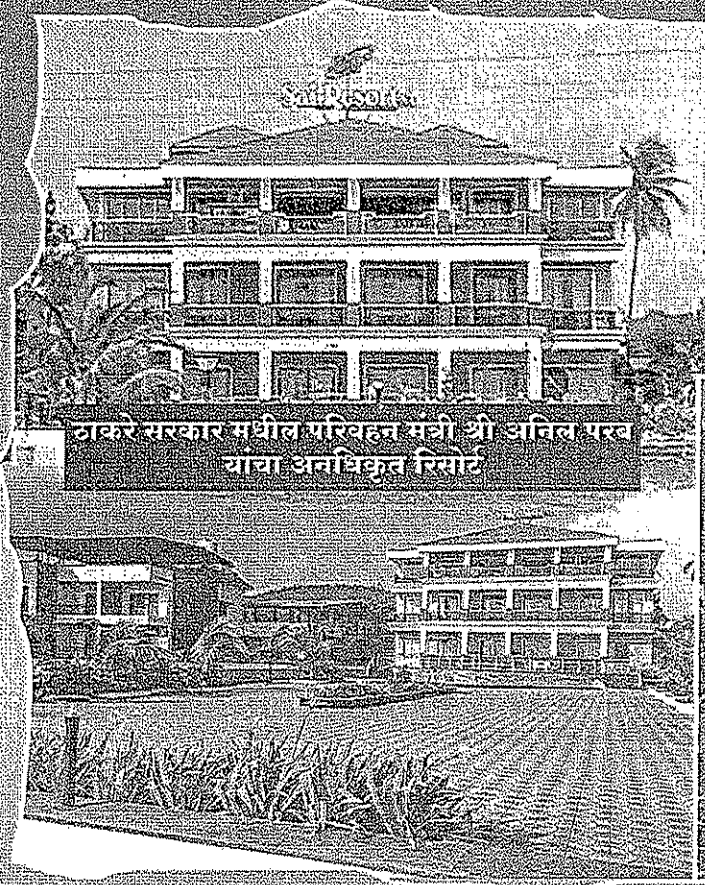
1477

EXHIBIT "RA-16"

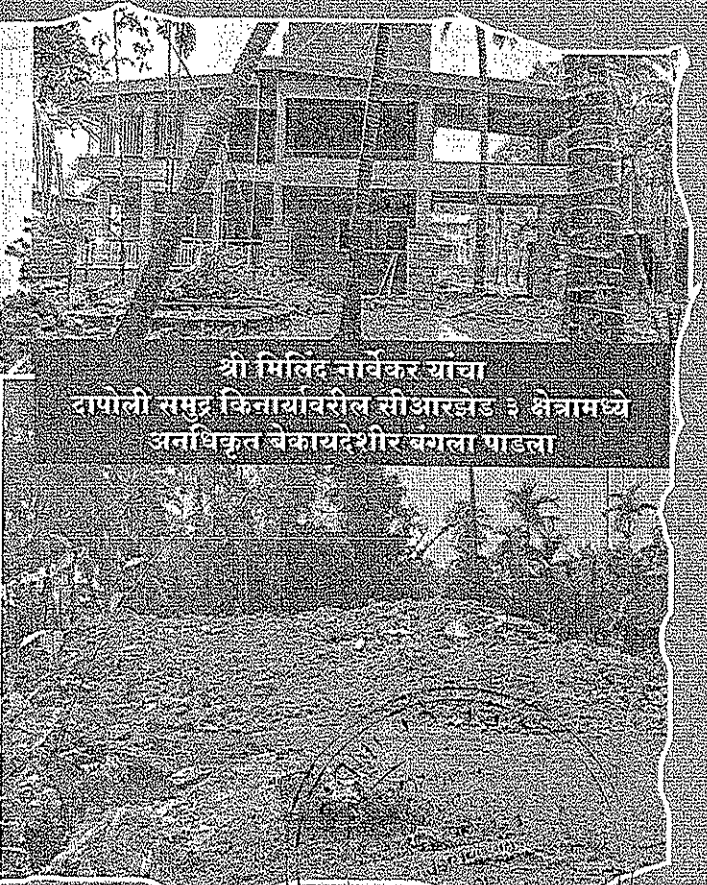
329

'महावसुली सरकार' चे घोटाळे

-डॉ. किरीट सोमैया



ठाकरे सरकार मधील परिवहन मंत्री श्री अनिल परब
याचा अनधिकृत रिसॉर्ट



श्री मिलिंद नार्वेकर यांचा
दापोली समुद्र किनाऱ्यावरील सीआरझेड ३ क्षेत्रामध्ये
अनधिकृत बेकायदेशीर बंगला पाडला

1 २४ महिन्यात २०० घोटाळे...

2 ६ नेता / मंत्रीना / अटक / जेल

3 २४ हुन अधिक घोटाळ्याची ई. डी, सी बी आय, आयकर, पोलीस ....द्वारा चौकशी सुरु

4 १८ प्रकरणात न्यायालय, लोकायुक्त, NGT ग्रीन प्राधिकरण, मानव अधिकार आयोग, पोलीस प्राधिकरण.... सुनावणी सुरू

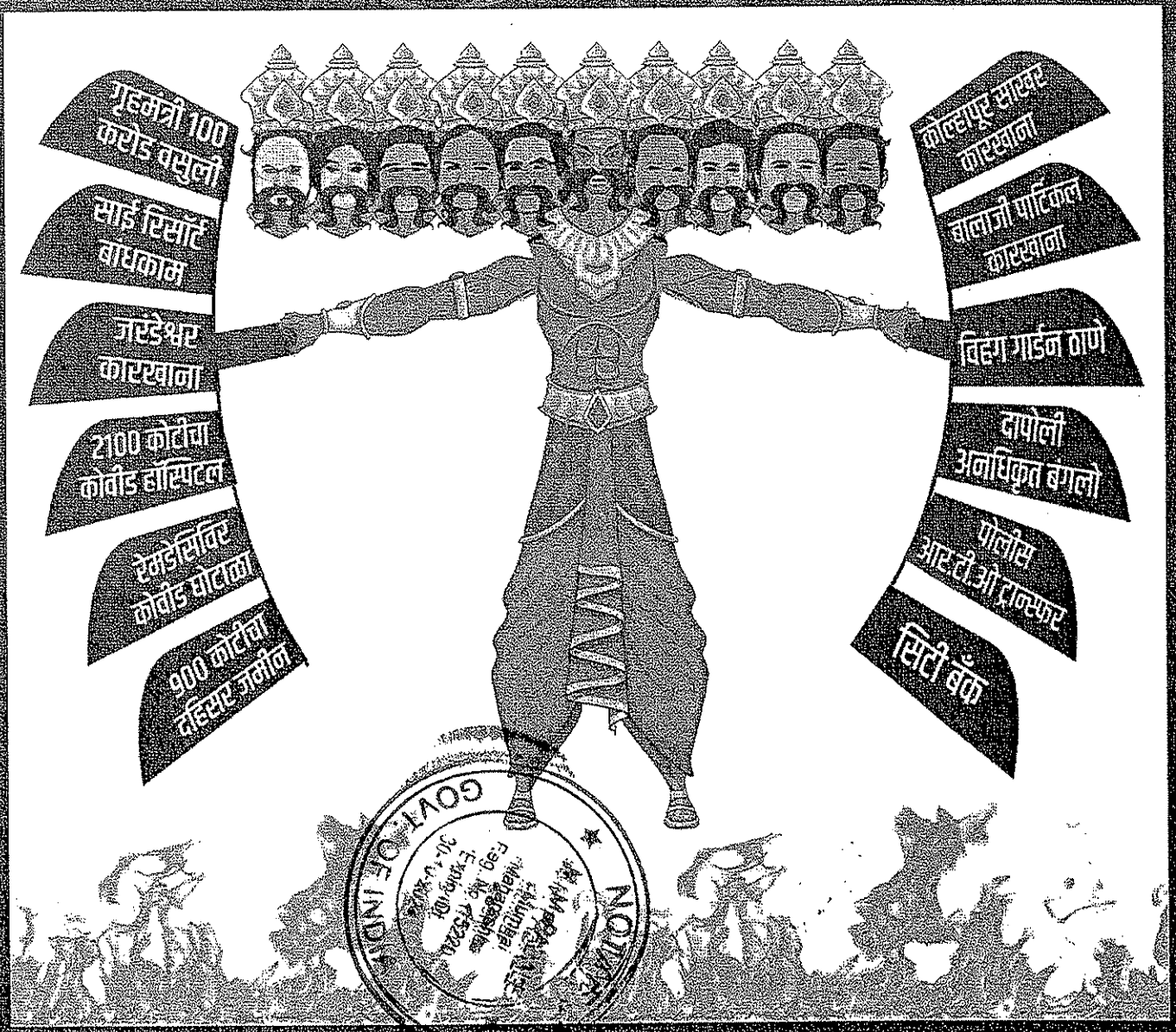
MUMBAI 30 NOV 2021

भारतीय जनता पार्टी

1478

330

'महावसूली' सरकार



ठाकरे सरकारचे घोटाळे

गेल्या २७ महिन्यात ठाकरे सरकारचे २ डझनहून अधिक मंत्री / नेते / अधिकारी घोटाळ्यात सापडले आहेत. हे घोटाळे उघडकीस आले, पुराव्यांसह विभिन्न यंत्रणेमार्फत त्याचा पाठपुरावा ही सुरु आहे. इन्कमटॅक्स, प्रवर्तन निदेशालय (ED), न्यायालय, लोकायुक्त, विभिन्न प्राधिकरण, सहकार मंत्रालय, आर्थिक गुन्हे अन्वेषण विभाग (EOW), कंपनी मंत्रालय अशा विभिन्न तपास यंत्रणेद्वारा तपास सुरु आहे, अनेकांवर कारवाई सुद्धा झाली आहे.

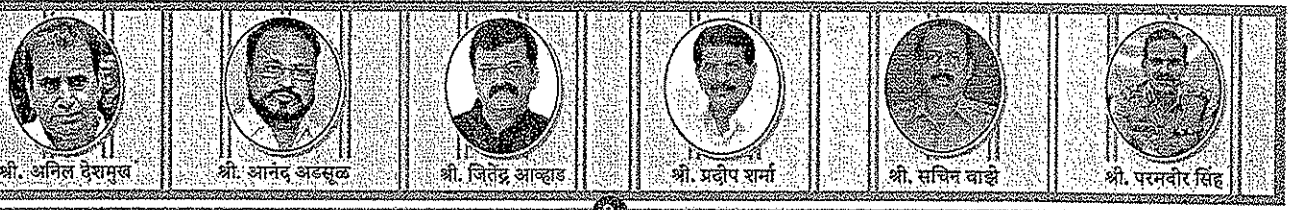
१. मंत्री अनिल देशमुख वसुली व मनी लाँडरींग
२. संजय राऊत रु.५५ लाख घोटाळा
३. मुख्यमंत्र्यांचे सचिव मिलिंद नार्वेकर यांचा अनधिकृत बंगला
४. मंत्री हसन मुश्रीफ रु.१५००० कोटी जवोस्तुते कंपनी घोटाळा
५. शिवसेना नेते श्री. आनंद अडसूळ सिटी बँक घोटाळा
६. पोलीस अधिकारी/ शिवसेना प्रवक्ते सचिन वाझे– वसुली कांड
७. शिवसेनेचे नेते/ पोलीस अधिकारी श्री. प्रदीप शर्मा– वसुली कांड
८. पोलीस आयुक्त श्री. परमबीर सिंह– फरार
९. उपमुख्यमंत्री अजित पवार मित्र – परिवार रु.१०५० कोटी बेनामी व्यवहार
१०. शिवसेनेचे नेते आमदार प्रताप सरनाईक अनेक घोटाळे
११. मंत्री अनिल परब अनधिकृत रिसॉर्ट
१२. खासदार भावना गवळी रु. १०० कोटी घोटाळा
१३. ठाकरे सरकार/ बृहन्मुंबई महानगरपालिका रु २.५५ कोटींची दहिसर येथील जमिन रु. ९०० कोटीमध्ये घेण्याचा घोटाळा
१४. कोविड रेमडेसिवीर घोटाळा
१५. मुंबई महानगरपालिका १ कोटी कोविड वॅक्सिन (लस) जागतिक निविदा घोटाळा
१६. मुंबई महानगरपालिका/ पालक मंत्री कोविड ऑक्सिजन टँक/ टाकी घोटाळा
१७. मुंबई महानगरपालिका/ मुख्यमंत्री कार्यालय " ५००० खाटांचे कोविड हॉस्पिटल रु. २१०० कोटींचा घोटाळा"
१८. शिवसेना नेते रविंद्र वायकर व भागिदार यांचा कोर्लई, अलिबाग जमिन/ बंगले घोटाळा
१९. मंत्री जितेंद्र आव्हाड व पोलिसांद्वारा ठाणे येथील करमुसे अपहरण, मारहाण
२०. नांदेड धर्माबाद येथील सहकारी पतसंस्था १२५० शेतकार्यांच्या नावे करोडो रुपयांचे बेनामी आर्थिक व्यवहार, रु २३५ कोटी कर्ज घोटाळा
२१. अर्जुन खोतकर मित्र – परिवार/ भागिदार बेनामी व्यवहार जालना साखर कारखाना घोटाळा
२२. लातुर बालाघाट, प्रियदर्शनी, जागृती कारखाना अपारदर्शक आर्थिक व्यवहार घोटाळा
२३. जरंडेश्वर साखर कारखाना घोटाळा
२४. पुणे येथील वक्फ बोर्ड जमिन घोटाळा

घोटाळ्यांचा पाठपुरावा–

- केंद्र सरकार, राज्य सरकार, मंत्रालयात पाठपुरावा
- मुंबई उच्च न्यायालयात १ + १ याचिका
- लोकायुक्तांकडे ७ याचिका (सुनावणी सुरु)
- मानव अधिकार आयोग ३ याचिका
- पोलिस प्राधिकरण २ याचिका
- नॅशनल ग्रीन ट्रिब्युनल (NGT) १ याचिका
- TRAI मध्ये १ याचिका
- अनुसूचित जाती आयोगमध्ये १ याचिका
- महिला आयोगाकडे १ याचिका

९ नेते / अधिकारी यांना अटक/जेल

- गृहमंत्री अनिल देशमुख जेल मध्ये
- आनंद अडसूळ ईडीद्वारा अटक, हॉस्पिटल मध्ये भरती
- मंत्री जितेंद्र आव्हाड अटक व जामिनावर सुटका
- शिवसेना उमेदवार प्रदिप शर्मा (पोलिस अधिकारी) जेल मध्ये
- शिवसेना प्रवक्ते पोलिस API सचिन वाझे जेल मध्ये
- मुंबई पोलिस आयुक्त श्री. परमबीर सिंह फरार



1480

इकडे तिकडे चोही कडे..... घोटाळेच घोटाळे
महिन्याची रु. १०० कोटीची वसूली ते मनसुख हिरेन हत्या ....

१. मंत्री **श्री. अनिल देशमुख** जेल मध्ये महिन्याची १०० कोटींची वसुली, १०० हून अधिक कोटींचे मनी लॉंडरिंग, बेनामी संपत्ती.....

२. **श्री. संजय राऊत** यांना भ्रष्ट पद्धतीने आलेले रु. ५५ लाख ईडीला परत द्यावे लागले.

"चोरी का माल वापस करना पडा"

पीएमसी बँक – एचडीआयएल – प्रवीण राऊतकडून हे ५५ लाख रुपये श्री. संजय राऊत परिवाराच्या खात्यात आले होते.

३. मुख्यमंत्री उद्धव ठाकरे यांचे सचिव **श्री. मिलिंद नार्वेकर** दापोली येथे समुद्र किनाऱ्यावर अनधिकृत बेकायदेशीर बंगला बांधत होते. आम्ही आक्षेप घेतला. भारत सरकारच्या पर्यावरण मंत्रालयाच्या टीमने भेट दिली. श्री. मिलिंद नार्वेकर यांनी स्वतः तो बंगला पाडला.

४. राष्ट्रवादी काँग्रेसचे मंत्री **श्री. हसन मुश्रीफ** यांनी रु. १५,००० कोटींचे त्यांच्याच ग्रामविकास खात्याचे कंत्राट आपल्याच कुटुंबाच्या जयोस्तुते मॅनेजमेंट प्रा. लि. कंपनीला दिले. आम्ही हा विषय मांडला अखेरीस ठाकरे सरकारलाहा कॉन्ट्रक्टरद्द करावा लागला.

५. शिवसेना नेते माजी खासदार **श्री. आनंद अडसूळ** सीटी को-ऑपरेटीव्ह बँकेच्या घोटाळ्यात गुंतले आहेत (रु. ९२० कोटी). त्यांना ईडीने अटक केली पण लगेचचत्यांना रुग्णालयात दाखल करून घ्यावे लागले.

६. निलंबित पोलीस अधिकारी व शिवसेना प्रवक्ते **श्री. सचिन वाझे** यांना ठाकरे सरकारनी परत नोकरीत घेतले. वाझेला ५० कोटी रुपयांच्या वसूलीची धमकी व मनसूख हिरेनच्या हत्या बद्दल वाझेची अटक झाली, ते सध्या तुरुंगात आहेत.

७. शिवसेनेचे २०१९ विधानसभा निवडणुकीतील उमेदवार **श्री. प्रदिप शर्मा** यांना ही नोकरीत परत घेण्यात आले वसुली व सुपारी घेऊन हत्याप्रकरणात ते ही तुरुंगात आहेत.

८. ठाकरे सरकारने **श्री. परमबीरसिंह** यांची मुंबई पोलिस आयुक्त म्हणून नियुक्ती केली व आता त्याच **परमबीर सिंह** वर ठाकरे सरकारने डझनभर खंडणीचे गुन्हे दाखल केले आहेत, परमबीर सिंह सध्या फरार आहेत.

९. उपमुख्यमंत्री **श्री. अजित पवार** अर्थमंत्री असताना ते महाराष्ट्र राज्य सहकारी बँकेचे सर्वेसर्वा होते. त्यांनी जरंडेश्वर साखर कारखाना बेनामी पद्धतीने आपल्याच एका कंपनीच्या ताब्यात आणला, बळकावला. ईडीने जरंडेश्वर साखर कारखाना नुकताच जप्त केला आहे.

१०. ईडी व आयकर खात्याची **श्री. अजित पवार, मिल, परिवार, कंपन्यांवर** १९ दिवस धाडीचालल्या. रु. १०५० कोटींची बेनामी संपत्ती बाहेर आली.

११. शिवसेनेचे नेते व प्रवक्ते **आ. प्रताप सरनाईक** यांनी एनएसईएल गैरव्यवहातील ३५ कोटी रुपये बळकावल्याचे आढळले. त्यांनी टिटवाळा येथे ७८ एकर जमीन खरेदी केली व ती ईडीने जप्त केली आहे.

१२. **श्री. प्रताप सरनाईक** यांनी त्यांच्या विहंग गार्डन बिल्डिंग प्रकल्पामध्ये बेकायदेशीरपणे पाच मजले बांधले आहेत. त्यांना २१ कोटी रुपये दंड भरण्यास सांगण्यात आले आहे. हा गैरव्यवहार आम्ही उघडकीस आणला आहे. लोकायुक्तांसमोर सुनावणी चालू आहे.



१३. शिवसेनेचे मंत्री **श्री. अनिल परब / सहकारी** यांचे बांद्रा पूर्व, मुंबई येथील म्हाडा इमारतीमधील कार्यालय बेकायदेशीर असल्याचे आढळले. लोकायुक्तांनी ते पाडण्याचे आदेश दिले.

१४. **श्री. अनिल परब** यांनी कोरोनाच्या कालावधीत दापोली येथे समुद्रकिनाऱ्यावर एक अनधिकृत पंचतारांकित रिसॉर्ट बांधले. आम्ही हा गैरव्यवहार उघड केला. अखेरीस महाराष्ट्र सरकारला अनिल परब यांचे रिसॉर्ट पाडण्याचा आदेश देणे भाग पडले आहे. सध्या लोकायुक्तांसमोर सुनावणी चालू आहे.

१५. शिवसेनेच्या **खा. भावना गवळी** या रु. १०० कोटींच्या गैरव्यवहारात गुंतल्याचे आढळले आहे. त्यांचे भागीदार आणि सहकारी **श्री. सईद खान** यांना एक महिन्यापूर्वी अटक केली असून ते तुरुंगात आहेत. भावना गवळी यांच्या विरोधात कठोर कारवाई अपेक्षित आहे.

१६. मुंबई महानगरपालिका **२१०० कोटी रुपयांच्या कोविड रुग्णालय गैरव्यवहारात** गुंतलेली आढळली आहे. ठाकरे सरकारने ही जमीन ६ ऑक्टोबर २०२० रोजी एका बिल्डरला ६२ कोटी रुपयांना मालकी हक्काने हस्तांतरित केली. ताबडतोब काही तासात मुंबई महानगरपालिकेने हीच जमीन त्या बिल्डरकडून २१०० कोटी रुपयांना खरेदी करण्याची तयारी दर्शविली, लोकायुक्तांसमोर झालेल्या सुनावणीत ठाकरे सरकारने आणि मुंबई महानगरपालिकेने मान्य केले की अपारदर्शीपणे व्यवहार झाला आणि कंत्राट रद्द केले.

१७. **शिवसेना, मुंबई महानगरपालिका** यांनी जागतिक टेंडर काढून एक कोटी कोरोना व्हॅक्सिन खरेदी करण्याची घोषणा केली. या जागतिक टेंडरसाठी जे अकरा प्रस्ताव आले होते ते सर्व संशयास्पद प्रस्ताव होते. मुख्यमंत्री श्री. उद्धव ठाकरे यांना, मुंबई महानगरपालिकेला सर्व प्रस्ताव फेटाळणे भाग पडले आणि एक कोटी व्हॅक्सिन्ससाठीचे संशयास्पद जागतिक टेंडरही रद्द करावे लागले.

१८. **ठाकरे सरकारचा रेमडेसिव्हीर घोटाळा** हाफकीन इन्स्टिट्यूटने ५२,००० रेमडिसिव्हर इंजेक्शनची खरेदी प्रत्येकी ६६८ रुपयांना केली. त्याच वेळी मुंबई महानगरपालिकेने प्रत्येकी १,६६८ रुपयांनी ७२,००० रेमडिसिव्हिर इंजेक्शन घेतले. एकाच कालावधीत हाफकीन इन्स्टिट्यूट या राज्य सरकारच्या संस्थेकडून रेमडिसिव्हरची प्रत्येकी ६६८ रुपये दराने खरेदी आणि मुंबई महानगरपालिकेकडून प्रत्येकी १,६६८ रुपये दराने.

१९. शिवसेना पक्षप्रमुख श्री. उद्धव ठाकरे यांनी २८ नोव्हेंबर २०१९ रोजी मुख्यमंत्रिपदाची शपथ घेतली. **मुंबई महानगरपालिकेने** दुसऱ्याच दिवशी २९ नोव्हेंबर २०१९ रोजी **अल्पेश अजमेरा बिल्डर्सकडून ९०० कोटी** रुपयांना जमीन खरेदी केली आणि ३४९ कोटी रुपये दिले सुद्धा. बिल्डरने ही जमीन २ कोटी ५५ लाख रुपयांना खरेदी केली होती.

२०. **शिवसेना नेते श्री. रविंद्र वायकर आणि भागीदार** यांनी कै. अन्वय नाईक यांच्याकडून जमीन आणि त्याच जमिनीवरील संशयास्पद १९ बंगलेही खरेदी केले. आम्ही हा विषय उपस्थित केला, घोटाळा उघड केला. अखेरीस घोटाळा सिद्ध झाला.

२१. **श्री अनंत करमुसे** यांचे त्यांच्या घरातून रात्री साडेअकरा वाजता **मंत्री श्री. जितेंद्र आव्हाड व पोलिस सुरक्षा रक्षकांनी** अपहरण केले होते. गेले १५ महिने अनंत करमुसे उच्च न्यायालयात न्याय मिळण्यासाठी धडपडत होते. काही दिवसांपूर्वी आव्हाड यांना अटक करण्यात आली आणि नंतर त्यांची जामीनावर मुक्तता करण्यात आली.

२२. मुंबईच्या **महापौर श्रीमती किशोरी पेडणेकर** यांनी वरळी येथील गोमाता जनता एसआरएस सोसायटी मध्ये अर्धा डझनहून अधिक गरिबांचे / लाभार्थींचे गाळे अनधिकृतरित्या स्वत:च्या ताब्यात घेतले आहेत. फोर्जरी ही केली आहे बनावटी / खोट्या सह्या व कागदपत्रांद्वारे हे गाळे ताब्यात घेतल्याचे पुरावे ही न्यायालयात सुपूर्त करण्यात आले आहेत व सुनावणी सुरु आहे.

NOTARY
M. M. PABALE
Mumbai
Maharashtra
Reg. No. 15226
Expiry Dt.
30.10.2024
GOVT. OF INDIA

1482

334 अनिल परब यांचा रिसॉर्ट अनधिकृत - महाराष्ट्र सरकार

ठाकरे सरकारचे मंत्री श्री अनिल परब यांनी मौजे मुरुड ता. दापोली येथे अनधिकृत साई रिसॉर्ट बांधला आहे त्या संबंधात भाजपा नेते डॉ. किरीट सोमैया यांनी महामहीम राज्यपाल यांच्याकडे तक्रार केली होती, डॉ. सोमैया समवेत खा. श्री गोपाळ शेट्टी, आमदार श्री मिहिर कोटेचा, आमदार श्री राम कदम, श्री राहुल नार्वेकर, श्री संजय उपाध्याय हे राज्यपालांना भेटले होते.

राज्यपालांनी याची चौकशी करण्याची सूचना लोकायुक्त यांना केली होती / आहे.

महाराष्ट्राचे लोकायुक्त जस्टिस विद्यासागर कानडे यांच्याकडे या याचिकेची सुनावणी सुरू झाली आहे. लोकायुक्त यांनी श्री किरीट सोमैया यांनाही या सुनावणीच्या वेळी बोलावले होते. 5 ऑक्टोबर रोजी लोकायुक्तांकडे सुनावणी झाली.

1. लोकायुक्त यांनी या याचिके संबंधी आंतरिम निर्देश सुनावणी दरम्यान दिले ज्यात, या रिसॉर्ट मध्ये झालेल्या फोर्जरी, फ्रॉड संबधात चौकशी साठी महाराष्ट्राचे गृह सचिवांना 7 डिसेंबरला हजर राहाण्याचे निर्देश दिले.

2. महाराष्ट्र पर्यावरण मंत्रालय व महाराष्ट्र सागरी किनारा प्राधिकरण यांना सुद्धा पुढच्या सुनावणी दरम्यान हजर राहण्यास सांगितले आहे.

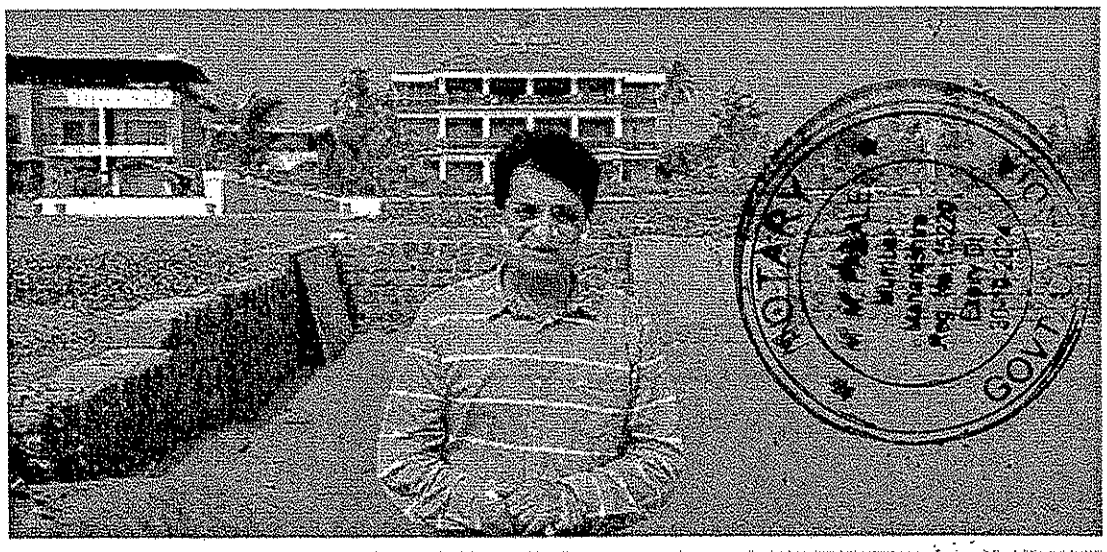
3. सुनावणीत महाराष्ट्र सरकारच्या वतीने हा रिसॉर्ट अनधिकृत असल्याचे मान्य करण्यात आले आहे.

4. महाराष्ट्र सरकारच्या वतीने महाराष्ट्राचे अतिरिक्त सचिव श्री नितीन करीर यांनी लोकायुक्तांकडे निवेदन करताना जी अकृषिक परवानगी घेतली गेली त्यात बनावट पद्धतीने फसवणूक केली गेल्याचे सांगितले.

5. पर्यावरण मंत्रालयाने सुद्धा हा रिसॉर्ट CRZ च्या प्रतिबंधीत क्षेत्रात (no development zone) बांधला आहे व तो तोडावाच लागणार असे म्हंटले.

6. अश्या प्रकारे फसवणूक, घोटाळा करून अकृषिक परवानगी देण्यात आली त्या अधिकाऱ्यांविरुद्ध चौकशी चे आदेश महाराष्ट्र सरकारने दिले आहेत.

श्री अनिल परबांचा रिसॉर्ट अनधिकृत आहे हे आता ठाकरे सरकारनेच मान्य केले आहे, हा रिसॉर्ट ताबडतोब तोडावा व अनिल परबांची मंत्रिमंडळातून त्वरित हकालपट्टी करावी अशी मागणी भाजपा नेते डॉ. किरीट सोमैया यांनी केली आहे.



मंत्री अनिल परब दापोली रिसॉर्टच्या विरुद्ध नॅशनल ग्रीन ट्रिब्यूनल (NGT) मध्ये सुनावणी सुरू

ठाकरे सरकारचे मंत्री श्री अनिल परब यांनी मौजे मुरुड, ता. दापोली, जि. रत्नागिरी येथे अनधिकृत साई रिसॉर्ट बांधले आहे त्या विरोधात भाजपा नेते डॉ किरीट सोमैया यांनी नॅशनल ग्रीन ट्रिब्यूनल (NGT) येथे याचिका दाखल केली आहे.

नॅशनल ग्रीन ट्रिब्यूनलने २९ सप्टेंबर २०२१ च्या सुनावणी दरम्यान श्री अनिल परब, श्री सदानंद कदम, श्री विभास साठे यांच्या विरुद्ध नोटीस जारी करण्याचे निर्देश दिले आहेत. त्या प्रमाणे श्री अनिल परब, श्री सदानंद कदम आणि श्री विभास साठे यांना या संबंधीची नोटीस जारी करण्यात आली आहे.

या अनधिकृत रिसॉर्टची मालकी कोणाची?

याचिकाकर्ते डॉ. किरीट सोमैया यांनी हा रिसॉर्ट अनधिकृतरीत्या श्री अनिल परब यांनी बांधला. ही जागा श्री विभास साठे यांच्याकडून श्री अनिल परब यांनी विकत घेतली. श्री विभास साठे यांनी किंवा त्यांच्या नावाने खाडाखोड (फोर्जरी) करून अकृषिक परवाना घेण्यात आला. तसेच हा अनधिकृत रिसॉर्ट श्री सदानंद कदम यांनी विकत घेतला असे आपल्या याचिकेत म्हटले आहे.

श्री अनिल परब, श्री सदानंद कदम आणि श्री विभास साठे यांना या संबंधात नोटीस जारी करण्यात आल्या आहेत, पुढची सुनावणी २५ नोव्हेंबर २०२१ ला होणार.

BEFORE THE NATIONAL GREEN TRIBUNAL,
WESTERN ZONE BENCH, PUNE

Original Application No. 58/2021 (WZ)
I.A. No. 73/2021 (WZ)

Dr. Kirit Somaiya
V/s.
State Of Maharashtra & Ors.

To

Shri Anil Dattatray Parab — Proposed Respondent No. 6
Transport Minister, Govt. Of Maharashtra
Ravi Kiran 58/2625, Gandhi Nagar,
Near Bank Of Maharashtra, Bandra (E), Mumbai- 400051
(9820413505: anildattatray@gmail.com)

NOTICE

1. The above titled Original Application is posted for **admission** on **25.11. 2021 at 10.30 AM through Video Conferencing** before The National Green Tribunal, Western Zone Bench, Pune.

2. Please note that you shall make yourself available, or represent through authorized legal representative, on the date and place indicated herein above, in default, the said Application will be heard and determined in your absence.

Given under my hand and the seal of this Tribunal, this the 05.10.2021.

National Green Tribunal Pune

05/10/2021

Assistant Registrar, NGT

NOTARY M.M. PABALE Mumbai Maharashtra Regd. No. 15220 Expiry Dt. 30-10-2024 GOVT. OF INDIA

Encl: Compilation I & II along with the order
(For Orders, Cause Lists & other information, please visit our website www.greentribunal.gov.in)

1584

राष्ट्रवादी काँग्रेसचे मंत्री श्री. हसन मुश्रीफ यांनी रु. १५,००० कोटींचे त्यांच्याच ग्रामविकास खात्याचे कंत्राट आपल्याच कुटुंबाच्या जयोस्तुते मॅनेजमेंट प्रा. लि. कंपनीला दिले. आम्ही हा विषय मांडला अखेरीस ठाकरे सरकारलाहा कॉन्ट्रक्ट रद्द करावा लागला.

नवभारत

भाजपा के आरोपों से डरी आघाड़ी सरकार

मुश्रीफ के दामाद का ठेका रद्द

मुंबई, नवभारत न्यूज नेटवर्क. भाजपा नेता एवं पूर्व सांसद किरीट सोमैया ने राज्य के ग्रामीण विकास मंत्री हसन मुश्रीफ पर एक बार फिर हमला बोला है. उन्होंने कहा कि कोरोना काल में जहां एक तरफ मुख्यमंत्री उद्धव ठाकरे ठाकरे सहित तमाम लोग घर में बैठे थे, वहीं दूसरी तरफ सरकार में बड़े पैमाने पर भ्रष्टाचार चल रहा था. सोमैया ने कहा कि शत-प्रतिशत मंत्रालय बंद होने के बावजूद शरद पवार के शिष्य 15,000 करोड़ रुपये लूट रहे थे. भाजपा कार्यालय में आयोजित पत्रकार परिषद में सोमैया ने कहा कि हसन मुश्रीफ के दामाद मतीन मंगोली की जयोस्तुते मैनजमेंट कंपनी को दिया गया 1,500 करोड़ रुपये का ठेका आखिरकार रद्द कर दिया गया है.



₹ 15,000 करोड़ के भ्रष्टाचार का आरोप

परब पर भी साधा निशाना



सोमैया ने मुश्रीफ के साथ ही शिवसेना नेता और परिवहन मंत्री अनिल परब पर भी निशाना साधा है. उन्होंने बताया कि अनिल परब को नेशनल ग्रीन ट्रिब्यूनल के सामने पेश होने का आदेश दिया गया है.

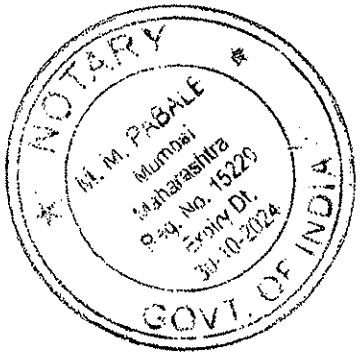
संजय राऊत को चुनौती

सोमैया ने पिंपरी-चिंचवड़ नगर निगम में कथित घोटाले के संबंध में संजय राऊत की तरफ से लिखे गए एक पत्र का भी जवाब दिया. उन्होंने कहा कि आपको जांच पड़ताल करने का अधिकार है. क्या मुख्यमंत्री पूछताछ नहीं कर सकते? जांच करें कि घोटाला कहां हुआ, कार्रवाई करें, आपको कौन रोक रहा है? अगर ईओडब्ल्यू की बात है तो पूछने दीजिए.

सोमैया ने बताया कि 27,000 ग्राम पंचायतों के टीडीएस रिटर्न का भुगतान करने के लिए 10 वर्षों के लिए अनुबंध दिया गया था. कंपनी को मतीन ने 8 महीने पहले खरीदा था.

Mumbai Edition
22-october-2021 Page No.
epaper.enavabharat.com

NOTARY
M. M. PASALE
Mumbai
Maharashtra
Reg. No. 15228
Expiry Dt. 30-10-2024
GOVT. OF INDIA



राज्यातील ग्रामपंचायती, पंचायत समित्या व जिल्हा परिषदांमध्ये तसेच ग्रामविकास विभागाच्या अधिपत्याखालील इतर कार्यालयांमध्ये GST TDS, Income Tax वरील TDS/TCS तसेच Labour Cess, रॉयल्टी आणि इंन्श्युरन्स इत्यादी प्रकारच्या वजावटी यांचा भरणा/ रिटर्न्स भरण्यासाठी एजन्सीची निवड करणेबाबत.

महाराष्ट्र शासन
ग्राम विकास विभाग
शासन निर्णय क्रमांक : संकीर्ण-२४२०/प्र.क्र.१९ /आपले सरकार कक्ष
बांधकाम भवन,२५,मर्झबान पथ.
फोर्ट,मुंबई-४०००० १
दिनांक: १३ सप्टेंबर, २०२१

वाचा : १. ग्रामविकास विभाग शासन निर्णय क्रमांक संकिर्ण-२४२०/प्र.क्र.१९/आसक, दि.१० मार्च, २०२१

२.ग्रामविकास विभाग शासन शुध्दीपत्रक क्रमांक संकिर्ण-२४२०/प्र.क्र.१९/आसक, दि.२९ जुलै, २०२१

३.ग्रामविकास विभाग शासन निर्णय क्रमांक संकिर्ण-२४२०/प्र.क्र.१९/आसक, दि.६ सप्टेंबर, २०२१

प्रस्तावना :-

वित्त मंत्रालय, भारत सरकार यांची शासन अधिसुचना क्रमांक ५०/२०१८, दि. १३ सप्टेंबर, २०१८ तसेच त्या अनुषंगाने वित्त विभाग, महाराष्ट्र शासन यांनी दि.१८ सप्टेंबर, २०१८ रोजी काढलेली अधिसुचना आणि वित्त विभाग परिपत्रक क्रमांक: संकीर्ण-२०१८/प्र.क्र.१४४/२०१८/ कोषा-५, दि. २८ सप्टेंबर, २०१८ अन्वये सर्व शासकीय, निम शासकीय संस्था, स्थानिक स्वराज्य संस्था, सार्वजनिक उपक्रमातील आस्थापनांना वस्तू व सेवा कर अधिनियमाखाली GST करावर २% TDS (१% CGST आणि १% SGST किंवा २% IGST) भरणे अनिवार्य आहे. त्याचप्रमाणे आयकर कायद्यातील तरतुदी नुसार आयकरावरील TDS/TCS भरणे अनिवार्य आहे. सदर TDS/TCS ची रक्कम शासनाने निर्धारीत केलेल्या वेळेपुर्वी भरणे अनिवार्य आहे. अन्यथा, या

1486

देखील अद्याप कोणत्याही ग्रामपंचायतीने सदर ससंस्थेकडून काम करून घेण्यासाठी प्रतिसाद दिलेला नसल्याची बाब निदर्शनास आली. वास्तविक GST वा तत्सम करांचे रिटर्न्स भरण्यासाठी शासनाने ग्रामपंचायतींना प्रशिक्षित मनुष्यबळ उपलब्ध करून दिले होते. परंतु ग्रामपंचायती सदर संस्थेकडून काम करून घेण्यास इच्छुक नसतील तर त्यांना सक्ती करणे योग्य नसल्याने यासंदर्भात शासनाने घेतलेल्या निर्णयाचा पुर्नविचार करण्याची बाब शासनाच्या विचाराधीन होती.

शासन निर्णय :

राज्यातील ग्रामपंचायती, पंचायत समित्या व जिल्हा परिषदांमध्ये तसेच या विभागाच्या अधिनस्त इतर शासकीय कार्यालयांमध्ये GST TDS, Income Tax वरील TDS/TCS तसेच Labour Cess, रॉयल्टी आणि इंन्श्युरन्स इत्यादी प्रकारच्या वजावटी यांचा भरणा/ रिटर्न्स भरणेकरिता मे जयोस्तुते मॅनेजमेंट प्रा.लि. या संस्थेची निबिदा प्रक्रियेद्वारे केलेली निवड रद्द करण्यात येत आहे.

२. यासंदर्भात शासनाने निर्गमित केलेला ग्रामविकास विभाग शासन निर्णय क्रमांक संकिर्ण-२४२०/प्र.क्र.१९/आसक, दि.१० मार्च, २०२१ व त्याअनुषंगाने निर्गमित केलेले शासन शुध्दीपत्रक दि.२९ जुलै, २०२१ आणि शासन निर्णय दि.६ सप्टेंबर, २०२१ रद्द करण्यात येत आहेत.

३. यासंदर्भात शासनाने मे जयोस्तुते मॅनेजमेंट प्रा.लि. या संस्थेसोबत दि.३० मार्च, २०२१ रोजी केलेला करारनामा रद्द करण्यात येत आहे.

सदर शासन निर्णय महाराष्ट्र शासनाच्या www.maharashtra.gov.in या संकेतस्थळावर उपलब्ध करण्यात आले असून त्याचा संकेताक **२०२११०१४०९४९३८३५२०** असा आहे. हा आदेश डिजीटल स्वाक्षरीने साक्षांकित करुन काढण्यात येत आहे.

महाराष्ट्राचे राज्यपाल यांच्या आदेशानुसार व नावाने,

NOTARY GOVT. OF INDIA M. M. PABALE Mumbai Maharashtra Reg. No. 15220 Expiry Dt. 30-10-2024

(प्रविण देविचंद जैन)
उप सचिव, महाराष्ट्र शासन

प्रत,

१. मा. राज्यपाल यांचे सचिव
२. मा.मुख्यमंत्री यांचे प्रधान सचिव
३. मा. उप मुख्यमंत्री यांचे प्रधान सचिव
४. मा. सभापती विधान परिषद यांचे खाजगी सचिव
५. मा. अध्यक्ष विधानसभा यांचे खाजगी सचिव, विधानभवन मुंबई
६. मा. विरोधी पक्ष नेते विधान परिषद/ विधानसभा यांचे खाजगी सचिव, विधानभवन मुंबई
७. सर्व विधानमंडळ सदस्य, विधानभवन मुंबई
८. शासनाचे मुख्य सचिव

Dr. Kirit Somaiya
Chartered Accountant,Ph.D
Former Member of Parliament

Bharatiya Janata Party

कृपया प्रकाशनार्थ **दि. २१ ऑक्टोबर, २०२१**

श्री हसन मुश्रीफ यांच्या जावयाला दिलेला १५०० कोटींचा कॉन्ट्रॅक्ट रद्द- डॉ. किरीट सोमैया

ठाकरे सरकारचे ग्राम विकास मंत्री श्री हसन मुश्रीफ यांनी आपल्या जावयाच्या जयोस्तूते मॅनेजमेंट प्रा. लि. कंपनीला १० वर्षांचा १५०० कोटींचा कॉन्ट्रॅक्ट दिला होता. महाराष्ट्रातील २७००० ग्राम पंचायतीचे TDS रिटर्न पुढच्या १० वर्षापर्यंतजयोस्तूते मॅनेजमेंट प्रा. लि. कंपनी फाइल करणार आणि त्यासाठी प्रत्येक ग्रामपंचायत ने सुमारे ५०,००० रुपये प्रती वर्षी द्यावयाचा हा कॉन्ट्रॅक्टहोता. दर वर्षी जयोस्तूते मॅनेजमेंट कंपनीला यातून १५०० रुपये आवक होणार होती.

भाजपा नेते डॉ. किरीट सोमैया यांनी या घोटाळे बाज कंपनीला घोटाळेबाज मंत्री श्री हसन मुश्रीफ यांनी अपारदर्शकरित्या १० मार्च २०२१ रोजी १० वर्षांचाकॉन्ट्रॅक्ट दिला हा घोटा ळा सप्टेंबर महिन्यात उघडकिस आणाला होता.जयोस्तूते मॅनेजमेंट प्रा. लि. कंपनीची स्थापना जरी २०१२-१३ मध्ये झाली असेल, परंतु श्री हसन मुश्रीफ यांचे जावईश्री मतीन यांनी ही कंपनी ८ महिन्यापूर्वीच विकत घेतली. गेल्या ८ वर्षात या कंपनीची काहीही आवक नाही, व्यवसाय नाही.२०१९-२० ची उलाढाल (Turnover) शून्य.

कशा पद्धतीने हा घोटाळा करण्यात आला, कंपन्यांची लेयर उभी करून श्री हसन मुश्रीफ यांच्या जावयाची मालकी लपवण्याचा अट्टाहास श्री मुश्रीफ यांनी केला होता. काल ग्रामविकास मंत्रालयात माहिती अधिकार अंतर्गत डॉ. किरीट सोमैया यांनी या कॉन्ट्रॅक्ट दिलेल्या फाईलचे इन्स्पेक्शन, अवलोकन केलं त्यात धक्कादायक बाब उघडकीस आली आहे.

1. अशा पद्धतीने केंद्र सरकारने जोनिधी ग्रामपंचायतच्या खात्यात जमा केला आहे तोलुटण्याचा डाव हा मे २०२० मध्ये रचण्यात आला.
2. ५ मे २०२० ला ग्रामविकास मंत्रालय, ग्रामविकास मंत्री यांनी अशा पद्धतीने सगळ्या ग्रामपंचायतींचा कॉन्ट्रॅक्ट एका कंपनीला द्यावा व त्याच्या टेंडर प्रक्रियेचा प्रारंभ करावा असा निर्णय घेतला.
3. डॉ. किरीट सोमैया यांनी काल फाईल नोटिंग पाहिले त्यात आश्चर्याजनक बाब समोर आली की ५ मे २०२० ला हा निर्णय घेण्यात आला त्याचे फाईल नोटिंगसग्रामविकास मंत्रालयाच्या फाईलीत उपलब्ध आहेत.
4. ज्यावेळी संपूर्ण महाराष्ट्र १००% लॉकडाऊन मध्ये होता, मंत्रालय, सरकारी कार्यालय, न्यायालय, मुख्यमंत्री सगळेच आपापल्या घरी बंद होते त्यावेळेला हा निर्णय करण्यात आला.
5. १० मार्च २०२१ ला मुश्रीफ साहेबांनी आदेश देऊन जयोस्तूते मॅनेजमेंट प्रा. लि. कंपनी ला हा कॉन्ट्रॅक्ट देण्यात आला.
6. भाजपा ने हा घोटाळा बाहेर काढला प्रदेशाध्यक्ष श्री चंद्रकांत पाटील यांनी या संबंधी आक्षेप घेतला. ग्रामविकास मंत्रालय, भारत सरकार यांनी या संबंधी महाराष्ट्र सरकारकडून स्पष्टता मागविली.
7. आता १४ ऑक्टोबर २०२१ रोजी श्री प्रविण देविचंद जैन या उपसचिवांच्या नावाने ग्रामविकास खात्याचे एक परिपत्रक हे सरकारी संकेतस्थळावर अपलोड करण्यात आली आहे त्यात १० मार्च २०२१ चा जयोस्तूते मॅनेजमेंट प्रा. लि. कंपनीला देण्यात आलेला कॉन्ट्रॅक्ट रद्द करण्यात येत आहे असे म्हंटलें आहे.

१५०० कोटींचा हा ठाकरे सरकारचे मंत्री श्री हसन मुश्रीफ यांचा घोटाळा आता सिद्ध झाला आहे त्यांची तडकाफडकी मंत्रीमंडळातून हकालपट्टी करावी अशी डॉ. किरीट सोमैया यांनी मागणी केली आहे.

(कार्यालय सचिव)

NOTARY M. M. PABALE Mumbai Maharashtra Regn. No. 45220 Expiry Dt. 15.10.2024 GOVT OF INDIA

kiritsomaiya@gmail.com www.kiritsomaiya.com KiritSomaiyaBJP @kiritsomaiya

Neelam Nagar, Mulund, Mumbai-400 081 • Tel.: 022-21634152 • Mob.: 9869220027

1488

340 पवार परिवाराचे जावई "श्री मोहन पाटील" करोडो चे आर्थिक व्यवहार

ठाकरे सरकारचे उपमुख्यमंत्री श्री. अजित पवार यांचे आर्थिक व्यवहार, उलाढाल आश्चर्य देणारीच आहे. पवारांचे मित्र, बिल्डरांकडून श्री. अजित पवार आणि त्यांच्या परिवाराच्या सदस्यांच्या खात्यात कोट्यावधी रुपयांची (शंभरहून अधिक) अपारदर्शक नामी व बेनामी आवक. पवार परिवाराचे जावई आणि अन्य सदस्यांच्या खात्यात कोट्यावधी रुपयांची ट्रान्सफर.

1. श्री. अजित पवार (स्वत:)
2. सौ. सुनेत्रा अजित पवार (पत्नी)
3. श्री. पार्थ अजित पवार (मुलगा)
4. श्रीमती आशाताई अनंतराव पवार (आई)
5. सौ. विजया मोहन पाटील (बहीण)
6. श्री. मोहन पाटील (जावई)
7. सौ. नीता पाटील (बहीण)

गेली १९ दिवस इन्कम टॅक्स आता ईडी ची धाड, शोध (सर्च) सुरु आहेत. १,०५० कोटी रुपयांची बेनामी संपत्ती समोर आली आहे, त्याचबरोबर १८४ कोटी रुपयांची रोख रक्कम, दागिने (ज्वेलरी), आर्थिक व्यवहारांचे कागदपत्र इ. इन्कम टॅक्सच्या हाती लागले.

जरंडेश्वर साखर कारखाना, दौंड साखर कारखाना, श्री. अंबालिका शुगर प्रा. लि. व अन्य कंपन्यांचे आर्थिक व्यवहार, तसेच श्री. अजित पवार मित्र परिवाराच्या, समूहाच्या विभिन्न कंपन्यांच्या बरोबरची हेराफेरी समोर येत आहे.

डझनावारी कंपन्यांचा आर्थिक व्यवहार अंतर्गत ट्रान्सफर हे बेनामी संपत्ती व मनी लॉंड्रीगसाठी कंपनीची लेयर / शिडी तयार करणं, करोडो रूपयांची हेराफेरी.

श्री. अजित पवारांनी नामीबेनामी संपत्तीसाठी पवार परिवाराचे जावई श्री. मोहन पाटील यांचा ही उपयोग केलेला दिसत आहे. ईडी व इन्कम टॅक्सची चौकशी चालू आहे.



अजित पवार, मित्र परिवार घोटाळा

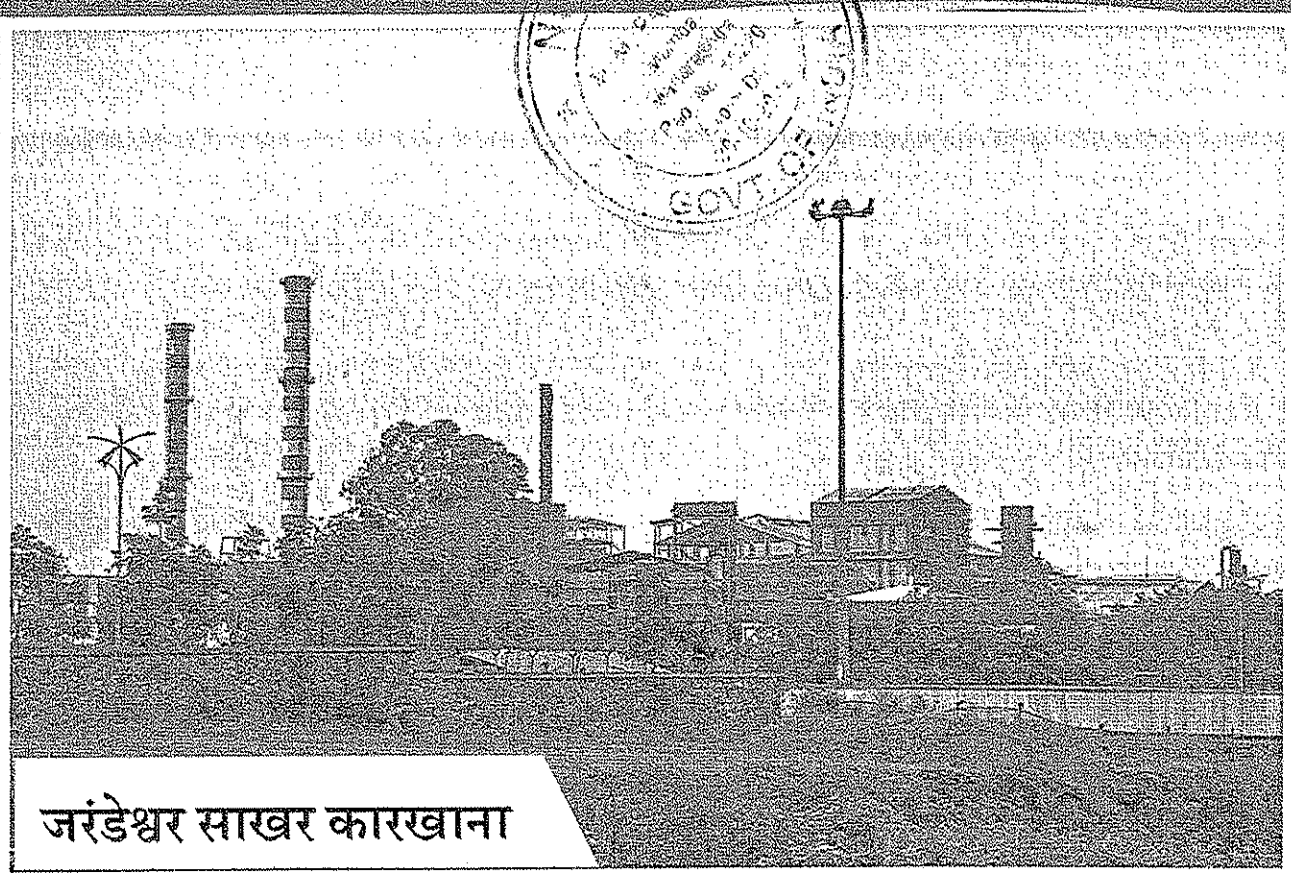
गुरू कमोडिटीजने स्पार्कलिंग सॉईल (अजित पवार), शिवालिक बिल्डर्स (विवेक जाधव), ओंकार रियल्टर्स (बाबुलाल वर्मा) यांच्या भागीदारीत जरंडेश्वर साखर कारखाना विकत घेतला.

गुरू कमोडिटीजने जरंडेश्वर साखर कारखाना जरंडेश्वर शुगर मिल्स लिमिटेडला ४५ वर्षांच्या दीर्घ मुदतीच्या भाडेतत्त्वावर दिला.

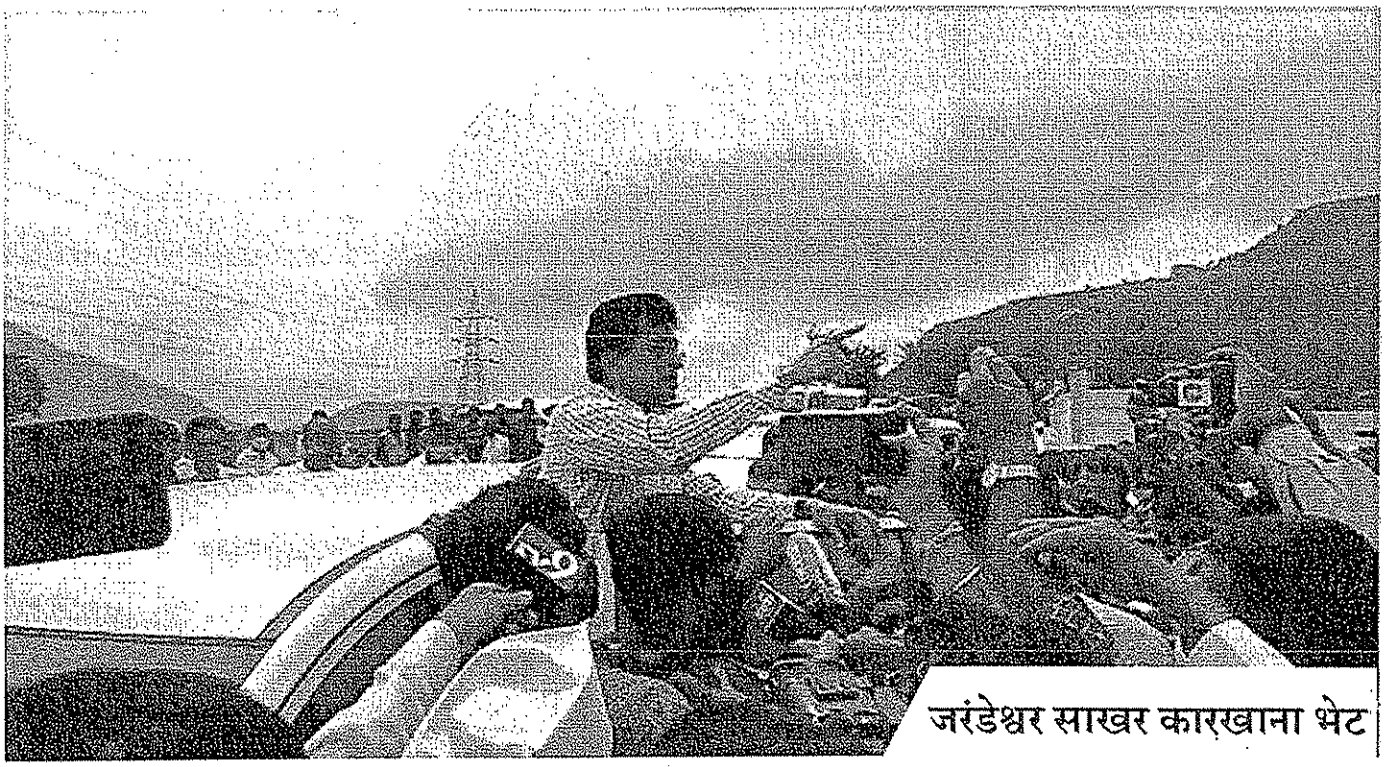
जरंडेश्वर साखर कारखाना हा स्तरित कंपन्यांच्या मालकीचा आहे, ज्यांचे मालक आहेत...

- मोहन पाटील (अजित पवार यांची बहीण सौ. विजया पाटील यांचे पती)
- नीता पाटील
- सुनेत्रा पवार

1489



जरंडेश्वर साखर कारखाना



जरंडेश्वर साखर कारखाना भेट

1490

342

ठाकरे सरकार - बीएमसी ९०० कोटींचा दहिसर जमीन घोटाळा

उद्धव ठाकरे यांनी २८ नोव्हेंबर रोजी मुख्यमंत्रीपदाची शपथ घेतली. ठाकरे सरकारने सत्तेवर आल्या आल्या कोणता निर्णय घेतला तर दहिसर येथील एका बिल्डरला ९०० कोटींची जमीन बहाल करण्याचा.

गेल्या १० वर्षांत दहिसर येथील ७ एकर जमिनीच्या खरेदीचा प्रस्ताव मांडला गेला होता , मात्र तो स्वीकारला गेला नव्हता. निशल्प रिॲलिटी ने हा भूखंड खरेदी करण्याचा प्रस्ताव दिला होता.

या जागेवर १०० टक्के अतिक्रमणे आहेत. बृहन्मुंबई महानगरपालिकेने या जमिनीच्या खरेदीचा प्रस्ताव फेटाळून लावला होता. ही जमीन खरेदी करण्याचा प्रस्ताव म्हणजे बृहन्मुंबई महापालिकेची कोट्यवधींची उधळपट्टी करण्यासारखे आहे, असे स्पष्ट मत नोंदविले होते.

बृहन्मुंबई महानगरपालिकेचे त्यावेळचे आयुक्त प्रवीण परदेशी यांनी महापालिकेच्या सुधार समितीला पत्र पाठवून या जमिनीचा ताबा घेण्यास स्पष्ट विरोध दर्शविला होता.

२ नोव्हेंबर २०१९ रोजी महापालिकेच्या सुधार समितीने या भूखंडाच्या ताब्याचा प्रस्ताव मांडला होता.

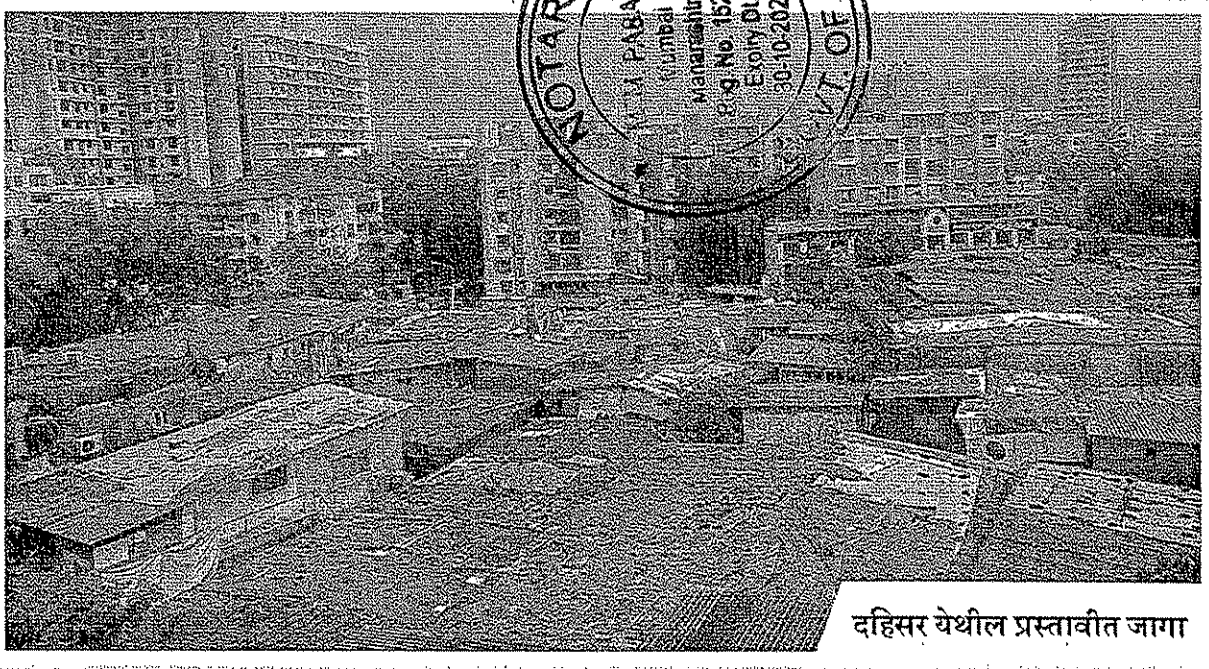
मात्र परदेशी यांनी तो फेटाळला. निशल्प रिॲलिटी ने मांडलेला हा प्रस्ताव कसा अव्यवहार्य आहे आणि त्यामुळे तो फेटाळणे कसे आवश्यक आहे, याबाबतची सविस्तर टिप्पण्णी दिली होती.

२ नोव्हेंबर रोजी झालेल्या सुधार समितीच्या बैठकीत या जागेची प्रत्यक्ष पाहणी करण्याचा प्रस्ताव मांडला.

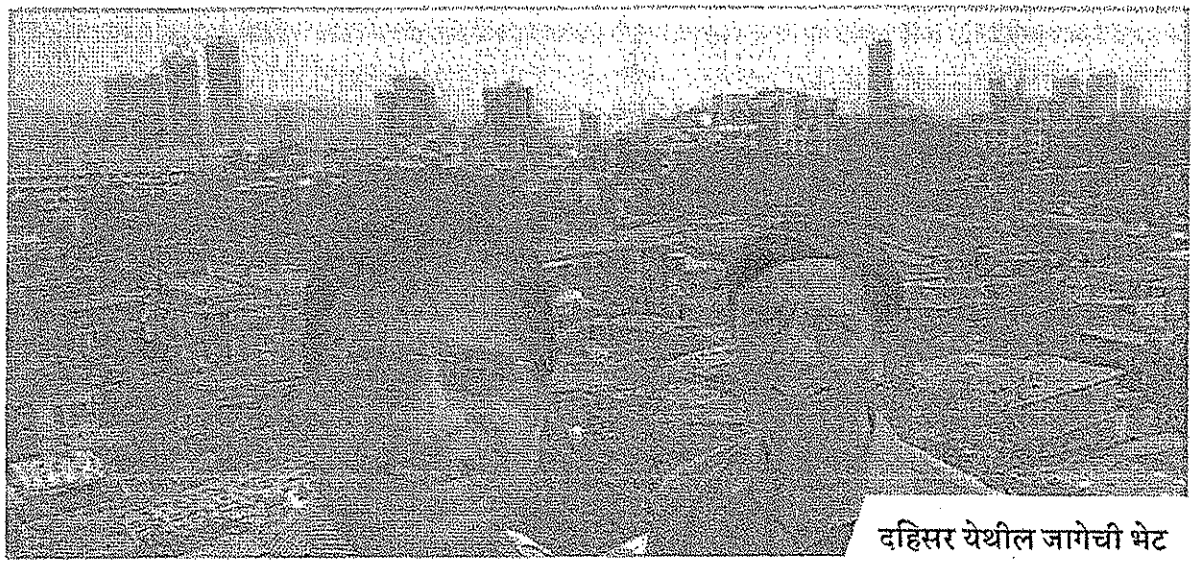
२८ नोव्हेंबर रोजी उद्धव ठाकरे यांनी मुख्यमंत्रीपदाची शपथ घेतली.

२९ नोव्हेंबर रोजी सुधार समितीची विविध विषयांवर चर्चा करण्यासाठी बैठक होणार होती. या बैठकीत दहिसर एकसर येथील भूखंडाच्या खरेदीचा विषय नव्हता. मात्र हा विषय तातडीचा विषय म्हणून हा भूखंड खरेदी विषय बैठकीच्या कार्यक्रमपत्रिकेत घुसडण्यात आला.

NOTARY
M. PARALE
Mumbai
Maharashtra
Reg. No. 15220
Expiry Dt.
30-10-2024
GOVT. OF INDIA



दहिसर येथील प्रस्तावीत जागा



दहिसर येथील जागेची भेट

प्रवीण परदेशी यांनी महापालिका आयुक्त असताना या भूखंडाची किंमत ५४ कोटी च्या आसपास आहे, असे स्पष्ट मत नोंदविले होते.

१५ ऑक्टोबर २०१९ रोजी तत्कालीन आयुक्त प्रवीण परदेशी यांनी काढलेल्या सूचनापत्रकात, अशा कोणत्याही जागेचा ताबा कोणत्याही अडचणीविना मिळाला पाहिजे, असे मत नोंदविले होते.

या भूखंडाचे मूल्य निर्धारण ३५४ कोटी करण्यात आले त्यावेळीही परदेशी यांनी त्यास तीव्र आक्षेप घेतला होता.

असे असताना ठाकरे सरकारकडून महापालिकेच्या वित्त विभागाला या भूखंडाच्या खरेदीपोटी ३४९ कोटी, १४ लाख १९ हजार १३ रु. इतकी रक्कम तातडीने देण्यात यावी, अशी सूचना देण्यात आली. बिल्डरकडून ५४ कोटी रु. चा भरणा अनामत रक्कम म्हणून अगोदरच करण्यात आला होता. त्यामुळे १५ फेब्रुवारी २०२० रोजी उर्वरीत २९४ कोटी रु. चा मोबदला निशल्प रिऍलिटी ला देण्यात आला.

आता संबंधित बिल्डर या जागेचे ३४९ कोटी रु. हे मूल्यनिर्धारण चुकीचे आहे, असा दावा करीत आहे. या बिल्डरने नागपूर येथील महसूल न्यायाधिकरणाकडे अपील करून या भूखंडाची किंमत ९०० कोटी रु . असल्याचा दावा केला आहे. या बिल्डरने मुंबई महापालिकेकडे उर्वरीत ५५० कोटी रु. देण्याची मागणी केली आहे.

सदर भूखंडाची मी प्रत्यक्ष पाहणी केली असून या भूखंडावरील अतिक्रमणे हटविणे शक्य नाही असे माझे स्पष्ट मत बनले आहे.

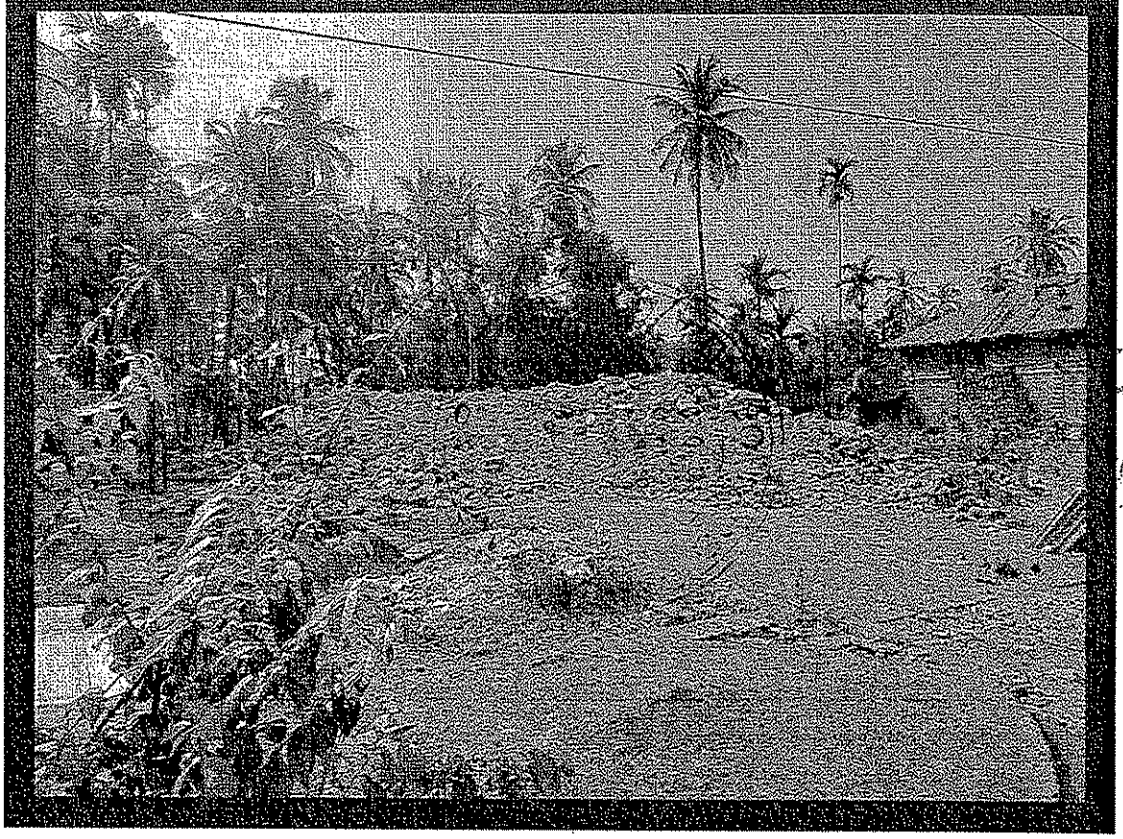
राज्य सरकार आणि बृहन्मुंबई महापालिका २८ नोव्हेम्बर २०१९ पर्यंत अतिक्रमण असलेला हा भूखंड एवढ्या चढ्या किमतीत घेण्यास विरोध करीत होते. मात्र उद्धव ठाकरे मुख्यमंत्री झाल्यावर एका रात्रीत राज्य सरकारची आणि महापालिकेची भूमिका बदलली आणि ९०० कोटींच्या भूखंडाची भेट एका बिल्डरला देण्यात आली.

NOTARY
M. M. PABALE
Mumbai
Maharashtra
Reg. No. 45220
Expiry Dt.



मिलिंद नार्वेकरनी स्वतःचा बंगला पाडला :- ठाकरे सरकार

रत्नागिरी जिल्हाधिकारी नी माझा तक्रारीचा उत्तरात मला कळविले आहे की " मौजे मुरुड ता. दापोली येथील गट नं. ४१० मधील बांधकाम श्री. मिलींद केशव नार्वेकर यांनी स्वतःच निष्कासीत केलेले असल्यामुळे सदयस्थितीमध्ये कोणतेही बांधकाम जागेवर अस्तित्वात नाही"



महाराष्ट्र शासन
महसूल व वनविभाग
जिल्हाधिकारी कार्यालय रत्नागिरी
मध्यवर्ती प्रशासकीय इमारत दुसरा मजला कक्ष क्र.२०१,महसूल शाखा जयस्तंभ ता.जि.रत्नागिरी
दुरध्वनी क्रमांक : ०२३५२-२२२४८३ फॅक्स क्रमांक : ०२३५२-२२६२५०
०२३५२-२२४२२२ Email ID:- revenuecollector@yahoo.in

क्र. महसूल/कार्या.३.के.-6/CRZ/SR-40/कावि 484/2021 दिनांक : 29 /10/2021

प्रति,

(1411 7)

डॉ. किरीट सोमैया
माजी संसद सदस्य,
रा. 9/सी, नीलम नगर, फेज-2,
मुलुंड (पुर्व), मुंबई-400 081

विषय : मौजे मुरुड ता. दापोली येथील श्री. मिलींद नार्वेकर यांच्या अनधिकृत बंगल्याचे बांधकामाबाबत .

संदर्भ : 1. आपला अर्ज क्र. KS/MUM/770/2021 दिनांक 26/06/2021

महोदय,

मौजे मुरुड ता. दापोली येथील स.नं. 410 मध्ये श्री. मिलिंद केशव नार्वेकर यांनी सीआरझेड क्षेत्रामध्ये विनापरवाना बांधकाम केले असलेबाबत संदर्भीय तक्रार अर्ज या कार्यालयाकडे प्राप्त झाले आहेत. सदर तक्रार अर्जप्रकरणी उपविभागीय अधिकारी दापोली, उपविभाग दापोली यांचेमार्फत चौकशी करण्यात आली असुन, उपविभागीय अधिकारी दापोली, उपविभाग दापोली यांचा चौकशी अहवाल दिनांक 22/09/2021 रोजीचे पत्रान्वये या कार्यालयाकडे प्राप्त झाला आहे.

उपविभागीय अधिकारी दापोली, उपविभाग दापोली यांच्या अहवालाचे अवलोकन केले असता मौजे मुरुड ता. दापोली येथील गट नं. 410 मधील बांधकाम श्री. मिलींद केशव नार्वेकर यांनी स्वत:च निष्कासीत केलेले असलेमुळे सदयस्थितीमध्ये कोणतेही बांधकाम जागेवर अस्तित्वात नाही. सबब वादातीत बांधकाम पुर्णत: निष्कासीत झालेले आहे. सोबत उपविभागीय अधिकारी दापोली, उपविभाग दापोली यांच्या अहवालाची प्रत माहितीस्तव सादर करणेत येत आहे.

आपला विश्वासु,

NOTARY M. M. PASALE Mumbai Maharashtra Reg. No. 15220 Expiry Dt. 30-10-2024 GOVT. OF INDIA

मा. जिल्हाधिकारी रत्नागिरी यांच्या मान्यतेने

(संजय शिंदे)
अपर जिल्हाधिकारी
जिल्हाधिकारी कार्यालय रत्नागिरी

प्रत : कक्ष अधिकारी, महसूल व वनविभाग, मंत्रालय, मुख्य इमारत, पहिला मजला, मादाम कामा मार्ग, हुतात्मा राजगुरु चौक, मुंबई-400 032 यांजकडे माहितीसाठी सादर

1494

346

Dr. Kirit Somaiya
Chartered Accountant,Ph.D
Former Member of Parliament

Bharatiya Janata Party

कृपया प्रसिद्धीसाठी **मुंबई, 16 डिसेंबर 2020**

श्री. प्रताप सरनाईकचे "विहंग गार्डन बी" बिल्डिंग्स अनधिकृत -किरीट सोमैया

विहांग ग्रुप ऑफ़ बिल्डर्स ने बांधलेले विहंग गार्डन ठाणे, चे बी 1 आणि बी 2 अशा दोन इमारती, अनधिकृत असून कारवाई करण्याचे आदेश 2012 मध्ये देण्यात आले होते. ह्या दोन्ही बी 1 आणि बी 2 ला अजून पर्यंत वापर परवाना (Occupation Certificate OC) मिळाले नाही. ह्या इमारतीचे 9 ते 13 मजले अनधिकृत आहे आणि ताबडतोब तोडण्याचे आदेश ही, 2012 मध्ये देण्यात आले होते.

भाजप नेते डॉ. किरीट सोमैया यांनी माहिती अधिकारा खाली केलेल्या अर्जाच्या उत्तरात ठाणे महापालिकांनी त्यांना ही माहिती दिली आहे.

ज्याच्या अंतर्गत विहंग गार्डनच्या इमारत 'A' साठी वापर परवाना प्रदान करण्यात आलेला आहे. परंतु, B1 व B2 इमारतीसाठी कोणताही वापर परवाना (O.C.) देण्यात आले नाही.

यासंबंधात ठाणे महानगरपालिकेकडे श्री. प्रताप सरनाईक यांनी अपिल केल्यानंतर काही अटीवर अनधिकृत बांधकाम तोडण्याचे काम तात्पुरते थांबवण्यात आले. ठाणे महापालिकेचे तत्कालीन आयुक्तांनी एकमहिन्याची मुदत दिली होती त्याला आता ८ वर्षे झाली.

शिवसेना नेते श्री. प्रताप सरनाईक यांनी विहंग गार्डनच्या B1 व B2 तेरा मजली इमारतीचे अनधिकृत बांधकाम केले, यातील सदनिकेची विक्री करून प्रामाणिक मध्यमवर्गीय ग्राहकांची फसवणूक केली आहे, शिवसेनेच्या अखत्यारीतील ठाणे महापालिकेने श्री. प्रताप सरनाईकच्या या फसवणूकीला संरक्षण दिले आहे.

डॉ. किरीट सोमैया यांनी या फसवणूकीच्या विरोधात, अनधिकृत बांधकामाच्या विरोधात श्री. प्रताप सरनाईक, विहंग ग्रुप ऑफ बिल्डर्सच्या विरोधात ताबडतोब कारवाई करावीअशी मागणी केली आहे.

डॉ. सोमैया यांनी भाजपात ठाणे महापालिका गटाचे नेते श्री. संजय वागुले सोबत काल ठाणे महापालिकेच्या संबंधित अधिकाऱ्यांशी प्रत्यक्ष भेट घेतली. या अनधिकृत बांधकामा विरोधात आतापर्यंत कारवाई का नाही? यासंबंधी तक्रारही केली.

श्री. सोमैया व श्री. वागुले यांनी विहंग गार्डन या इमारतीची पण प्रत्यक्ष पाहणी केली.

या इमारतीत श्री. प्रताप सरनाईक यांचे कार्यालयही आहे, तसेच प्रताप सरनाईक यांचे ताळेबाज भागीदार श्री. अमित चंदोळे तेही या इमारतीत 12/13 व्या मजल्यावर राहत आहेत.

(सचिव)

kiritsomaiya@gmail.com www.kiritsomaiya.com KiritSomaiyaBJP @kiritsomaiya

Neelam Nagar, Mulund, Mumbai-400 081 • Tel.: 022-21634152 • Mob.: 9869220027

शिवसेनेचे नेते व प्रवक्ते आ. प्रताप सरनाईक यांनी एनएसईएल गैरव्यवहारातील ३५ कोटी रुपये बळकावल्याचे आढळले. त्यांनी टिटवाळा येथे ७८ एकर जमीन खरेदी केली व ती ईडीने जप्त केली आहे. श्री. प्रताप सरनाईक यांनी त्यांच्या विहंग गार्डन बिल्डिंग प्रकल्पामध्ये बेकायदेशीरपणे पाच मजले बांधले आहेत. त्यांना २१ कोटी रुपये दंड भरण्यास सांगण्यात आले आहे. हा गैरव्यवहार आम्ही उघडकीस आणला आहे. लोकायुक्तांसमोर सुनावणी चालू आहे.

ठाणे महानगरपालिका, ठाणे

THE MUNICIPAL CORPORATION OF THE CITY OF THANE- 400602

विषय :- नागरी पायाभूत सुविधांच्या अधिसूचित इमारतीचे विकासाबाबतची माहिती.

संदर्भ :- आपले दि. ०४/०७/२००७ रोजीचे पत्र (क्रमांक. एएएस/ दि. ०४/०७/२००७)

महोदय,

आपणास संदर्भिय पत्रान्वये कळविण्यात येते की या विभागाची संपूर्ण आरक्षणाची व या विभागातील अधिसूचित इमारतीची खालीलप्रमाणे देण्यात येत आहे.

(माहितीचा कालावधी २००१-२००७)

अ.क्र.	माहितीचा तपशील	पुरविलेला माहिती
१.	Request to give information whether OC is given / issued by TMC to Vihang Garden Dev. Reynolds Company, Vartak Nagar, Thane (West). Please give details..... If any part OC given, when how much...	आपला माहिती अधिनियम इमारत प्रस्ताव क्र. २००४/८४, जोगांचा मंजूर लेआउट, प्लॉट क्र. ८३, ८४, ८५, ८६, ८७, ८८, ९०, ९१, ९२, ९३, ९४, ९५, ९६, ९७, ९८, ९९, १००, १०१, १०२, १०३, १०४, १०५, १०६, १०७, १०८, १०९, ११०, १११, ११२, ११३, ११४, ११५, ११६, ११७, ११८, ११९, १२०, १२१, १२२, १२३, १२४, १२५, १२६, १२७, १२८, १२९,

1496

348

Dr. Kirit Somaiya
Chartered Accountant,Ph.D
Former Member of Parliament

Bharatiya Janata Party

कृपया प्रकाशनार्थ

दि. 10 जानेवारी, 2021

ED यांनी श्री.प्रताप सरनाईक यांच्या विहंग आस्था हौसिंग कंपनीच्या गुरवली, टिटवाळा येथील 112 जमिनी/मिळकतींचा ताबा घेतला !!! - किरीट सोमैया

शिवसेना नेते श्री. प्रताप सरनाईक आणि श्री. मोहित अग्रवाल यांनी NSEL घोटाळ्याचे ₹100 कोटी विहांग आस्था हौसिंग कंपनी LLP मधे वळविले (diverted) होते. टिटवाळा येथील गुरवली गावात 112 जमिनी घेतल्या होत्या.

दि. 31 जानेवारी, 2014 रोजी प्रवर्तन निदेशालय (ED) यांनी या जमिनी संबंधी Attachment/जप्तीचे आदेश दिले होते. न्यायालयीन प्रक्रियेत ट्रिब्यूनल Tribunal ने त्याला मान्यता ही दिली होती/आहे.

आता या जमिनीचा प्रत्यक्ष ताबाही ED ने काल घेतला. श्री. प्रताप सरनाईक यांचा असा एकशे बारा सात बारा (112, 7/12) एकंदर 78.27 एकर जमिनीचा ताबा काल ED ने घेतला. ED ने या जागेवर आपले बोर्डही लावले आहेत.

"PMLA कायद्यातर्गत या जमिनींचा कब्जा Directorate of Enforcement, Mumbai तर्फे घेण्यात आला आहे. Prevention of Money Laundering Act, 2002 च्या अंतर्गत या जमिनींचा ताबा अधिकृतरित्या घेण्यात आला आहे. या जमिनींवर अतिक्रमण (Trespassing Prohibited) करण्यास बंदी आहे. या जमिनी संबंधी कोणीही कोणत्याही प्रकारचा आर्थिक व्यवहार करण्यात येऊ नये बोर्ड ही ED अधिकारी यांच्या आदेशावरून लावण्यात आले आहे.

भाजप नेते श्री. किरीट सोमैया यांनी एक महिन्यापूर्वी या जागेची भेट घेतली होती. श्री. प्रताप सरनाईकच्या NESL घोटाळ्यातंर्त या जमिनींवर ED ने जप्तीची नोटिस काढली होती. या जमिनींचे पाठच्या दारातून व्यवहार होत असल्याची तक्रार डॉ. किरीट सोमैया यांनी ED कडे केली होती. याचा भाग म्हणून ED ने आता या तक्रारी संदर्भात कारवाई करताना ED नेच जागेचा ताबाच घेतला आहे.

श्री. प्रताप सरनाईकचे भागीदार श्री. मोहित [illegible] NSEL चा 250 कोटी रुपयांचा घोटाळा केला होता, त्यातले ₹100 कोटी, ह्या विहांग आस्था कंपनी [illegible] अशा जमिनी/मिळकती घेण्यासाठी वापरले होते. त्यामुळे ही जप्तीची कारवाई झाली आहे.

सचिव

kiritsomaiya@gmail.com www.kiritsomaiya.com KiritSomaiyaBJP @kiritsomaiya
Neelam Nagar, Mulund, Mumbai-400 081 • Tel.: 022-21634152 • Mob.: 9869220027



श्री. अनंत करमुसे यांचे त्यांच्या घरातून राती साडेअकरा वाजता मंत्री श्री. जितेंद्र आव्हाड व पोलिस सुरक्षा रक्षकांनी अपहरण केले होते. गेले १५ महिने अनंत करमुसे उच्च न्यायालयात न्याय मिळण्यासाठी धडपडत होते. काही दिवसांपूर्वी आव्हाड यांना अटक करण्यात आली आणि नंतर त्यांची जामीनावर मुक्तता करण्यात आली.



मुंबईचे नं. १

www.maharashtratimes.com

महाराष्ट्र टाइम्स

दिव्य वैचारिकतेचा हार्दिक गुलदस्ता

१२०८४७४ वर कॉल करा. महाराष्ट्र टाइम्स चा अंक मिळवण्यासाठी 1800 1200 004 वर कॉल करा किंवा subscribe.timesgroup.com इथे जा.

आव्हाड यांना अटक, सुटका

करमुसे मारहाणप्रकरणी गृहनिर्माणमंत्र्यांवर अखेर कारवाई

म. टा. प्रतिनिधी, ठाणे

आक्षेपार्ह फेसबुक पोस्टवरून सिनेअभिनेता अनंत करमुसे यांना झालेल्या मारहाणप्रकरणी गृहनिर्माणमंत्री जितेंद्र आव्हाड यांना गुरुवारी पोलिसांनी अटक केली. न्यायालयाने आव्हाड यांना जामीन मंजूर केला असल्याची माहिती ठाण्याचे पोलिस आयुक्त जयजीत सिंह यांनी दिली.

वांद्रेस्थित भागात राहणारे करमुसे यांनी आव्हाड यांच्याविषयी आक्षेपार्ह फेसबुक पोस्ट केली होती. या पोस्टनंतर पोलिसांनी करमुसे यांना त्यांच्या घरातून ताब्यात घेऊन आव्हाड यांच्या ठाण्यातील बंगल्यावर नेले. तिथे त्यांना १५ ते २० जणांनी बेदम मारहाण केली होती. या मारहाणप्रकरणी पोलिसांनी २९ जणांना अटक केली होती. त्यानंतर या प्रकरणी गृहनिर्माणमंत्री आव्हाडदेखील वादात सापडले होते. या प्रकरणी आव्हाड यांच्यासह ३० जणांविरोधात गुन्हा दाखल करण्यात आला होता. त्यांच्यावर एप्रिल महिन्यात पोलिसांनी पाच आरोपपत्रे दाखल केली होती. या प्रकरणात तीन आरोपपत्रे दाखल झाली असून दोन आरोपपत्रे दाखल होणे बाकी आहे.

असल्याचे करमुसे यांनी आपल्या तक्रारीत म्हटले होते. गेल्या वर्षी ८ एप्रिल रोजी घडलेल्या या घटनाप्रकरणी वर्तकनगर पोलिस ठाण्यात गुन्हा दाखल करण्यात आला होता. त्यावेळी एप्रिल महिन्यात पोलिसांनी पाच आरोपपत्रे दाखल केली होती. या प्रकरणात तीन आरोपपत्रे दाखल झाली असून दोन आरोपपत्रे दाखल होणे बाकी आहे.

लवकर सुनावणीच्या विनंतीनंतर...

पोलिसांकडून जितेंद्र आव्हाड यांच्याविरोधात कारवाई होत नसल्याने अनंत करमुसे यांनी ॲड. अनिरुद्ध गानू यांच्यामार्फत सुरुवातीला उच्च न्यायालयात फौजदारी रिट याचिका केली आहे. या याचिकेची दखल घेत उच्च न्यायालयाने कथित मारहाणीविषयीचे पुरावे असलेले सर्व सीसीटीव्ही फुटेज आणि कॉल रेकॉर्ड्स ठाण्यातील न्यायदंडाधिकारी न्यायालयात जमा करण्याचे निर्देश गेल्या वर्षी २३ एप्रिल रोजी वर्तकनगर पोलिसांना दिले होते. त्यानंतर आव्हाड यांच्या अटकेची पोलिसांकडे जमा केलेली खात्रीशीर व अद्ययावत माहिती करमुसे यांनी यापूर्वी जानेवारी महिन्यात प्रतिज्ञापत्राद्वारे उच्च न्यायालयातही जमा केली. त्यानंतर याप्रकरणी सुनावणी झाली नव्हती. मात्र, काही दिवसांपूर्वीच करमुसे यांनी याचिकेची लवकर सुनावणी ठेवण्याची विनंती करणारा अर्ज उच्च न्यायालयात केला आहे. यात आरोपांवरून पोलिसांकडून झालेल्या अटकेची कारवाई आत्ताचे बोलले जात आहे.

जितेंद्र आव्हाड यांना गुरुवारी अटक करण्यात आली. आव्हाड स्वत: वर्तकनगर पोलिस ठाण्यात हजर झाले. त्यानंतर त्यांना ठाणे न्यायालयात हजर केले असता त्यांना जामीन मंजूर केला. एक लाख रुपयांच्या जातमुचलक्यावर त्यांचा जामीन मंजूर करण्यात आला.

66 दीड वर्षानंतर शेवटी न्यायालयाने न्याय दिला. गृहनिर्माणमंत्री जितेंद्र आव्हाड यांना अटक करण्याचे आदेश दिले. ठाणे पोलिसांनी त्यांना अटक केली. अनंत करमुसेला न्याय मिळाला. आता अशा गुंड मंत्र्यांना मंत्रिमंडळात ठेवू नये. आम्ही राज्यपालांकडे जितेंद्र आव्हाड यांची हकालपट्टी करण्याची मागणी करणार आहोत.

– चित्रा वाघ, भाजपच्या नेत्या

मारहाणीच्या या प्रकरणामध्ये मुख्य सूत्रधाराला अटक करणे गरजेचे होते. अशा प्रसंगी मंत्रिपदी असलेल्या आव्हाड यांच्यावर नैतिक दबाव होता.

NOTARY
M. M. P. SALE
Mumbai
Maharashtra
Reg. No. 15220
Expiry Dt.
30.11.2024
GOVT. OF INDIA

1498

सकाळ

सकाळ

'जरंडेश्वर'चा मालक कोण?

» पान ११ वरून

तुम्हाला सात तासांमध्ये ८५ कोटींचे कर्ज कसे मिळाले. लवकरच हा घोटाळा समोर येणार आहे. मी पाच [illegible] माहिती घेण्याचा प्रयत्न केला.

वक्तव्यासंदर्भात 'आता अजित पवार यांची नजर किसन वीर कारखान्यावर गेली आहे का?' असा प्रतिप्रश्न करत श्री. सोमय्या यांनी थेट बोलणे टाळून कोणत्याही कारखान्यासंदर्भात

'जरंडेश्वर'संबंधित कंपन्यांचा अजित पवार यांच्याशी संबंध

(पान १ वरून) उपमुख्यमंत्री अजित पवार यांच्यासह खासदार सुप्रिया सुळे, मुख्यमंत्री उद्धव ठाकरे तसेच महाविकास आघाडी सरकारमधील मंत्र्यांवर शरसंधान साधले.

सोमय्या म्हणाले, उपप्रादेशिक परिवहन अधिकारी बजरंग खरमाटे यांच्या मालमत्तेची पाहणी करण्यासाठी बारामतीत आलो आहे. खरमाटे यांच्यासंबंधी बुधवारी लोकायुक्तांपुढे झालेल्या सुनावणीत राज्य सरकारने खुली चौकशी करणार [illegible]

[illegible]

मंत्री [illegible] यांच्यासंबंधी [illegible] एखादा [illegible] असल्याच्या [illegible] सोमय्या म्हणाले, [illegible] रामदास कदम यांच्याकडून [illegible] ठाकरे यांच्या [illegible] सांगावे.

मेसर्स शिवालिक विल्ड [illegible] जरंडेश्वर शुगर मिल्स प्रा. लि. [illegible] एकमेकांशी, अजित पवार [illegible] संबंध व भूमिका आहे, असा आरोप करून त्याची चौकशी व्हावी, अशी [illegible] हा विषय राज्याच्या पर्यावरण [illegible] आहे. मुख्यमंत्री उद्धव ठाकरे, पर्यावरणमंत्री आदित्य ठाकरे यांनी त्यात लक्ष घालावे, [illegible] मागणी त्यांनी केली.

जरंडेश्वर साखर कारखाना चे संस्थापक शेतकऱ्या सोबत ई डी कार्यालयात तक्रार दाखल केली



NOTARY
M. PARALE
Mumbai
Maharashtra
Reg. No. 15220
Expiry Dt.
01-10-2024
INDIA

1500

352

घोटाळा मुक्त महाराष्ट्र

किरीट सोमैया - वसई कार्यकर्ता संवाद





भारतीय जनता पार्टी

Neelam Nagar, Mulund, Mumbai-400 081 • Tel.: 022-21634152

EXHIBIT "RA-17"

Sero-Survey shows Delhi has 97% antibodies, Mumbai over 85%, and India over 67%.

Two-thirds of India's population have antibodies against novel coronavirus: ICMR 4th serosurvey.

At least two-thirds of India's population has developed antibodies against the novel coronavirus (SARS-CoV-2) by now. This is according to the fourth national serosurvey that was conducted in June-July 2021, after the massive second wave of the novel coronavirus disease (COVID-19) in India.

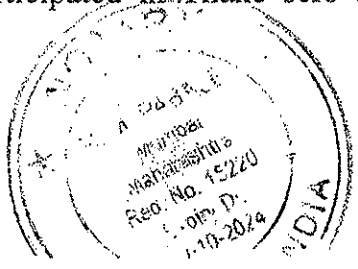
This is a significant increase as compared to the third national serosurvey in December 2020-January 2021 that pegged seroprevalence merely at 24.1 per cent. Such an increase can be attributed to the exceptionally high number of COVID-19 cases in India during the second wave and to some extent, the ongoing vaccination drive.

The serosurvey was conducted in the same 70 districts of 21 states where three rounds were conducted earlier. As many as 28,975 people were enrolled, of which, 20 per cent were people of age 10-17 years.

The age disaggregation of the findings is important as it suggests that more than half the children of age 6-18 years, have antibodies by now. As many as 57.2 per cent children of age 6-9 years and 61.6 per cent children of age 10-17 years have already been infected once.

Source:https://www.downtoearth.org.in/news/health/two-thirds-of-india-s-population-have-antibodies-against-novel-coronavirus-icmr-4th-serosurvey-78045

91% of those who participated in Thane sero survey had Covid antibodies.



1502

~~354~~

More than 90% of Thane's residents who participated in the first-ever sero survey had antibodies to the Covid-causing SARS-CoV-2 virus, said a Thane Municipal Corporation report on Friday.

Of the 1,571 samples analysed, 1,425 had the antibodies. Mayor Naresh Mhaske said, "Although the sero positivity is 90.6%, we will continue our surveillance through testing and tracing as the virus is still mutating."

Source:https://timesofindia.indiatimes.com/city/thane/91-of-those-who-participated-in-thane-sero-survey-had-antibodies/articleshow/87939339.cms?from=mdr

Over 85% Mumbai population has Covid-19 antibodies: BMC sero survey. The fifth sero survey conducted by the Brihanmumbai Municipal Corporation (BMC) in Mumbai in August 2021 shows that 86.64 per cent of the 8,674 people surveyed have antibodies against Covid-19. This is significantly higher than the third sero-surveillance conducted in March this year, which found 36.3 per cent of those surveyed had antibodies against Covid-19.

The latest survey, which covered 8,674 people, found a sero positivity rate of 87.02 per cent in slums, and 86.22 per cent in non-slum areas. This is the first time that there is a meagre difference in the sero positivity of the slum and non-slum population in the city.

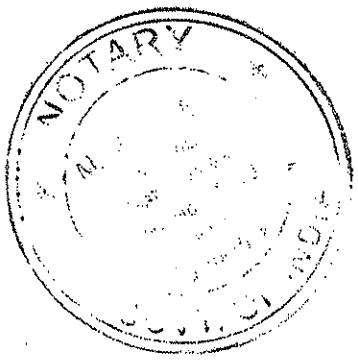
Source:https://indianexpress.com/article/cities/mumbai/over-85-mumbai-population-has-covid-19-antibodies-latest-bmc-sero-survey-7515921/

6th Delhi sero survey shows 97% prevalence of antibodies

For every 100 people in Delhi, 97 have some level of antibodies that react with Sars-CoV-2 because they have had an infection or a vaccine dose, the latest

serological survey suggests, according to preliminary results released by the government on Thursday.

Source:https://www.hindustantimes.com/india-news/6th-delhi-sero-survey-shows-97-prevalence-101635443569509.html



1504
~~356~~

EXHIBIT "RA-18"

Indian studies conducted on Natural Immunity

Indian study shows Natural Immunity is better than Vaccine Immunity. "Moreover, the overall immune response resulting from natural infection in and around Kolkata is not only to a certain degree better than that generated by vaccination, especially in the case of the Delta variant, but cell mediated immunity to SARS-CoV-2 also lasts for at least ten months after the viral infection."

Source:https://www.medrxiv.org/content/10.1101/2021.11.08.21266055v1

Indian study shows reinfection after natural immunity is exceedingly rare, and suggests those who have recovered need not be vaccinated.

Background: A total of 5000 participants were tested for SARS-CoV-2 antibodies in a serosurvey in a twin township of Maharashtra, India in October 2020. A total of 1,726 were found to have IgG antibodies against this novel coronavirus. We followed them up after 8 months to ascertain reinfections.

Methods: An attempt was made to contact all the 1,726 participants who had tested positive for IgG antibodies against the novel coronavirus. Out of these 1081 could be contacted on telephone. Reinfection was identified by asking for symptoms like fever, cough, body ache, loss of smell and history of contact with positive patient and being found positive on being tested by RT-PCR.

Results: Out of the 1,726 participants, 1,081(62.6%) could be contacted. Only 13 (1.2%) got re-infected by covid-19. All the cases were mild and recovered uneventfully.

Conclusion: The study suggests that re-infection after recovering from natural infection was very low during 8 months of follow up. The findings could guide rational vaccine policies particularly as there is crises of supply in most

developing countries. Those who have recovered may not be included in mass vaccination campaigns on priority.

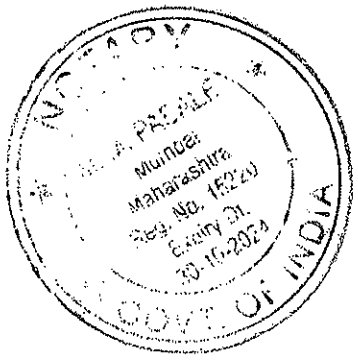
Source:**https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3882415**

Dr. Sanjay K. Rai, President of Indian Public Health Association (IPHA) and Proessor at Department of Community Medicine at AIIMS , Delhi in his interview at

Link: https://www.youtube.com/watch?v=-btDk0eSi5U&feature=youtu.be

He made it clear that,

> *"the best protection and possibly life time immunity only comes from Natural immunity/natural infection i.e. those who have recovered from COVID-19. He further stated that death due to Covid-19, among those who acquired Natural Immunity is nearly zero and possibility of re-infection is rare. Further those vaccines could cause harm or result in adverse effects if administered to those who have already acquired natural immunity and are also non-susceptible.*



1506
~~358~~

EXHIBIT "RA-19"

138 papers published in pre-print servers & peer reviewed medical journals confirm natural immunity is equal to or better than vaccine immunity.

Study/report title, author, and year published and interactive url link	Predominant finding on natural immunity
1) Necessity of COVID-19 vaccination in previously infected individuals, Shrestha, 2021 https://www.medrxiv.org/content/10.1101/2021.06.01.21258176v2 Published in a PrePrint Server	"Cumulative incidence of COVID-19 was examined among 52,238 employees in an American healthcare system. The cumulative incidence of SARS-CoV-2 infection remained almost zero among previously infected unvaccinated subjects, previously infected subjects who were vaccinated, and previously uninfected subjects who were vaccinated, compared with a steady increase in cumulative incidence among previously uninfected subjects who remained unvaccinated. Not one of the 1359 previously infected subjects who remained unvaccinated had a SARS-CoV-2 infection over the duration of the study. Individuals who have had SARS-CoV-2 infection are unlikely

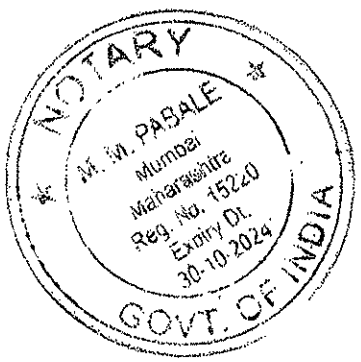
	to benefit from COVID-19 vaccination…"
2) <u>SARS-CoV-2-specific T cell immunity in cases of COVID-19 and SARS, and uninfected controls</u>, Le Bert, 2020 <u>https://www.nature.com/articles/s41586-020-2550-z</u> Published in Peer-Reviewed Science Journal Nature	"Studied T cell responses against the structural (nucleocapsid (N) protein) and non-structural (NSP7 and NSP13 of ***ORF1***) regions of SARS-CoV-2 in individuals convalescing from coronavirus disease 2019 (COVID-19) ($n = 36$). In all of these individuals, we found CD4 and CD8 T cells that recognized multiple regions of the N protein…showed that patients ($n = 23$) who recovered from SARS possess long-lasting memory T cells that are reactive to the N protein of SARS-CoV 17 years after the outbreak of SARS in 2003; these T cells displayed robust cross-reactivity to the N protein of SARS-CoV-2."
3) <u>Comparing SARS-CoV-2 natural immunity to vaccine-induced immunity: reinfections versus breakthrough infections</u>,Gazit, 2021	"A retrospective observational study comparing three groups: (1) SARS-CoV-2-naïve individuals who received a two-dose regimen of the BioNTech/Pfizer mRNA BNT162b2

NOTARY M. M. PABALE Mumbai Maharashtra Reg. No. 15220 Expiry Dt. 31.10.2024 GOVT. OF INDIA

1508
~~360~~

https://www.medrxiv.org/content/10.1101/2021.08.24.21262415v1.full Published in a PrePrint Server	vaccine, (2) previously infected individuals who have not been vaccinated, and (3) previously infected ***and*** single dose vaccinated individuals found para a 13 fold increased risk of breakthrough Delta infections in double vaccinated persons, and a 27 fold increased risk for symptomatic breakthrough infection in the double vaccinated relative to the natural immunity recovered persons…the risk of hospitalization was 8 times higher in the double vaccinated (para)…this analysis demonstrated that natural immunity affords longer lasting and stronger protection against infection, symptomatic disease and hospitalization due to the Delta variant of SARS-CoV-2, compared to the BNT162b2 two-dose vaccine-induced immunity."
4) **Highly functional virus-specific cellular immune response in asymptomatic SARS-CoV-2 infection**, Le Bert, 2021	"Studied SARS-CoV-2–specific T cells in a cohort of asymptomatic (n = 85) and symptomatic (n = 75) COVID-19 patients after seroconversion…thus, asymptomatic

https://rupress.org/jem/article/218/5/e20202617/211835/Highly-functional-virus-specific-cellular-immune Published in Peer-Reviewed Science Journal, Journal of Experimental Medicine	SARS-CoV-2–infected individuals are not characterized by weak antiviral immunity; on the contrary, they mount a highly functional virus-specific cellular immune response."
5) **Large-scale study of antibody titer decay following BNT162b2 mRNA vaccine or SARS-CoV-2 infection**, Israel, 2021 https://www.medrxiv.org/content/10.1101/2021.08.19.21262111v1.full Published in a PrePrint Server	"A total of 2,653 individuals fully vaccinated by two doses of vaccine during the study period and 4,361 convalescent patients were included. Higher SARS-CoV-2 IgG antibody titers were observed in vaccinated individuals (median 1581 AU/mL IQR [533.8-5644.6]) after the second vaccination, than in convalescent individuals (median 355.3 AU/mL IQR [141.2-998.7]; $p<0.001$). In vaccinated subjects, antibody titers decreased by up to 40% each subsequent month while in convalescents they decreased by less than 5% per month…this study demonstrates individuals who received the Pfizer-BioNTech mRNA vaccine have different kinetics of antibody levels compared



1510
~~362~~

	to patients who had been infected with the SARS-CoV-2 virus, with higher initial levels but a much faster exponential decrease in the first group".
6) **SARS-CoV-2 re-infection risk in Austria**, Pilz, 2021 **https://onlinelibrary.wiley.com/doi/full/10.1111/eci.13520** Published in Peer-Reviewed Science Journal European Journal of Clinical Investigation	Researchers recorded "40 tentative re-infections in 14, 840 COVID-19 survivors of the first wave (0.27%) and 253 581 infections in 8, 885, 640 individuals of the remaining general population (2.85%) translating into an odds ratio (95% confidence interval) of 0.09 (0.07 to 0.13)…relatively low re-infection rate of SARS-CoV-2 in Austria. Protection against SARS-CoV-2 after natural infection is comparable with the highest available estimates on vaccine efficacies." Additionally, hospitalization in only five out of 14,840 (0.03%) people and death in one out of 14,840 (0.01%) (tentative re-infection).
7) **mRNA vaccine-induced SARS-CoV-2-specific T cells recognize B.1.1.7 and B.1.351 variants but**	"Spike-specific T cells from convalescent vaccinees differed strikingly from those of infection-

differ in longevity and homing properties depending on prior infection status, Neidleman, 2021 https://www.biorxiv.org/content/10.1101/2021.05.12.443888v1 Published in a PrePrint Server	naïve vaccinees, with phenotypic features suggesting superior long-term persistence and ability to home to the respiratory tract including the nasopharynx. These results provide reassurance that vaccine-elicited T cells respond robustly to the B.1.1.7 and B.1.351 variants, confirm that convalescents may not need a second vaccine dose."
8) Good news: Mild COVID-19 induces lasting antibody protection, Bhandari, 2021 https://medicine.wustl.edu/news/good-news-mild-covid-19-induces-lasting-antibody-protection/ Published in Peer-Reviewed Science Journal Nature	"Months after recovering from mild cases of COVID-19, people still have immune cells in their body pumping out antibodies against the virus that causes COVID-19, according to a study from researchers at Washington University School of Medicine in St. Louis. Such cells could persist for a lifetime, churning out antibodies all the while. The findings, published May 24 in the journal Nature, suggest that mild cases of COVID-19 leave those infected with lasting antibody protection and that repeated bouts of illness are likely to be uncommon."

NOTARY Adv. M. PARALE Mumbai Maharashtra Reg. No. 15220 Expiry Dt. 30-10-2024 GOVT. OF INDIA

1512

~~364~~

9) **Robust neutralizing antibodies to SARS-CoV-2 infection persist for months**, Wajnberg, 2021 **https://science.org/doi/10.1126/science.abd7728** Published in Peer-Reviewed Science Journal, Science	"Neutralizing antibody titers against the SARS-CoV-2 spike protein persisted for at least 5 months after infection. Although continued monitoring of this cohort will be needed to confirm the longevity and potency of this response, these preliminary results suggest that the chance of reinfection may be lower than is currently feared."
10) **Evolution of Antibody Immunity to SARS-CoV-2**, Gaebler, 2020 https://www.biorxiv.org/content/10.1101/2020.11.03.367391v2 Published in a PrePrint Server	"Concurrently, neutralizing activity in plasma decreases by five-fold in pseudo-type virus assays. In contrast, the number of RBD-specific memory B cells is unchanged. Memory B cells display clonal turnover after 6.2 months, and the antibodies they express have greater somatic hypermutation, increased potency and resistance to RBD mutations, indicative of continued evolution of the humoral response…we conclude that the memory B cell response to SARS-CoV-2 evolves between 1.3 and 6.2 months after infection in a manner that is consistent with antigen

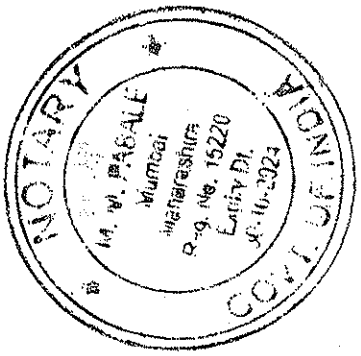
NOTARY GOVT. OF INDIA M. M. PADALE Mumbai Maharashtra Reg. No. 15220 Expiry Dt. 30-10-2024

	persistence."
11) **Persistence of neutralizing antibodies a year after SARS-CoV-2 infection in humans**, Haveri, 2021 **https://onlinelibrary.wiley.com/doi/10.1002/eji.202149535** Published in Peer-Reviewed Science Journal European Journal of Immunology	"Assessed the persistence of serum antibodies following WT SARS-CoV-2 infection at 8 and 13 months after diagnosis in 367 individuals…found that NAb against the WT virus persisted in 89% and S-IgG in 97% of subjects for at least 13 months after infection."
12) **Quantifying the risk of SARS-CoV-2 reinfection over time**, Murchu, 2021 **https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8209951/pdf/RMV-9999-e2260.pdf** Published in Peer-Reviewed Science Journal Wiley	"Eleven large cohort studies were identified that estimated the risk of SARS-CoV-2 reinfection over time, including three that enrolled healthcare workers and two that enrolled residents and staff of elderly care homes. Across studies, the total number of PCR-positive or antibody-positive participants at baseline was 615,777, and the maximum duration of follow-up was more than 10 months in three studies. Reinfection was an uncommon event (absolute rate 0%–

NOTARY M. M. PABALE Mumbai Maharashtra Reg. No. 15220 Expiry Dt. 31.10.2024 GOVT. OF INDIA

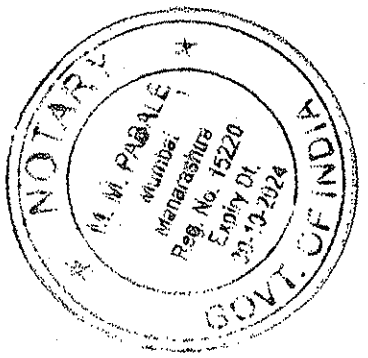
	1.1%), with no study reporting an increase in the risk of reinfection over time."
13) **Natural immunity to covid is powerful. Policymakers seem afraid to say so**, Makary, 2021 **The Western Journal-Makary** **https://www.westernjournal.com/johns-hopkins-doc-says-natural-immunity-27-times-effective-vaccine/** Article by a doctor from John Hopkins	Makary writes "it's okay to have an incorrect scientific hypothesis. But when new data proves it wrong, you have to adapt. Unfortunately, many elected leaders and public health officials have held on far too long to the hypothesis that natural immunity offers unreliable protection against covid-19 — a contention that is being rapidly debunked by science. More than 15 studies have demonstrated the power of immunity acquired by previously having the virus. A 700,000-person study from Israel two weeks ago found that those who had experienced prior infections_were 27 times less likely to get a second symptomatic covid infection than those who were vaccinated. This affirmed a June Cleveland Clinic study of health-care workers (who are often exposed to the virus), in which none_who had previously

NOTARY M. M. PARALE Mumbai Maharashtra Reg. No. 15229 Expiry Dt. 30-10-2024 GOVT. OF INDIA

	tested positive for the coronavirus got reinfected. The study authors concluded that "individuals who have had SARS-CoV-2 infection are unlikely to benefit from covid-19 vaccination." And in May, a Washington University study found that even a mild covid infection resulted in long-lasting immunity." "The data on natural immunity are now overwhelming," Makary told the Morning Wire. "It turns out the hypothesis that our public health leaders had that vaccinated immunity is better and stronger than natural immunity was wrong. They got it backwards. And now we've got data from Israel showing that natural immunity is 27 times more effective than vaccinated immunity."
14) **SARS-CoV-2 elicits robust adaptive immune responses regardless of disease severity**, Nielsen, 2021 **https://www.thelancet.com/journa**	"203 recovered SARS-CoV-2 infected patients in Denmark between April 3rd and July 9th 2020, at least 14 days after COVID-19 symptom recovery… report broad serological profiles

1516
~~368~~

ls/ebiom/article/PIIS2352-3964(21)00203-6/fulltext Published in Peer-Reviewed Science Journal Lancet	within the cohort, detecting antibody binding to other human coronaviruses… the viral surface spike protein was identified as the dominant target for both neutralizing antibodies and CD8+ T-cell responses. Overall, the majority of patients had robust adaptive immune responses, regardless of their disease severity."
15) **Protection of previous SARS-CoV-2 infection is similar to that of BNT162b2 vaccine protection: A three-month nationwide experience from Israel**, Goldberg, 2021 https://www.medrxiv.org/content/10.1101/2021.04.20.21255670v1 Published in a PrePrint Server	"Analyze an updated individual-level database of the entire population of Israel to assess the protection efficacy of both prior infection and vaccination in preventing subsequent SARS-CoV-2 infection, hospitalization with COVID-19, severe disease, and death due to COVID-19… vaccination was highly effective with overall estimated efficacy for documented infection of 92·8% (CI:[92·6, 93·0]); hospitalization 94·2% (CI:[93·6, 94·7]); severe illness 94·4% (CI:[93·6, 95·0]); and death 93·7% (CI:[92·5, 94·7]). Similarly, the

	overall estimated level of protection from prior SARS-CoV-2 infection for documented infection is 94·8% (CI: [94·4, 95·1]); hospitalization 94·1% (CI: [91·9, 95·7]); and severe illness 96·4% (CI: [92·5, 98·3])…results question the need to vaccinate previously-infected individuals."
16) <u>Incidence of Severe Acute Respiratory Syndrome Coronavirus-2 infection among previously infected or vaccinated employees</u>, Kojima, 2021 <u>https://www.medrxiv.org/content/10.1101/2021.07.03.21259976v2</u> Published in a PrePrint Server	"Employees were divided into three groups: (1) SARS-CoV-2 naïve and unvaccinated, (2) previous SARS-CoV-2 infection, and (3) vaccinated. Person-days were measured from the date of the employee first test and truncated at the end of the observation period. SARS-CoV-2 infection was defined as two positive SARS-CoV-2 PCR tests in a 30-day period… 4313, 254 and 739 employee records for groups 1, 2, and 3…previous SARS-CoV-2 infection and vaccination for SARS-CoV-2 were associated with decreased risk for infection or re-infection with SARS-CoV-2 in a routinely screened workforce. The

1518

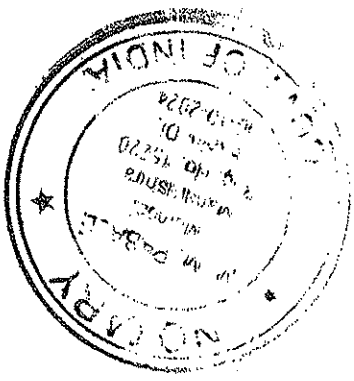
~~370~~

	was no difference in the infection incidence between vaccinated individuals and individuals with previous infection."
17) **Having SARS-CoV-2 once confers much greater immunity than a vaccine—but vaccination remains vital**, Wadman, 2021 https://www.medrxiv.org/content/10.1101/2021.08.24.21262415v1 Published in a PrePrint Server	"Israelis who had an infection were more protected against the Delta coronavirus variant than those who had an already highly effective COVID-19 vaccine...the newly released data show people who once had a SARS-CoV-2 infection were much less likely than never-infected, vaccinated people to get Delta, develop symptoms from it, or become hospitalized with serious COVID-19."
18) **One-year sustained cellular and humoral immunities of COVID-19 convalescents**, Zhang, 2021 **https://academic.oup.com/cid/advance-article/doi/10.1093/cid/ciab884/6381561**	"A systematic antigen-specific immune evaluation in 101 COVID-19 convalescents; SARS-CoV-2-specific IgG antibodies, and also NAb can persist among over 95% COVID-19 convalescents from 6 months to 12 months after disease onset. At least 19/71 (26%) of COVID-19 convalescents (double positive in ELISA and MCLIA) had

Published in Peer-Reviewed Science Journal Clinical Infectious Diseases	detectable circulating IgM antibody against SARS-CoV-2 at 12m post-disease onset. Notably, the percentages of convalescents with positive SARS-CoV-2-specific T-cell responses (at least one of the SARS-CoV-2 antigen S1, S2, M and N protein) were 71/76 (93%) and 67/73 (92%) at 6m and 12m, respectively."
19) **Functional SARS-CoV-2-Specific Immune Memory Persists after Mild COVID-19**, Rodda, 2021 **https://www.cell.com/cell/fulltext/S0092-8674(20)31565-8?_returnURL=https://linkinghub.elsevier.com/retrieve/pii/S0092867420315658?showall=true** Published in Peer-Reviewed Science Journal Cell	"Recovered individuals developed SARS-CoV-2-specific immunoglobulin (IgG) antibodies, neutralizing plasma, and memory B and memory T cells that persisted for at least 3 months. Our data further reveal that SARS-CoV-2-specific IgG memory B cells increased over time. Additionally, SARS-CoV-2-specific memory lymphocytes exhibited characteristics associated with potent antiviral function: memory T cells secreted cytokines and expanded upon antigen re-encounter, whereas memory B cells expressed receptors capable of neutralizing

NOTARY M. M. PABALE Mumbai Maharashtra Reg. No. 15220 Expiry Dt. 30-10-2022 GOVT. OF INDIA

1520
~~372~~

	virus when expressed as monoclonal antibodies. Therefore, mild COVID-19 elicits memory lymphocytes that persist and display functional hallmarks of antiviral immunity."
20) **Discrete Immune Response Signature to SARS-CoV-2 mRNA Vaccination Versus Infection**, Ivanova, 2021 **https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3838993** Published in Peer-Reviewed Science Journal Cell 	"Performed multimodal single-cell sequencing on peripheral blood of patients with acute COVID-19 and healthy volunteers before and after receiving the SARS-CoV-2 BNT162b2 mRNA vaccine to compare the immune responses elicited by the virus and by this vaccine…both infection and vaccination induced robust innate and adaptive immune responses, our analysis revealed significant qualitative differences between the two types of immune challenges. In COVID-19 patients, immune responses were characterized by a highly augmented interferon response which was largely absent in vaccine recipients. Increased interferon signaling likely contributed to the observed dramatic upregulation of cytotoxic genes in

	the peripheral T cells and innate-like lymphocytes in patients but not in immunized subjects. Analysis of B and T cell receptor repertoires revealed that while the majority of clonal B and T cells in COVID-19 patients were effector cells, in vaccine recipients clonally expanded cells were primarily circulating memory cells…we observed the presence of cytotoxic CD4 T cells in COVID-19 patients that were largely absent in healthy volunteers following immunization. While hyper-activation of inflammatory responses and cytotoxic cells may contribute to immunopathology in severe illness, in mild and moderate disease, these features are indicative of protective immune responses and resolution of infection."
21) **SARS-CoV-2 infection induces long-lived bone marrow plasma cells in humans**, Turner, 2021 https://www.nature.com/articles/s41	"Bone marrow plasma cells (BMPCs) are a persistent and essential source of protective antibodies… durable serum antibody titres are maintained by long-lived plasma cells—non-replicating,

1522
374

586-021-03647-4 Published in Peer-Reviewed Science Journal Nature	antigen-specific plasma cells that are detected in the bone marrow long after the clearance of the antigen … S-binding BMPCs are quiescent, which suggests that they are part of a stable compartment. Consistently, circulating resting memory B cells directed against SARS-CoV-2 S were detected in the convalescent individuals. Overall, our results indicate that mild infection with SARS-CoV-2 induces robust antigen-specific, long-lived humoral immune memory in humans…overall, our data provide strong evidence that SARS-CoV-2 infection in humans robustly establishes the two arms of humoral immune memory: long-lived bone marrow plasma cells (BMPCs) and memory B-cells."
22) **SARS-CoV-2 infection rates of antibody-positive compared with antibody-negative health-care workers in England: a large, multicentre, prospective cohort study (SIREN)**, Jane Hall, 2021	"The SARS-CoV-2 Immunity and Reinfection Evaluation study… 30 625 participants were enrolled into the study… a previous history of SARS-CoV-2 infection was associated with an 84% lower risk of

https://thelancet.comx/journals/lancet/article/PIIS0140-6736(21)00675-9/fulltext Published in Peer-Reviewed Science Journal Lancet	infection, with median protective effect observed 7 months following primary infection. This time period is the minimum probable effect because seroconversions were not included. This study shows that previous infection with SARS-CoV-2 induces effective immunity to future infections in most individuals."
23) **Pandemic peak SARS-CoV-2 infection and seroconversion rates in London frontline health-care workers**, Houlihan, 2020 https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)31484-7/fulltext Published in Peer-Reviewed Science Journal Lancet	"Enrolled 200 patient-facing HCWs between March 26 and April 8, 2020…represents a 13% infection rate (i.e. 14 of 112 HCWs) within the 1 month of follow-up in those with no evidence of antibodies or viral shedding at enrolment. By contrast, of 33 HCWs who tested positive by serology but tested negative by RT-PCR at enrolment, 32 remained negative by RT-PCR through follow-up, and one tested positive by RT-PCR on days 8 and 13 after enrolment."

NOTARY
M. M. PABALE
Mumbai
Maharashtra
Reg. No. 15220
Expiry On
30-10-2024
GOVT. OF INDIA

24) **Antibodies to SARS-CoV-2 are associated with protection against reinfection**, Lumley, 2021 https://www.medrxiv.org/content/10.1101/2020.11.18.20234369v1 Published in a PrePrint Server	"Critical to understand whether infection with Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) protects from subsequent reinfection… 12219 HCWs participated…prior SARS-CoV-2 infection that generated antibody responses offered protection from reinfection for most people in the six months following infection."
25) **Longitudinal analysis shows durable and broad immune memory after SARS-CoV-2 infection with persisting antibody responses and memory B and T cells**, Cohen, 2021 https://www.cell.com/cell-reports-medicine/fulltext/S2666-3791(21)00203-2 Published in Peer-Reviewed Science Journal Cell	"Evaluate 254 COVID-19 patients longitudinally up to 8 months and find durable broad-based immune responses. SARS-CoV-2 spike binding and neutralizing antibodies exhibit a bi-phasic decay with an extended half-life of >200 days suggesting the generation of longer-lived plasma cells… most recovered COVID-19 patients mount broad, durable immunity after infection, spike IgG+ memory B cells increase and persist post-infection, durable polyfunctional CD4 and CD8 T cells recognize distinct viral epitope regions."

NOTARY
M. M. PABALE
Mumbai
Maharashtra
Reg. No. 15220
Expiry Dt.
30-10-2024
GOVT. OF INDIA

26) **Single cell profiling of T and B cell repertoires following SARS-CoV-2 mRNA vaccine**, Sureshchandra, 2021 https://www.biorxiv.org/content/10.1101/2021.07.14.452381v1 Published in a PrePrint Server	"Used single-cell RNA sequencing and functional assays to compare humoral and cellular responses to two doses of mRNA vaccine with responses observed in convalescent individuals with asymptomatic disease… natural infection induced expansion of larger CD8 T cell clones occupied distinct clusters, likely due to the recognition of a broader set of viral epitopes presented by the virus not seen in the mRNA vaccine."
27) **SARS-CoV-2 antibody-positivity protects against reinfection for at least seven months with 95% efficacy**, Abu-Raddad, 2021 https://www.thelancet.com/journals/eclinm/article/PIIS2589-5370(21)00141-3/fulltext Published in Peer-Reviewed Science Journal Lancet	"SARS-CoV-2 antibody-positive persons from April 16 to December 31, 2020 with a PCR-positive swab ≥14 days after the first-positive antibody test were investigated for evidence of reinfection, 43,044 antibody-positive persons who were followed for a median of 16.3 weeks…reinfection is rare in the young and international population of Qatar. Natural infection appears to elicit strong protection against reinfection with an efficacy ~95% for at least seven months."

NOTARY M. M. PABALE Nanded Maharashtra Reg. No. 15220 Expiry Dt. 30-10-2024 GOVT. OF INDIA

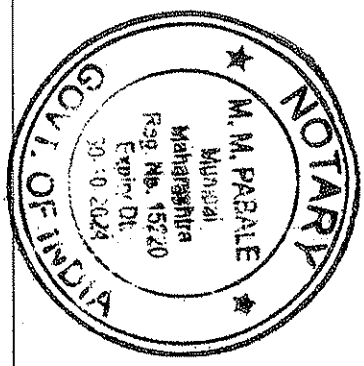
1526
~~378~~

28) **Orthogonal SARS-CoV-2 Serological Assays Enable Surveillance of Low-Prevalence Communities and Reveal Durable Humoral Immunity**, Ripperger, 2020 https://www.cell.com/immunity/fulltext/S1074-7613(20)30445-3 Published in Peer-Reviewed Science Journal Cell	"Conducted a serological study to define correlates of immunity against SARS-CoV-2. Compared to those with mild coronavirus disease 2019 (COVID-19) cases, individuals with severe disease exhibited elevated virus-neutralizing titers and antibodies against the nucleocapsid (N) and the receptor binding domain (RBD) of the spike protein…neutralizing and spike-specific antibody production persists for at least 5–7 months… nucleocapsid antibodies frequently become undetectable by 5–7 months."
29) **Anti-spike antibody response to natural SARS-CoV-2 infection in the general population**, Wei, 2021 https://www.medrxiv.org/content/10.1101/2021.07.02.21259897v1 Published in a PrePrint Server	"In the general population using representative data from 7,256 United Kingdom COVID-19 infection survey participants who had positive swab SARS-CoV-2 PCR tests from 26-April-2020 to 14-June-2021…we estimated antibody levels associated with protection against reinfection likely last 1.5-2 years on average, with levels associated with protection from

GOVT. OF INDIA
NOT A PUBLIC
M. M. PABALE
Mumbai
Maharashtra
Reg. No. 15220
Expiry Dt.
30-10-2024

	severe infection present for several years. These estimates could inform planning for vaccination booster strategies."
30) **Researchers find long-lived immunity to 1918 pandemic virus**, CIDRAP, 2008 and the actual **2008 NATURE journal publication** by Yu https://www.nature.com/articles/nature07231 Published in Peer-Reviewed Science Journal Nature	"A study of the blood of older people who survived the 1918 influenza pandemic reveals that antibodies to the strain have lasted a lifetime and can perhaps be engineered to protect future generations against similar strains...the group collected blood samples from 32 pandemic survivors aged 91 to 101..the people recruited for the study were 2 to 12 years old in 1918 and many recalled sick family members in their households, which suggests they were directly exposed to the virus, the authors report. The group found that 100% of the subjects had serum-neutralizing activity against the 1918 virus and 94% showed serologic reactivity to the 1918 hemagglutinin. The investigators generated B lymphoblastic cell lines from the peripheral blood mononuclear cells

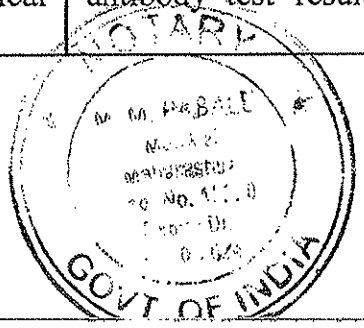
1528
~~380~~

	of eight subjects. Transformed cells from the blood of 7 of the 8 donors yielded secreting antibodies that bound the 1918 hemagglutinin." Yu: "here we show that of the 32 individuals tested that were born in or before 1915, each showed sero-reactivity with the 1918 virus, nearly 90 years after the pandemic. Seven of the eight donor samples tested had circulating B cells that secreted antibodies that bound the 1918 HA. We isolated B cells from subjects and generated five monoclonal antibodies that showed potent neutralizing activity against 1918 virus from three separate donors. These antibodies also cross-reacted with the genetically similar HA of a 1930 swine H1N1 influenza strain."
31) **Live virus neutralisation testing in convalescent patients and subjects vaccinated against 19A, 20B, 20I/501Y.V1 and 20H/501Y.V2 isolates of SARS-CoV-2**, Gonzalez, 2021	"No significant difference was observed between the 20B and 19A isolates for HCWs with mild COVID-19 and critical patients. However, a significant decrease in neutralisation ability was found for 20I/501Y.V1 in comparison with

https://www.medrxiv.org/content/10.1101/2021.05.11.21256578v1 Published in a PrePrint Server	19A isolate for critical patients and HCWs 6-months post infection. Concerning 20H/501Y.V2, all populations had a significant reduction in neutralising antibody titres in comparison with the 19A isolate. Interestingly, a significant difference in neutralisation capacity was observed for vaccinated HCWs between the two variants whereas it was not significant for the convalescent groups…the reduced neutralising response observed towards the 20H/501Y.V2 in comparison with the 19A and 20I/501Y.V1 isolates in fully immunized subjects with the BNT162b2 vaccine is a striking finding of the study."
32) **Differential effects of the second SARS-CoV-2 mRNA vaccine dose on T cell immunity in naïve and COVID-19 recovered individuals**, Camara, 2021 https://www.biorxiv.org/content/10.	"Characterized SARS-CoV-2 spike-specific humoral and cellular immunity in naïve and previously infected individuals during full BNT162b2 vaccination…results demonstrate that the second dose increases both the humoral and cellular immunity in naïve

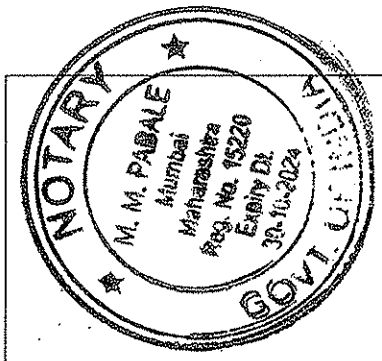
1530
382

1101/2021.03.22.436441v1 Published in a PrePrint Server	individuals. On the contrary, the second BNT162b2 vaccine dose results in a reduction of cellular immunity in COVID-19 recovered individuals."
33) **Op-Ed: Quit Ignoring Natural COVID Immunity**, Klausner, 2021 **https://www.medpagetoday.com/infectiousdisease/covid19/92836?xid=nl_secondopinion_2021-06-01&eun=g1666187d0r** Published in MedPage Today	"Epidemiologists estimate over 160 million people worldwide have recovered from COVID-19. Those who have recovered have an astonishingly low frequency of repeat infection, disease, or death."
34) **Association of SARS-CoV-2 Seropositive Antibody Test With Risk of Future Infection**, Harvey, 2021 https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2776810 Published in Peer-Reviewed Science Journal JAMA (The Journal of the American Medical	"To evaluate evidence of SARS-CoV-2 infection based on diagnostic nucleic acid amplification test (NAAT) among patients with positive vs negative test results for antibodies in an observational descriptive cohort study of clinical laboratory and linked claims data…the cohort included 3 257 478 unique patients with an index antibody test…patients with positive antibody test results were initially



Association)	more likely to have positive NAAT results, consistent with prolonged RNA shedding, but became markedly less likely to have positive NAAT results over time, suggesting that seropositivity is associated with protection from infection."
35) SARS-CoV-2 seropositivity and subsequent infection risk in healthy young adults: a prospective cohort study, Letizia, 2021 https://www.thelancet.com/journals/lanres/article/PIIS2213-2600(21)00158-2/fulltext Published in Peer-Reviewed Science Journal Lancet	"Investigated the risk of subsequent SARS-CoV-2 infection among young adults (CHARM marine study) seropositive for a previous infection…enrolled 3249 participants, of whom 3168 (98%) continued into the 2-week quarantine period. 3076 (95%) participants…Among 189 seropositive participants, 19 (10%) had at least one positive PCR test for SARS-CoV-2 during the 6-week follow-up (1·1 cases per person-year). In contrast, 1079 (48%) of 2247 seronegative participants tested positive (6·2 cases per person-year). The incidence rate ratio was 0·18 (95% CI 0·11–0·28; p<0·001)…infected seropositive participants had viral loads that were

1532
~~384~~

	about 10-times lower than those of infected seronegative participants (ORF1ab gene cycle threshold difference 3·95 [95% CI 1·23–6·67]; p=0·004)."
36) **Associations of Vaccination and of Prior Infection With Positive PCR Test Results for SARS-CoV-2 in Airline Passengers Arriving in Qatar**, Bertollini, 2021 https://jamanetwork.com/journals/jama/article-abstract/2781112 Published in Peer-Reviewed Science Journal JAMA	"Of 9,180 individuals with no record of vaccination but with a record of prior infection at least 90 days before the PCR test (group 3), 7694 could be matched to individuals with no record of vaccination or prior infection (group 2), among whom PCR positivity was 1.01% (95% CI, 0.80%-1.26%) and 3.81% (95% CI, 3.39%-4.26%), respectively. The relative risk for PCR positivity was 0.22 (95% CI, 0.17-0.28) for vaccinated individuals and 0.26 (95% CI, 0.21-0.34) for individuals with prior infection compared with no record of vaccination or prior infection."
37) **Natural immunity against COVID-19 significantly reduces the risk of reinfection: findings from a cohort of sero-survey**	"Followed up with a subsample of our previous sero-survey participants to assess whether natural immunity against SARS-

participants, Mishra, 2021 https://www.medrxiv.org/content/10.1101/2021.07.19.21260302v1 Published in a PrePrint Server	CoV-2 was associated with a reduced risk of re-infection (India)... out of the 2238 participants, 1170 were sero-positive and 1068 were sero-negative for antibody against COVID-19. Our survey found that only 3 individuals in the sero-positive group got infected with COVID-19 whereas 127 individuals reported contracting the infection the sero-negative group...from the 3 sero-positives re-infected with COVID-19, one had hospitalization, but did not require oxygen support or critical care...development of antibody following natural infection not only protects against re-infection by the virus to a great extent, but also safeguards against progression to severe COVID-19 disease."
38) **Lasting immunity found after recovery from COVID-19**, NIH, 2021 **https://www.nih.gov/news-events/nih-research-**	"The researchers found durable immune responses in the majority of people studied. Antibodies against the spike protein of SARS-CoV-2, which the virus uses to get inside cells, were found in 98% of

NOTARY
M. M. PABALE
Mumbai
Maharashtra
Reg. No. 15220
Expiry Dt.
30-10-2021
GOVT. OF INDIA

1834
386

matters/lasting-immunity-found-after-recovery-covid-19 Data from NIH (National Institutes of Health, USA)	participants one month after symptom onset. As seen in previous studies, the number of antibodies ranged widely between individuals. But, promisingly, their levels remained fairly stable over time, declining only modestly at 6 to 8 months after infection… virus-specific B cells increased over time. People had more memory B cells six months after symptom onset than at one month afterwards… levels of T cells for the virus also remained high after infection. Six months after symptom onset, 92% of participants had CD4+ T cells that recognized the virus… 95% of the people had at least 3 out of 5 immune-system components that could recognize SARS-CoV-2 up to 8 months after infection."
39) **SARS-CoV-2 Natural Antibody Response Persists for at Least 12 Months in a Nationwide Study From the Faroe Islands,** Petersen, 2021	"The seropositive rate in the convalescent individuals was above 95% at all sampling time points for both assays and remained stable over time; that is, almost all convalescent individuals developed

https://academic.oup.com/ofid/article/8/8/ofab378/6322055 Published in Peer-Reviewed Science Journal Open Forum Infectious Diseases	antibodies… results show that SARS-CoV-2 antibodies persisted at least 12 months after symptom onset and maybe even longer, indicating that COVID-19-convalescent individuals may be protected from reinfection."
40) SARS-CoV-2-specific T cell memory is sustained in COVID-19 convalescent patients for 10 months with successful development of stem cell-like memory T cells, Jung, 2021 https://www.nature.com/articles/s41467-021-24377-1?utm_source=other&utm_medium=other&utm_content=null&utm_campaign=JRCN_1_LW01_CN_natureOA_article_paid_XMOL Published in Peer-Reviewed Science Journal Nature	"ex vivo assays to evaluate SARS-CoV-2-specific CD4+ and CD8+ T cell responses in COVID-19 convalescent patients up to 317 days post-symptom onset (DPSO), and find that memory T cell responses are maintained during the study period regardless of the severity of COVID-19. In particular, we observe sustained polyfunctionality and proliferation capacity of SARS-CoV-2-specific T cells. Among SARS-CoV-2-specific CD4+ and CD8+ T cells detected by activation-induced markers, the proportion of stem cell-like memory T (TSCM) cells is increased, peaking at approximately 120 DPSO."
41) Immune Memory in Mild	"Analyzed 42 unexposed healthy

NOTARY
Mumbai
Maharashtra
No. 15220
Expiry Dt. 30-10-2024
GOVT. OF INDIA

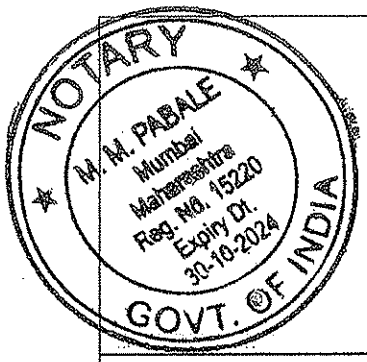
1536
388

COVID-19 Patients and Unexposed Donors Reveals Persistent T Cell Responses After SARS-CoV-2 Infection, Ansari, 2021 **https://pubmed.ncbi.nlm.nih.gov/33777028/** Published in Peer-Reviewed Science Journal Frontiers in Immunology	donors and 28 mild COVID-19 subjects up to 5 months from the recovery for SARS-CoV-2 specific immunological memory. Using HLA class II predicted peptide megapools, we identified SARS-CoV-2 cross-reactive CD4+ T cells in around 66% of the unexposed individuals. Moreover, we found detectable immune memory in mild COVID-19 patients several months after recovery in the crucial arms of protective adaptive immunity; CD4+ T cells and B cells, with a minimal contribution from CD8+ T cells. Interestingly, the persistent immune memory in COVID-19 patients is predominantly targeted towards the Spike glycoprotein of the SARS-CoV-2. This study provides the evidence of both high magnitude pre-existing and persistent immune memory in Indian population."
42) **COVID-19 natural immunity**, WHO, 2021	"Current evidence points to most individuals developing strong protective immune responses

https://apps.who.int/iris/bitstream/handle/10665/341241/WHO-2019-nCoV-Sci-Brief-Natural-immunity-2021.1-eng.pdf?sequence=3&isAllowed=y WHO scientific brief on Natural Immunity	following natural infection with SARSCoV-2. Within 4 weeks following infection, 90-99% of individuals infected with the SARS-CoV-2 virus develop detectable neutralizing antibodies. The strength and duration of the immune responses to SARS-CoV-2 are not completely understood and currently available data suggests that it varies by age and the severity of symptoms. Available scientific data suggests that in most people immune responses remain robust and protective against reinfection for at least 6-8 months after infection (the longest follow up with strong scientific evidence is currently approximately 8 months)."
43) Antibody Evolution after SARS-CoV-2 mRNA Vaccination, Cho, 2021 https://www.biorxiv.org/content/10.1101/2021.07.29.454333v1 Published in a PrePrint Server	"We conclude that memory antibodies selected over time by natural infection have greater potency and breadth than antibodies elicited by vaccination…boosting vaccinated individuals with currently available mRNA vaccines would produce a quantitative

1538

~~390~~



	increase in plasma neutralizing activity but not the qualitative advantage against variants obtained by vaccinating convalescent individuals."
44) **Humoral Immune Response to SARS-CoV-2 in Iceland**, Gudbjartsson, 2020 https://www.nejm.org/doi/full/10.1056/NEJMoa2026116 Published in Peer-Reviewed Science Journal, New England Journal of Medicine	"Measured antibodies in serum samples from 30,576 persons in Iceland…of the 1797 persons who had recovered from SARS-CoV-2 infection, 1107 of the 1215 who were tested (91.1%) were seropositive…results indicate risk of death from infection was 0.3% and that antiviral antibodies against SARS-CoV-2 did not decline within 4 months after diagnosis (para)."
45) **Immunological memory to SARS-CoV-2 assessed for up to 8 months after infection**, Dan, 2021 **https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7919858/** Published in Peer-Reviewed Science Journal Science	"Analyzed multiple compartments of circulating immune memory to SARS-CoV-2 in 254 samples from 188 COVID-19 cases, including 43 samples at ≥ 6 months post-infection…IgG to the Spike protein was relatively stable over 6+ months. Spike-specific memory B cells were more abundant at 6 months than at 1 month post

	symptom onset."
46) **The prevalence of adaptive immunity to COVID-19 and reinfection after recovery – a comprehensive systematic review and meta-analysis of 12 011 447 individuals**, Chivese, 2021 https://www.medrxiv.org/content/10.1101/2021.09.03.21263103v3 Published in a PrePrint Server	"Fifty-four studies, from 18 countries, with a total of 12 011 447 individuals, followed up to 8 months after recovery, were included. At 6-8 months after recovery, the prevalence of detectable SARS-CoV-2 specific immunological memory remained high; IgG – 90.4%… pooled prevalence of reinfection was 0.2% (95%CI 0.0 – 0.7, I2 = 98.8, 9 studies). Individuals who recovered from COVID-19 had an 81% reduction in odds of a reinfection (OR 0.19, 95% CI 0.1 – 0.3, I2 = 90.5%, 5 studies)."
47) **Reinfection Rates among Patients who Previously Tested Positive for COVID-19: a Retrospective Cohort Study**, Sheehan, 2021 **https://pubmed.ncbi.nlm.nih.gov/33718968/** Published in Peer-Reviewed	"Retrospective cohort study of one multi-hospital health system included 150,325 patients tested for COVID-19 infection…prior infection in patients with COVID-19 was highly protective against reinfection and symptomatic disease. This protection increased over time, suggesting that viral shedding or ongoing immune response may

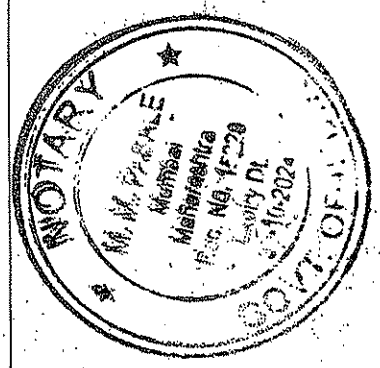
NOTARY M. M. PABALE Mumbai Maharashtra Reg. No. 15220 Expiry Dt. 30-10-2024 GOVT. OF INDIA

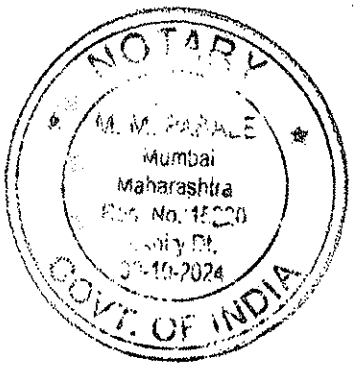
Science Journal Clinical Infectious Diseases	persist beyond 90 days and may not represent true reinfection."
48) **Assessment of SARS-CoV-2 Reinfection 1 Year After Primary Infection in a Population in Lombardy, Italy**, Vitale, 2020 https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2780557 Published in Peer-Reviewed Science Journal JAMA	"The study results suggest that reinfections are rare events and patients who have recovered from COVID-19 have a lower risk of reinfection. Natural immunity to SARS-CoV-2 appears to confer a protective effect for at least a year, which is similar to the protection reported in recent vaccine studies."
49) **Prior SARS-CoV-2 infection is associated with protection against symptomatic reinfection**, Hanrath, 2021 **https://www.journalofinfection.com/article/S0163-4453(20)30781-7/fulltext** Published in Peer-Reviewed Science Journal, Journal of Infection	"We observed no symptomatic reinfections in a cohort of healthcare workers…this apparent immunity to re-infection was maintained for at least 6 months…test positivity rates were 0% (0/128 [95% CI: 0–2.9]) in those with previous infection compared to 13.7% (290/2115 [95% CI: 12.3–15.2]) in those without (P<0.0001 $\chi 2$ test)."
50) **Targets of T Cell Responses to**	"Using HLA class I and II predicted

SARS-CoV-2 Coronavirus in Humans with COVID-19 Disease and Unexposed Individuals, Grifoni, 2020 https://www.cell.com/cell/fulltext/S0092-8674(20)30610-3 Published in Peer-Reviewed Science Journal Cell	peptide "megapools," circulating SARS-CoV-2-specific CD8+ and CD4+ T cells were identified in ~70% and 100% of COVID-19 convalescent patients, respectively. CD4+ T cell responses to spike, the main target of most vaccine efforts, were robust and correlated with the magnitude of the anti-SARS-CoV-2 IgG and IgA titers. The M, spike, and N proteins each accounted for 11%–27% of the total CD4+ response, with additional responses commonly targeting nsp3, nsp4, ORF3a, and ORF8, among others. For CD8+ T cells, spike and M were recognized, with at least eight SARS-CoV-2 ORFs targeted."
51) **NIH Director's Blog: Immune T Cells May Offer Lasting Protection Against COVID-19**, Collins, 2021 https://directorsblog.nih.gov/2020/07/28/immune-t-cells-may-offer-lasting-protection-against-covid-19/	"Much of the study on the immune response to SARS-CoV-2, the novel coronavirus that causes COVID-19, has focused on the production of antibodies. But, in fact, immune cells known as memory T cells also play an important role in the ability of our immune systems to protect us against many viral infections,

1542

~~394~~

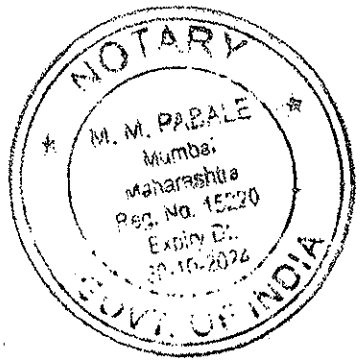
Article from NIH 	including—it now appears—COVID-19.An intriguing new study of these memory T cells suggests they might protect some people newly infected with SARS-CoV-2 by remembering past encounters with other human coronaviruses. This might potentially explain why some people seem to fend off the virus and may be less susceptible to becoming severely ill with COVID-19."
52) **Ultrapotent antibodies against diverse and highly transmissible SARS-CoV-2 variants**, Wang, 2021 https://www.science.org/doi/full/10.1126/science.abh1766 Published in Peer-Reviewed Science Journal Science	"Our study demonstrates that convalescent subjects previously infected with ancestral variant SARS-CoV-2 produce antibodies that cross-neutralize emerging VOCs with high potency…potent against 23 variants, including variants of concern."
53) **Why COVID-19 Vaccines Should Not Be Required for All Americans**, Makary, 2021	"Requiring the vaccine in people who are already immune with natural immunity has no scientific support. While vaccinating those

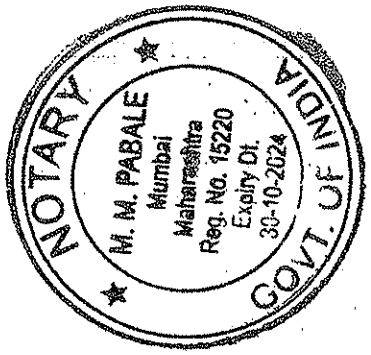
https://www.medrxiv.org/content/10.1101/2021.06.01.21258176v2 Published in a PrePrint Server  	people may be beneficial – and it's a reasonable hypothesis that vaccination may bolster the longevity of their immunity – to argue dogmatically that they ***must*** get vaccinated has zero clinical outcome data to back it. As a matter of fact, we have data to the contrary: A Cleveland Clinic study found that vaccinating people with natural immunity did not add to their level of protection."
54) **Protracted yet coordinated differentiation of long-lived SARS-CoV-2-specific CD8+ T cells during COVID-19 convalescence**, Ma, 2021 https://www.biorxiv.org/content/10.1101/2021.04.28.441880v1 Published in a PrePrint Server	"Screened 21 well-characterized, longitudinally-sampled convalescent donors that recovered from mild COVID-19…following a typical case of mild COVID-19, SARS-CoV-2-specific CD8+ T cells not only persist but continuously differentiate in a coordinated fashion well into convalescence, into a state characteristic of long-lived, self-renewing memory."
55) **Decrease in Measles Virus-Specific CD4 T Cell Memory in Vaccinated Subjects**, Naniche,	"Characterized the profiles of measles vaccine (MV) vaccine-induced antigen-specific T cells over

1542
396

2004 **https://academic.oup.com/jid/article/190/8/1387/878306** Published in Peer-Reviewed Science Journal, The Journal of Infectious Diseases	time since vaccination. In a cross-sectional study of healthy subjects with a history of MV vaccination, we found that MV-specific CD4 and CD8 T cells could be detected up to 34 years after vaccination. The levels of MV-specific CD8 T cells and MV-specific IgG remained stable, whereas the level of MV-specific CD4 T cells decreased significantly in subjects who had been vaccinated >21 years earlier."
56) **Remembrance of Things Past: Long-Term B Cell Memory After Infection and Vaccination**, Palm, 2019 **https://www.frontiersin.org/articles/10.3389/fimmu.2019.01787/full** Published in Peer-Reviewed Science Journal Frontiers in Immunology	"The success of vaccines is dependent on the generation and maintenance of immunological memory. The immune system can remember previously encountered pathogens, and memory B and T cells are critical in secondary responses to infection. Studies in mice have helped to understand how different memory B cell populations are generated following antigen exposure and how affinity for the antigen is determinant to B cell fate… upon re-exposure to an antigen the memory recall response

NOTARY GOVT. OF INDIA M. M. PARALE Mumbai Maharashtra Reg. No. 15229 Expiry D: 30-10-2024

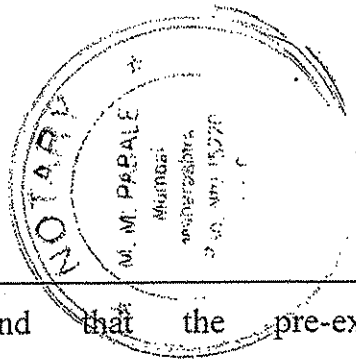
	will be faster, stronger, and more specific than a naïve response. Protective memory depends first on circulating antibodies secreted by LLPCs. When these are not sufficient for immediate pathogen neutralization and elimination, memory B cells are recalled."
57) SARS-CoV-2 specific memory B-cells from individuals with diverse disease severities recognize SARS-CoV-2 variants of concern, Lyski, 2021 https://www.medrxiv.org/content/10.1101/2021.05.28.21258025v1.full Published in a PrePrint Server	"Examined the magnitude, breadth, and durability of SARS-CoV-2 specific antibodies in two distinct B-cell compartments: long-lived plasma cell-derived antibodies in the plasma, and peripheral memory B-cells along with their associated antibody profiles elicited after ***in vitro*** stimulation. We found that magnitude varied amongst individuals, but was the highest in hospitalized subjects. Variants of concern (VoC) -RBD-reactive antibodies were found in the plasma of 72% of samples in this investigation, and VoC-RBD-reactive memory B-cells were found in all but 1 subject at a single time-point. This finding, that VoC-RBD-

	reactive MBCs are present in the peripheral blood of all subjects including those that experienced asymptomatic or mild disease, provides a reason for optimism regarding the capacity of vaccination, prior infection, and/or both, to limit disease severity and transmission of variants of concern as they continue to arise and circulate."
58) **Exposure to SARS-CoV-2 generates T-cell memory in the absence of a detectable viral infection**, Wang, 2021 https://www.nature.com/articles/s41467-021-22036-z Published in Peer-Reviewed Science Journal Nature	"T-cell immunity is important for recovery from COVID-19 and provides heightened immunity for re-infection. However, little is known about the SARS-CoV-2-specific T-cell immunity in virus-exposed individuals…report virus-specific CD4+ and CD8+ T-cell memory in recovered COVID-19 patients and close contacts…close contacts are able to gain T-cell immunity against SARS-CoV-2 despite lacking a detectable infection."
59) **CD8+ T-Cell Responses in**	"The CD4 and CD8 responses

COVID-19 Convalescent Individuals Target Conserved Epitopes From Multiple Prominent SARS-CoV-2 Circulating Variants, Redd, 2021and Lee, 2021 **https://academic.oup.com/ofid/article/8/7/ofab143/6189113** Published in Peer-Reviewed Science Journal Open Forum Infectious Diseases NOTARY M. M. PABALE Mumbai Maharashtra Reg. No. 15220 Exp. Dt. 30-10-2026 GOVT. OF INDIA	generated after natural infection are equally robust, showing activity against multiple "epitopes" (little segments) of the spike protein of the virus. For instance, CD8 cells responds to 52 epitopes and CD4 cells respond to 57 epitopes across the spike protein, so that a few mutations in the variants cannot knock out such a robust and in-breadth T cell response...only 1 mutation found in Beta variant-spike overlapped with a previously identified epitope (1/52), suggesting that virtually all anti-SARS-CoV-2 CD8+ T-cell responses should recognize these newly described variants."
60) **Exposure to common cold coronaviruses can teach the immune system to recognize SARS-CoV-2**,La Jolla, Crotty and Sette, 2020 **https://www.lji.org/news-events/news/post/exposure-to-common-cold-coronaviruses-can-**	"Exposure to common cold coronaviruses can teach the immune system to recognize SARS-CoV-2"

1548

~~400~~

teach-the-immune-system-to-recognize-sars-cov-2/ Published by La Jolla Institute for Immunology	
61) **Selective and cross-reactive SARS-CoV-2 T cell epitopes in unexposed humans**, Mateus, 2020 https://www.science.org/doi/10.1126/science.abd3871 Published in Peer-Reviewed Science Journal Science	"Found that the pre-existing reactivity against SARS-CoV-2 comes from memory T cells and that cross-reactive T cells can specifically recognize a SARS-CoV-2 epitope as well as the homologous epitope from a common cold coronavirus. These findings underline the importance of determining the impacts of pre-existing immune memory in COVID-19 disease severity."
62) **Longitudinal observation of antibody responses for 14 months after SARS-CoV-2 infection**, Dehgani-Mobaraki, 2021 **https://www.sciencedirect.com/science/article/pii/S1521661621001510**	"Better understanding of antibody responses against SARS-CoV-2 after natural infection might provide valuable insights into the future implementation of vaccination policies. Longitudinal analysis of IgG antibody titers was carried out in 32 recovered COVID-19 patients based in the Umbria region

Published in Peer-Reviewed Science Journal Clinical Immunology	of Italy for 14 months after Mild and Moderately-Severe infection…study findings are consistent with recent studies reporting antibody persistency suggesting that induced SARS-CoV-2 immunity through natural infection, might be very efficacious against re-infection (>90%) and could persist for more than six months. Our study followed up patients up to 14 months demonstrating the presence of anti-S-RBD IgG in 96.8% of recovered COVID-19 subjects."
63) **Humoral and circulating follicular helper T cell responses in recovered patients with COVID-19**, Juno, 2020 https://www.nature.com/articles/s41591-020-0995-0 Published in Peer-Reviewed Science Journal Nature	"Characterized humoral and circulating follicular helper T cell (cTFH) immunity against spike in recovered patients with coronavirus disease 2019 (COVID-19). We found that S-specific antibodies, memory B cells and cTFH are consistently elicited after SARS-CoV-2 infection, demarking robust humoral immunity and positively associated with plasma neutralizing activity."

1556

~~402~~

64) **Convergent antibody responses to SARS-CoV-2 in convalescent individuals**, Robbiani, 2020 https://www.nature.com/articles/s41586-020-2456-9 Published in Peer-Reviewed Science Journal Nature	"149 COVID-19-convalescent individuals…antibody sequencing revealed the expansion of clones of RBD-specific memory B cells that expressed closely related antibodies in different individuals. Despite low plasma titres, antibodies to three distinct epitopes on the RBD neutralized the virus with half-maximal inhibitory concentrations (IC50 values) as low as 2 ng ml−1."
65) **Rapid generation of durable B cell memory to SARS-CoV-2 spike and nucleocapsid proteins in COVID-19 and convalescence**, Hartley, 2020 https://www.science.org/doi/10.1126/sciimmunol.abf8891 Published in Peer-Reviewed Science Journal Science	"COVID-19 patients rapidly generate B cell memory to both the spike and nucleocapsid antigens following SARS-CoV-2 infection…RBD- and NCP-specific IgG and Bmem cells were detected in all 25 patients with a history of COVID-19"
66) **Had COVID? You'll probably make antibodies for a lifetime**, Callaway, 2021	"People who recover from mild COVID-19 have bone-marrow cells that can churn out antibodies for decades…the study provides

NOTARY M. M. PABALE Mumbai Maharashtra Reg. No. 15228 Expiry Dt. 30-10-2024 GOVT. OF INDIA

https://www.nature.com/articles/d41586-021-01442-9 Published in Peer-Reviewed Science Journal Nature	evidence that immunity triggered by SARS-CoV-2 infection will be extraordinarily long-lasting."
67) **A majority of uninfected adults show preexisting antibody reactivity against SARS-CoV-2**, Majdoubi, 2021 **https://insight.jci.org/articles/view/146316** Published in JCI Insight	In greater Vancouver Canada, "using a highly sensitive multiplex assay and positive/negative thresholds established in infants in whom maternal antibodies have waned, we determined that more than 90% of uninfected adults showed antibody reactivity against the spike protein, receptor-binding domain (RBD), N-terminal domain (NTD), or the nucleocapsid (N) protein from SARS-CoV-2."
68) **SARS-CoV-2-reactive T cells in healthy donors and patients with COVID-19**, Braun, 2020 **Presence of SARS-CoV-2-reactive T cells in COVID-19 patients and healthy donors**, Braun, 2020 https://www.nature.com/articles/s41586-020-2598-9	"The results indicate that spike-protein cross-reactive T cells are present, which were probably generated during previous encounters with endemic coronaviruses." "The presence of pre-existing SARS-CoV-2-reactive T cells in a

NOTARY
M. M. PABALE
Mumbai
Maharashtra
Reg. No. 15220
Expiry Dt.
30-10-2024

https://www.medrxiv.org/content/10.1101/2020.04.17.20061440v1 Published in Peer-Reviewed Science Journal Nature	subset of SARS-CoV-2 naïve HD is of high interest."
69) **Naturally enhanced neutralizing breadth against SARS-CoV-2 one year after infection**, Wang, 2021 https://www.nature.com/articles/s41586-021-03696-9 Published in Peer-Reviewed Science Journal Nature	"A cohort of 63 individuals who have recovered from COVID-19 assessed at 1.3, 6.2 and 12 months after SARS-CoV-2 infection…the data suggest that immunity in convalescent individuals will be very long lasting."
70) **One Year after Mild COVID-19: The Majority of Patients Maintain Specific Immunity, But One in Four Still Suffer from Long-Term Symptoms**, Rank, 2021 **https://pubmed.ncbi.nlm.nih.gov/34362088/** Published in Peer-Reviewed	"Long-lasting immunological memory against SARS-CoV-2 after mild COVID-19… activation-induced marker assays identified specific T-helper cells and central memory T-cells in 80% of participants at a 12-month follow-up."

NOTARY M. M. PABALE Mumbai Maharashtra Reg. No. 15220 Expiry Dt. 30-10-2024 GOVT. OF INDIA

Science Journal, Journal of Clinical Medicine	
71) IDSA, 2021 https://www.idsociety.org/globalassets/idsa/media/clinician-call-slides--qa/07-17-21-clinician-call-slides-1.pdf	"Immune responses to SARS-CoV-2 following natural infection can persist for at least 11 months... natural infection (as determined by a prior positive antibody or PCR-test result) can confer protection against SARS-CoV-2 infection."
72) Assessment of protection against reinfection with SARS-CoV-2 among 4 million PCR-tested individuals in Denmark in 2020: a population-level observational study, Holm Hansen, 2021 https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(21)00575-4/fulltext Published in Peer-Reviewed Science Journal Lancet	Denmark, "during the first surge (ie, before June, 2020), 533 381 people were tested, of whom 11 727 (2·20%) were PCR positive, and 525 339 were eligible for follow-up in the second surge, of whom 11 068 (2·11%) had tested positive during the first surge. Among eligible PCR-positive individuals from the first surge of the epidemic, 72 (0·65% [95% CI 0·51–0·82]) tested positive again during the second surge compared with 16 819 (3·27% [3·22–3·32]) of 514 271 who tested negative during the first surge (adjusted RR 0·195 [95% CI 0·155–0·246])."

NOTARY
M. M. PARALE
Mumbai
Maharashtra
Reg. No. 15220
Expiry Dt.
30-10-2024
GOVT. OF INDIA

1554
406

73) **Antigen-Specific Adaptive Immunity to SARS-CoV-2 in Acute COVID-19 and Associations with Age and Disease Severity**, Moderbacher, 2020 https://www.cell.com/cell/fulltext/S0092-8674(20)31235-6?_returnURL=https://linkinghub.elsevier.com/retrieve/pii/S0092867420312356?showall=true Published in Peer-Reviewed Science Journal Cell	"Adaptive immune responses limit COVID-19 disease severity…multiple coordinated arms of adaptive immunity control better than partial responses…completed a combined examination of all three branches of adaptive immunity at the level of SARS-CoV-2-specific CD4+ and CD8+ T cell and neutralizing antibody responses in acute and convalescent subjects. SARS-CoV-2-specific CD4+ and CD8+ T cells were each associated with milder disease. Coordinated SARS-CoV-2-specific adaptive immune responses were associated with milder disease, suggesting roles for both CD4+ and CD8+ T cells in protective immunity in COVID-19."
74) **Detection of SARS-CoV-2-Specific Humoral and Cellular Immunity in COVID-19 Convalescent Individuals**, Ni, 2020 https://www.cell.com/immunity/full	"Collected blood from COVID-19 patients who have recently become virus-free, and therefore were discharged, and detected SARS-CoV-2-specific humoral and cellular immunity in eight newly discharged patients. Follow-up analysis on

text/S1074-7613(20)30181-3?_returnURL=https://linkinghub.elsevier.com/retrieve/pii/S1074761320301813?showall=true Published in Peer-Reviewed Science Journal Cell	another cohort of six patients 2 weeks post discharge also revealed high titers of immunoglobulin G (IgG) antibodies. In all 14 patients tested, 13 displayed serum-neutralizing activities in a pseudotype entry assay. Notably, there was a strong correlation between neutralization antibody titers and the numbers of virus-specific T cells."
75) **Robust SARS-CoV-2-specific T-cell immunity is maintained at 6 months following primary infection**, Zuo, 2020 https://www.biorxiv.org/content/10.1101/2020.11.01.362319v1 Published in a PrePrint Server	"Analysed the magnitude and phenotype of the SARS-CoV-2 cellular immune response in 100 donors at six months following primary infection and related this to the profile of antibody level against spike, nucleoprotein and RBD over the previous six months. T-cell immune responses to SARS-CoV-2 were present by ELISPOT and/or ICS analysis in all donors and are characterised by predominant CD4+ T cell responses with strong IL-2 cytokine expression... functional SARS-CoV-2-specific T-cell responses are retained at six months

NOTARY
M. M. PABALE
Mumbai
Maharashtra
Reg. No. 15220
Expiry Dt.
10-2024
INDIA

1556
~~408~~

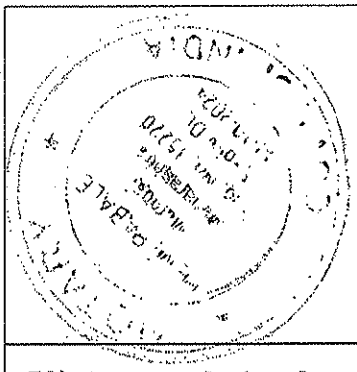
	following infection."
76) **Negligible impact of SARS-CoV-2 variants on CD4+ and CD8+ T cell reactivity in COVID-19 exposed donors and vaccinees**, Tarke, 2021 https://www.biorxiv.org/content/10.1101/2021.02.27.433180v1 Published in a PrePrint Server	"Performed a comprehensive analysis of SARS-CoV-2-specific CD4+ and CD8+ T cell responses from COVID-19 convalescent subjects recognizing the ancestral strain, compared to variant lineages B.1.1.7, B.1.351, P.1, and CAL.20C as well as recipients of the Moderna (mRNA-1273) or Pfizer/BioNTech (BNT162b2) COVID-19 vaccines… the sequences of the vast majority of SARS-CoV-2 T cell epitopes are not affected by the mutations found in the variants analyzed. Overall, the results demonstrate that CD4+ and CD8+ T cell responses in convalescent COVID-19 subjects or COVID-19 mRNA vaccinees are not substantially affected by mutations."
77) **A 1 to 1000 SARS-CoV-2 reinfection proportion in members of a large healthcare provider in Israel: a preliminary report**, Perez, 2021	Israel, "out of 149,735 individuals with a documented positive PCR test between March 2020 and January 2021, 154 had two positive PCR tests at least 100 days apart, reflecting a reinfection proportion of

https://www.medrxiv.org/content/10.1101/2021.03.06.21253051v1 Published in a PrePrint Server	1 per 1000."
78) **Persistence and decay of human antibody responses to the receptor binding domain of SARS-CoV-2 spike protein in COVID-19 patients**, Iyer, 2020 https://www.science.org/doi/10.1126/sciimmunol.abe0367 Published in Peer-Reviewed Science Journal Science	"Measured plasma and/or serum antibody responses to the receptor-binding domain (RBD) of the spike (S) protein of SARS-CoV-2 in 343 North American patients infected with SARS-CoV-2 (of which 93% required hospitalization) up to 122 days after symptom onset and compared them to responses in 1548 individuals whose blood samples were obtained prior to the pandemic…IgG antibodies persisted at detectable levels in patients beyond 90 days after symptom onset, and seroreversion was only observed in a small percentage of individuals. The concentration of these anti-RBD IgG antibodies was also highly correlated with pseudovirus NAb titers, which also demonstrated minimal decay. The observation that IgG and

NOTARY
M. M. PABALE
Mumbai
Maharashtra
Reg. No. 15220
Expiry Dt.
31-10-2024
GOVT. OF INDIA

1558

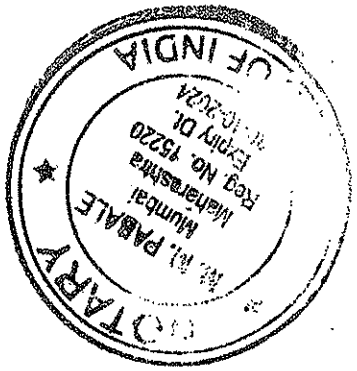
~~410~~

	neutralizing antibody responses persist is encouraging, and suggests the development of robust systemic immune memory in individuals with severe infection."
79) **A population-based analysis of the longevity of SARS-CoV-2 antibody seropositivity in the United States**, Alfego, 2021 https://www.thelancet.com/action/showPdf?pii=S2589-5370(21)00182-6 Published in Peer-Reviewed Science Journal Lancet	"To track population-based SARS-CoV-2 antibody seropositivity duration across the United States using observational data from a national clinical laboratory registry of patients tested by nucleic acid amplification (NAAT) and serologic assays… specimens from 39,086 individuals with confirmed positive COVID-19…both S and N SARS-CoV-2 antibody results offer an encouraging view of how long humans may have protective antibodies against COVID-19, with curve smoothing showing population seropositivity reaching 90% within three weeks, regardless of whether the assay detects N or S-antibodies. Most importantly, this level of seropositivity was sustained with little decay through ten months after initial positive PCR."

80) <u>What are the roles of antibodies versus a durable, high-quality T-cell response in protective immunity against SARS-CoV-2?</u> Hellerstein, 2020 <u>https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7452821/</u> Published in Peer-Reviewed Science Journal Vaccine X	"Progress in laboratory markers for SARS-CoV2 has been made with identification of epitopes on CD4 and CD8 T-cells in convalescent blood. These are much less dominated by spike protein than in previous coronavirus infections. Although most vaccine candidates are focusing on spike protein as antigen, natural infection by SARS-CoV-2 induces broad epitope coverage, cross-reactive with other betacoronviruses."
81) <u>Broad and strong memory CD4+ and CD8+ T cells induced by SARS-CoV-2 in UK convalescent COVID-19 patients,</u> Peng, 2020 <u>https://www.biorxiv.org/content/10.1101/2020.06.05.134551v1</u> Published in a PrePrint Server	"Study of 42 patients following recovery from COVID-19, including 28 mild and 14 severe cases, comparing their T cell responses to those of 16 control donors…found the breadth, magnitude and frequency of memory T cell responses from COVID-19 were significantly higher in severe compared to mild COVID-19 cases, and this effect was most marked in response to spike, membrane, and ORF3a proteins…total and spike-specific T cell responses correlated

1560

~~412~~

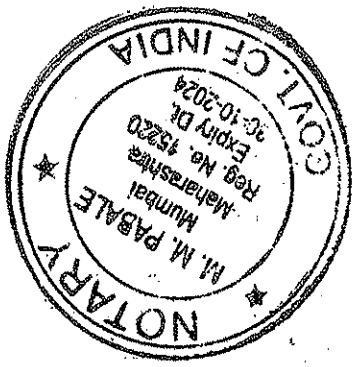
	with the anti-Spike, anti-Receptor Binding Domain (RBD) as well as anti-Nucleoprotein (NP) endpoint antibody titre…furthermore showed a higher ratio of SARS-CoV-2-specific CD8+ to CD4+ T cell responses…immunodominant epitope clusters and peptides containing T cell epitopes identified in this study will provide critical tools to study the role of virus-specific T cells in control and resolution of SARS-CoV-2 infections."
82) **Robust T Cell Immunity in Convalescent Individuals with Asymptomatic or Mild COVID-19**, Sekine, 2020 **https://pubmed.ncbi.nlm.nih.gov/32979941/** Published in Peer-Reviewed Science Journal Cell	"SARS-CoV-2-specific memory T cells will likely prove critical for long-term immune protection against COVID-19…mapped the functional and phenotypic landscape of SARS-CoV-2-specific T cell responses in unexposed individuals, exposed family members, and individuals with acute or convalescent COVID-19…collective dataset shows that SARS-CoV-2 elicits broadly directed and functionally replete memory T cell

	responses, suggesting that natural exposure or infection may prevent recurrent episodes of severe COVID-19."
83) **Potent SARS-CoV-2-Specific T Cell Immunity and Low Anaphylatoxin Levels Correlate With Mild Disease Progression in COVID-19 Patients**, Lafron, 2021 https://www.frontiersin.org/articles/10.3389/fimmu.2021.684014/full Published in Peer-Reviewed Science Journal Frontiers in Immunology	"Provide a full picture of cellular and humoral immune responses of COVID-19 patients and prove that robust polyfunctional CD8+ T cell responses concomitant with low anaphylatoxin levels correlate with mild infections."
84) **SARS-CoV-2 T-cell epitopes define heterologous and COVID-19 induced T-cell recognition**, Nelde, 2020 **https://www.researchsquare.com/article/rs-35331/v1** Published in a PrePrint Server	"The first work identifying and characterizing SARS-CoV-2-specific and cross-reactive HLA class I and HLA-DR T-cell epitopes in SARS-CoV-2 convalescents (n = 180) as well as unexposed individuals (n = 185) and confirming their relevance for immunity and COVID-19 disease course…cross-reactive SARS-CoV-2 T-cell

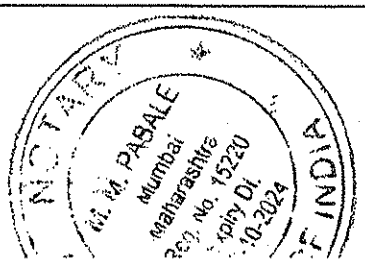
NOTARY Mumbai Maharashtra GOVT. OF INDIA

1562

414

	epitopes revealed pre-existing T-cell responses in 81% of unexposed individuals, and validation of similarity to common cold human coronaviruses provided a functional basis for postulated heterologous immunity in SARS-CoV-2 infection…intensity of T-cell responses and recognition rate of T-cell epitopes was significantly higher in the convalescent donors compared to unexposed individuals, suggesting that not only expansion, but also diversity spread of SARS-CoV-2 T-cell responses occur upon active infection."
85) **Karl Friston: up to 80% not even susceptible to Covid-19**, Sayers, 2020 **https://unherd.com/2020/06/karl-friston-up-to-80-not-even-susceptible-to-covid-19/** Article by Academic Freddie Sayers	"Results have just been published of a study suggesting that 40%-60% of people who have not been exposed to coronavirus have resistance at the T-cell level from other similar coronaviruses like the common cold…the true portion of people who are not even susceptible to Covid-19 may be as high as 80%."
86) **CD8+ T cells specific for an**	"Screening of SARS-CoV-2 peptide

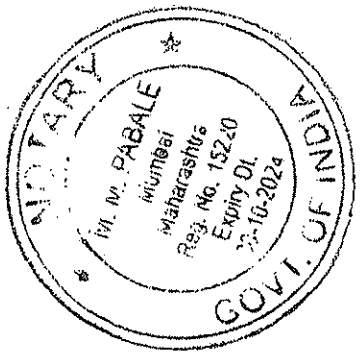
immunodominant SARS-CoV-2 nucleocapsid epitope cross-react with selective seasonal coronaviruses, Lineburg, 2021 https://www.cell.com/immunity/fulltext/S1074-7613(21)00168-0 Published in Peer-Reviewed Science Journal Cell	pools revealed that the nucleocapsid (N) protein induced an immunodominant response in HLA-B7+ COVID-19-recovered individuals that was also detectable in unexposed donors…the basis of selective T cell cross-reactivity for an immunodominant SARS-CoV-2 epitope and its homologs from seasonal coronaviruses, suggesting long-lasting protective immunity."
87) **SARS-CoV-2 genome-wide mapping of CD8 T cell recognition reveals strong immunodominance and substantial CD8 T cell activation in COVID-19 patients**, Saini, 2020 https://www.biorxiv.org/content/10.1101/2020.10.19.344911v1?rss=1 Published in a PrePrint Server	"COVID-19 patients showed strong T cell responses, with up to 25% of all CD8+ lymphocytes specific to SARS-CoV-2-derived immunodominant epitopes, derived from ORF1 (open reading frame 1), ORF3, and Nucleocapsid (N) protein. A strong signature of T cell activation was observed in COVID-19 patients, while no T cell activation was seen in the 'non-exposed' and 'high exposure risk' healthy donors."
88) **Equivalency of Protection from Natural Immunity in**	"Systematic review and pooled analysis of clinical studies to date,



1564

~~416~~

COVID-19 Recovered Versus Fully Vaccinated Persons: A Systematic Review and Pooled Analysis, Shenai, 2021 https://www.medrxiv.org/content/10.1101/2021.09.12.21263461v1 Published in a PrePrint Server  	that (1) specifically compare the protection of natural immunity in the COVID-recovered versus the efficacy of full vaccination in the COVID-naive, and (2) the added benefit of vaccination in the COVID-recovered, for prevention of subsequent SARS-CoV-2 infection…review demonstrates that natural immunity in COVID-recovered individuals is, at least, equivalent to the protection afforded by full vaccination of COVID-naïve populations. There is a modest and incremental relative benefit to vaccination in COVID-recovered individuals; however, the net benefit is marginal on an absolute basis."
89) **ChAdOx1nCoV-19 effectiveness during an unprecedented surge in SARS CoV-2 infections**, Satwik, 2021 **https://www.ejinme.com/article/S0953-6205(21)00271-5/fulltext** Published in Peer-Reviewed	"The third key finding is that previous infections with SARS-CoV-2 were significantly protective against all studied outcomes, with an effectiveness of 93% (87 to 96%) seen against symptomatic infections, 89% (57 to 97%) against moderate to severe disease and 85% (-9 to 98%) against supplemental oxygen

Science Journal, European Journal of Internal Medicine	therapy. All deaths occurred in previously uninfected individuals. This was higher protection than that offered by single or double dose vaccine."
90) <u>SARS-CoV-2 specific T cells and antibodies in COVID-19 protection: a prospective study,</u> Molodtsov, 2021 <u>https://www.medrxiv.org/content/10.1101/2021.08.19.21262278v2</u> Published in a PrePrint Server 	"Explore the impact of T cells and to quantify the protective levels of the immune responses…5,340 Moscow residents were evaluated for the antibody and cellular immune responses to SARS-CoV-2 and monitored for COVID-19 up to 300 days. The antibody and cellular responses were tightly interconnected, their magnitude inversely correlated with infection probability. Similar maximal level of protection was reached by individuals positive for both types of responses and by individuals with antibodies alone…T cells in the absence of antibodies provided an intermediate level of protection."
91) <u>Anti- SARS-CoV-2 Receptor Binding Domain Antibody Evolution after mRNA</u>	"SARS-CoV-2 infection produces B-cell responses that continue to evolve for at least one year. During

1566

~~418~~

Vaccination, Cho, 2021 https://www.biorxiv.org/content/10.1101/2021.07.29.454333v2.full Published in a PrePrint Server	that time, memory B cells express increasingly broad and potent antibodies that are resistant to mutations found in variants of concern."
92) **Seven-month kinetics of SARS-CoV-2 antibodies and role of pre-existing antibodies to human coronaviruses**, Ortega, 2021 **https://www.nature.com/articles/s41467-021-24979-9** Published in Peer-Reviewed Science Journal Nature	"Impact of pre-existing antibodies to human coronaviruses causing common cold (HCoVs), is essential to understand protective immunity to COVID-19 and devise effective surveillance strategies…after the peak response, anti-spike antibody levels increase from ~150 days post-symptom onset in all individuals (73% for IgG), in the absence of any evidence of re-exposure. IgG and IgA to HCoV are significantly higher in asymptomatic than symptomatic seropositive individuals. Thus, pre-existing cross-reactive HCoVs antibodies could have a protective effect against SARS-CoV-2 infection and COVID-19 disease."



93) **Immunodominant T-cell epitopes from the SARS-CoV-2 spike antigen reveal robust pre-existing T-cell immunity in unexposed individuals**, Mahajan, 2021 https://www.nature.com/articles/s41598-021-92521-4 Published in Peer-Reviewed Science Journal Nature	"Findings suggest that SARS-CoV-2 reactive T-cells are likely to be present in many individuals because of prior exposure to flu and CMV viruses."
94) **Neutralizing Antibody Responses to Severe Acute Respiratory Syndrome Coronavirus 2 in Coronavirus Disease 2019 Inpatients and Convalescent Patients**, Wang, 2020 **https://academic.oup.com/cid/article/71/10/2688/5851474** Published in Peer-Reviewed Science Journal Clinical Infectious Diseases	"117 blood samples were collected from 70 COVID-19 inpatients and convalescent patients…the neutralizing antibodies were detected even at the early stage of disease, and a significant response was shown in convalescent patients."
95) **Not just antibodies: B cells and T cells mediate immunity to**	"Reports that antibodies to SARS-CoV-2 are not maintained in the

1568
~~420~~

COVID-19, Cox, 2020 **https://pubmed.ncbi.nlm.nih.gov/32839569/** Published in Peer-Reviewed Science Journal Nature	serum following recovery from the virus have caused alarm…the absence of specific antibodies in the serum does not necessarily mean an absence of immune memory."
96) **T cell immunity to SARS-CoV-2 following natural infection and vaccination**, DiPiazza, 2020 **https://www.ncbi.nlm.nih.gov/labs/pmc/articles/PMC7584424/** Published in Peer-Reviewed Science Journal Biochem Biophys Res Comm.	"Although T cell durability to SARS-CoV-2 remains to be determined, current data and past experience from human infection with other CoVs demonstrate the potential for persistence and the capacity to control viral replication and host disease, and importance in vaccine-induced protection."
97) **Durable SARS-CoV-2 B cell immunity after mild or severe disease**, Ogega, 2021 **https://pubmed.ncbi.nlm.nih.gov/33571162/** Published in Peer-Reviewed Science Journal, Journal of Clinical	"Multiple studies have shown loss of severe acute respiratory syndrome coronavirus 2-specific (SARS-CoV-2-specific) antibodies over time after infection, raising concern that humoral immunity against the virus is not durable. If immunity wanes quickly, millions of people may be at risk for reinfection after recovery

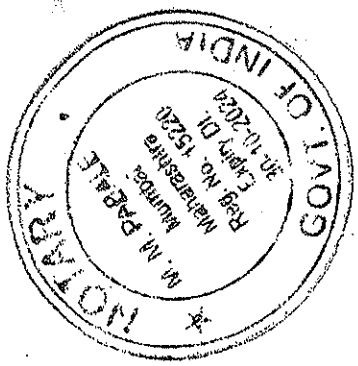
Investigation 	from coronavirus disease 2019 (COVID-19). However, memory B cells (MBCs) could provide durable humoral immunity even if serum neutralizing antibody titers decline… data indicate that most SARS-CoV-2-infected individuals develop S-RBD-specific, class-switched rMBCs that resemble germinal center-derived B cells induced by effective vaccination against other pathogens, providing evidence for durable B cell-mediated immunity against SARS-CoV-2 after mild or severe disease."
98) **Memory T cell responses targeting the SARS coronavirus persist up to 11 years post-infection.**, Ng, 2016 **https://pubmed.ncbi.nlm.nih.gov/26954467/** Published in Peer-Reviewed Science Journal Vaccine	"All memory T cell responses detected target the SARS-Co-V structural proteins… these responses were found to persist up to 11 years post-infection… knowledge of the persistence of SARS-specific cellular immunity targeting the viral structural proteins in SARS-recovered individuals is important."
99) **Adaptive immunity to SARS-**	"The adaptive immune system is

1570

~~422~~

CoV-2 and COVID-19, Sette, 2021 https://www.cell.com/cell/pdf/S0092-8674(21)00007-6.pdf Published in Peer-Reviewed Science Journal Cell	important for control of most viral infections. The three fundamental components of the adaptive immune system are B cells (the source of antibodies), CD4+ T cells, and CD8+ T cells…a picture has begun to emerge that reveals that CD4+ T cells, CD8+ T cells, and neutralizing antibodies all contribute to control of SARS-CoV-2 in both non-hospitalized and hospitalized cases of COVID-19."
100) **Early induction of functional SARS-CoV-2-specific T cells associates with rapid viral clearance and mild disease in COVID-19 patients**, Tan, 2021 **https://www.sciencedirect.com/science/article/pii/S2211124721000413** Published in Peer-Reviewed Science Journal Cell	"These findings provide support for the prognostic value of early functional SARS-CoV-2-specific T cells with important implications in vaccine design and immune monitoring."
101) **SARS-CoV-2–specific CD8+ T cell responses in convalescent COVID-19 individuals**, Kared,	"A multiplexed peptide-MHC tetramer approach was used to screen 408 SARS-CoV-2 candidate

NOTARY
M. M. PADALE
Mumbai
Maharashtra
Reg. No. 15220
Expiry Dt.
30-10-2024
GOVT. OF INDIA

2021 **https://www.jci.org/articles/view/145476** Published in Peer-Reviewed Science Journal Journal of Clinical Investigation 	epitopes for CD8+ T cell recognition in a cross-sectional sample of 30 coronavirus disease 2019 convalescent individuals…Modelling demonstrated a coordinated and dynamic immune response characterized by a decrease in inflammation, increase in neutralizing antibody titer, and differentiation of a specific CD8+ T cell response. Overall, T cells exhibited distinct differentiation into stem cell and transitional memory states (subsets), which may be key to developing durable protection."
102) **S Protein-Reactive IgG and Memory B Cell Production after Human SARS-CoV-2 Infection Includes Broad Reactivity to the S2 Subunit**, Nguyen-Contant, 2021 **https://pubmed.ncbi.nlm.nih.gov/32978311/** Published in Peer-Reviewed Science Journal American Society	"Most importantly, we demonstrate that infection generates both IgG and IgG MBCs against the novel receptor binding domain and the conserved S2 subunit of the SARS-CoV-2 spike protein. Thus, even if antibody levels wane, long-lived MBCs remain to mediate rapid antibody production. Our study results also suggest that SARS-CoV-2 infection strengthens pre-existing

1572

~~424~~

for Microbiology	broad coronavirus protection through S2-reactive antibody and MBC formation."
103) **Persistence of Antibody and Cellular Immune Responses in Coronavirus Disease 2019 Patients Over Nine Months After Infection**, Yao, 2021 **https://pubmed.ncbi.nlm.nih.gov/33978754/** Published in Peer-Reviewed Science Journal, The Journal of Infectious Diseases	"A cross-sectional study to assess the virus-specific antibody and memory T and B cell responses in coronavirus disease 2019 (COVID-19) patients up to 343 days after infection…found that approximately 90% of patients still have detectable immunoglobulin (Ig)G antibodies against spike and nucleocapsid proteins and neutralizing antibodies against pseudovirus, whereas ~60% of patients had detectable IgG antibodies against receptor-binding domain and surrogate virus-neutralizing antibodies…SARS-CoV-2-specific IgG+ memory B cell and interferon-γ-secreting T cell responses were detectable in more than 70% of patients…coronavirus 2-specific immune memory response persists in most patients approximately 1 year after infection, which provides a promising sign for prevention from reinfection and

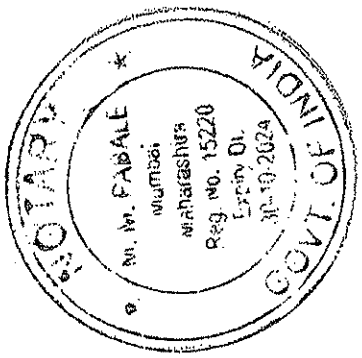
GOVT. OF INDIA
M. M. FABALE
Mumbai
Maharashtra
Reg. No. 15220
Expiry Dt.
30-10-2024
NOTARY

	vaccination strategy."
104) **Naturally Acquired SARS-CoV-2 Immunity Persists for Up to 11 Months Following Infection**, De Giorgi, 2021 **https://pubmed.ncbi.nlm.nih.gov/34089610/** Published in Peer-Reviewed Science Journal, The Journal of Infectious Diseases	"A prospective, longitudinal analysis of COVID-19 convalescent plasma donors at multiple time points over an 11-month period to determine how circulating antibody levels change over time following natural infection… data suggest that immunological memory is acquired in most individuals infected with SARS-CoV-2 and is sustained in a majority of patients."
105) **Decreasing Seroprevalence of Measles Antibodies after Vaccination – Possible Gap in Measles Protection in Adults in the Czech Republic**, Smetana, 2017 **https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0170257** Published in Peer-Reviewed Science Journal PlosOne	"A long-term high rate of seropositivity persists after natural measles infection. By contrast, it decreases over time after vaccination. Similarly, the concentrations of antibodies in persons with measles history persist for a longer time at a higher level than in vaccinated persons."
106) **Broadly cross-reactive**	"The expansion of these rare types

NOTARY GOVT. OF INDIA
Dr. M. PABALE
Mumbai
Maharashtra
Reg. No. 15220
Expiry Dt.
30-10-2024

1574
426

antibodies dominate the human B cell response against 2009 pandemic H1N1 influenza virus infection, Wrammert, 2011 **https://pubmed.ncbi.nlm.nih.gov/21220454/** Published in Peer-Reviewed Science Journal, Journal of Experimental Medicine  	of memory B cells may explain why most people did not become severely ill, even in the absence of pre-existing protective antibody titers"…found "extraordinarily" powerful antibodies in the blood of nine people who caught the swine flu naturally and recovered from it."…unlike antibodies elicited by annual influenza vaccinations, most neutralizing antibodies induced by pandemic H1N1 infection were broadly cross-reactive against epitopes in the hemagglutinin (HA) stalk and head domain of multiple influenza strains. The antibodies were from cells that had undergone extensive affinity maturation."
107) **Reinfection With Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) in Patients Undergoing Serial Laboratory Testing**, Qureshi, 2021 **https://academic.oup.com/cid/advance-article/doi/10.1093/cid/ciab345/62**	"Reinfection was identified in 0.7% (n = 63, 95% confidence interval [CI]: .5%–.9%) during follow-up of 9119 patients with SARS-CoV-2 infection."

51701 Published in Peer-Reviewed Science Journal Clinical Infectious Diseases	
108) **Distinct antibody and memory B cell responses in SARS-CoV-2 naïve and recovered individuals following mRNA vaccination**, Goel, 2021 **https://pubmed.ncbi.nlm.nih.gov/33858945/** Published in Peer-Reviewed Science Journal Science Immunology 	"Interrogated antibody and antigen-specific memory B cells over time in 33 SARS-CoV-2 naïve and 11 SARS-CoV-2 recovered subjects… In SARS-CoV-2 recovered individuals, antibody and memory B cell responses were significantly boosted after the first vaccine dose; however, there was no increase in circulating antibodies, neutralizing titers, or antigen-specific memory B cells after the second dose. This robust boosting after the first vaccine dose strongly correlated with levels of pre-existing memory B cells in recovered individuals, identifying a key role for memory B cells in mounting recall responses to SARS-CoV-2 antigens."
109) **Covid-19: Do many people have pre-existing immunity?** Doshi, 2020	"Six studies have reported T cell reactivity against SARS-CoV-2 in 20% to 50% of people with no

https://pubmed.ncbi.nlm.nih.gov/32943427/ Published in Peer-Reviewed Science Journal, British Medical Journal	known exposure to the virus... in a study of donor blood specimens obtained in the US between 2015 and 2018, 50% displayed various forms of T cell reactivity to SARS-CoV-2... Researchers are also confident that they have made solid inroads into ascertaining the origins of the immune responses. "Our hypothesis, of course, was that it's so called 'common cold' coronaviruses, because they're closely related...we have really shown that this is a true immune memory and it is derived in part from common cold viruses."
110) **Pre-existing and de novo humoral immunity to SARS-CoV-2 in humans**, Ng, 2020 https://www.biorxiv.org/content/10.1101/2020.05.14.095414v2?ijkey=dfcf42f2081abdbd0dc04cb0a20465344e2f9169&keytype2=tf_ipsecsha Published in a PrePrint Server	"We demonstrate the presence of pre-existing humoral immunity in uninfected and unexposed humans to the new coronavirus. SARS-CoV-2 S-reactive antibodies were readily detectable by a sensitive flow cytometry-based method in SARS-CoV-2-uninfected individuals and were particularly prevalent in children and adolescents."

NOTARY
M. M. PADALE
Mumbai
Maharashtra
Reg. No. 15226
Expiry Dt.
30-10-2024
GOVT. OF INDIA

111) **Phenotype of SARS-CoV-2-specific T-cells in COVID-19 patients with acute respiratory distress syndrome**, Weiskopf, 2020 https://www.medrxiv.org/content/10.1101/2020.04.11.20062349v2?ijkey=747f090d21ac4834150ea548be0f6628059c1053&keytype2=tf_ipsecsha Published in a PrePrint Server	"We detected SARS-CoV-2-specific CD4+ and CD8+ T cells in 100% and 80% of COVID-19 patients, respectively. We also detected low levels of SARS-CoV-2-reactive T-cells in 20% of the healthy controls, not previously exposed to SARS-CoV-2 and indicative of cross-reactivity due to infection with 'common cold' coronaviruses."
112) **Pre-existing immunity to SARS-CoV-2: the knowns and unknowns**, Sette, 2020 **https://pubmed.ncbi.nlm.nih.gov/32636479/** Published in Peer-Reviewed Science Journal Nature	"T cell reactivity against SARS-CoV-2 was observed in unexposed people…it is speculated that this reflects T cell memory to circulating 'common cold' coronaviruses."
113) **Pre-existing immunity against swine-origin H1N1 influenza viruses in the general human population**, Greenbaum, 2009	"Memory T-cell immunity against S-OIV is present in the adult population and that such memory is of similar magnitude as the pre-existing memory against seasonal H1N1 influenza…the conservation

1578

~~430~~

https://www.pnas.org/content/106/48/20365?ijkey=c1bfac7eed2d11f75c08fb2c9dd523a8aa6a0ea5&keytype2=tf_ipsecsha Published in Peer-Reviewed Science Journal PNAS	of a large fraction of T-cell epitopes suggests that the severity of an S-OIV infection, as far as it is determined by susceptibility of the virus to immune attack, would not differ much from that of seasonal flu."
114) Cellular immune correlates of protection against symptomatic pandemic influenza, Sridhar, 2013 https://pubmed.ncbi.nlm.nih.gov/24056771/ Published in Peer-Reviewed Science Journal Nature	"The 2009 H1N1 pandemic (pH1N1) provided a unique natural experiment to determine whether cross-reactive cellular immunity limits symptomatic illness in antibody-naive individuals… Higher frequencies of pre-existing T cells to conserved CD8 epitopes were found in individuals who developed less severe illness, with total symptom score having the strongest inverse correlation with the frequency of interferon-γ (IFN-γ)(+) interleukin-2 (IL-2)(-) CD8(+) T cells (r = -0.6, P = 0.004)… CD8(+) T cells specific to conserved viral epitopes correlated with cross-protection against symptomatic influenza."
115) Preexisting influenza-specific	"Precise role of T cells in human

CD4+ T cells correlate with disease protection against influenza challenge in humans, Wilkinson, 2012 https://pubmed.ncbi.nlm.nih.gov/22286307/ Published in Peer-Reviewed Science Journal Nature 	influenza immunity is uncertain. We conducted influenza infection studies in healthy volunteers with no detectable antibodies to the challenge viruses H3N2 or H1N1…mapped T cell responses to influenza before and during infection…found a large increase in influenza-specific T cell responses by day 7, when virus was completely cleared from nasal samples and serum antibodies were still undetectable. Pre-existing CD4+, but not CD8+, T cells responding to influenza internal proteins were associated with lower virus shedding and less severe illness. These CD4+ cells also responded to pandemic H1N1 (A/CA/07/2009) peptides and showed evidence of cytotoxic activity."
116) Serum cross-reactive antibody response to a novel influenza A (H1N1) virus after vaccination with seasonal influenza vaccine, CDC, MMWR,	"No increase in cross-reactive antibody response to the novel influenza A (H1N1) virus was observed among adults aged >60 years. These data suggest that

1580
432

2009 **https://pubmed.ncbi.nlm.nih.gov/19478718/** Published in Peer-Reviewed Science Journal MMWR	receipt of recent (2005–2009) seasonal influenza vaccines is unlikely to elicit a protective antibody response to the novel influenza A (H1N1) virus."
117) **No one is naive: the significance of heterologous T-cell immunity**, Welsh, 2002 **https://pubmed.ncbi.nlm.nih.gov/12093008/** Published in Peer-Reviewed Science Journal Nature	"Memory T cells that are specific for one virus can become activated during infection with an unrelated heterologous virus, and might have roles in protective immunity and immunopathology. The course of each infection is influenced by the T-cell memory pool that has been laid down by a host's history of previous infections, and with each successive infection, T-cell memory to previously encountered agents is modified."
118) **Intrafamilial Exposure to SARS-CoV-2 Induces Cellular Immune Response without Seroconversion**, Gallais, 2020 **https://www.medrxiv.org/content/**	"Individuals belonging to households with an index COVID-19 patient, reported symptoms of COVID-19 but discrepant serology results… All index patients recovered from a mild COVID-19.

GOVT. OF INDIA
Mumbai
Maharashtra
Reg. No. 15228
Expiry Dt.
20-10-2024

10.1101/2020.06.21.20132449v1 Published in a PrePrint Server	They all developed anti-SARS-CoV-2 antibodies and a significant T cell response detectable up to 69 days after symptom onset. Six of the eight contacts reported COVID-19 symptoms within 1 to 7 days after the index patients but all were SARS-CoV-2 seronegative... exposure to SARS-CoV-2 can induce virus-specific T cell responses without seroconversion. T cell responses may be more sensitive indicators of SARS-Co-V-2 exposure than antibodies...results indicate that epidemiological data relying only on the detection of SARS-CoV-2 antibodies may lead to a substantial underestimation of prior exposure to the virus."
119) **Protective immunity after recovery from SARS-CoV-2 infection**, Kojima, 2021 https://www.thelancet.com/journals/laninf/article/PIIS1473-3099(21)00676-9/fulltext	"It important to note that antibodies are incomplete predictors of protection. After vaccination or infection, many mechanisms of immunity exist within an individual not only at the antibody level, but also at the level of cellular immunity. It is known that SARS-

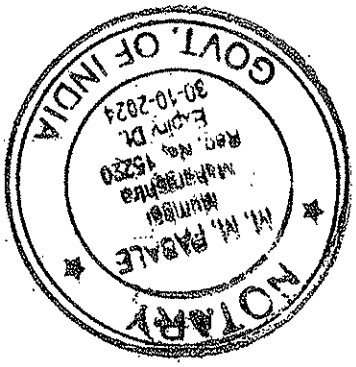
1582
~~434~~

Published in Peer-Reviewed Science Journal Lancet	CoV-2 infection induces specific and durable T-cell immunity, which has multiple SARS-CoV-2 spike protein targets (or epitopes) as well as other SARS-CoV-2 protein targets. The broad diversity of T-cell viral recognition serves to enhance protection to SARS-CoV-2 variants, with recognition of at least the alpha (B.1.1.7), beta (B.1.351), and gamma (P.1) variants of SARS-CoV-2. Researchers have also found that people who recovered from SARS-CoV infection in 2002–03 continue to have memory T cells that are reactive to SARS-CoV proteins 17 years after that outbreak. Additionally, a memory B-cell response to SARS-CoV-2 evolves between 1·3 and 6·2 months after infection, which is consistent with longer-term protection."
120) **This 'super antibody' for COVID fights off multiple coronaviruses**, Kwon, 2021 https://www.nature.com/articles/d4	"This 'super antibody' for COVID fights off multiple coronaviruses…12 antibodies…that was involved in the study, isolated from people who had been infected

1586-021-01917-9 Published in Peer-Reviewed Science Journal Nature	with either SARS-CoV-2 or its close relative SARS-CoV."
121) **SARS-CoV-2 infection induces sustained humoral immune responses in convalescent patients following symptomatic COVID-19**, Wu, 2020 https://www.medrxiv.org/content/10.1101/2020.07.21.20159178v1 Published in a PrePrint Server	"Taken together, our data indicate sustained humoral immunity in recovered patients who suffer from symptomatic COVID-19, suggesting prolonged immunity."
122) **Evidence for sustained mucosal and systemic antibody responses to SARS-CoV-2 antigens in COVID-19 patients**, Isho, 2020 https://www.medrxiv.org/content/10.1101/2020.08.01.20166553v1 Published in a PrePrint Server	"Whereas anti-CoV-2 IgA antibodies rapidly decayed, IgG antibodies remained relatively stable up to 115 days PSO in both biofluids. Importantly, IgG responses in saliva and serum were correlated, suggesting that antibodies in the saliva may serve as a surrogate measure of systemic immunity."
123) **The T-cell response to SARS-CoV-2: kinetic and**	"Early appearance, multi-specificity and functionality of SARS-CoV-2-

1584
436

quantitative aspects and the case for their protective role, Bertoletti, 2021 **https://academic.oup.com/ooim/article/2/1/iqab006/6146940** Published in Peer-Reviewed Science Journal Oxford Open Immunology	specific T cells are associated with accelerated viral clearance and with protection from severe COVID-19."
124) **The longitudinal kinetics of antibodies in COVID-19 recovered patients over 14 months**, Eyran, 2020 https://www.medrxiv.org/content/10.1101/2021.09.16.21263693v1 Published in a PrePrint Server	"Found a significantly faster decay in naïve vaccinees compared to recovered patients suggesting that the serological memory following natural infection is more robust compared to vaccination. Our data highlights the differences between serological memory induced by natural infection vs. vaccination."



125) **Continued Effectiveness of COVID-19 Vaccination among Urban Healthcare Workers during Delta Variant Predominance**, Lan, 2021 https://www.medrxiv.org/content/10.1101/2021.11.15.21265753v1.full Published in a PrePrint Server	"Followed a population of urban Massachusetts HCWs…we found no re-infection among those with prior COVID-19, contributing to 74,557 re-infection-free person-days, adding to the evidence base for the robustness of naturally acquired immunity."
126) **Immunity to COVID-19 in India through vaccination and natural infection**, Sarraf, 2021 https://www.medrxiv.org/content/10.1101/2021.11.08.21266055v1 Published in a PrePrint Server	"Compared the vaccination induced immune response profile with that of natural infection, evaluating thereby if individuals infected during the first wave retained virus specific immunity…the overall immune response resulting from natural infection in and around Kolkata is not only to a certain degree better than that generated by vaccination, especially in the case of the Delta variant, but cell mediated immunity to SARS-CoV-2 also lasts for at least ten months after the viral infection."
127) **Asymptomatic or mild**	"Evaluated humoral immune

1586
438

symptomatic SARS-CoV-2 infection elicits durable neutralizing antibody responses in children and adolescents, Garrido, 2021 **https://pubmed.ncbi.nlm.nih.gov/34228642/** Published in Peer-Reviewed Science Journal JCI	responses in 69 children and adolescents with asymptomatic or mild symptomatic SARS-CoV-2 infection. We detected robust IgM, IgG, and IgA antibody responses to a broad array of SARS-CoV-2 antigens at the time of acute infection and 2 and 4 months after acute infection in all participants. Notably, these antibody responses were associated with virus-neutralizing activity that was still detectable 4 months after acute infection in 94% of children. Moreover, antibody responses and neutralizing activity in sera from children and adolescents were comparable or superior to those observed in sera from 24 adults with mild symptomatic infection. Taken together, these findings indicate that children and adolescents with mild or asymptomatic SARS-CoV-2 infection generate robust and durable humoral immune responses that can likely contribute to protection from reinfection."

GOVT. OF INDIA
NOTARY

128) **T cell response to SARS-CoV-2 infection in humans: A systematic review**, Shrotri, 2021 https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0245532 Published in Peer-Reviewed Science Journal PLOS	"Symptomatic adult COVID-19 cases consistently show peripheral T cell lymphopenia, which positively correlates with increased disease severity, duration of RNA positivity, and non-survival; while asymptomatic and paediatric cases display preserved counts. People with severe or critical disease generally develop more robust, virus-specific T cell responses. T cell memory and effector function has been demonstrated against multiple viral epitopes, and, cross-reactive T cell responses have been demonstrated in unexposed and uninfected adults, but the significance for protection and susceptibility, respectively, remains unclear."

1588
~~440~~

129) **Severity of SARS-CoV-2 Reinfections as Compared with Primary Infections**, Abu-Raddad, 2021 https://www.nejm.org/doi/10.1056/NEJMc2108120?url_ver=Z39.88-2003&rfr_id=ori:rid:crossref.org&rfr_dat=cr_pub%20%200pubmed Published in Peer-Reviewed Science Journal NEJM	"Reinfections had 90% lower odds of resulting in hospitalization or death than primary infections. Four reinfections were severe enough to lead to acute care hospitalization. None led to hospitalization in an ICU, and none ended in death. Reinfections were rare and were generally mild, perhaps because of the primed immune system after primary infection."
130) **Assessment of the Risk of Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) Reinfection in an Intense Re-exposure Setting**, Abu-Raddad, 2021 **https://pubmed.ncbi.nlm.nih.gov/33315061/** Published in Peer-Reviewed Science Journal Clinical Infectious Diseases	"SARS-CoV-2 reinfection can occur but is a rare phenomenon suggestive of protective immunity against reinfection that lasts for at least a few months post primary infection."
131) **Increased risk of infection**	"Analyzed 28,578 sequenced SARS-

GOVT. OF INDIA
NOTARY
M.H. PARMALE
Mumbai
Page No. 15228
Expiry Dt. 30-10-2024

with SARS-CoV-2 Beta, Gamma, and Delta variant compared to Alpha variant in vaccinated individuals, Andeweg, 2021 https://www.medrxiv.org/content/10.1101/2021.11.24.21266735v1 Published in a PrePrint Server	CoV-2 samples from individuals with known immune status obtained through national community testing in the Netherlands from March to August 2021. They found evidence for an "increased risk of infection by the Beta (B.1.351), Gamma (P.1), or Delta (B.1.617.2) variants compared to the Alpha (B.1.1.7) variant after vaccination. No clear differences were found between vaccines. However, the effect was larger in the first 14-59 days after complete vaccination compared to 60 days and longer. In contrast to vaccine-induced immunity, no increased risk for reinfection with Beta, Gamma or Delta variants relative to Alpha variant was found in individuals with infection-induced immunity."
132) Prior COVID-19 protects against reinfection, even in the absence of detectable antibodies, Breathnach, 2021 https://www.journalofinfection.com/article/S0163-4453(21)00266-	"Studies did not address whether prior infection is protective in the absence of a detectable humoral immune response. Patients with primary or secondary antibody deficiency syndrome and reduced or absent B cells can recover from

1590
~~442~~

8/fulltext Published in Peer-Reviewed Science Journal, Journal of Infectionx	COVID-19…Although there have been few mechanistic studies, preliminary data show that such individuals generate striking T-cell immune responses against SARS-CoV-2 peptide pools…SARS-CoV-2 specific T cell immune responses but not neutralising antibodies are associated with reduced disease severity suggesting the immune system may have considerable redundancy or compensation following COVID-19…our results add to the emerging evidence that detectable serum antibody may be an incomplete marker of protection against reinfection. This could have implications for public health and policy-making, for example if using seroprevalence data to assess population immunity, or if serum antibody levels were to be taken as official evidence of immunity – a minority of truly immune patients have no detectable antibody and could be disadvantaged as a result. Our findings highlight the need for further studies of immune correlates

	of protection from infection with SARS-CoV-2, which may in turn enhance development of effective vaccines and treatments."
133) Natural infection vs vaccination: Which gives more protection?, Rosenberg, 2021 https://www.israelnationalnews.com/news/309762 Data from Israel	"With a total of 835,792 Israelis known to have recovered from the virus, the 72 instances of reinfection amount to 0.0086% of people who were already infected with COVID…By contrast, Israelis who were vaccinated were 6.72 times more likely to get infected after the shot than after natural infection, with over 3,000 of the 5,193,499, or 0.0578%, of Israelis who were vaccinated getting infected in the latest wave."
134) Community transmission and viral load kinetics of the SARS-CoV-2 delta (B.1.617.2) variant in vaccinated and unvaccinated individuals in the UK: a prospective, longitudinal, cohort study, Singanayagam, 2021 https://www.thelancet.com/action/s	"Nonetheless, fully vaccinated individuals with breakthrough infections have peak viral load similar to unvaccinated cases and can efficiently transmit infection in household settings, including to fully vaccinated contacts."

1592

~~444~~

howPdf?pii=S1473-3099(21)00648-4 Published in Peer-Reviewed Science Journal Lancet	
135) **Antibodies elicited by mRNA-1273 vaccination bind more broadly to the receptor binding domain than do those from SARS-CoV-2 infection,** Greaney, 2021 **https://pubmed.ncbi.nlm.nih.gov/34103407/** Published in Peer-Reviewed Science Journal Science	"The neutralizing activity of vaccine-elicited antibodies was more targeted to the receptor-binding domain (RBD) of the SARS-CoV-2 spike protein compared to antibodies elicited by natural infection. However, within the RBD, binding of vaccine-elicited antibodies was more broadly distributed across epitopes compared to infection-elicited antibodies. This greater binding breadth means that single RBD mutations have less impact on neutralization by vaccine sera compared to convalescent sera. Therefore, antibody immunity acquired by natural infection or different modes of vaccination may have a differing susceptibility to erosion by SARS-CoV-2 evolution."
136) **Antigen-Specific Adaptive**	"Limited knowledge is available on

1593
~~445~~

Immunity to SARS-CoV-2 in Acute COVID-19 and Associations with Age and Disease Severity, Moderbacker, 2020 https://www.cell.com/cell/fulltext/S0092-8674(20)31235-6?_returnURL=https://linkinghub.elsevier.com/retrieve/pii/S0092867420312356?showall=true Published in Peer-Reviewed Science Journal Cell	the relationship between antigen-specific immune responses and COVID-19 disease severity. We completed a combined examination of all three branches of adaptive immunity at the level of SARS-CoV-2-specific CD4+ and CD8+ T cell and neutralizing antibody responses in acute and convalescent subjects. SARS-CoV-2-specific CD4+ and CD8+ T cells were each associated with milder disease. Coordinated SARS-CoV-2-specific adaptive immune responses were associated with milder disease, suggesting roles for both CD4+ and CD8+ T cells in protective immunity in COVID-19. Notably, coordination of SARS-CoV-2 antigen-specific responses was disrupted in individuals ≥ 65 years old. Scarcity of naive T cells was also associated with aging and poor disease outcomes. A parsimonious explanation is that coordinated CD4+ T cell, CD8+ T cell, and antibody responses are protective, but uncoordinated responses

	frequently fail to control disease, with a connection between aging and impaired adaptive immune responses to SARS-CoV-2."
137) **Protection and waning of natural and hybrid COVID-19 immunity**, Goldberg, 2021 https://www.medrxiv.org/content/10.1101/2021.12.04.21267114v1 Published in a PrePrint Server	"Protection from reinfection decreases with time since previous infection, but is, nevertheless, higher than that conferred by vaccination with two doses at a similar time since the last immunity-conferring event."
138) **A Systematic Review of the Protective Effect of Prior SARS-CoV-2 Infection on Repeat Infection**, Kojima, 202 https://www.medrxiv.org/content/10.1101/2021.08.27.21262741v1 Published in a PrePrint Server	"The protective effect of prior SARS-CoV-2 infection on re-infection is high and similar to the protective effect of vaccination."

GOVT. OF INDIA
NOTARY
M. H. PABALE
Mumbai
Maharashtra
Regd. No. 15228
Expiry Dt.
30-10-2024

1596
~~1596~~
~~447~~

EXHIBIT "RA-20"

Studies which show that vaccinated people have just as much, or more viral load than the UN-vaccinated

" Found no significant difference in cycle threshold values between vaccinated and unvaccinated, asymptomatic and symptomatic groups infected with SARS-CoV-2 Delta."

https://www.medrxiv.org/content/10.1101/2021.09.28.21264262v2

"No difference in viral loads when comparing unvaccinated individuals to those who have vaccine "breakthrough" infections.

"Furthermore, individuals with vaccine breakthrough infections frequently test positive with viral loads consistent with the ability to shed infectious viruses …

https://www.medrxiv.org/content/10.1101/2021.07.31.21261387v1

" if vaccinated individuals become infected with the delta variant, they may be sources of SARS-CoV-2 transmission to others …

"data substantiate the idea that vaccinated individuals who become infected with the Delta variant may have the potential to transmit SARS-CoV-2 to others."

https://www.medrxiv.org/content/10.1101/2021.07.31.21261387v2

" Viral loads of breakthrough Delta variant infection cases were 251 times higher than those of cases infected with old strains detected between March-April 2020."

https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3897733



1597
~~448~~

Barnstable, Massachusetts, July 2021 CDC MMWR study found that in 469 cases of COVID-19, there were 74% that occurred in fully vaccinated persons.

"The vaccinated had on average more virus in their nose than the unvaccinated who were infected."

https://pubmed.ncbi.nlm.nih.gov/34351882/

Also shows a pronounced and very troubling trend, which is that the "double vaccinated persons are showing greater infection (per 100,000) than the unvaccinated, and especially in the older age groups e.g. 30 years and above."

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1031157/Vaccine-surveillance-report-week-44.pdf

Similar viral loads in vaccinated and unvaccinated individuals infected with Delta question how much vaccination prevents onward transmission

https://www.medrxiv.org/content/10.1101/2021.09.28.21264260v1

Fully vaccinated individuals with breakthrough infections have peak viral load similar to unvaccinated cases and can efficiently transmit infection in household settings, including to fully vaccinated contacts.

https://www.thelancet.com/journals/laninf/article/PIIS1473-3099(21)00648-4/fulltext



1598
~~449~~

EXHIBIT "RA-21"

2k serious cases of AEFI, 0.004% of 123 crore of shots given: Government

Source: The Times of India

Link: https://timesofindia.indiatimes.com/india/2k-serious-cases-of-aefi-0-004-of-123-crore-of-shots-given-government/articleshow/88153594.cms

Published on: December 8, 2021

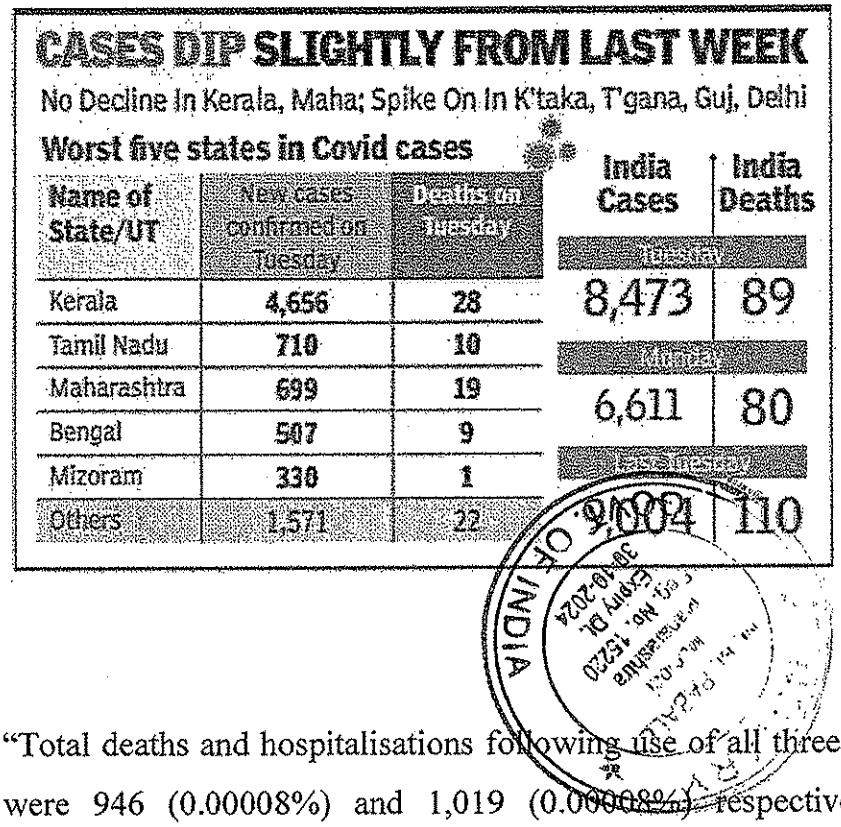
NEW DELHI: Adverse events following immunisation (AEFI) were recorded after 0.004% of the total around 123 crore Covid jabs administered till November 30. Of the 49,819 reported adverse events, 47,691 were minor, 163 severe and 1,965 were serious cases, the government told the Parliament on Tuesday.

AEFI is any untoward medical occurrence that follows innoculation and does not necessarily have a causal relationship with the Covid-19 vaccine. They are reported through the AEFI surveillance system.

An AEFI is considered serious if it results in death, requires hospitalisation, results in persistent or significant disability or a cluster (two or more cases) of AEFIs in a geographical area. Investigations and causality assessment help in establishing a cause and effect relationship, junior health minister Bharati Pravin Pawar said.

1599

~~450~~



CASES DIP SLIGHTLY FROM LAST WEEK

No Decline In Kerala, Maha; Spike On In K'taka, T'gana, Guj, Delhi

Worst five states in Covid cases

Name of State/UT	New cases confirmed on Tuesday	Deaths on Tuesday
Kerala	4,656	28
Tamil Nadu	710	10
Maharashtra	699	19
Bengal	507	9
Mizoram	330	1
Others	1,571	22

India Cases	India Deaths
Tuesday	
8,473	89
Monday	
6,611	80
Last Tuesday	
9,004	110

"Total deaths and hospitalisations following use of all three Covid-19 vaccines were 946 (0.00008%) and 1,019 (0.00008%) respectively. The causality assessment of 89 deaths have been completed," the minister said her reply to a query raised in the Rajya Sabha.

"The number of deaths classified under different causality assessment categories is — vaccine product-related 4, coincidental 58, indeterminate 16 and unclassifiable 11," she further stated.

In response to a separate question on whether the government has ascertained the efficacy of Covishield and Covaxin, the minister said Covishield, manufactured by the Serum Institute of India, is technology transfer of Oxford/AstraZeneca vaccine developed by Oxford University and AstraZeneca.

The efficacy studies for Oxford/AstraZeneca vaccine were conducted overseas by Oxford University and AstraZeneca. Serum Institute of India has conducted Phase II/III immune-bridging clinical trials in the country, she said.

"The overall interim efficacy of the Oxford/AstraZeneca vaccine at the time of approval of Covishield has been reported to be 63%. Bharat Biotech International has conducted Phase III efficacy trial of Covaxin in the country wherein the efficacy of the vaccine has been reported as 77.8%," she informed the House.

Covaxin was granted Emergency Use Listing (EUL) by the World Health Organisation (WHO) on November 3, 2021. The WHO EUL is sufficient for travelling to a large number of countries. However, some countries issue specific notifications for the inclusion of vaccines for travel purposes, Pawar said.

1601

~~452~~

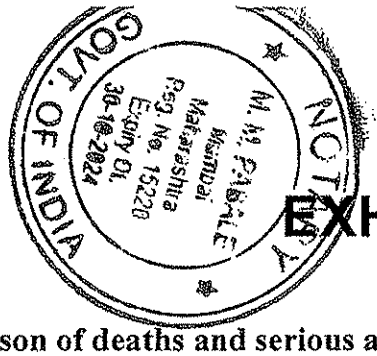


EXHIBIT "RA-22"

Comparison of deaths and serious adverse events in India and other countries

A comparative table of Vaccine adverse events between Europe (27 countries), USA and India is reproduced asunder:

Sr. No.	Description	USA*	UK**	Europe***	India****
1.	Total No. of Doses administered	462 million	94.5 million	606 million	1.29 billion
2.	Total Population Size	333.8 million	68.4 million	748 million	1.4 billion
3.	% of Population given single dose	72.00%	74.5%	71.10%	58.90%
4.	% of Population given both doses	60.40%	68.7%	66.80%	35.60%
5.	Number of people given first dose	240.3 million	51 million	531.8 million	824.6 million
6.	Number of people given second dose	201.6 million	47 million	499.6 million	498.4 million
7.	Number of Injuries Reported post vaccination	6,64,745	3,81,731	28,90,600	49,819
8.	Number of Deaths Reported post vaccination	8,898	1,822	31,014	946
9.	Number of Injuries Reported post AZ/Covishield		2,38,641	10,75,335	
10.	Number of Deaths reported post		1,138	6145	

1602

~~453~~

	AZ/Covishield				

Note:

* Data for the USA is captured from VAERS

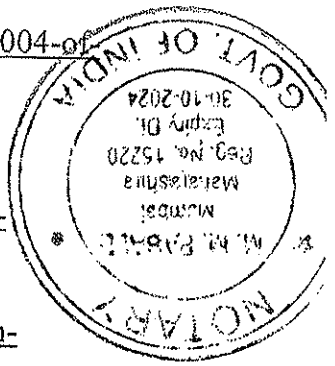
** Data from Medicines & Healthcare Products Regulatory Agency's Yellow Card System

*** Data for 27 countries of Europe is captured from EUDRA

**** Data for India is taken from ToI news report published on 8.12.21

Sources :

- https://timesofindia.indiatimes.com/india/2k-serious-cases-of-aefi-0-004-of-123-crore-of-shots-given-government/articleshow/88153594.cms
- https://ourworldindata.org/covid-vaccinations
- https://www.nytimes.com/interactive/2021/world/covid-vaccinations-tracker.html
- https://www.statista.com/statistics/1218676/full-covid-19-vaccination-uptake-in-europe/
- https://tradingeconomics.com/european-union/coronavirus-vaccination-rate
- https://graphics.reuters.com/world-coronavirus-tracker-and-maps/vaccination-rollout-and-access/
- https://www.nytimes.com/interactive/2021/world/covid-vaccinations-tracker.html
- https://www.bloomberg.com/graphics/covid-vaccine-tracker-global-distribution/
- https://ig.ft.com/coronavirus-vaccine-tracker/?areas=gbr&areas=isr&areas=usa&areas=eue&areas=can&areas=ch



1603

~~454~~

n&areas=ind&cumulative=1&doses=total&populationAdjusted=1

- https://childrenshealthdefense.org/defender/vaers-cdc-omicron-vaccine-makers-stock-adverse-events-deaths/
- https://vaccineimpact.com/2021/31014-deaths-2890600-injuries-following-covid-shots-in-european-database-of-adverse-reactions-as-young-previously-healthy-people-continue-to-die/

https://vaccinetracker.ecdc.europa.eu/public/extensions/COVID-19/vaccine-tracker.html#uptake-tab

-

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1041489/Coronavirus_Vaccines_summary_of_Yellow_Card_reporting_081221.pdf

	UK	India
No. Of people who received Covishield	25 million (approx 50% of total number of vaccinated people)	740 million (approx 90% of total number of vaccinated people)
No. Of deaths reported after Covishield	1,138	850

As can be seen above, the number of people in India who have received Covishield is approximately 30 times than in UK. However, the number of deaths reported after administering of Covidshield in India is less than in UK.

EXHIBIT "RA-23"

Under reporting in VAERS & India.

VAERS is a passive system that is severely under reported. The CDC and FDA have never conducted a study to determine what this under-reported factor is, but independent scientists have, and we have previously published the analysis conducted by Dr. Jessica Rose, who has determined that a conservative under-reported factor would be X41.

Source:

https://downloads.regulations.gov/CDC-2021-0089-0024/attachment_1.pdf

In a separate 2011 study titled "Electronic Support for Public Health-Vaccine Adverse Event Reporting System" commissioned by Department of Health and Human Services (U.S.A) and performed by Harvard Consultants, concluded that "fewer than 1 % of vaccine adverse events are reported". The link of this report can be found at:

https://digital.ahrq.gov/sites/default/files/docs/publication/r18hs017045-lazarus-final-report-2011.pdf

Under reporting of AEFI in India

The incidents of deaths and serious adverse events following immunization is also deliberately not being reported by the state authorities. This is being done to suppress the data of death and serious adverse events following immunization. By way of example petitioners gives below transcripts of the video and audio calls with government authorities refusing to record AEFI complaints or claiming that they are unaware of the requirement of recording AEFI complaints.

The transcript of the videos are as under:

1605
456

Video recorded on 05.05.2021

Nikita Patel – Government Official

Aarogya Vibhaag, Opp. Fire Station, Vesu, Surat

By: Minal Madhwani, Dharmesh, Kirit Bhalani

https://u.pcloud.link/publink/show?code=XZsK2eXZ4zobpIVuOGy38iFyCCMezfORj9ky

Nikita Patel: In this there is nothing which shows that the death is caused by the vaccine.

Unknown: So then what is the cause?

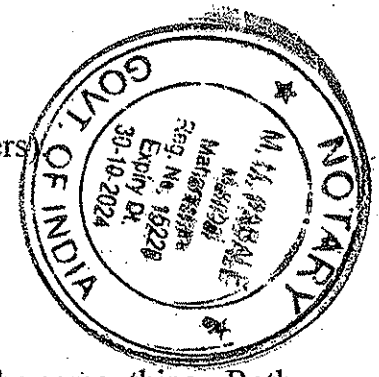
Nikita: Death due to vaccine has not been proven here and vaccines have no such side effects that cause death after 20 days. After taking the vaccine, you can get Covid positive.

Who are you? (someone asking the videographer)

Is he your father (someone asking the victim family members)

Who are you (someone asking Kirit Bhalani)

Minal: His father also went through the same problem275



Nikita: I told her the same thing and I am telling you also the same thing., Both doses of the vaccine including 1 st dose and 2nd dose takes a total of 45 days. 14 days after the 2nd vaccine, we find out the effectiveness of the vaccine. Whenever we get a vaccine, if within 30 minutes there is some allergic reaction then it is a serious side effect, only if there is a known allergy to one of the ingredients of the vaccine. Only then, there is a chance of serious side effect for 1 individual out of 10 lacs. If we give proper treatment to them, there is a chance to save their life. The other side effects of vaccines like headaches, slight

fever or anything else stays for 2-3 days and it is minor. That we can call AEFI but that is also very minor. ***There are no known cases of death after vaccine.*** I am still trying to explain to you that effectiveness of vaccines starts only after 45 days. From your father's report it looks like he took the vaccine on the 20th and then he tested positive, that doesn't mean it was because of the vaccine. I have explained the same thing to this lady as well. Please wear your mask (to the videographer). You ask me your questions because I don't want to repeat the same thing again and again. 276

Kirit: My father's age was 60 years. He had no other type of disease, no pressure or nothing else. So then why this happened only after the vaccine?

Nikita: It is not like that. We cannot prove that it happened because of the vaccine, whatever you have written is not proof.

Kiritbhai: We don't have any proof

Minal: In other states such cases are being registered, we are with an organization and we are going to file a case in the Supreme Court.

Nikita: Which states? It is important for us to register.

Kirit: Every state is doing it in AEFI

Nikita: We are also doing. But until YOU prove that this death is caused by the vaccine we will not register.



Kirit: But what proof I can find for it? How to give that proof?

Minal: Post Mortems are not happening

Nikita: When did the death happen?

Kirit: He had no other illness, otherwise we could have thought its because of that. 277

Nikita: In this there is not proof that they came positive because of the vaccine.

1607

~~458~~

Cross Talk between Nikita, Minal and Kirit

Minal: We are not coming here because we are enjoying this. My mother has died.

Nikita: Covid is not happening because of the vaccine. It is happening after the vaccine.

Another Official: We empathise with the death in your family. It is a very sad experience. But how the vaccine works and how disease happens, we should understand that first.

Minal: Are you a doctor? Did you go to the Lab to make the vaccine?

Unknown: Yes I am a doctor.278

Audio clip- 1

Call recording file link:

https://drive.google.com/file/d/1VfCLe1K4l1gZnDt98iAqdgcv0tRK79f

e/view?usp=sharing

Conversation Transcript:

Note:

a = caller

h= helpline



Welcome covid19 helpline 1075

press 1 for general covid queries

press 2 for queries related to cowin software

helpline: welcome to covid helpline

a: I want to know that adverse event following immunization, side effects that happen after taking the vaccine. To report that, what system is provided by the cowin app?

h: for what sir? I didn't understand279

a: the side effects after taking the vaccine. The adverse effects following immunization data that is provided by the cowin app. for example, someone in mu family has had a side effect, they want to report it. So how will they report it on the cowin app? The adverse effect following immunization (AEFI) data that the cowin app provides.

h: this is what I understood. After taking the vaccine there are some side effects. You have called to enquire how to report this right?!

a: yes yes

h: don't worry. i will help you in your situation. Tell me your name.

a: yes my name is vikas diwan. I am talking from Bihar

h: after calling on this number, did you press 1 or 2?

a: I pressed 2 because my question was related to the covid software

(app)

h: ok sir tell me your phone number

a: 7004657611

h: where are you calling from vikasji? Which state are you from?

a: Bihar, gaya 280

h: thank you very much for sharing your details Okay, for now please confirm, someone in your family has taken the vaccine and has side effects?

1609
460

a: yes. There is a side effect and we want to know how and where to report this side effect. AEFI- adverse effect following immunization data provided by your software or app. in our case how should we report it?

h: okay sir. As of now there is no provision to report this online. **online isko report karne ki ko suvidha nahi hai** vikas ji, on the cowin app. What you can do is, after taking the vaccine, the side effect that has come, you can directly go to the vaccination centre and talk to them there. Or else I'll give you a helpline number and you can call and talk to them there.

a: tell me the helpline number

h: write it down 01

a: wait a minute

h: sure sir281

a: yes tell me

h: 01204473222

a: okay okay



h: you can call on this number and tell them, or else you can go to the place where you got the vaccine and tell them.

a: okay. In case someone dies, then what is the system for reporting

such a case?

h: you will have to go to the place where you got the vaccine. They will collect your report. You have to go there only and report. There is no facility to report online for that.

a: okay, online there are facilities for only registering before getting the vaccine. If something happens after getting the vaccine, there is no facility to report that.

h: there are no online facilities for reporting that sir.

a: okay. For that we have to go to the vaccine centre, where we have got the vaccine, and there is a facility to report any kind of side effect or death after taking the vaccine over there only. Or else the number you have provided, which department's number is this?282

h: this is our department's number only

a: So is this number for counselling or for reporting an adverse effect following immunization? This number that you have provided.

h: yes sir

a: will this provide counselling or will it record our adverse effect case?

h: counselling can be done with them, and they take reports also.

a: okay. The also take reports? So our feedback or report, they record that as well.

h: exactly

a: okay thankyou

h: would you like to know anything else?

a: no, no this is all I wanted to know.

h: okay, to know more you can call on this 1075 number. You can whatsapp as well.

whatsapp number is 9013151515 thank you for calling on national corona helpline283

Audio Clip-2

Call recording file link:

1611
~~462~~

https://drive.google.com/file/d/1tbAF4Z2ex1Cj9D1md2cSSpnBD5BqoTs/view?usp=sharing

Conversation Transcript:

Call center representative:- (Name not clear) how may I help you?

Caller:- ma'am I wanted to know that one of my friend died after taking the vaccine so where am I supposed to report it? It has been few days already I contacted the centre where he/she got vaccinated they are not ready to accept it only.

Representative:- So that person died after getting vaccinated?

Caller:- yes

Representative:- hold for 2 minutes

After few minutes

Representative:- did you inform at that particular centre from where he/she got vaccinated?284

Caller:- so the thing is this is not just one case i know 2/3 friends more who got the jab now doctors and vaccinator are saying that they died due to heart attack and diabetes means they already had diabetes. So now my friends are asking me where we shall proceed now.

Representative:- okay ma'am Actually the process is first of all whenever you get the side effects And this is severe side effect case Right so you have to inform the vaccinators only that centre only from you get vaccinated.

Caller:- is there any website for this where we can directly report our side effects? Like after getting vaccine only my legs started having pain even weakness and the death happened slowly. Or what if after taking vaccine

immediately started feeling unwell.There are examples where death happened within 5 days of vaccination even 18 days but in all of these it started gradually only And they were perfectly fine people.

Representative:- i get your point 285

Listen to me

Caller:- vaccinators are also not listening to us

Representative:- if there's mild side effects or severe side effects or death has happened then you have to inform the authorities available at vaccine centre only and it's their responsibility only to pass on this suggestion or whatever information you have to share with them. So they are the only ones who can pass on this.

Caller:- so there's nothing else at all?

Representative:- yes there's no other way.. we don't have any other information regarding this.

Caller:- is there any other place where i can check with this?

Representative:- no only that vaccinator or near by any authorised vaccine centre only.

Caller:- but is there any other way or place i can go for this?

Representative:- no no sorry we don't have any information regarding this

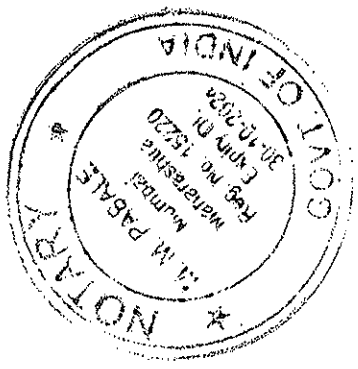
Caller:- okay

Representative:- can you share your name please?286

Caller :- Maya valecha

Representative:- where are you from?

Caller :- Bharuch287



1613
~~464~~

Audio Clip- 3

Call recording link:

https://drive.google.com/file/d/1gBEdPwalCHTNf5qkowcsDJnmxs06ZGcl/view

Transcript:

C = Caller

R = Representative

R: Hello, welcome you to the 104 medical advice. Is this the first time you are calling 104 or have you called before?

C: First time.

R: Sir, can I have your name?

C: Deepak Kumar Shukla

R: Can I have your age sir?

C: 50

R: District?

C: Dhanbad

R: Block?288

C: Jharia

R: Yes sir, tell me what your issue is?

C: On the CoWin App I am not receiving OTP.

R: OTP is not coming?



C: Yes, I am trying since yesterday from different mobile numbers, I am not getting OTP from CoWin app.

R: For what were you trying to register sir?

C: But its a feature to do registration, for whatever.

R: There must be a technical issue sir, that's why it may not have come. There must be a network problem, some problem that's why it may not be coming.

C: Its not coming since yesterday evening. Also I have another question. If any adverse effect happens is there any link to report it?

R: As in sir? Meaning?

C: For example if in an hour, hour and a half after taking the injection some adverse event happens, some problem happens, head starts spinning or a person dies. So for that is there any feature? Any link given? Yes?

R: No sir, no.

C: There's nothing at all?

R: No.

C: So if something like this

R: As far as getting sick after vaccine, weakness, fever happens only. For some people it stays for even one week.

C: No, I am not talking about that. I am talking about adverse effect. What if someone..

R: No sir. There's nothing of that sort.

C: If something like this happens. Then what does one have to do, any idea?

R: Right now there is no information. There is no such link right now.

C: If some person take vaccine..

R: Even if it will be there, we will come to know in future only of any such information. If any such rule like this is made.

C: No no, but if right now a death is happening due to vaccination. After taking the people who are dying. So is there any protocol given by the Indian Government, to register it and if we can give such information.290

R: Sir please stay on the line we will give you information

C: Please give

R: Are you able to hear me sir?

C: Yes

R: There is no such thing made sir yet.

C: So if you don't have this information, would anyone further above you can be spoken to?

R: No sir, you can't speak with them

C: So you'll can't give me any information about this right?

R: No

C: Give me someone else's number whom I can speak with and take information. If some of your representative is there.

R: Sir you have called 104 healthcare, here who's number can we give you? We can't give you anyone's number.

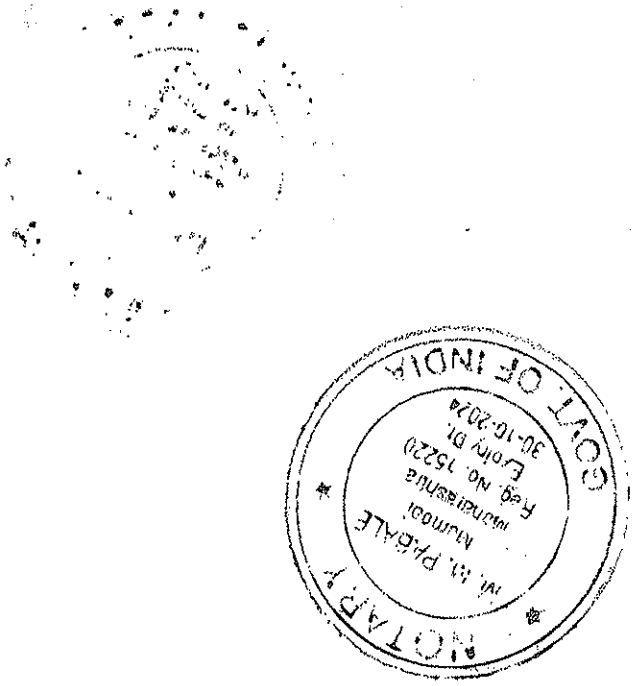
C: So why has this number been issued?

R: Sir there is no such information yet sir

1616

~~467~~

C: So for what information are you guys made to sit? Why has the 104 number been issued by the government? What is the purpose of it?

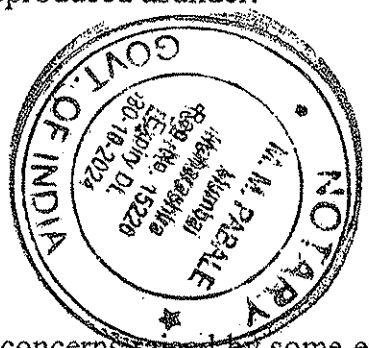


1617
~~468~~

EXHIBIT "RA-24"

Letters from Indian Doctors Opining on the State of AEFI Reporting in India

An email was sent by Dr. Amitav Banerjee, Professor & Head, Community Medicine Clinical Epidemiologist, to a Health Rights Activist on the subject: "My concerns about indiscriminate and mass vaccination of populations with Covid-19 vaccine", which is being reproduced asunder:



Dear Yohan,

Greetings from Pune!

I have been following the concerns ~~raised by~~ some eminent scientists and other citizens across the world since the vaccine rollout which was done in unholy haste and is still under "emergency use authorization" in trial mode. I have also been closely following your well researched arguments put forward from time to time on the Covid-19 situation in the country. I am sharing my concerns, based on my analysis of the opinions of independent scientists, on mass vaccination on your platform.

Geert VanDen Bossche, an independent vaccine researcher and virologist, formerly with Bill & Melinda Gates Foundation, had warned that indiscriminate mass vaccination would give rise to more virulent mutants. We are already seeing such mutations in parts of the world after vaccines were rolled out.

Besides, eminent scientists have cautioned about the short and long term adverse events which are largely unknown. Robert Malone, one

of the pioneers of mRNA technology is one of them.

Mass vaccination & vaccine mandates of experimental vaccines will blur the scientific evidence of the efficacy of the vaccines since such a strategy will deprive the comparison between vaccinated and unvaccinated groups on effectiveness of the vaccines as well as short term and long term harms, if any.

Of much greater concern in a large country with poor public health infrastructure is the inadequate monitoring and surveillance of adverse events following immunization (AEFI) for which a robust public health infrastructure is needed. Indiscriminate and rapid roll out of mass vaccination in a country with poor health resources is like running a superfast train on old rickety rail tracks.

Even Western countries with their far smaller population and much better health infrastructure capture only 1% of the adverse events following immunization according to a peer reviewed research paper in a prestigious journal Toxicology Reports (Kostoff et al, Why are we vaccinating children? available at: https://www.sciencedirect.com/science/article/pii/S221475002100161X)

So one can imagine the difficulty of ascertaining the side effects of vaccination in our country with far less resources and much larger population.

There is also no scientific evidence for mass vaccine roll out presently in India, given that serosurveys have found that more than 80% of our

1619
~~470~~

densely crowded population in many parts of the country, have acquired antibodies after recovering from natural infection.

Around 132 research studies show that recovery after natural infection renders more robust immunity compared to vaccine induced immunity: https://brownstone.org/articles/79-research-studies-affirm-naturally-acquired-immunity-to-covid-19-documented-linked-and-quoted/

This is also evident from our rapidly declining trends of cases and deaths compared to the Western countries which have a much higher vaccine coverage of their population, almost two to three times higher than ours. From the data it is evident we have reached herd immunity, naturally.

Given the current epidemiology of Covid-19 in India, there is no indication for mass vaccination at a huge cost and more importantly due to concern of short term and long term adverse effects. Vaccines can be offered to high risk groups on merits of each case on the opinion of a personal physician instead of mass indiscriminate and unmonitored roll out.

With warm personal regards,

Amitav

Dr Amitav Banerjee
Professor & Head, Community Medicine
Clinical Epidemiologist.

1626
~~471~~

Editor in Chief, Medical Journal Dr DY Patil Vidyapeeth, Pune, India
Formerly Epidemiologist with the Indian Armed Forces.
Also headed the Mobile Epidemic Investigating Team at AFMC, Pune.
https://amitavb.wixsite.com/amitav-banerjee
Mobile: 9372434017

Source:
https://drive.google.com/file/d/1STscqXa5cvFdPVzGtpSDjrTcmPFrei8f/view?usp=sharing

A Letter has been sent to the Hon'ble Prime Minister by a group of Indian Doctors on the subject: **"Petition to improve and make functional, AEFI Reporting and it's active Monitoring in India"**. Relevant extracts from the letter are reproduced asunder:

"We, Indian Doctors for Truth, are alarmed that there is practically no proper protocol to report Adverse Event Following Immunization (AEFI) in India, as mass vaccination drive for Covid vaccines is implemented."

"Briefing the press, Dr NK Arora had said, "As of now, monitoring the vaccine recipient up to 72 hours post-vaccination is the norm. It should be done in at least 28 days. There must be a proper mechanism to report AEFI on the CoWin app and all the data should be available in the public domain," adding that severe AEFIs were reported in less than 0.5 percent of recipients out of seven crore vaccinated people assessed so far. This translates to 5 severe cases out of 1,000 vaccinations."

"Though some advisory might exist on paper, "there is so much chaos that nobody knows who to approach in the system and how," says Shobhit, son of a

1621
472

victim."

"However, in the absence of proper reporting mechanism and proactive approach of authorities to trace vaccinated people after they leave the vaccination site, such a claim may not be reflecting the true picture and full magnitude of AEFI and it is possible several cases of AEFI may be going unreported or undetected, says Vineeta Pandey, while writing about her first hand struggle to get her 21 yr old son's AEFI."

"The National AEFI Committee has assessed only 363 of severe or serious AEFIs till 18th October 2021, of which only 4 cases of death were found to be directly linked to Covid Vaccine Product Related. Though 3 out of 4 were cases of anaphylaxis, there was one case where the diagnosis given was "Right transverse sinus thrombosis with right temporal haemorrhagic infarct, right posterior frontal haemorrhagic infarct with thrombocytopaenia". We beg to ask the question, is it really possible that we have only one confirmed case Vaccine-Induced Immune Thrombotic Thrombocytopenia (VITT), when 16 countries have banned or age-restricted Astrazeneca (Covishield) Covid vaccine for the same reason?!"

"In the EU, anyone can report post-vaccine illness directly to the national authority or vaccine makers. The patient volunteers are followed up for at least six weeks post-vaccination and tracking of even long-term effects, says European Medicines Agency (EMA) rules for COVID vaccines. In the US there is an online system of reporting VAERS. Given the scale of vaccination in India, why isn't there a proper AEFI reporting mechanism in India? In the US, we can see 18,853 deaths as per the official US VAERS database (a total of 894,143 Adverse Event reports till 12/11/21). In Europe, in just 27 countries, 31,014 death reports are available in the official European Union database

Eudra Vigilance (a total of 2,890,600 Adverse Event reports till 20/11/21). What are the equivalent numbers in a huge country such as India? It is unbelievable that a country of our size with the largest Covid Vaccination drive on this planet has only 2116 AEFIs which also includes death."

Source:https://awakenindiamovement.com/letter-to-pm-3-0/

Mail Communication from Dr. Sanjay Rai (credentials asunder) to a Health Rights Activist:

Dr. Sanjay K. Rai, MD, FIPHA
Professor, Centre for Community Medicine, AIIMS, New Delhi
· Editor, WHO-South-East Asia Journal of Public Health
· Nodal person for HIV Sentinel Surveillance at National Institute AIIMS (NI-AIIMS).
· National President, Indian Public Health Association (2019-2022)
· Vice President, National Medical Organization (NMO), Delhi State

"AEFI reporting is very important and mandatory step to track the short term and long term side effects of vaccines. Ideally an independent body should investigate all the reported AEFI. However, in India reported AEFI are reviewed by same implementing agency that are involved in vaccine administration. Therefore there is a strong possibility of conflict of interest. Such a situation is not desirable and doesn't inspire confidence in their impartiality. It is likely that the reported AEFI is an underestimate of the total incidence.

Therefore a separate independent body to investigate all the AEFI including fetal AEFI is the need of the hour.

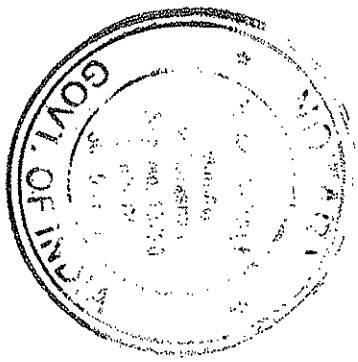
Thanks & Regards

1623

~~474~~

Sanjay Rai"

Source:https://drive.google.com/file/d/1dwS0k0sOdgjZStk6rSRqyEnGbfiFq6eL/view?usp=sharing



1624
475

EXHIBIT "RA-25"

Covid Deaths in India and Infection Fatality Rate

Total Covid Deaths in India are presently at **4,76,000.** Compared to the size of the population of 140 crore, that amounts to a mortality rate of **0.00033%.**

Source:https://www.worldometers.info/coronavirus/country/india/

India's CFR & IFR.

The Case Fatality Rate in India (which is the number of deaths dividedby the number of cases which tested positive) has fallen from over 3% in the beginning of the pandemic to less than 1.5 percent now.

India's Infection Fatality Rate is 0.1%.

https://www.hindustantimes.com/india-news/one-year-of-covid-19-how-india-fought-the-virus-101614553310402.html

"Combining waves 1 and 2, as of May 15, while India reported a total of nearly 25 million cases and 270 thousand deaths, the estimated number of infections and deaths stand at 491 million (36% of the population) and 1.21 million respectively, yielding an estimated (combined) infection fatality rate of **0.25%.**"
Source:https://bmcresnotes.biomedcentral.com/articles/10.1186/s13104-021-05652-2

Global Data

The latest Infection Fatality Rate (the number of deaths divided by the number of actual infections) was calculated by John Ioannidis for Covid 19 in his peer-reviewed study titled: "Infection fatality rate of

COVID-19 inferred from seroprevalence data".

1625
476

Source:https://www.who.int/bulletin/volumes/99/1/20-265892.pdf

Here he calculated the IFR for COVID-19 in a review of 61 seroprevalence studies, which was a median of 0.23%, and 0.05% in people younger than 70. There's a 1,000 times difference in mortality among those younger than 19 and those older than 70 — something that should have been taken into account in the pandemic response. The CEBM (Centre for Evidence Based Medicine) at the University of Oxford, currently estimates the CFR (which is the number of deaths divided by the number of cases which tested positive) globally at 0.51%, and the IFR to be at 0.1%-0.26%.

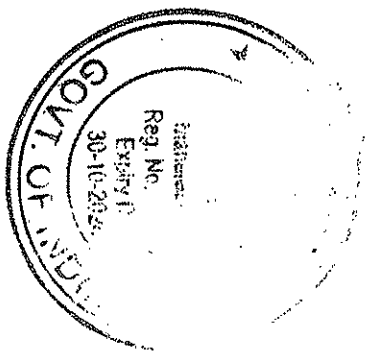
Source:https://microbiologyjournal.org/covid-19-case-fatality-rate-misapprehended-calculations/

The CFR for Influenza is about 3%, & the IFR for Influenza is 0.1%.

Source:https://wattsupwiththat.com/2020/09/08/covid-19-cfr-and-ifr-confused/

CFR = Total number of Covid deaths / Number of Covid Cases
IFR = Total number of Covid deaths / Number of actual infections as determined by serosurveys.

The CFR only looks at those who have been tested via RT-PCR or RAT, whereas the IFR considers all actual infections by the data generated from serosurveys which tell us about how many people have had the infection and developed antibodies.



1626

EXHIBIT "RA-26"

~~477~~

Studies & Data which link AstraZeneca (Covishield) to serious adverse events

"The first cases of large vessel arterial occlusion strokes linked to the AstraZeneca COVID-19 vaccine have been described in the United Kingdom.

The three cases (one of which was fatal) occurred in two women and one man in their 30s or 40s and involved blockages of the carotid and middle cerebral artery. Two of the three patients also had venous thrombosis involving the portal and cerebral venous system. All three also had extremely low platelet counts, confirmed antibodies to platelet factor 4, and raised D-dimer levels, all characteristic of the vaccine-induced immune thrombotic thrombocytopenia (VITT) reaction associated with the AstraZeneca vaccine."

They are described in detail in a letter published online on May 25 in the Journal of Neurology, Neurosurgery & Psychiatry.

"These are first detailed reports of arterial stroke believed to be caused by VITT after the AstraZeneca COVID vaccine, although stroke has been mentioned previously in the VITT data," senior author, David Werring, PhD, FRCP, commented to Medscape Medical News.

"VITT has more commonly presented as CVST [Cerebral venous sinus thrombosis] which is stroke caused by a venous thrombosis; these cases are showing that it can also cause stroke caused by an arterial thrombosis," Werring, who is professor of clinical neurology at the Stroke Research Centre, University College London Queen Square Institute of Neurology, United Kingdom, explained."

"In patients who present with ischemic stroke, especially younger patients, and

1627
~~478~~

who have had the AstraZeneca vaccine within the past month, clinicians need to consider VITT as a possible cause, as there is a specific treatment needed for this syndrome," he said.

Young patients presenting with ischemic stroke after receiving the AstraZeneca vaccine should urgently be evaluated for VITT with laboratory tests, including platelet count, D-dimers, fibrinogen, and anti-PF4 antibodies, the authors write, and then managed by a multidisciplinary team including hematology, neurology, stroke, neurosurgery, neuroradiology, for rapid access to treatments including intravenous immune globulin, methylprednisolone, plasmapheresis and nonheparin anticoagulants such as fondaparinux, argatroban, or direct oral anticoagulants."

NOTARY GOVT. OF INDIA M. M. PABALE Mumbai Maharashtra Reg. No. 15229 Expiry Bl. 30-10-2024

Source:

- https://www.medscape.com/viewarticle/961854
- https://jnnp.bmj.com/content/92/11/1247

New research published in The BMJ confirmed evidence of blood clotting and found a small risk after receiving just one dose of AstraZeneca's vaccine.

"We did, however, observe an increased rate of venous thromboembolic events, corresponding to 11 excess venous thromboembolic events per 100,000 vaccinations and including a clearly increased rate of cerebral venous thrombosis with 7 observed events versus 0.3 expected events among the 282,572 vaccine recipients."

Researchers investigated the likelihood of blood clotting events for 282,572 people in Denmark and Norway. Using data from healthcare registries, they reviewed information on people 18 to 65 years old who received their first dose of AstraZeneca between Feb. 9 and March 11.

About 83 arterial events were found with a morbidity ratio of 0.97. Of the 83 events, researchers observed increases in intracerebral hemorrhages. This was estimated to occur 1.7 times for every 100,000 vaccinations.

The team expected to find 30 venous thromboembolic events, but found 59 with a morbidity ratio of 1.97. About 11 excess events were estimated to occur for every 100,000 vaccinations. There was also a small increased risk of pulmonary embolism, lower limb venous thrombosis and other venous thrombosis.

Researchers found 2.5 events of blood clotting in the brain for every 100,000 vaccinations, and the morbidity ratio was estimated to be 20.25 after observing seven instances of cerebral venous thrombosis, according to the study.

The morbidity ratio for any type of blood clotting disorder was 1.52, which corresponded with three excess events for every 100,000 vaccinations. About 5.1 excess bleeding events were observed for every 100,000 vaccinations.

Of the entire vaccinated cohort, there were 15 deaths in the general population. Researchers concluded that blood clotting is a very rare side effect, but the benefits of vaccination continue to outweigh the risks.

"Our study provides evidence of an excess rate of venous thromboembolism, including cerebral venous thrombosis, among recipients of the Oxford AstraZeneca COVID-19 vaccine ChAdOx1-S within 28 days of the first dose. The absolute risks of these events were, however, small," researchers said.

Source : https://www.bmj.com/content/373/bmj.n1114

This article was published on December 10 2021 in Business Today. Following are the relevant excerpts from the article:

The AEFI committee has completed an in-depth case review of 498 serious and

1629
480

severe events, of which 26 cases have been reported to be potential thromboembolic (formation of a clot in a blood vessel that might also break loose and carried by the bloodstream to plug another vessel) events - following the administration of Covishield vaccine - with a reporting rate of 0.61 cases/ million doses," the statement said.

Source:https://www.businesstoday.in/coronavirus/story/india-has-26-cases-of-blood-clotting-after-covishield-vaccination-healthmin-296278-2021-05-17

"A private hospital has confirmed the incidence of a rare but potentially life-threatening, vaccine-induced blood clotting disorder among some Covishield recipients in India through what doctors have described as a "gold-standard" confirmatory test.

The findings corroborate observations from other countries that vaccine-induced thrombosis and thrombocytopenia (VITT) is an extremely rare adverse event, but underline the need for national guidelines to raise awareness on diagnosis and treatment, the doctors said.

Doctors at the Sir Ganga Ram Hospital, New Delhi, diagnosed VITT through an initial test that detects antibodies against a substance called platelet factor 4 (PF4), and then a confirmatory test that observes how normal platelets respond to the patient's serum.

The first patient that the SGRH doctors diagnosed as suffering from VITT was an 18-year-old boy brought to the Army Hospital, New Delhi, from Mathura in June, 17 days after he had received his first dose of Covishield. The boy, who had a persistent headache and recurrent vomiting, died in hospital."

The World Health Organisation had in April this year flagged reports of thrombosis (formation of blood clots in blood vessels) and thrombocytopenia

NOTARY M. M. PADALE Mumbai Maharashtra Reg. No. 15... Expiry 30-10-... GOVT. OF

(low platelet counts) as a rare adverse event following vaccination with Vazeria and Covishield, the AstraZeneca-Oxford vaccines produced by AstraZeneca and the Serum Institute of India, respectively."

Source:https://www.telegraphindia.com/india/rare-blood-clot-tied-to-covishield/cid/1835038

This study was published on April 9 2021 in The New England Journal of Medicine by Sabine Eichinger et al. Following are the relevant excerpts from the study:

"Vaccination with ChAdOx1 nCov-19 can result in the rare development of immune thrombotic thrombocytopenia mediated by platelet-activating antibodies against PF4, which clinically mimics autoimmune heparin-induced thrombocytopenia."

Source: https://www.nejm.org/doi/10.1056/NEJMoa2104840

"EMA's safety committee (PRAC) has concluded today that unusual blood clots with low blood platelets should be listed as very rare side effects of Vaxzevria (formerly COVID-19 Vaccine AstraZeneca).

In reaching its conclusion, the committee took into consideration all currently available evidence, including the advice from an ad hoc expert group.

EMA is reminding healthcare professionals and people receiving the vaccine to remain aware of the possibility of very rare cases of blood clots combined with low levels of blood platelets occurring within 2 weeks of vaccination. So far, most of the cases reported have occurred in women under 60 years of age within 2 weeks of vaccination. Based on the currently available evidence, specific risk factors have not been confirmed.

LC31
~~482~~

People who have received the vaccine should seek medical assistance immediately if they develop symptoms of this combination of blood clots and low blood platelets (see below).

The PRAC noted that the blood clots occurred in veins in the brain (cerebral venous sinus thrombosis, CVST) and the abdomen (splanchnic vein thrombosis) and in arteries, together with low levels of blood platelets and sometimes bleeding.

The Committee carried out an in-depth review of 62 cases of cerebral venous sinus thrombosis and 24 cases of splanchnic vein thrombosis reported in the EU drug safety database (EudraVigilance) as of 22 March 2021, 18 of which were fatal.1 The cases came mainly from spontaneous reporting systems of the EEA and the UK, where around 25 million people had received the vaccine."

Source:-https://www.ema.europa.eu/en/news/astrazenecas-covid-19-vaccine-ema-finds-possible-link-very-rare-cases-unusual-blood-clots-low-blood

NOTARY
M. M. PABALE
Mumbai
Maharashtra
Reg. No. 15220
Expiry Dt
30-10-2024
GOVT. OF INDIA

1632

~~483~~

EXHIBIT "RA-27"

Research showing that giving vaccines to person with earlier infection causes serious harm.

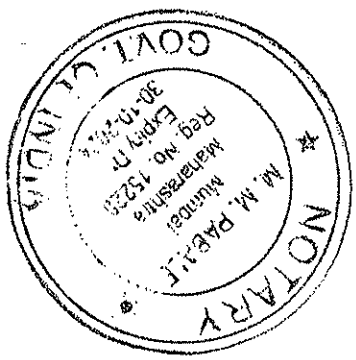
An international survey published in mid-March 2021 surveyed 2,002 people who had received a first dose of COVID-19 vaccine, finding that those who had previously had COVID-19 experienced "significantly increased incidence and severity" of side effects, compared to those who did not have natural immunity.

The mRNA COVID-19 injections were linked to a higher incidence of side effects compared to the viral vector-based COVID-19 vaccines, but tended to be milder, local reactions. Systemic reactions, such as anaphylaxis, flu-like illness and breathlessness, were more likely to occur with the viral vector COVID-19 vaccines.

"People with prior COVID-19 exposure were largely excluded from the vaccine trials and, as a result, the safety and reactogenicity of the vaccines in this population have not been previously fully evaluated. For the first time, this study demonstrates a significant association between prior COVID19 infection and a significantly higher incidence and severity of self-reported side effects after vaccination for COVID-19.

Consistently, compared to the first dose of the vaccine, we found an increased incidence and severity of self-reported side effects after the second dose, when recipients had been previously exposed to viral antigen.

Link: https://www.mdpi.com/2075-1729/11/3/249/html



1633

~~484~~

EXHIBIT "RA-28"

Covishield banned/age restricted in 15 countries Countries other than Europe include Brazil, Venezuela, & Canada.

Brazil: This article was published on May 11, 2021 on Reuters by Pedro Fonseco and Ricardo Brito. Following are the relevant excerpts from the article:

Brazil's federal government on Tuesday nationally suspended the vaccination of pregnant women with the AstraZeneca (AZN.L) COVID-19 shot, after an expectant mother in Rio de Janeiro died from a stroke possibly related to the inoculation.

Franciele Francinato, coordinator of the Health Ministry's vaccination program, told reporters the suspension was enacted as a precautionary measure after health regulator Anvisa issued a warning about the vaccine's use in pregnant women earlier in the day.

Authorities are investigating the incident. The suspension applies only to AstraZeneca's shot and not to vaccines developed by Sinovac (SVA.O) and Pfizer Inc (PFE.N) that are also being used in the country.

The pregnant woman in Rio de Janeiro died after receiving the AstraZeneca shot, according to state Health Secretary Alexandre Chieppe.

Anvisa said the 35-year-old woman, who was 23 weeks pregnant, died of a hemorrhagic stroke on Monday after checking into a hospital five days earlier.

"The serious adverse event of a hemorrhagic stroke was assessed as possibly related to the use of the vaccine given to the pregnant woman," Anvisa said in a statement.

Source:https://www.reuters.com/business/healthcare-pharmaceuticals/brazil-health-agency-calls-halt-astrazeneca-vaccine-pregnant-women-2021-05-11/

Norway: This article was published on May 10, 2021 on Reuters by Terje Solsvik and Gwladys Fouche. Following are the relevant excerpts from the article:

Norway should exclude the COVID-19 vaccines made by AstraZeneca (AZN.L) and Johnson & Johnson (JNJ.N) from its inoculation programme due to a risk of rare but harmful side-effects, a government-appointed commission said on Monday.

However, those who volunteer to take either vaccine should be allowed to do so, it said, stressing the importance of dispelling any vaccine hesitancy.

Norway suspended the AstraZeneca vaccine rollout on March 11 after a small number of younger inoculated people suffered a combination of blood clots, bleeding and a low platelet count. read more

The Norwegian Institute of Public Health (FHI) urgedon April 15 that the AstraZeneca shot be dropped entirely but the government sought the advice of its commission on both it and on the J&J shot, which has not been used in Norway despite European Medicines Agency (EMA) approval. read more

Explaining its recommendations, the commission said eight Norwegian cases of severe clotting had been linked to the AstraZeneca vaccine, and four of those recipients had died.

Source:https://www.reuters.com/world/europe/norway-should-exclude-jj-astrazeneca-covid-vaccination-scheme-says-commission-2021-05-10/

Sweden: This article was published on March 15, 2021 on National Public Radio (NPR) by Jaclyn Diaz. Following are the relevant excerpts from the article:

1635

~~486~~

Sweden is the latest European country to suspend the administration of a COVID-19 vaccine made by AstraZeneca following reports of abnormal blood clotting in recipients.

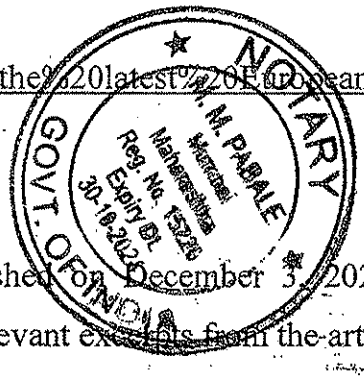
Venezuela on Monday announced it wouldn't authorize use of the vaccine in the country at all following those reports.

The Swedish Public Health Agency said early Tuesday that as a precautionary measure it would suspend use of the Oxford-AstraZeneca COVID-19 vaccine until the European Medicines Agency, or EMA, reveals findings from its ongoing investigation into reports of negative side effects in patients.

The country joins several other European nations including France, Germany, the Netherlands and Ireland that suspended administration of the vaccine this week.

In a briefing with reporters on Tuesday, EMA's Executive Director Emer Cooke said the agency was investigating reports of at least 30 cases of unusual blood disorders and would release its findings on Thursday.

Source:https://www.npr.org/sections/coronavirus-live-updates/2021/03/16/977731757/sweden-venezuela-latest-countries-to-question-astrazeneca-vaccine#:~:text=Sweden%20is%20the%20latest%20European,at%20all%20following%20those%20reports.



Bulgaria: This article was published on December 3, 2021 on Reuters by Reuters Staff. Following are the relevant excerpts from the article:

Bulgaria on Friday temporarily halted COVID-19 inoculations using the AstraZeneca vaccine after a woman died hours after receiving a shot, and

said it wanted the European Medicine Agency (EMA) to dispel all doubts about the vaccine's safety.

Several other countries have also temporarily suspended their rollout of the AstraZeneca vaccine, but the EMA said on Thursday the shots should continue to be administered, saying the benefits outweighed any risks.

"Until all doubts are dispelled... we are halting inoculations with this vaccine," Bulgarian Prime Minister Boyko Borissov said in a statement.

Health Minister Kostadin Angelov said a 57-year-old woman from a village in southern Bulgaria had died of heart failure some 15 hours after receiving an AstraZeneca shot on Thursday.

Source:https://www.reuters.com/article/us-health-coronavirus-astrazeneca-bulgar/bulgaria-suspends-rollout-of-astrazeneca-covid-19-vaccine-idUSKBN2B4196

Slovakia: This article was published on May 11, 2021 on EuroNews. Following are the relevant excerpts from the article:

Slovakia has suspended the use of the AstraZeneca COVID-19 jab for first-time vaccinations.

"People who are waiting for the second dose of this vaccine are currently being vaccinated with Astra Zeneca," said the country's health ministry. "Vaccination with this company for first-time vaccines has been suspended.

"The Ministry of Health is currently considering several alternatives for how we will proceed in this matter in Slovakia.

"We are completing all expert opinions and will follow up on this later this week.

The decision comes after the country's State Institute for Drug Control (ŠÚKL) ruled that the death of a 47-year-old woman was likely connected to the jab.

In a statement, issued on Friday, ŠÚKL said that it had determined the cause of death to be related to cerebral venous sinus thrombosis, a blood clotting disorder that sees clots form in the veins that drain blood from the brain.

"Genetic examination also revealed blood clotting disorders in the patient," the regulator said.

"Due to the existence of a genetic predisposition to a thrombophilic state, an association between [the AstraZeneca jab] and subsequent venous sinus thrombosis was established as likely," it said.

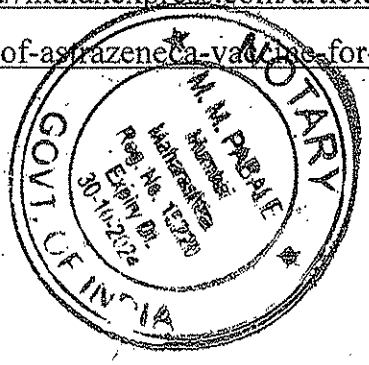
Source:https://www.euronews.com/2021/05/11/slovakia-suspends-use-of-the-astrazeneca-jab-for-first-time-vaccinations

Canada: This article was published on April 26, 2021 on Indian Express. Following are the relevant excerpts from the article:

Canada's National Advisory Committee on Immunization (NACI) has recommended that the AstraZeneca Covid-19 vaccine not be used for individuals below the age of 55.

The committee stated that until a type of an adverse event associated with the vaccine is investigated, its usage should for those below the age of 55 be stopped. Even so, individuals above the age of 55 can continue getting the AstraZeneca vaccine in Canada, considering that the adverse event is more common in people below the age of 55, the committee said.

Source:https://indianexpress.com/article/explained/explained-why-canada-has-stopped-use-of-astrazeneca-vaccine-for-those-below-55-years-7251250/



Denmark:- This article was published on March 11, 2021 on Euronews by Lauren Chadwick. Following are the relevant excerpts from the article:

The Danish health authority said that there was a reported death in the country but that "at present, it cannot be concluded whether there is a link between the vaccine and the blood clots."

Use of the vaccine will be suspended until further notice, the health authority said on Thursday, but the decision will be reviewed in two weeks' time.

Source:https://www.euronews.com/2021/03/11/denmark-suspends-astrazeneca-covid-19-vaccinations-as-a-precaution-after-blood-clot-report

Iceland: This article was published on March 25, 2021 on NDTV by Agence France - Presse. Following are the relevant excerpts from the article:

As a precaution while tests continue, the vaccine will remain suspended for those aged under 65, the agency added.

Source:https://www.ndtv.com/world-news/finland-iceland-approve-astrazeneca-covid-19-vaccine-for-seniors-2398488

Italy: This article was published on June 12, 2021 on Business Standard by IANS. Following are the relevant excerpts from the article:

Italy on Friday suspended the use of the AstraZeneca vaccine for people under 60 years old, health officials announced at a weekly press conference on the Covid-19 pandemic.

The move came after an 18-year-old woman died of a blood clot Thursday after receiving an initial dose of AstraZeneca on May 25, Xinhua reported.

1639
~~490~~

According to local media reports, the young woman suffered from autoimmune thrombocytopenia (meaning that she had a low blood platelet count) and was on double hormone therapy.

Source:https://www.business-standard.com/article/current-affairs/italy-suspends-use-of-astrazeneca-vaccine-for-people-under-60-year-old-121061200086_1.html

Venezuela – This article was published on March 16, 2021 on France 24 by Agence France - Presse. Following are the relevant excerpts from the article:

Venezuela decided it will not authorize or license AstraZeneca's COVID vaccine at all due to complications in vaccinated recipients. The country had reserved 1.4 to 2.4 million doses through COVAX.

Source:https://www.france24.com/en/live-news/20210316-venezuela-will-not-authorize-astrazeneca-covid-vaccine

France: This article was published on March 15, 2021 on Reuters by Thomas Escritt and Stephanie Nebehay. Following are the relevant excerpts from the article:

Germany, France and Italy said on Monday they would suspend AstraZeneca COVID-19 shots after several countries reported possible serious side-effects.

France said it was suspending the vaccine's use pending an assessment by EMA.

"The decision taken, in conformity also with our European policy, is to suspend, out of precaution, vaccination with the AZ shot, hoping that we can resume quickly if the EMA's guidance allows," French President Emmanuel Macron said.

NOTARY GOVT. OF INDIA M. M. PABALE Maharashtra Reg. No. 15220 Expiry Dt. 30-10-2024

Source:https://www.reuters.com/article/us-health-coronavirus-idUSKBN2B722U

Portugal: This article was published on April 9, 2021 on Reuters by Caterina Demony. Following are the relevant excerpts from the article:

Portugal will from now on recommend the AstraZeneca COVID-19 vaccine only for people aged over 60, the health authority DGS said on Thursday, amid concerns over possible links between the shot and very rare cases of blood clots.

Source:https://www.reuters.com/article/us-health-coronavirus-portugal-astrazene-idUSKBN2BV2RF

Netherlands: This article was published on April 2, 2021 on Reuters by Reuters Staff. Following are the relevant excerpts from the article:

The Netherlands on Friday temporarily suspended use of the AstraZeneca COVID-19 vaccine for people under 60 following the death of a woman who had received a shot, the Health Ministry said.

About 10,000 scheduled appointments for vaccinations were to be scrapped as a result of the decision, news agency ANP reported.

The decision was made following new reports from medicine monitoring agency Lareb and discussions with health authorities, a Health Ministry statement said.

Source:https://www.reuters.com/article/us-health-coronavirus-netherlands-astraz-idUSKBN2BP13Q

United Kingdom: This article was published on May 7, 2021 on The Guardian by Ian Sample. Following are the relevant excerpts from the article:



People under 40 will be offered an alternative to the Oxford/AstraZeneca vaccine where possible and while infection rates remain low, following a recommendation from government advisers.

It comes after the Joint Committee on Vaccination and Immunisation (JCVI) reviewed the speed and uptake of Covid vaccines in the UK and the latest figures on very rare blood clots after first shots of the AstraZeneca vaccine.

Source:https://www.theguardian.com/world/2021/may/07/people-under-40-in-uk-to-be-offered-alternative-to-astrazeneca-jab

Austria: This article was published on May 18, 2021 on Medical Express. Following are the relevant excerpts from the article:

Austria will phase out AstraZeneca from its COVID-19 immunisation programme because of delivery problems and wariness among the population following reports of the vaccine's rare side effects, the health minister said.

Austria becomes the third European country to drop AstraZeneca, after Norway and Denmark ditched the vaccine over rare cases of severe blood clots in people receiving the jab.

Source:https://medicalxpress.com/news/2021-05-austria-phase-astrazeneca-virus-vaccine.html

NOTARY
M. M. PABALE
Mumbai
Maharashtra
Reg. No. 15220
Expiry Dt.
30-10-2024
GOVT. OF INDIA

1642
~~493~~

EXHIBIT "RA-29"

How vaccines don't reduce Covid cases even at a country level.

Israel had a huge surge in mid-September despite leading most countries in vaccination levels.

> *"Health Ministry Director-General Nachman Ash said Tuesday that the current wave of coronavirus infections is surpassing anything seen in previous outbreaks and that he is disappointed that a recent downward trend appeared to be reversing....pointing out that there is an average of 8,000 new infections each day, with occasional peaks over 10,000, he said, "That is a record that did not exist in the previous waves,,, including the massive third wave at the end of last year."*

Source:https://www.timesofisrael.com/health-ministry-chief-says-coronavirus-spread-reaching-record-heights/

We investigate the relationship between the percentage of population fully vaccinated and new COVID-19 cases across 68 countries and across 2947 counties in the US.

At the country-level, there appears to be no discernable relationship between percentage of population fully vaccinated and new COVID-19 cases in the last 7 days. In fact, the trend line suggests a marginally positive association such that countries with higher percentage of population fully vaccinated have higher COVID-19 cases per 1 million people. Notably, Israel with over 60% of their population fully vaccinated had the highest COVID-19 cases per 1 million people in the last 7 days. The lack of a meaningful association between percentage population fully vaccinated and new COVID-19 cases is further exemplified, for instance, by comparison of Iceland and Portugal. Both countries have over 75% of their population fully vaccinated and have more

COVID-19 cases per 1 million people than countries such as Vietnam and South Africa that have around 10% of their population fully vaccinated.

Of the top 5 counties that have the highest percentage of population fully vaccinated (99.9–84.3%), the US Centers for Disease Control and Prevention (CDC) identifies 4 of them as "High" Transmission counties. Chattahoochee (Georgia), McKinley (New Mexico), and Arecibo (Puerto Rico) counties have above 90% of their population fully vaccinated with all three being classified as "High" transmission. Conversely, of the 57 counties that have been classified as "low" transmission counties by the CDC, 26.3% (15) have percentage of population fully vaccinated below 20%.

Link:-https://link.springer.com/article/10.1007/s10654-021-00808-7

Amid a surge in Covid-19 cases, Gibraltar has canceled official Christmas events and "strongly" discouraged people from hosting private gatherings for four weeks. Gibraltar's entire eligible population is vaccinated.
The government of Gibraltar recently announced that *"official Christmas parties, official receptions and similar gatherings"* have been canceled, and advised the public to avoid social events and parties for the next four weeks. Outdoor spaces are recommended over indoor ones, touching and hugging is discouraged, and mask wearing is advised.

More than 118% of Gibraltar's population are fully vaccinated against Covid-19, with this figure stretching beyond 100% due to doses given to Spaniards who cross the border to work or visit the territory every day. Masks are still required in shops and on public transport.

The initial vaccine campaign on the British outpost came to a conclusion in early spring 2021, with a large proportion of the population fully inoculated

NOTARY
M. M. PABALE
Mumbai
Maharashtra
Reg. No. 17229
Expiry Dt.
30-10-2026
GOVT. OF INDIA

against Covid-19. It became one of the first places in Europe to reduce restrictions following a winter of lockdowns, in what was dubbed 'Operation Freedom'.

Gibraltar is currently doling out booster doses to the over-40s, healthcare workers, and other *"vulnerable groups,"* and administering vaccines to children aged between five and 12.

Similarly, well-vaccinated countries have also reported surges in Covid-19 infections recently. In Singapore, where 94% of the eligible population have been inoculated, cases and deaths soared to record highs at the end of October, and have since subsided slightly. In Ireland, where around 92% of the adult population is fully vaccinated, cases of Covid-19 and deaths from the virus have roughly doubled since August.

https://www.rt.com/news/540442-gibraltar-cancels-christmas-covid/



1645
496

EXHIBIT "RA-30"

Vaccinated people are at higher risk of testing positive, hospitalization, & death

"A majority of gravely ill patients in Israel are double vaccinated. A majority of deaths over 50 in England are also double vaccinated.

Link: https://www.science.org/content/article/grim-warning-israel-vaccination-blunts-does-not-defeat-delta

https://cdn.nexusnewsfeed.com/images/2021/8/new-severe-covid-19-patients-thumb-1631973102161.png

https://cdn.nexusnewsfeed.com/images/2021/8/covid-19-delta-variant-hospital-admission-and-death-in-england-1631973123881.png

https://cdn.nexusnewsfeed.com/images/2021/8/covid-19-delta-variant-hospital-admission-and-death-in-england-1631973123881.png

A paper published Sept. 30 in Euro surveillance raises questions about the legitimacy of "vaccine-generated herd immunity."

The study cites a COVID outbreak which spread rapidly among hospital staff at an Israeli Medical Center — despite a 96% vaccination rate, use of N-95 surgical masks by patients and full personal protective equipment worn by providers.

The calculated rate of infection among all exposed patients and staff was 10.6% (16/151) for staff and 23.7% (23/97) for patients, in a population with a 96.2% vaccination rate (238 vaccinated/248 exposed individuals).

NOTARY M. M. PABALE Mumbai Maharashtra Reg. No. 15220 Expiry Dt. 30-10-2024 GOVT. OF INDIA

The paper noted several transmissions likely occurred between two individuals both wearing surgical masks, and in one instance using full PPE, including N-95 mask, face shield, gown and gloves.

Link: https://www.eurosurveillance.org/content/10.2807/1560 7917.ES.2021.26.39.2100822

Assam: 80% Covid-19 infections among vaccinated in Guwahati

https://timesofindia.indiatimes.com/city/guwahati/assam-80-covid-19-infections-among-vaccinated-in-guwahati/articleshow/86791235.cms

Over 50% new COVID-19 cases, deaths in Kerala from vaccinated section.

https://www.onmanorama.com/news/kerala/2021/10/12/kerala-covid-cases-deaths-among-vaccinated.html

More than half of hospitalised Covid-19 cases among vaccinated in Bengaluru

https://www.deccanherald.com/state/top-karnataka-stories/more-than-half-of-hospitalised-covid-19-cases-among-vaccinated-in-bengaluru-1015918.html

Half of India's 87k breakthrough Covid cases in Kerala

Contributing over half of the new Covid positive cases in the country, the state has also accounted for half of the breakthrough infections reported till date.

https://www.newindianexpress.com/states/kerala/2021/aug/20/half-of-indias-87k-breakthrough-covid-cases-in-kerala-2347145.html

1647
~~498~~

Nearly 80% (91 out of 114) Covid-19 cases reported from Sept 1 till Oct 23 in Lucknow were of breakthrough infections, according to data accessed by TOI from the office of Chief Medical Officers.

http://timesofindia.indiatimes.com/articleshow/87277252.cms?utm_source=contentofinterest&utm_medium=text&utm_campaign=cppst

Gurgaon : Over half of Covid Cases in October were breakthrough infections https://timesofindia.indiatimes.com/city/gurgaon/over-half-of-covid-cases-in-oct-were-breakthrough-infections/articleshow/87746000.cms

77% of those tested Covid-19 +ve in Chandigarh in November were fully vaccinated.

About 77 per cent of the new cases of Covid reported from the city in November were fully vaccinated, as per the data shared by the UT health authorities.

Source: https://www.tribuneindia.com/news/chandigarh/77-of-those-tested-ve-in-chandigarh-in-november-were-fully-vaccinated-349688

Whistleblower: FDA and CDC Ignore Damning Report that over 90% of a Hospital's Admissions were Vaccinated for Covid-19 and No One Was Reporting This to VAERS.

A concerned Physician Assistant from America, Deborah Conrad, convinced her hospital to carefully track the Covid-19 vaccination status of every patient admitted to her hospital. The result is shocking.

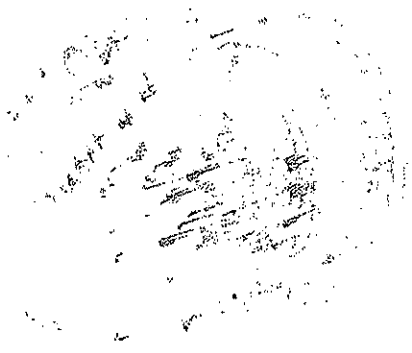
NOTARY
M. M. PABALE
Mumbai
Maharashtra
Reg. No. 15220
Expiry Dt.
30-10-2024
GOVT. OF INDIA

As Ms. Conrad has detailed, her hospital serves a community in which less than 50% of the individuals were vaccinated for Covid-19 but yet, during the same time period, approximately 90% of the individuals admitted to her hospital were documented to have received this vaccine.

One would think that after an association was identified by a healthcare professional, our health authorities would at least review this finding, right? Sadly, when Ms. Conrad reached out to health authorities herself, she was ignored. My firm then sent a letter to the CDC and FDA on July 19, 2021 on Ms. Conrad's behalf (see letter below), yet neither agency has responded. Even worse, when doctors came to Ms. Conrad for assistance with filing VAERS report for their patients, the hospital prohibited her from filing these reports.

https://aaronsiri.substack.com/p/whistleblower-fda-and-cdc-ignore-3e2





1649

~~500~~

EXHIBIT "RA-31"

Research shows vaccinated people are 13 times more likely to get infected than those who are naturally immune.

"Most recently, researchers in Israel report that fully vaccinated persons are up to 13 times more likely to get infected than those who have had a natural COVID infection.

"As explained by ScienceMag: The study' found in two analyses that people who were vaccinated in January and February were, in June, July and the first half of August, six to 13 times more likely to get infected than unvaccinated people who were previously infected with the coronavirus.

'"In one analysis, comparing more than 32,000 people in the health system, the risk of developing symptomatic COVID-19 was 27 times higher among the vaccinated, and the risk of hospitalization eight times higher.'

"The study also said that, while vaccinated persons who also had natural infection did appear to have additional protection against the Delta variant, the vaccinated were still at a greater risk for COVID-19-related-hospitalizations compared to those without the vaccine, but who were previously infected.

"Vaccinees who hadn't had a natural infection also had a 5.96-fold increased risk for breakthrough infection and a 7.13-fold increased risk for symptomatic disease.

https://www.sciencemag.org/news/2021/08/having-sars-cov-2-once-confers-much-greater-immunity-vaccine-no-infection-parties

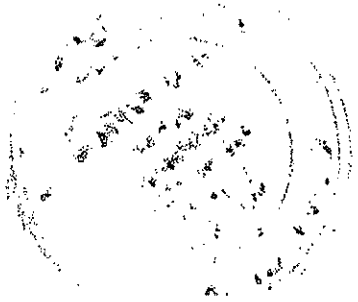
"'This study demonstrated that natural immunity confers longer lasting and stronger protection against infection, symptomatic disease and hospitalization

NOTARY A. M. PEALE Mumbai Maharashtra Reg. No. 15220 Expiry Dt. 30-14-2024 GOVT. OF INDIA

caused by the Delta variant of SARS-CoV-2, compared to the BNT162b2 two-dose vaccine-induced immunity,' study authors said.

https://www.medrxiv.org/content/10.1101/2021.08.24.21262415v1





1651
~~502~~

EXHIBIT "RA-32"

Evidence that Covid Vaccines compromise Natural Immunity

According to a 2021 study by a team of scientists from the

Netherlands and Germany, titled, "The BNT162b2 mRNA vaccine against SARS-CoV-2 reprograms both adaptive and innate immune responses," the vaccine "modulated the production of inflammatory cytokines by innate immune cells upon stimulation with both specific (SARS-CoV-2) and non-specific (viral, fungal and bacterial) stimuli.

The response of innate immune cells to TLR4 and TLR7/8 ligands was lower after BNT162b2 vaccination, while fungi-induced cytokine responses were stronger."

The paper further stated the following: **This may hamper the initial innate immune response against the virus , as defects in TLR7 have been shown to result in and increased susceptibility to COVID-19 in young males.**

These results collectively demonstrate that the effects of the BNT162b2 vaccine go beyond the adaptive immune system and can also modulate innate immune responses."

[emphasis mine]

In other words, the BNT162b2 injection modified the innate immune response and seemingly weakened certain aspects of it, and no one really knows or understands the details and the very long-term consequences.

NOTARY
M. M. PARALE
Mumbai
Maharashtra
Reg. No. 15220
Expiry Dt.
30-10-2024
GOVT. OF INDIA

Source:https://www.medrxiv.org/content/10.1101/2021.05.03.21256520v1

A study titled, "Hepatitis C Virus Reactivation Following COVID-19 Vaccination - A Case Report," deserved to be quoted in detail:

"Materials and methods: Here, we report a case of an 82-year old patient with dementia who was admitted to a nursing home in the Netherlands. After vaccination with COVID-19 vaccination, physical examinations and lab tests were performed.

Results: She had a reactivation of hepatitis C infection after vaccination with the mRNA-based Pfizer-BioNTech COVID-19 vaccine. This reactivation manifested with jaundice, loss of consciousness, hepatic coma and death.

Conclusion: This reactivation of hepatitis C virus after vaccination with the Pfizer-BioNTech COVID-19 vaccine suggests a need for critical consideration ofindividuals with prior HCV infection and considered for COVID-19 vaccination."

In other words, she passed away as a result of a hepatitis C infection that, according to the researchers, activated after she received the injection. While she luckily lived a long life and passed away at 82, no one knows how long she would have lived if she didn't get the injection. It's as simple as nobody knows, and it doesn't look like our leaders care to make sure that this is studied thoroughly before mandating the product on everyone.

Source:https://pubmed.ncbi.nlm.nih.gov/34512037/

Another study titled, "Varicella zoster virus reactivation and mRNA vaccines as

1653
~~504~~

a trigger" talks about the reactivation of the zoster virus following the mRNA vaccines. It states the following:

"The suggested pathogenic mechanism was induced lymphopenia and the functional impairment of lymphocytes, particularly CD8+ T cells and natural killer cells. With regard to COVID-19 vaccines, it is postulated that, as a product of a massive shifting of naïve CD8+ cells, VZV-specific CD8+ cells are not temporarily capable of controlling VZV. The question of why VZV reactivation occurs almost exclusively with mRNA-based COVID-19 vaccines and not with viral vector or inactivated COVID-19 vaccines remains to be answered."

Source:https://www.ncbi.nlm.nih.gov/labs/pmc/articles/PMC8298014/

In this informative video, Dr. Ryan Cole, Board Certified Anatomic and Clinical Pathologist trained at Mayo Clinic, with a specialty expertise in skin pathology, provides a good explanation of the potential mechanisms of immunosuppression as a result of COVID injections. He also mentions his observations regarding an alarming trend of previously-under-control cancers going out of remission after the administration of COVID injections. In another video, he goes further into what he believes to be a great uptick in cancers post-vaccination, based on the results that he is seeing in his labs.

Source:https://thehighwire.com/videos/do-covid-mrna-vaccines-disrupt-the-innate-immune-system/

https://www.bitchute.com/video/wGKbPz19ju3V/

NOTARY
M. M. PARALE
Mumbai
Maharashtra
Reg. No. 15220
Expiry On
31-10-2024
GOVT. OF INDIA

1654
~~505~~

EXHIBIT "RA-33"

Ways other than vaccination of reducing Covid-19 infection, hospitalization, & death

Ivermectin

Conclusions: Moderate-certainty evidence finds that large reductions in COVID-19 deaths are possible using ivermectin. Using ivermectin early in the clinical course may reduce numbers progressing to severe disease. The apparent safety and low cost suggest that ivermectin is likely to have a significant impact on the SARS-CoV-2 pandemic globally.

Source:https://www.ncbi.nlm.nih.gov/labs/pmc/articles/PMC8248252/

Ivermectin for Prevention and Treatment of COVID-19 Infection: A Systematic Review, Meta-analysis, and Trial Sequential Analysis to Inform Clinical Guidelines. American Journal of Therapeutics, 28, e434–e460, July 2021

https://www.ncbi.nlm.nih.gov/labs/pmc/articles/PMC8415517/#R1

Nutritional & Oxidative Therapies

Interventions: Oral Vitamins A, C, D, and iodine were given to 107 subjects (99%). Intravenous solutions of hydrogen peroxide and Vitamin C were given to 32 (30%) and 37 (35%) subjects.

Thirty-seven (35%) of the cohort was treated with intramuscular ozone. A dilute, nebulized hydrogen peroxide/saline mixture, with Lugol's iodine, was used by 91 (85%).

1655
~~506~~

Main Outcome Measures: History and physical exam were reviewed for COVID-19 symptoms including cough, fever, shortness of breath, and gastrointestinal complaints. Laboratory reports were examined for SARS-CoV-2 results. Symptomatic improvement after treatment was reported for each patient consisting of first improvement, mostly better, and completely Better

Results: There were a total of 107 patients diagnosed with COVID-19. Thirtyfour were tested for SARS-CoV-2(32%) and twenty-seven (25%) tested positive. Three were hospitalized (3%) with two of the three hospitalized before instituting treatment and only one requiring hospitalization after beginning treatment. There were no deaths. The most common symptoms in the cohort were fever (81%), shortness of breath (68%), URI which included cough (69%), and gastrointestinal distress symptoms (27%). For the entire cohort, first improvement was noted in 2.4 days. The cohort reported symptoms mostly better after 4.4 days and completely better 6.9 days after starting the program. For the SARS-CoV-2 test positive patients, fever was present in 25 (93%), shortness of breath in 20 (74%) and upper respiratory symptoms including cough in 21 (78%) while gastrointestinal symptoms were present in 9 (33%).

The time to improvement in the SARS-CoV2 test positive group was slightly longer than the entire cohort.

Conclusion: At present, there is no published cure, treatment, or preventive for

COVID-19 except for a recent report on dexamethasone for seriously ill patients. A novel treatment program combining nutritional and oxidative therapies was shown to successfully treat the signs and symptoms of 100% of 107 patients diagnosed with COVID-19.

NOTARY M. M. PARALE Mumbai Maharashtra Reg. No. 15220 Expiry Dt. 30-10-2024 GOVT. OF INDIA

Each patient was treated with an individualized plan consisting of a combination of oral, IV, IM, and nebulized nutritional and oxidative therapies which resulted in zero deaths and recovery from COVID-19.

Source:https://cf5e727d-d02d-4d71-89ff-9fe2d3ad957f.filesusr.com/ugd/adf864_cc5004cfa84a46d3b1a0338d4308c42c.pdf

Omega 3 Fatty Acids

Two peer-reviewed randomized, controlled trials suggest that omega-3 fatty acids help hasten recovery from COVID, and when given to ICU patients may make them six times more likely to survive.

https://www.sciencedirect.com/science/article/pii/S2589004221010087

Results

The intervention group had significantly higher 1-month survival rate and higher levels of arterial pH, HCO3, and Be and lower levels of BUN, Cr, and K compared with the control group after intervention (all $P < 0.05$). There were no significant differences between blood glucose, Na, HCT, Ca, P, MAP, O2sat, PO2, PCO2, WBCs, GCS, Hb, Plt, PTT, and albumin between two groups.

Conclusion

Omega-3 supplementation improved the levels of several parameters of respiratory and renal function in critically ill patients with COVID-19. Further clinical studies are warranted.

1657
~~508~~

Source:https://translational-medicine.biomedcentral.com/articles/10.1186/s12967-021-02795-5 https://translational-medicine.biomedcentral.com/articles/10.1186/s12967-021-02795-5

Arginine

An Italian clinical trial peer-reviewed and published this past month in EClinical Medicine, one of the journals published by The Lancet, is nothing short of incredible.

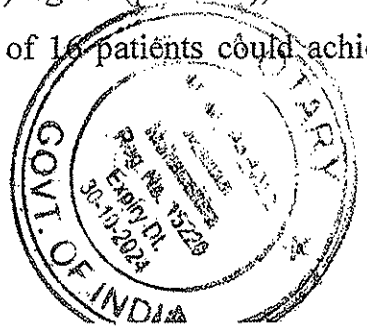
It provides rigorous evidence that 3.2 grams per day of the amino acid L-arginine dramatically hastens the improvement in respiratory function in patients that already have confirmed pneumonia and are already suffering from hypoxemic respiratory distress. It may turn out to be lifesaving.

Source:https://www.thelancet.com/journals/eclinm/article/PIIS2589-5370(21)00405-3/fulltext

Vitamin D Randomized Controlled Trial from North India: https://pmj.bmj.com/content/early/2020/11/12/postgradmedj-2020-139065

Aim Effect of high dose, oral cholecalciferol supplementation on SARS-CoV-2 viral clearance.

Results Forty SARS-CoV-2 RNA positive individuals were randomised to intervention (n=16) or control (n=24) group. Baseline serum 25(OH)D was 8.6 (7.1 to 13.1) and 9.54 (8.1 to 12.5) ng/ml (p=0.730), in the intervention and control group, respectively. 10 out of 16 patients could achieve 25(OH)D>50



ng/ml by day-7 and another two by day-14 [day-14 25(OH)D levels 51.7 (48.9 to 59.5) ng/ml and 15.2 (12.7 to 19.5) ng/ml ($p<0.001$) in intervention and control group, respectively]. 10 (62.5%) participants in the intervention group and 5 (20.8%) participants in the control arm ($p<0.018$) became SARS-CoV-2 RNA negative. Fibrinogen levels significantly decreased with cholecalciferol supplementation (intergroup difference 0.70 ng/ml; P=0.007) unlike other inflammatory biomarkers.

Conclusion Greater proportion of vitamin D-deficient individuals with SARS-CoV-2 infection turned SARS-CoV-2 RNA negative with a significant decrease in fibrinogen on high-dose cholecalciferol supplementation.

Another trial from India:

https://www.ncbi.nlm.nih.gov/labs/pmc/articles/PMC8339450/

Conclusion

Vitamin D status appears to be strongly associated with COVID-19 clinical severity. After COVID-19 confirmation, Vitamin D level should be measured in all patients and curative plus preventive therapy should be initiated.

Observational Studies:

-https://onlinelibrary.wiley.com/doi/10.1111/ijcp.14675

-https://www.thelancet.com/journals/eclinm/article/PIIS2589-5370(21)00247-9/fulltext

-https://www.metabolismjournal.com/article/S0026-0495(21)00053-6/fulltext

1659

~~510~~

Population Wide Studies:

Europe :

-https://link.springer.com/article/10.1007/s00508-021-01833-y

-

https://www.sciencedirect.com/science/article/pii/S1876034120305311?via%3Dihub

-https://www.wjgnet.com/2220-3249/full/v10/i3/111.htm

-https://www.medrxiv.org/content/10.1101/2021.03.11.21253361v2

-https://www.medrxiv.org/content/10.1101/2021.03.04.21252885v2

47 countries from Asia and Europe :

-https://clinicalnutritionespen.com/article/S2405-4577(21)00191-1/fulltext

-https://www.liebertpub.com/doi/10.1089/hs.2020.0137

Asian countries:

https://www.sciencedirect.com/science/article/pii/S1871402121000746?via%3Dihub

-https://link.springer.com/article/10.1007%2Fs12291-020-00950-1

Studies which looked at blood levels as a measure to prevent hospitalization and death:

-https://journals.sagepub.com/doi/10.1177/00368504211036854

-https://link.springer.com/article/10.1007%2Fs00394-020-02411-0

-https://www.tandfonline.com/doi/full/10.1080/07315724.2021.1877580

-https://academic.oup.com/jn/article/151/8/2199/6274957

-https://www.tandfonline.com/doi/full/10.1080/07315724.2020.1856013

NOTARY
M. M. PARMAR
Mumbai
Reg. No. 15220
Expiry Dt. 30-10-2024
GOVT. OF IND

1660

~~511~~

Randomized Controlled Trials :

https://www.sciencedirect.com/science/article/pii/S0960076020302764?via%3Dihub

-https://jamanetwork.com/journals/jama/fullarticle/2776738

-https://www.mdpi.com/2077-0383/10/11/2378

-https://www.mdpi.com/2072-6643/13/7/2170

-https://www.nature.com/articles/s41598-021-90189-4

Povidone Iodine

A randomized controlled trial suggesting that gargling with povidone-iodine clears the virus from the nose and throat within four days.

20 asymptomatic or pre-symptomatic COVID-19 patients from a Malaysian university hospital were randomly allocated into four groups:

Group A gargled with 10 milliliters of 1% povidone-iodine for 30 seconds, three times per day.

Group B did the same with 20 milliliters of Listerine.

Group C did the same thing with 100 milliliters of tap water.

Group D acted as untreated controls.



The patients ranged in age from 22 to 56, had positive PCR tests for COVID-19 but hadn't developed any symptoms yet, were enrolled within 5 days of being tested, and did not receive any other treatments.

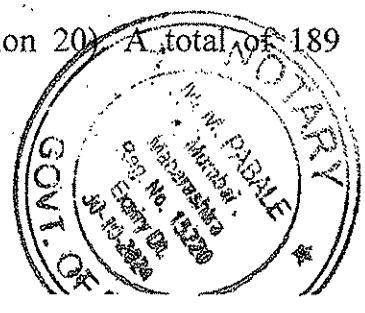
Two patients had co-morbidities: one had asthma and one had obesity. Unfortunately, they didn't report which groups these two patients were in.

On day 4, 100% of those in the povidone-iodine group had cleared the virus.

Source:https://www.medrxiv.org/content/10.1101/2020.09.07.20180448v1

Povidone Iodine prevents Covid-19 in a study

"Povidone-iodine (PVP-I) is a time-tested antiseptic agent with excellent virucidal (99.99%) properties. Repurposing it against coronavirus disease-19 (COVID-19) is a relatively newer concept and has been sparsely tested in vivo. The most common route of entry of severe acute respiratory syndrome coronavirus 2 (SARS CoV-2) is the nasopharynx. Averting colonization of the virus could be one of the best options to reduce the incidence of infection. PVP-I gargle and mouthwash were found to be effective in vitro rapid inactivation against SARS-CoV-2 on a smaller scale (Hassandarvish et al. in BDJ 1–4, 2020, Pelletier et al. in ENTJ 1–5, 2020). However, efficacy in humans is lacking. To assess the virucidal effect of PVP-I against SARS-CoV-2 located in the nasopharynx was the objective of this parallel armed randomized clinical trial. We screened all RT-PCR-confirmed COVID-19 cases aged 18 years and above with symptoms. Written informed consent was obtained before randomization. Nasopharyngeal clearance of SARS-CoV-2 was tested after single time application of PVP-I nasal irrigation (NI) at diluted concentrations of .4%, .5% and .6% and PVP-I nasal spray (NS) at diluted concentrations of .5% and .6%. All groups were compared to the corresponding controls (distilled water). The primary outcome was viral clearance in a repeat RT-PCR (qualitative), and the secondary outcome was the number of adverse events. Final data analysis was performed using the statistical software SPSS (Version 20). A total of 189



confirmed COVID-19 cases were randomized into seven groups: 27 patients in each group. Of all, 159 (84.1%) were male, and 30 (15.9%) were female. We observed a statistically significant proportion of nasopharyngeal clearance with all strengths of PVP-I NI and PVP-I NS compared to the corresponding controls. Additionally, 0.5% NI was significantly better than 0.5% NS for viral clearance ($p = 0.018$) and had the highest nasopharyngeal clearance among all strengths ($n = 25$, 92.6%). 0.6% NS is better than CNS and 0.5%NS in viral clearance. The only adverse event was nasal irritation recorded in two patients each in the 0.4% and 0.6% PVP-I NI groups (Tables 1 and 2). PVP-I NI and NS are proved as effective virucidal agent against SARS-CoV-2 in human body. Our recommendation is to use PVP-I in naopharynx (as well as oropharynx) to prevent COVID-19."

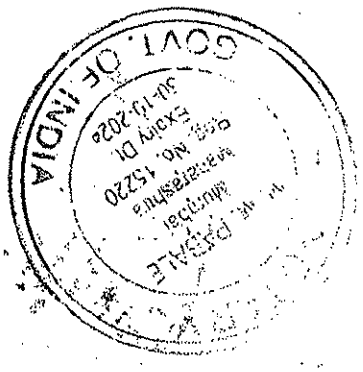
Source:https://www.ncbi.nlm.nih.gov/labs/pmc/articles/PMC8130786/

Black Seed (Nigella Sativa) use in Clinical Trials find 70-80% reduction in Covid Death Rate

https://www.researchgate.net/publication/352134969_Clinical_Trial_of_Black_Seeds_Against_COVID_-19_in_Kirkuk_City_Iraq

https://www.researchgate.net/publication/350467852_Preventive_Value_of_Black_Seed_in_People_at_Risk_of_Infection_with_COVID_-19

https://www.medrxiv.org/content/10.1101/2020.10.30.20217364v4



1663
514

EXHIBIT "RA-34"

GOVERNMENT OF MAHARASHTRA
Department of Revenue and Forest, Disaster Management, Relief and Rehabilitation, Mantralaya, Mumbai- 400 032
No: DMU/2020/CR. 92/DisM-1, Dated: 27th November, 2021

ORDER

Reference:

a. The Epidemic Diseases Act, 1897
b. The Disaster Management Act, 2005

The State Government is currently recording fewer number of COVID 19 positive cases consistently over the past few months. Also, there has been a steady as well as consistent decline in the trend curve of COVID cases in the country and nearby states. All these succusses are due to discipline in adherence by various establishments to various necessary restrictions that have been imposed on various activities as well as discipline in Covid Appropriate Behaviour shown by majority of public at large. Vaccination drive in the state and the country also has seen reasonable uptake and has contributed immensely to reduction in pressure on health infrastructure, public as well as private. In the light of the said fact the State Government is now considering to open up economic, social, entertainment and cultural activities with fewer restrictions, especially for fully vaccinated persons.

Thus in exercise of the powers conferred under the Disaster Management Act, 2005, the undersigned in the capacity of the Chairperson of the State Executive Committee of the State Disaster Management Authority, in super cession of all earlier orders by the State Government with regard to imposition of restrictions for preventing the transmission of the COVID 19 virus, decrees with immediate effect that all economic, cultural, social, sports and entertainment activities will now be allowed as per the normal timings decided by various local or other competent authorities before the advent of the COVID 19 pandemic, subject to the following conditions:

1. **Adherence to CAB (Covid Appropriate Behaviour):** Strict adherence to CAB as laid down by the State and Central Government from time to time shall be observed by all, including the service providers, owners of premises, licensees, organizers etc. as well as all visitors, service takers, customers, guests etc. Detailed guidelines for CAB (Covid Appropriate Behaviour) as well as fines in case of breach shall be as per CAB Guidelines and Fines stated hereinafter.

NOTARY GOVT. OF INDIA N. M. PAGALE Mumbai Maharashtra Reg. No. 15229 Expiry Dt. 30-10-2024

2. **Requirement of being Fully Vaccinated:**
   a. All persons connected with the organization of any program, event or show, ticketed or non-ticketed, as well as all service providers and participants (like players, actors etc.), visitors, guests, customers shall be fully vaccinated as per the definition of the same given hereinafter.
   b. Any shop, establishment, mall, event, gathering etc. where a member of public has a right to come and get services must be manned by fully vaccinated persons and all visitors, customers for such places shall be fully vaccinated.
   c. All public transport shall be used only by fully vaccinated persons.
   d. The Universal Pass created by the State Government (https://epassmsdma.mahait.org or telegram-MahaGovUniversalPass Bot) shall be a valid proof for status of full vaccination. Or else, Cowin Certificate with a valid ID proof carrying photo may be taken a valid proof for the same. For citizens bellow 18 years, other Government or school issued photo identity and for those who are unable to take the vaccine due to medical reasons, a certificate from a certified medical practitioner may serve as documentary evidence for entry.
   e. Though offices and other establishments where there is no visit by any person of general public as well as private transport does not have this requirement of being open to fully vaccinated persons, they are strongly advised to go for full vaccination.
3. **Travel into Maharashtra State:** All travellers into state from any international destination shall be governed by directions of Government of India in this respect. All domestic travellers into the state shall either be fully vaccinated as defined hereinafter or shall carry a RT-PCR test valid for 72 hours.
4. **Restriction on attendance in any program, event etc.:**
   a. In case of any program/ event/ activity happening in an enclosed/ closed space like a cinema hall, theatre, marriage hall, convention hall etc, people up to 50 percent of the capacity of the space will be allowed.
   b. In the case of open to sky spaces, for any events or gatherings, people up to 25 percent of space capacity will be allowed. Concerned DDMA shall have authority to decide the capacity in case of such locations of gatherings or events, if not already declared formally (like stadiums).

1665

516 c. In the case the total number of people present for any gathering in accordance with the above rules exceeds 1 thousand, then the local disaster management authority will have to be informed of the same and the local disaster management authority may send their representative to supervise as observers any such gathering and to ensure that there is strict adherence to the above mentioned rules. The said representative of DDMA shall have authority to order closure of part or full activity if CAB is seen to be violated in large scale endangering spread of Covid 19.

5. **Other reasonable restrictions by DDMA:** Restrictions and conditions mentioned herein may be augmented, but not diluted, by any DDMA for their respective jurisdiction, if deemed fit at any moment of time, but not without giving 48 hours of information through public notice. Any restrictions that are in force on the date of this order, levied by DDMA shall cease to operate after 48 hours unless re-issued with a public notice for continuation.

6. **Definition of being Fully Vaccinated:**

A fully vaccinated person will mean-

- Any person who has received both doses of the vaccine and 14 days have lapsed since the administration of the second dose; or
- Any person having a medical condition that does not allow him or her to take the vaccine and has a certificate to that extent from a recognised doctor; or
- A person who is less than 18 years of age.

7. **CAB rules and fines:**

Definition: *CAB can be defined as the everyday common behaviour needed to be followed by individuals and organisations to curb the spread of the COVID 19 virus and thereby breaking the chain of transmission of the same. Aspects of behaviour that's characterised as CAB include those mentioned below and also all such rational aspects that may hinder spread of Covid 19 virus given its methodology of spread indicated herein.*

Following are some aspects of basic COVID appropriate behaviour that have to be followed by everyone at all times. All organisations are to ensure that all their employees, visitors to their campuses, customers or anyone engaged in any activity of the organisations, directly or indirectly, follow the same and shall be responsible for enforcing the same on their campus and/ or while transacting the transactions related to business or other activities related to concerned organization. Organisations are also responsible for

NOTARY M. M. PAGALE Mumbai Maharashtra Reg. No. 15220 Expiry Dt. 30-10-2024 GOVT. OF INDIA

vailability of hand sanitisers, soap & water, thermal scanners etc. required for following CAB by all such personnel at all such locations that are under its control or where it is transacting its business or other activities.

1. Wear a mask at all times in the right way. Mask should cover nose and mouth at all times. (An handkerchief will not be considered as mask & person using would be liable for fine.)
2. Maintain social distancing (6 feet distance) at all times wherever possible.
3. Wash hands frequently and thoroughly by soaps or sanitisers.
4. Avoid touching nose/ eyes/ mouth without washing your hands with soap or without use of sanitiser.
5. Maintain proper respiratory hygiene.
6. Regularly clean and disinfect frequently cleaned surfaces.
7. When coughing or sneezing, cover the mouth and nose using tissue and throw used tissues in the trash; if one doesn't have tissue, one should cough and sneeze into bent elbow and not one's hand.
8. Do not spit in public places.
9. Avoid crowds and maintain safe distance *(6 feet distance)* in public places.
10. Greet anyone without physical contact.
11. Any other rational behaviour required for avoiding spread of Covid 19 virus.

Penalties:

- Any individual not following CAB expected is these rules shall be fined Rs. 500/- for each instance of default.
- If the default by an individual is seen in any premises of organization or establishment that is supposed to impose CAB on their visitors, customers etc., in addition to imposing fine on the individual, these organizations or establishments shall also be fined Rs. 10,000/-. If any organization or establishment is seen to be a regular defaulter in ensuring discipline for CAB in its visitors, customers etc. such organization or establishment shall be closed till the notification of Covid 19 as a disaster remains in force.
- If an organization or establishment fails to follow CAB or SOP itself, it will be liable to be fine of Rs. 50000/- for each instance. Frequent

1667

~~518~~

defaults shall lead to closure of the organization or establishment till the notification of Covid 19 as a disaster remains in force.

- If a default is found inside any taxi or private transport four- wheeler or inside any bus, along with the individual defaulting CAB being fined Rs. 500/-, driver, helper or conductor who are providing service shall also be fined Rs. 500/-. Owner transport agency in cases of buses shall be fined Rs. 10000/- for each instance of default. Frequent defaults shall lead to withdrawal of license or closure of operations for the owner agency till the notification of Covid 19 as a disaster remains in force.
- The above mentioned rules regarding COVID appropriate behavior to be followed mandatorily and violation of the same will result in fines and penalties as stated above as well as any other fine or penalty may be levied on the violators by any disaster management authority in accordance with the Disaster Management Act, 2005. The rules/ polices for CAB shall be in accordance with the above and any other issue regarding CAB not specifically mentioned herein shall be in accordance with the current rules/ orders of the State Government that are in force.

BY ORDER OF AND IN THE NAME OF THE GOVERNOR OF MAHARASHTRA

27/11/21

(Sitaram Kunte)

Chief Secretary

NOTARY
M. M. PABALE
Mumbai
Maharashtra
Reg. No. 15220
Expiry Dt.
30-10-2024
GOVT. OF INDIA

1668
~~519~~

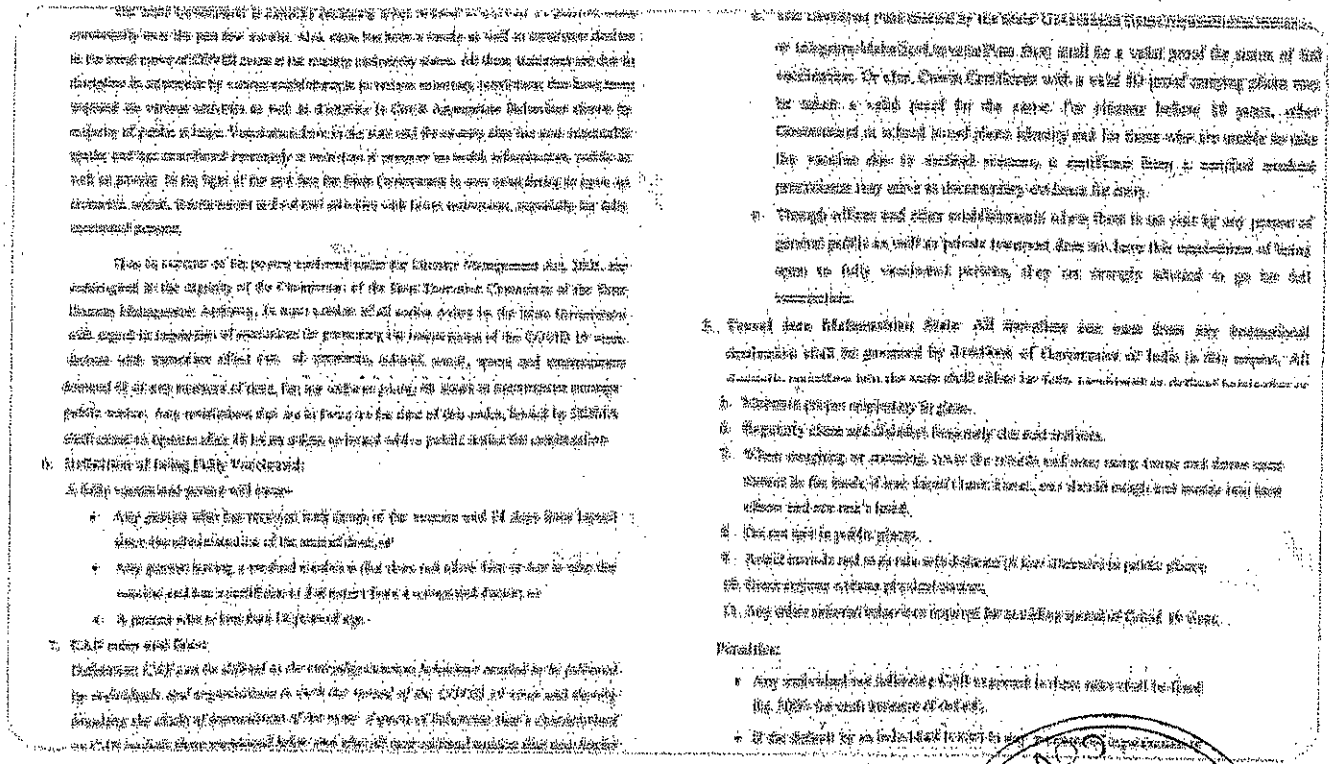
← Thread

ANI
@ANI

...

#COVID19 | Maharashtra Govt issues fresh restrictions & permissions.

All travellers into state from any int'l destination shall be governed by directions of Govt of India in this respect. Domestic travellers shall either be fully vaccinated or carry RT-PCR test valid for 72 hrs.



3:19 PM · Nov 27, 2021 · Twitter Web App

113 Retweets 25 Quote Tweets 427 Likes

Don't miss what's happening
People on Twitter are the first to know.

~~1670~~ 1670

~~520~~

EXHIBIT "RA-35"

CoWIN launches new API: 'Know Your Customer's/Client's Vaccination Status'

Source: Money Control

Link: https://www.moneycontrol.com/news/technology/cowin-launches-new-api-know-your-customersclients-vaccination-status-7453181.html

Published on: September 10, 2021

To use this API, an individual needs to enter his/her mobile number and name. Thereafter, they will get an OTP which they have to enter. In return, Co-WIN will send a response to the verifying entity on the individual's status of vaccination, which will be be as follows:- Person is not vaccinated – Person is partially vaccinated – Person is fully vaccinated.

Co-WIN has developed a new API called 'Know Your Customer's/Client's Vaccination Status', or KYC-VS, which will enable a verifying entity to know whether a person has been vaccinated against coronavirus or not, the Union Health Ministry said on September 10.

Over 72 crore vaccine doses have been administered since the vaccination campaign against COVID-19 was flagged off on January 16 this year in the country.

To provide proof of vaccination for each of these individuals, Co-WIN is already issuing a digitally verifiable certificate. This certificate can be saved on a digital device (smartphone, tablet, laptop etc), or stored in Digi Locker from where it can be digitally shared as and when required as proof of vaccination, the ministry said in a statement. Similarly, at entry points where such certificate

NOTARY M. M. KABALE Mumbai Maharashtra Reg. No. 15279 Expiry Dt. 30-10-2024 GOVT. OF INDIA

is required (e.g., in malls, office complexes, public events etc), it may be shown in both digital and physical forms.

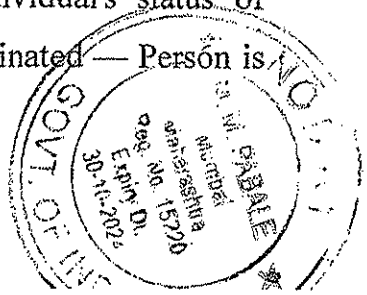
However, there may be instances where an entity does not need to see the certificate in full and would just need to know whether an individual has been vaccinated or not, the ministry said. An enterprise/employer may like to know the vaccination status of its employees to resume functions in offices, workplaces etc, it added.

The Railways may want to get the status of vaccination of the passengers who are getting their seats reserved in the trains. Airlines may want to get the status of vaccination of the passengers who are booking their flight tickets, and/or airports may only want to allow vaccinated passengers to pass through. Hotels may want to know the vaccination status of the residents at the time they are checking into the hotel, or at the time of making online bookings, it further said.

"As the socio-economic activities are being gradually revived while maintaining everyone's safety, there is a need for a way to digitally convey the status of individuals' vaccination to entities with whom they may be engaging with for any or all reasons, as employees, passengers, residents etc."

"Therefore, there is a need to enable an Aadhaar like authentication service for the status of vaccination through Co-WIN. To take care of these cases and others that may come up, Co-WIN has developed a new API called 'Know Your Customer's/Client's Vaccination Status' or KYC-VS," the ministry said in the statement.

To use this API, an individual needs to enter his/her mobile number and name. Thereafter, they will get an OTP which they have to enter. In return, Co-WIN will send a response to the verifying entity on the individual's status of vaccination, which will be as follows: — Person is not vaccinated — Person is



1672
522

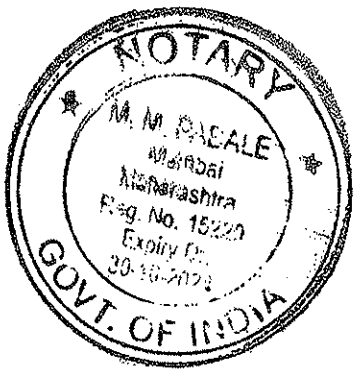
partially vaccinated — Person is fully vaccinated.

This response will be digitally signed and can be shared instantly with the verifying entity, the ministry said.

The KYC-VS is consent-based and privacy-preserving, it added. Additionally, in order to facilitate quick integration and faster adoption, the Co-WIN Team has prepared a webpage with the API, which may be embedded in any system.

This will allow for seamless integration with any system in no time, the statement said. Additionally, in order to facilitate quick integration and faster adoption, the Co-WIN Team has prepared a webpage with the API, which may be embedded in any system.

Besides the use cases pointed out, this service may be utilised by any service provider, private or public, for whom verifying an individual's vaccination status is critical for facilitating a service requested, it said.



1673
523

EXHIBIT "RA-36"

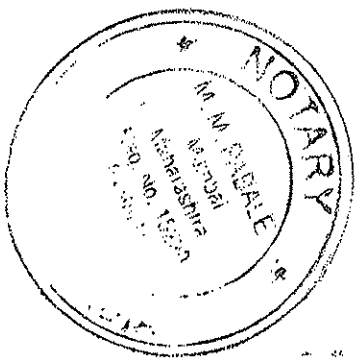
National Disaster Management Authorities website contains advisories from Ministry of Home Affairs & Ministry of Health & Family Welfare. Both MHA & MOHFW have made it clear that vaccines are voluntary in India.

https://ndma.gov.in/covid-19

https://ndma.gov.in/covid/MHA-Orders-Guidelines

https://ndma.gov.in/index.php/covid/MoHFW-Medical-Health

https://ndma.gov.in/index.php/covid/NDMA-Orders_Advisories



1674
524

EXHIBIT "RA-37"

Omicron Coronavirus Highlights: Serum Institute's Covovax vaccine gets WHO nod

Source: The Indian Express

Link: https://indianexpress.com/article/india/covid-19-omicron-variant-india-who-cases-deaths-vaccine-live-updates-7673555/

Published on: December 18, 2021

Warning against lowering the guard to prevent the disease, ICMR DG Dr Balram Bhargava said, "This is the time to avoid non-essential travel, mass gatherings and it is very important to observe low-intensity festivities."

World Health Organisation (WHO) has approved Covid-19 vaccine Covovax, manufactured by Serum Institute of India (SII), for emergency use. Sharing the information on Friday, SII CEO Adar Poonawalla said, "This is yet another milestone in our fight against Covid-19, Covovax is now WHO approved for emergency use, showing excellent safety and efficacy. Thank you all for a great collaboration."

NOTARY M. M. PABALE Mumbai Maharashtra No. 15220 Expiry Dt. 30-10-2024 GOVT. OF INDIA

Covovax is SII's version of NVX-CoV2373, the protein-based Covid-19 vaccine developed by Novavax, headquartered in USA. Like several other Covid-19 vaccines, Covovax targets the spike protein on the surface of the SARS-CoV-2 coronavirus — the protein that allows the virus to penetrate the human cell. Once launched, the vaccine will be available to be administered to beneficiaries starting from as young as three-year olds.

The Health Ministry on Friday said 101 cases of Omicron variant of Covid-19 infection have been recorded across 11 states so far. Briefing the media, Health Ministry Joint Secretary Lav Agrawal said, "Omicron variant reported in 91

countries in the world. WHO has said that Omicron is spreading faster than the Delta variant in South Africa where Delta circulation was low. It's likely Omicron will outpace Delta variant where community transmission occurs, WHO added."

Warning against lowering the guard to prevent the disease, ICMR DG Dr Balram Bhargava said, "This is the time to avoid non-essential travel, mass gatherings and it is very important to observe low-intensity festivities."

Delhi health minister Satyendar Jain said that the national capital has logged 10 new Omicron cases, taking the total tally in the city to 20. Of this, 10 people have been discharged, he said.

India logged 7,447 new coronavirus infections taking the total tally of Covid-19 cases to 3,47,26,049, while the active cases declined to 86,415, according to the Union Health Ministry data updated on Friday. The death toll climbed to 4,76,869 with 391 fresh fatalities, according to the data updated at 8 am. A decline of 830 cases has been recorded in the active Covid-19 caseload in a span of 24 hours.

Earlier today, Delhi Health Minister Satyendar Jain said that four more cases of Omicron have been detected in the national capital, taking the city's count to 10. Jain said there are currently 40 people, who are suspected cases of the variant, admitted to Lok Nayak Hospital, of whom 38 are Covid-19 positive. "None of the cases have displayed any severe symptoms till now," he said.

Meanwhile, India on Thursday recorded 7,974 Covid-19 cases and 343 deaths. With 7,948 recoveries, the active cases in the country stood at 87,245.

Covid shot for kids above 3 years will be ready in 6 months: Adar Poonawalla

1676

~~526~~

With the opening of schools across the country underscoring the need for the Covid vaccination drive to cover children, Covishield manufacturer Serum Institute of India's CEO Adar Poonawalla said Tuesday that SII is

to launch a vaccine for those below the age of 18 "all the way down to the age of three" within the next six months.

[youtube https://www.youtube.com/watch?v=Cvic6EUBQ-w]

Speaking at the 27th CII Partnership Summit 2021 during a virtual conference, Poonawalla said the vaccine, Covovax, is under trial.

"We are going to be launching a vaccine in six months for children all the way down to the age of three... At the moment, Covishield is not recommended or approved in people below the age of 18 so that's why Covovax is under trials and has shown excellent data all the way down to the age group of 3," he said.

NOTARY
M. M. PABALE
Mumbai
Maharashtra
Reg. No. 15220
Expiry Dt.
30-10-2024
GOVT. OF INDIA

1677
~~527~~

8 more Omicron cases found in Maharashtra: 6 in rural Pune, 2 in MMR

Source: The Times of India

Link: https://timesofindia.indiatimes.com/city/mumbai/mumbai-8-more-omicron-cases-found-in-state-6-in-rural-pune-2-in-mmr/articleshow/88348393.cms

Author: Pradeep Gupta

Published on: Dec 18, 2021

Mumbai: Eight new cases of the Omicron variant were detected in the state on Friday, taking the tally in Maharashtra to 40. Six were from Pune, and one each from Mumbai and Kalyan-Dombivli. All of them had been fully vaccinated, and one had even got a booster, said health authorities.

The 29-year-old from Mumbai was vaccinated with three doses of the Pfizer vaccine, confirmed civil authorities. He returned from Newark, US, on December 9. He tested positive at the airport, and his samples were sent for genome sequencing. The National Institute of Virology, Pune, confirmed the presence of Omicron on Friday. A civic official said he has been hospitalized, but has no symptoms. Two of his high risk contacts have tested negative, The city's count has gone up to 14, of whom 13 have been discharged.

All six cases in Pune were from rural areas. Four had a history of travel to Dubai while two others were their contacts. The person found with Omicron in Kalyan-Dombivli had travelled to Nigeria.

NOTARY
M. M. PADALE
Mumbai
Maharashtra
Reg. No. 15220
Expiry 21
20.10.2022
GOVT. OF INDIA

1678
528

The health department said all those infected were men between 29 and 45 years. Seven patients were asymptomatic, and one had mild symptoms. Only two out of eight were in hospital. Of the total 40 infected, 33 were vaccinated. Five of the infected were minors. Around 25 of them have already been discharged. Dr. Pradeep Awate, state surveillance officer. Said more than 50% didn't have any symptoms at all.

A 45-year-old man, his wife and two children had returned to Dombivli on November 23. They tested positive on December 3 and their samples were sent for genome sequencing the same day. Both husband and wife had taken two doses of vaccines and did not have any symptoms. Interestingly, only the man had been infected with Omicron. He was discharged on Friday.

Kalyan-Dombivli has had two Omicron patients so far. The health department had tested 24 close and 62 low-risk contacts of the Kalyan-Dombivli patients, and four were found positive. None of them had symptoms.

Of the 40 cases in Maharashtra, Mumbai has reported 14, Pimpri Chinchwad 10, Pune (rural) six, Pune city, KalyanDombivli, Osmanabad have reported two cases each, while Latur, Buldhana, Nagpur and Vasai Virar have one case each. Officials said more than 525 samples of people with international travel history have been sent for sequencing.

NOTARY
M. M. PABALE
Mumbai
Maharashtra
Reg. No. 15720
Expiry D
GOVT. OF INDIA

EXHIBIT "RA-38"

CDC Announces 79% of All US Omicron Cases Have Occurred in Vaccinated Individuals

"Among these [43] cases of COVID-19 attributed to the Omicron variant, 34 (79%) occurred in persons who completed the primary series of an FDA-authorized or approved COVID-19 vaccine ≥14 days before symptom onset or receipt of a positive SARS-CoV-2 test result," the report noted.

This figure included 14 individuals, or nearly a third, who had also received an additional or booster dose of the vaccine.

Source:https://www.cdc.gov/mmwr/volumes/70/wr/mm7050e1.htm?s_cid=mm7050e1_w

NOTARY
M. M. PEGALE
Mumbai
Maharashtra
Reg. No. 15159
Expiry Date

1680
530

SARS-CoV-2 B.1.1.529 (Omicron) Variant — United States, December 1–8, 2021

CDC COVID-19 Response Team

On December 10, 2021, this report was posted as an MMWR *Early Release on the* MMWR *website (https://www.cdc.gov/mmwr)*

A new variant of SARS-CoV-2 (the virus that causes COVID-19), B.1.1.529 (Omicron) (*1*), was first reported to the World Health Organization (WHO) by South Africa on November 24, 2021. Omicron has numerous mutations with potential to increase transmissibility, confer resistance to therapeutics, or partially escape infection- or vaccine-induced immunity (*2*). On November 26, WHO designated B.1.1.529 as a variant of concern (*3*), as did the U.S. SARS-CoV-2 Interagency Group (SIG)* on November 30. On December 1, the first case of COVID-19 attributed to the Omicron variant was reported in the United States. As of December 8, a total of 22 states had identified at least one Omicron variant case, including some that indicate community transmission. Among 43 cases with initial follow-up, one hospitalization and no deaths were reported. This report summarizes U.S. surveillance for SARS-CoV-2 variants, characteristics of the initial persons investigated with COVID-19 attributed to the Omicron variant and public health measures implemented to slow the spread of Omicron in the United States. Implementation of concurrent prevention strategies, including vaccination, masking, increasing ventilation, testing, quarantine, and isolation, are recommended to slow transmission of SARS-CoV-2, including variants such as Omicron, and to protect against severe illness and death from COVID-19.

Surveillance for SARS-CoV-2 Variants and Initial Detection of Omicron in the United States

CDC has a multifaceted surveillance system for analyzing SARS-CoV-2 variants circulating in the United States. This system obtains genomic surveillance data from 1) National SARS-CoV-2 Strain Surveillance, 2) CDC-supported contracts with several commercial diagnostic laboratories, and 3) public repositories (the Global Initiative on Sharing Avian Influenza Data [GISAID]† and the National Center for Biotechnology Information [NCBI]§) of randomly sampled viruses with metadata tagging of sequences by various partners. Genomic surveillance is implemented in partnership with state and local public health laboratories, the Association of Public Health Laboratories, and other academic and government partners.¶ As of the week ending December 4, the SARS-CoV-2 B.1.617.2 (Delta) variant was estimated to account for 99.9% of SARS-CoV-2 circulating in the United States.** Based on CDC analysis of the sequences currently available, and accounting for clustering, CDC estimates a 95% chance of detecting the Omicron variant if it accounted for ≥0.03% of circulating SARS-CoV-2 lineages during the week ending November 13 and for ≥0.05% of circulating lineages during the week ending November 20 (*4*).

To accelerate detection of COVID-19 cases attributed to the Omicron variant until they are common enough to be reliably measured by routine genomic surveillance, enhanced surveillance was initiated through National SARS-CoV-2 Strain Surveillance on November 28. The method is based on rapid screening for S-gene target failures (SGTFs) by polymerase chain reaction (PCR)–based diagnostic assays to flag potential cases of Omicron variant infection for confirmation by genomic sequencing (*5*). Specimens that display SGTFs have a higher likelihood to be Omicron (although SGTFs are not unique to Omicron) based on a mutation (69–70 deletion) that reduces S-gene target amplification in some PCR assays.

The first U.S. case of COVID-19 attributed to the Omicron variant was identified on December 1. As of December 8, cases had been reported from across the country; 22 states have reported at least one case (Arizona, California, Colorado, Connecticut, Florida, Georgia, Hawaii, Illinois, Louisiana, Maryland, Massachusetts, Minnesota, Mississippi, Missouri, Nebraska, New Jersey, New York, Pennsylvania, Texas, Utah, Washington, and Wisconsin) (Figure). This activity was reviewed by CDC and was conducted consistent with applicable federal law and CDC policy.††

Characteristics of the First Investigated U.S. COVID-19 Cases Attributed to the Omicron Variant

Details are available for 43 cases of COVID-19 attributed to the Omicron variant; 25 (58%) were in persons aged

* SIG includes representatives from CDC, the National Institutes of Health (NIH), the Food and Drug Administration (FDA), the Biomedical Advanced Research and Development Authority (BARDA), the U.S. Department of Defense (DoD), the U.S. Department of Agriculture (USDA), and the U.S. Department of Health and Human Services (HHS). This interagency group focuses on the rapid characterization of emerging variants and actively monitors their potential impact on critical SARS-CoV-2 countermeasures, including vaccines, therapeutics, and diagnostics.

† https://www.gisaid.org

§ https://www.ncbi.nlm.nih.gov/sars-cov-2

¶ https://www.cdc.gov/coronavirus/2019-ncov/variants/spheres.html

** https://covid.cdc.gov/covid-data-tracker/#variant-proportion

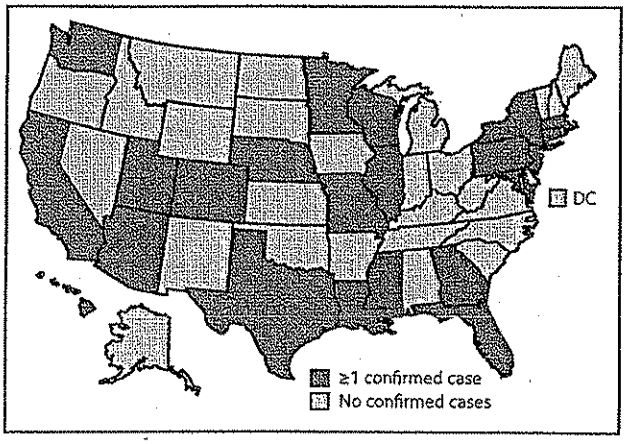
†† 45 C.F.R. part 46.102(l)(2); 21 C.F.R. part 56; 42 U.S.C. Sect. 241(d); 5 U.S.C. Sect. 552a; 44 U.S.C. Sect. 3501 et seq.

NOTARY M. M. PABALE Mumbai Maharashtra Reg. No. 1522 Expiry Dt. 10.2023 GOVT. OF INDIA

1681
~~531~~

18–39 years (Table). The earliest date of symptom onset was November 15 in a person with a history of international travel. Fourteen (33%) persons reported international travel during the 14 days preceding symptom onset or receipt of a positive test result. Among these cases of COVID-19 attributed to the Omicron variant, 34 (79%) occurred in persons who completed the primary series of an FDA-authorized or approved COVID-19 vaccine ≥14 days before symptom onset or receipt of a positive SARS-CoV-2 test result, including 14 who had received an additional or booster dose; five of the 14 persons had received the additional dose <14 days before symptom onset. Six (14%) persons had a documented previous SARS-CoV-2 infection. The most commonly reported symptoms were cough, fatigue, and congestion or runny nose. One vaccinated patient was hospitalized for 2 days, and no deaths have been reported to date. Case investigations have identified exposures associated with international and domestic travel, large public events, and household transmission.

FIGURE. States reporting at least one confirmed SARS-CoV-2 B.1.1.529 (Omicron) variant COVID-19 case — United States, December 1–8, 2021



Abbreviation: DC = District of Columbia.

Measures to Slow Initial Travel-Related Spread of the Omicron Variant

On November 26, a Presidential Proclamation[§§] suspended entry into the United States for noncitizens (as immigrants and nonimmigrants) who were present in any of eight countries in southern Africa (Botswana, Eswatini, Lesotho, Malawi, Mozambique, Namibia, South Africa, and Zimbabwe) during the 14 days preceding travel to the United States. This policy was intended to reduce overall travel volume from the region where Omicron was first identified to delay the introduction and spread of Omicron while U.S. public health measures were enhanced. Multiple factors were considered in determining the eight countries based on what was known about the spread of the Omicron variant at the time, including case counts, community transmission levels, and U.S.-bound travel volume from countries with cases. On December 2, CDC amended its existing Order requiring predeparture testing for all air passengers to the United States from any other country.[¶¶] The Amended Order, effective December 6, shortened the window for obtaining a negative SARS-CoV-2 viral test result to no more than 1 day before the flight's departure. A negative test result closer to the time of travel enhances reduction in transmission risk during travel (*6*).

On November 28, CDC expanded a voluntary airport-based genomic surveillance program in Atlanta, New York City, Newark, and San Francisco to prioritize recruitment of travelers from southern Africa for testing. The four participating airports receive a large, diverse volume of international travelers, including direct flights from southern Africa. Through this program, international air travelers are offered molecular testing of pooled samples collected upon arrival and a take-home collection kit (saliva collection for nucleic acid amplification test) to be used 3–5 days after arrival with subsequent sequencing of SARS-CoV-2–positive specimens; persons in pools with a positive test result are contacted and advised to get retested using the home collection kit or another method. Five pools collected November 30–December 6, representing 59 travelers, had evidence of SGTF. As of December 8, one of these pools was confirmed positive for Omicron, and four were pending. CDC continues to work with state and local health departments and other public health partners to conduct case investigation and contact tracing of travelers into and within the United States with confirmed COVID-19 attributed to the Omicron variant. As of November 8, all airlines are required to collect contact information for all inbound passengers to the United States to facilitate aircraft contact investigations and other follow-up of travelers when indicated.[***] To date, at least one confirmed case attributed to the Omicron variant has been identified in the United States through these aircraft contact investigation efforts.

Measures to Slow Domestic Spread of the Omicron Variant

CDC recommends prioritizing case investigation and contact tracing[†††] for confirmed COVID-19 cases attributed to

[§§] https://www.whitehouse.gov/briefing-room/presidential-actions/2021/11/26/a-proclamation-on-suspension-of-entry-as-immigrants-and-nonimmigrants-of-certain-additional-persons-who-pose-a-risk-of-transmitting-coronavirus-disease-2019

[¶¶] https://www.cdc.gov/quarantine/fr-proof-negative-test.html

[***] https://www.cdc.gov/quarantine/order-collect-contact-info.html

[†††] https://www.cdc.gov/coronavirus/2019-ncov/php/contact-tracing/contact-tracing-plan/overview.html

NOTARY M. PABALE Mumbai Maharashtra Reg. No. 15220 Expiry Dt. 30.10.2023 GOVT. OF INDIA

1682
532

TABLE. Characteristics of reported confirmed B.1.1.529 (Omicron) variant SARS-CoV-2 cases (n = 43) — United States, December 1–8, 2021

Characteristic	No. (%)
Age group, yrs	
<18	4 (9)
18–39	25 (58)
40–64	10 (23)
≥65	4 (9)
Sex	
Male	17 (40)
Female	25 (58)
Unknown	1 (2)
International travel*	14 (33)
COVID-19 vaccination status†	
Unvaccinated	8 (19)
Partially vaccinated	0 (—)
Vaccinated	20 (47)
Vaccinated plus an additional dose§	14 (33)
Unknown	1 (2)
Previous SARS-CoV-2 infection	
Yes	6 (14)
No	21 (49)
Unknown	16 (37)
Symptom profile	
Symptomatic	40 (93)
Asymptomatic/Unknown	3 (7)
Initial signs or symptoms¶	
Cough	33 (89)
Fatigue	24 (65)
Congestion or runny nose	22 (59)
Fever	14 (38)
Nausea or vomiting	8 (22)
Shortness of breath or difficulty breathing	6 (16)
Diarrhea	4 (11)
Loss of taste or smell	3 (8)
Outcomes	
Hospitalization	1 (2)
Death	0 (—)

* International travel within 14 days of symptom onset or, if asymptomatic, first positive SARS-CoV-2 test result.

† An unvaccinated person had received no COVID-19 vaccine. A partially vaccinated person had received a COVID-19 vaccine but not completed the primary series ≥14 days before illness onset or receipt of a positive SARS-CoV-2 test result. A vaccinated person had completed the primary series of a Food and Drug Administration–authorized or approved COVID-19 vaccine ≥14 days before illness onset or receipt of a positive SARS-CoV-2 test result.

§ Among the 14 persons who were vaccinated and had received an additional dose, five had received the additional dose <14 days before symptom onset.

¶ Specific symptom information was available from 37 symptomatic persons.

the Omicron variant. This prioritization should be balanced with maintaining case investigation and contact tracing for outbreaks of confirmed cases of SARS-CoV-2 infection in high-risk congregate settings (e.g., long-term care facilities, correctional facilities, and homeless shelters) and for persons at increased risk for severe COVID-19–related health outcomes. Timely case investigation and contact tracing can help ensure compliance with isolation and quarantine guidance§§§ and link persons with positive SARS-CoV-2 test results and their close contacts to testing and supportive services.

§§§ https://www.cdc.gov/coronavirus/2019-ncov/your-health/quarantine-isolation.html

Discussion

The first U.S. case of COVID-19 attributed to the Omicron variant was detected on December 1, 2021. Among the cases described in this report, the earliest report of symptom onset was November 15. For the week ending December 4, the Delta variant accounted for >99.9% of circulating SARS-CoV-2 variants. Given the 2–3 weeks from the time of specimen collection to availability of sequence data for analysis, it is likely that additional infections with Omicron from late November will be detected during the coming days. Scientists around the world are working to rapidly learn more about the Omicron variant to better understand how easily it might be transmitted and the effectiveness of current diagnostic tests, vaccines, and therapeutics against this variant. Many of the first reported cases of Omicron variant infection appear to be mild (*7*), although as with all variants, a lag exists between infection and more severe outcomes, and symptoms would be expected to be milder in vaccinated persons and those with previous SARS-CoV-2 infection than in unvaccinated persons. Characteristics of the cases described in this report might also not be generalizable because case findings might be associated with individual characteristics (e.g., persons with recent international travel might be more likely to be younger and vaccinated). Even if most infections are mild, a highly transmissible variant could result in enough cases to overwhelm health systems. The clinical severity of infection with the Omicron variant will become better understood as additional cases are identified and investigated. Scientists in South Africa and elsewhere have established systems that allow study of the laboratory, clinical, and epidemiologic characteristics; CDC is collaborating with health officials around the world to learn more about the characteristics of patients with Omicron variant infections.

The rapid emergence and worldwide detection of the SARS-CoV-2 Omicron variant underscores the importance of robust genomic surveillance systems and prompt information-sharing among global public health partners. During the past several years, CDC has intensified efforts to significantly expand genomic sequencing capacity at the federal and state levels. Through these investments, an average of 50,000–60,000 positive specimens are sequenced weekly as part of national SARS-CoV-2 genomic surveillance, which assisted with identifying initial cases of COVID-19 attributed to the Omicron variant in the United States.

A number of measures have been implemented throughout the COVID-19 pandemic to reduce the introduction and spread of SARS-CoV-2 in the United States through travel. For example, masks are required in indoor areas on public

NOTARY M. PARAL Mumbai Maharashtra Regd No. 15229 Expiry Dt. GOVT. OF INDIA

1683

~~533~~

transportation conveyances traveling into, within, or out of the United States, and on the indoor premises of U.S. transportation hubs.[§§§] Current travel requirements and recommendations,[****] surveillance programs, and efforts to educate travelers are intended to reduce COVID-19 transmission and support safer global travel. CDC is also supporting efforts to prevent, detect, and respond to COVID-19 internationally, including through support for laboratory and sequencing capacity and strengthening global vaccine programs.

Implementation of concurrent prevention strategies, including vaccination, masking, improving ventilation, testing, quarantine, and isolation, are recommended to slow transmission of SARS-CoV-2 and to protect against severe illness, hospitalization, and death from COVID-19. All persons aged ≥5 years should be vaccinated against COVID-19. Persons aged ≥18 years who completed a primary mRNA COVID-19 vaccination series ≥6 months previously or who received an initial Janssen (Johnson & Johnson) vaccine dose ≥2 months previously should receive a booster dose; persons aged 16–17 years are eligible to receive a Pfizer-BioNTech COVID-19 booster dose >6 months after completion of the primary series. Booster doses are especially urgent for those at higher risk of severe disease, such as persons residing in nursing homes and long-term care facilities. In addition, CDC recommends that everyone aged ≥2 years wear masks in public indoor places in areas of substantial or high transmission.

§§§ https://www.cdc.gov/quarantine/masks/mask-travel-guidance.html
**** https://www.cdc.gov/coronavirus/2019-ncov/travelers/international-travel/index.html

Acknowledgments

Public health departments and laboratories in Arizona, California (including Alameda County, Los Angeles, and San Francisco), Colorado, Connecticut, Florida, Georgia, Hawaii, Illinois, Louisiana, Maryland, Massachusetts, Minnesota, Mississippi, Missouri, Nebraska, New Jersey, New York, (including New York City), Pennsylvania, Texas, Utah, Washington, and Wisconsin.

Corresponding author: Cria G. Perrine, hgk3@cdc.gov.

All authors have completed and submitted the International Committee of Medical Journal Editors form for disclosure of potential conflicts of interest. No potential conflicts of interest were disclosed.

Summary

What is already known about this topic?

SARS-CoV-2 variant B.1.1.529 (Omicron), first reported to WHO on November 24, 2021, has been designated a variant of concern. Mutations in Omicron might increase transmissibility, confer resistance to therapeutics, or partially escape infection- or vaccine-induced immunity.

What is added by this report?

During December 1–8, 2021, 22 U.S. states reported at least one COVID-19 case attributed to the Omicron variant. Among 43 cases with initial follow-up, one hospitalization and no deaths were reported.

What are the implications for public health practice?

Implementation of concurrent prevention strategies, including vaccination, masking, improving ventilation, testing, quarantine, and isolation are recommended to slow transmission of SARS-CoV-2, including variants such as Omicron, to protect against severe illness and death from COVID-19.

References

1. O'Toole Á, Scher E, Underwood A, et al. Assignment of epidemiological lineages in an emerging pandemic using the pangolin tool. Virus Evol 2021;7:veab064. PMID:34527285 https://doi.org/10.1093/ve/veab064
2. CDC. Science brief: Omicron (B.1.1.529) variant. Atlanta, GA: US Department of Health and Human Services, CDC; 2021. Accessed December 2, 2021. https://www.cdc.gov/coronavirus/2019-ncov/science/science-briefs/scientific-brief-omicron-variant.html
3. World Health Organization. Classification of Omicron (B.1.1.529): SARS-CoV-2 variant of concern. Geneva, Switzerland: World Health Organization; 2021. Accessed December 3, 2021. https://www.who.int/news/item/26-11-2021-classification-of-omicron-(b.1.1.529)-sars-cov-2-variant-of-concern
4. University of Texas at Austin. User's guide to variant detection calculators. Austin, TX: University of Texas at Austin; 2021. https://covid-19.tacc.utexas.edu/media/filer_public/d9/d9/d9d99a16-704e-4c00-ab41-069957c6c25e/variant_calculator_user_guide.pdf
5. ThermoFisher Scientific. TaqPath COVID-19 Multiplex Diagnostic Solution. Waltham, MA: ThermoFisher Scientific; 2021. Accessed December 3, 2021. https://www.thermofisher.com/us/en/home/clinical/clinical-genomics/pathogen-detection-solutions/covid-19-sars-cov-2/multiplex.html
6. Johansson MA, Wolford H, Paul P, et al. Reducing travel-related SARS-CoV-2 transmission with layered mitigation measures: symptom monitoring, quarantine, and testing. BMC Med 2021;19:94. PMID:33849546 https://doi.org/10.1186/s12916-021-01975-w
7. National Institute for Communicable Diseases. Frequently asked questions for the B.1.1.529 mutated SARS-CoV-2 lineage in South Africa. Johannesburg, South Africa: National Institute for Communicable Diseases; 2021. Accessed December 3, 2021. https://www.nicd.ac.za/frequently-asked-questions-for-the-b-1-1-529-mutated-sars-cov-2-lineage-in-south-africa/

NOTARY M. M. PADALE Mumbai Maharashtra Reg. No. 15220 Expiry Dt. 30-10-2021 GOVT. OF INDIA

1684
~~534~~

EXHIBIT "RA-39"

Omicron In India: Five Reasons Why Top Experts Are Saying No To Booster Dose

Source: Outlook

Link: https://www.outlookindia.com/website/story/india-news-omicron-in-india-five-reasons-why-some-top-experts-say-no-to-booster-dose/405012

Author: Jeevan Prakash Sharma

Published on: December 25, 2021

Omicron Covid-19 in India has raised a debate regarding boosters shots of the Covid-19 vaccine. Some experts, however, believe that there are several concerns that need to be addressed before any booster dose is approved.

It has been more than a week since India reported its first two cases of Omicron infection on December 2 in Karnataka. The genetic sequencing of samples of two travellers, aged 66 and 46, were found to be infected with this new variant which was originated from Botswana in Africa on November 9.

Since then over 40 cases of Omicron infections have been reported from various states like Maharashtra, Delhi, Chandigarh, Andhra Pradesh, Kerala etc. The variant hasn't shown a high rate of transmission in India as of now as there is no report of any large outbreak from infected people in their respective areas.

Even the Ministry of Health and Family Welfare has predicted a low impact due to the presence of natural antibodies in a large number of people.

NOTARY M. M. PAEALE Mumbai Maharashtra Reg. No. 15220 Expiry Dt. 30-10-2024 GOVT. OF INDIA

Despite that, a section of health experts has raised their concern in favour of booster doses of vaccine as they believe that it can increase the level of immunity in the body and will help protect from the new variant.

The US Food and Drug Administration (FDA) had introduced a booster dose in August for people above 18 years of age. Later on, on December 12, adolescents, aged 16 and 17, have also been made eligible for this additional dose.

Global shreds of evidence, incidentally, suggest that fully-vaccinated people or even those with booster doses are being infected with Omicron as well.

Besides, experts believe, there are several concerns that need to be addressed before any such booster shot is approved in India where people's immune profile is quite unique.

At present, two vaccines, Covishield and Covaxin, are being administered to people above 18 years of age under the adult vaccination programme for Covid-19. The gap between two doses of Covishield and Covaxin is 12 and 4 weeks respectively.

Here're the five most prominent concerns of a section of scientists and public health experts before the government in India takes a decision for the third dose.

Mumbai
Maharashtra
Reg. No. 15220
Expiry Dt.
30-10-2024

No clinical trial of booster dose

Countries like the USA have introduced the booster dose, however there is no clinical trial to assess its safety and efficacy anywhere in the world.

"I believe that we should first gather the clinical data of the third dose so that we can make out how safe and effective it is. Without proper study, I will not advise the government to authorise any additional dose," Dr Syamal Roy, a

1686
536

noted immunologist, said. Dr Roy retired as Head of the Department of Infectious Diseases and Immunology, Indian Institute of Chemical Biology, Kolkata.

Some immunologists believe that higher antibodies, that a booster dose of a vaccine can produce, might not always work against the antigen but sometimes it can cause harm to the body itself.

"Such situations are known as Antibody-dependent Enhancement (ADE) under which the antibody, instead of preventing infection, starts helping the antigen infect more number of cells," Dr Roy said.

"That's why I am emphasizing the need for clinical data," he added.

Does high antibody prevent infection?

There is no denying the fact that a booster dose increases the level of antibody in an individual. However, there is no scientific evidence to suggest that the high antibody, acquired with the help of vaccines, can prevent infection from the variants of SARS-CoV-2.

Experts say that whenever a naturally infected person or a vaccinated person comes in contact with the virus, its antibody level shoots up as the body produces immunity for its protection. Since the vaccine also has dead viruses or parts of the virus, the body responds against this antigen and produces antibodies.

"Had high antibody helped in preventing transmission, fully vaccinated people or those with booster doses might not have been infected with Omicron. There is no study to find out the correlation between high antibody and its protection from infection," Dr Sanjay Rai, Professor, Community Medicine in All India Institute of Medical Sciences (AIIMS), New Delhi.

There are 25 vaccines already approved by various authorities all over the world and 326 vaccines are currently at different stages of development. Dr Rai, who was a principal investigator of the Covaxin trial in AIIMS, said that any additional dose of a vaccine will enhance the antibody but its side effect needs to be measured.

"The main indicator should not be the increase in the level of antibody but its effectiveness in providing protection," Dr Rai said.

Not enough study on the presence of memory cells

During the clinical trial, it was found that vaccines not only produce antibodies to fight against the virus but also produce memory cells. These cells help recognise the virus if it will try to enter the body in future.

So the antibody gradually declines and disappears after a few months but the moment a vaccinated or naturally recovered person comes in contact with the virus, these cells help produce antibodies once again to provide protection against the specific antigen.

After rolling out the universal adult vaccination, such studies haven't been conducted on large samples size to find out the memory cell response in vaccinated individuals. A couple of studies with small sample size, like the one done by the Asian Institute of Gastroenterology in Hyderabad, have confirmed the presence of memory cells in vaccinated or naturally recovered people.

Well-known scientist and a member of the National Technical Advisory Group on Immunization (NTAGI) Dr Jayaprakash Muliyil is of the view that the boisterous response of an additional dose goes on to confirm the formation of the memory cell which produces antibody after identifying the same antigen.

1688
~~538~~

"It shows that there is no need for a booster dose as the memory cells will produce the specific antibody once the virus comes in contact with a vaccinated or a naturally recovered person," Dr Muliyil said.

"B cells and T cells in the human body memorize the antigen and the moment the same virus infects the body, they make antibodies specific to target the virus. That's why reinfection is very low and even if it occurs, the severity is not as high as it was during the first infection," he added.

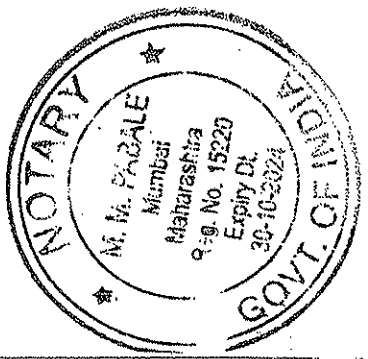
Gyaneshwar Chaubey, a professor of genetics at Banaras Hindu University (BHU), agreed with Dr Muliyil. "Antibody starts declining after three months and the virus will continue to mutate. So after the third dose, we will start talking about the fourth dose and so on. So, instead of that, we should research on the aspects of the memory cell of people rather."

Omicron hasn't caused many deaths globally

As of now, there are around 3,000 confirmed cases of Omicron in over 60 countries but only one death has been reported in the UK due to its infection so far. Its symptoms are reported to be milder than all other variants present in the environment.

"How will you evaluate a vaccine against a variant which is neither causing hospitalizations or deaths? It has been conceded by manufacturers and experts that vaccines do not prevent transmission but only reduce hospitalizations and deaths and this variant is not causing any severity. So what endpoints or goalposts are you going to consider when testing a vaccine against this benign variant?" Dr Amitav Banerjee, a clinical epidemiologist at Dr D Y Patil Medical College, Pune, said.

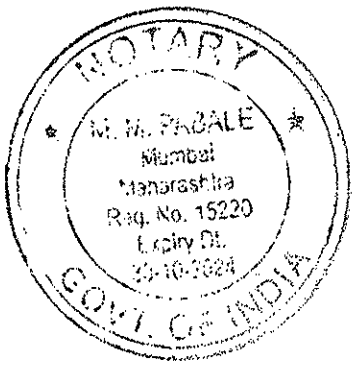
Natural immunity provides better protection



Since the reinfection rate has been very low in the case of all the available variants of SARS-CoV-2, this tends to show that natural immunity, acquired after recovery from Covid-19, provides a better antibody than that of vaccines. The reinfection rate has been between 5 to 10 per cent.

Many public health experts say that despite the presence of Omicron in India, its transmission is very slow and there is no large outbreak witnessed anywhere yet.

"This is because a huge population in India has natural antibodies which can prevent transmission and stop the spread of the virus. Besides, they are being vaccinated as well. So, according to me, two doses of vaccine in India along with natural antibody provides far better protection as compared to three or more doses in other countries like USA etc," Dr Banerjee said.



1690
~~540~~

EXHIBIT "RA-40"

How Mass Vaccination is Giving Rise to New Variants

Geert Vanden Bossche is a virologist and vaccinologist who worked with GSK Biologicals, Novartis Vaccines, Solvay Biologicals, Bill & Melinda Gates Foundation's Global Health Discovery team in Seattle and GAVI, The Global Alliance for Vaccines and Immunization in Geneva.
In an Aug. 12 article, Vanden Bossche said universal mass vaccination will prompt dominant propagation of highly infectious, neutralization escape mutants, and naturally acquired — or vaccinal neutralizing antibodies — will no longer offer any protection to immunized individuals.

"This is to say that every further increase in vaccine coverage rates will further contribute to forcing the virus into resistance to neutralizing, S-specific Abs [antibodies]. Increased viral infectivity, combined with evasion from antiviral immunity, will inevitably result in an additional toll taken on human health and human lives,"Vanden Bossche said.

As far back as March, Vanden Bossche said:

"There can be no doubt that continued mass vaccination campaigns will enable new, more infectious viral variants to become increasingly dominant and ultimately result in a dramatic incline in new cases despite enhanced vaccine coverage rates. There can be no doubt either that this situation will soon lead to complete resistance of circulating variants to the current vaccines."

Vanden Bossche said a combination of lockdowns and extreme selection pressure on the virus and global mass vaccination might diminish the number of cases, hospitalizations and deaths in the short-term, but ultimately, would induce the creation of more escape mutants.

NOTARY GOVT. OF INDIA
M. M. PABANI
Mumbai
Maharashtra
Reg. No. 15220
Expiry Dt.

This will trigger vaccine companies to further refine vaccines that will add to the selection pressure, producing ever more transmissible and potentially deadly variants, he added.

Source:https://www.voiceforscienceandsolidarity.org/scientific-blog/c-19-pandemia-quo-vadis-homo-sapiens

According to Dr. Robert Malone, inventor of mRNA and DNA vaccines, worldwide expert in RNA technologies and Harvard-trained physician, even if we had complete uptake in vaccines and complete masking, CDC data makes it clear that at best we can slow the spread of Delta but we can't stop it.

Malone, who believes death and disability still warrant vaccination in high-risk populations, subscribes to Vanden Bossche's theory that continued mass vaccination campaigns will enable new, more infectious viral variants.

"Geert Vanden Bossche — I am on board with that now," Malone said, "that we really shouldn't be doing universal vaccination because we're just going to be generating escape mutants."

https://childrenshealthdefense.org/defender/vaccinated-people-key-role-evolution-dangerous-covid-variants/

NOTARY
M. M. PABALE
Mumbai
Maharashtra
GOVT. OF INDIA

According to research published in Scientific Reports, vaccinated people may play a key role in helping SARS-CoV-2 variants evolve into those that evade existing COVID vaccines.

The researchers concluded three specific risk factors that favor the emergence and establishment of a vaccine-resistant strain. They are: a high probability of

initial emergence of the resistant strain; high number of infected individuals; and low rate of vaccination.

However, the analysis also showed the highest risk for establishing a resistant strain occurs when a large fraction of the population has already been vaccinated but the transmission is not controlled.

Virologists have a name for variations of a virus that slip past vaccine- or illness-induced immune defenses — they're called "escape mutants."

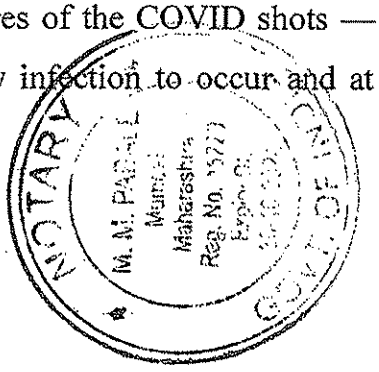
"When most people are vaccinated, the vaccine-resistant strain has an advantage over the original strain," Simon Rella of the Institute of Science and Technology Austria, told CNN.

"This means the vaccine-resistant strain spreads through the population faster at a time when most people are vaccinated," said Rella, who worked on the study. Based on the scientific evidence, the narrative that unvaccinated people are viral factories for more dangerous variants is false, according to Dr. Joseph Mercola.

Mercola, a physician and best-selling author, said just as antibiotics breed resistance in bacteria, vaccines put evolutionary pressure on viruses to speed up mutations and create more virulent and dangerous variants.

Mercola explained:

"Viruses mutate all the time, and if you have a vaccine that doesn't block infection completely, then the virus will mutate to evade the immune response within that person. That is one of the distinct features of the COVID shots — they're not designed to block infection. They allow infection to occur and at best lessen the symptoms of that infection."



"In an unvaccinated person, the virus does not encounter the same evolutionary pressure to mutate into something stronger," Mercola added.

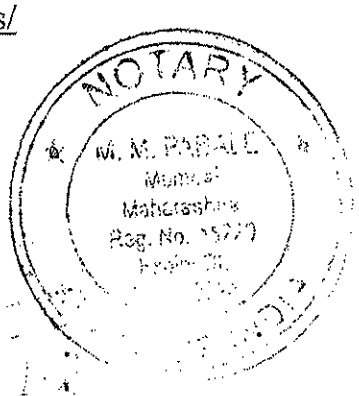
"So, if SARS-CoV-2 does end up mutating into more lethal strains, then mass vaccination is the most likely driver," he said.

According to Rob Verkerk Ph.D., founder, scientific and executive director of Alliance for Natural Health International, variants can become more virulent and transmissible, while also including immune (or vaccine) escape mutations if we continue on the vaccine treadmill — trying to develop new vaccines that outsmart the virus.

Verkerk said, "if we put all our eggs" in the basket of vaccines that target the very part of the virus that is most subject to mutation, we place a selection pressure on the virus that favors the development of immune escape variants.

Scientists and vaccine developers are trying to work their way around these viral variants, but there's no guarantee of the outcomes. It's an experiment in which vast numbers of citizens have become unwitting participants, Verkerk explained.

Source:https://www.nature.com/articles/s41598-021-95025-3#Sec2
https://childrenshealthdefense.org/defender/vaccinated-people-key-role-evolution-dangerous-covid-variants/



1694

544

EXHIBIT "RA-41"

12/4/2021 • COVID › VIEWS

Media Stirs Up Omicron Hysteria, Points Finger at Unvaccinated

No sooner had the Omicron hysteria hit the headlines, politicians, aided by a compliant global lockstep media, started identifying scapegoats and telling the world's population to prepare to roll up their sleeves.

By Rob Verkerk Ph.D.

Miss a day, miss a lot. *Subscribe to The Defender's Top News of the Day.* ***It's free.***

Topline:

- Lockstep political decision to roll out leaky "vaccines" occurred around the world immediately following the Omicron announcement.
- Circumstances with a new, heavily mutated variant, vastly different population immunity and knowledge about "genetic vaccine" effectiveness, nothing like those 12 months ago when first generation COVID injections were rolled out globally.
- Omicron may be more infective, is likely no more dangerous — but may be more likely to evade injection-induced immunity.
- There is no conclusive evidence that Omicron originated in Africa — which happens to have the lowest injection rate and case rate of COVID-19.
- Mass injection of first gen injections, followed by re-worked Omicron-specific jabs, could cause disastrous consequences, including accelerating development of further variants and antibody-dependent enhancement (ADE) of disease.
- We consider some of the possible political and economic drivers behind the new unscientifically backed policy to up the ante on injections.

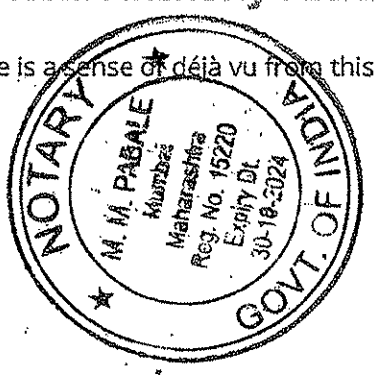
No sooner had the Omicron hysteria hit the headlines, politicians, aided by a compliant global lockstep media, started telling the world's population to prepare to roll up their sleeves.

What's more, three scapegoats have been identified: the unvaccinated, HIV patients and the least vaccinated continent on the planet: Africa.

One of many similar calls was made in the influential Scientific American magazine by Southampton University public health and vaccine hesitancy researcher, Michael Head Ph.D., not unsurprisingly a Gates Foundation funding recipient.

BUY TODAY: Robert F. Kennedy, Jr.'s New Book — 'The Real Anthony Fauci'

For many in the industrialized world, there is a sense of déjà vu from this time last year — but with a twist.



Last year the population had been primed to expect almost impossibly high levels of protection from infection based on the results of phase 3 clinical trials. Only recently have these trials been brought into question.

Last year, the majority had also bought the line that these new generation "genetic vaccines" would stop transmission and yield herd immunity. The head of the Oxford Vaccine Group, Prof. Andrew Pollard, subsequently told the world that possibility is now "mythical."

Knowing what they knew then, people flocked to the vaccination centers as the promise being offered was a return to normal life. Only time would tell how misplaced that view was.

This time around things are very different.

The COVID-19 injections have been shown to increasingly fail even with delta, hence the re-casting of the 'vaccine effectiveness' correlates from protection against infection now to protection against severe disease.

The indisputable reality is that the COVID-19 injections are "leaky." The spike-targeting neutralizing IgG antibodies they so readily elicit just don't neutralize (block) very well so they can't stop infection or subsequent transmission.

What drives the creation of immune escape variants?

Perceptions among politicians, the public and even scientists as to the main drivers of mutations that can escape the effects of the immune system, whether from naturally-acquired infection or the response generated by injections, differ wildly.

Smack in the middle of this lack of consensus comes Omicron, and a high chance that policies based on one line of thinking will be viewed as counterproductive or even potentially disastrous and life threatening by others.

We've reported on the underlying science at length before, and supported the evolutionary arguments elaborated in the public domain by Belgian vaccinologist, Geert Vanden Bossche, VDM, Ph.D., David Lorimer, program director of the Scientific and Medical Network and I have, this week, released a short article that attempts to summarize in layperson's language the central tenets of Vanden Bossche's thesis.

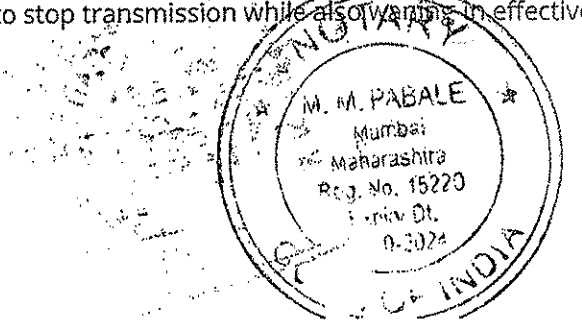
The opposing arguments ignore entirely evolutionary pressure and focus on the unvaccinated and the immune compromised as the reservoirs that provide more opportunities to breed mutants.

The logic — at face value — seems reasonable. If the virus is able to replicate more often in people who suffer COVID-19 disease for longer, and people who can't effectively neutralize the virus, the increased replication increases the probability of mutants emerging.

More rolls of the dice, if you like. The trouble is that this argument is fundamentally flawed for a number of reasons.

We've seen previous mutants by and large being generated under high vaccination pressures, with increases in cases being associated with expanding "vaccine" coverage.

Also, clear evidence that the vaccines are increasingly unable to neutralize the virus, especially more recently emerging variants, so being unable to stop transmission while also waning in effectiveness within a few months post-jab.



1696

546

What is more, they also interfere with innate immune training which is our primary defence against different variants of this (and other) pathogens and our only means of developing herd immunity given the "leakiness" of the current "genetic vaccines."

Omicron focus

In a sea of immense uncertainty, one thing that is more or less certain, now that the initial errors in the claimed mutations were corrected, is the 32 spike protein mutations of Omicron.

But it's not just the, comparatively speaking, high number of significant mutations in the spike protein (Table 1), it's their potential impacts on both the virus and the human immune systems with which the virus interacts that are key.

It's of course too early to know exactly what effects these mutations will have on the very diverse and varied populations of humans, and potentially other species if spill-over continues.

Table 1. SARS-CoV-2 "Variants of concern"

Variant	Spike protein mutations	Earliest documented samples	No. of countries reporting
Omicron (B.1.1.529)	32	Multiple countries* (11/21)	20†
Delta (B.1.617.2)	10	India (10/20)	196
Gamma (P.1)	12	Brazil (11/20)	103
Beta (B.1.351)	10	South Africa (05/20)	146
Alpha (B.1.1.7)	11	UK (09/20)	197

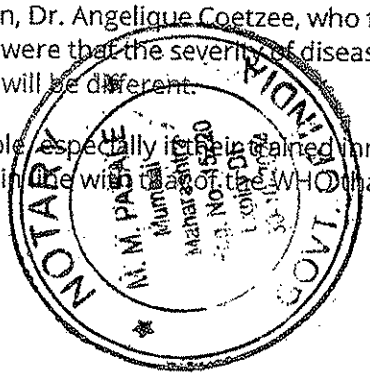
Main data sources: WHO and GISAID. *Note that the WHO has not claimed either Botswana or South Africa as countries of first documentation — see discussion below. † Based on media reports by Dr. Anthony Fauci

The limited information available from the small numbers of cases that have been reported so far is that disease severity (i.e., deadliness) is not significantly greater than with delta.

It's too early to say if Omicron will out-compete delta as this depends on many factors, such as the ability or otherwise of Omicron to evade innate and/or adaptive immunity in populations with different immune backgrounds (generated by COVID injections and naturally-acquired infection), and latency prior to high viral loads being generated.

Early reports, such as those by South African, Dr. Angelique Coetzee, who first spotted the new symptoms of Omicron-mediated COVID-19 were that the severity of disease wasn't worse than delta. It's likely though that the pattern of symptoms will be different.

Younger people may also be more vulnerable, especially if their trained innate immunity is damaged by injections. This view is of course not wholly in line with that of the WHO that stated the following on Nov. 28:



> "There is currently no information to suggest that symptoms associated with Omicron are different from those from other variants. Initial reported infections were among university students—younger individuals who tend to have more mild disease — but understanding the level of severity of the Omicron variant will take days to several weeks."

Many independent experts have opined that transmission might be higher based on the configuration of the mutations and if that's the case and latency isn't extended significantly over delta — Omicron may readily replace delta as the dominant variant in most countries.

Early reports from South Africa also suggest transmission will be high.

While it will likely be days or weeks before Omicron's potential virulence and transmissibility can be better appreciated, the configuration of mutations — highly conserved within the spike protein itself — tells us that there's a high likelihood that existing injections will be even less effective than on delta.

This view is confirmed by none other than Dr. Anthony Fauci, as well as others, such as Dr. Samiran Panda who heads the Epidemiology and Communicable Diseases Division of the Indian Council of Medical Research.

The pace at which the new variant has been used by politicians to push first-generation injections on the public, along with everything else we know about the host-pathogen-injection interaction, is breathtaking given the uncertainties involved with this policy.

They know, for example, these injections were designed to elicit antibodies that are highly specific to the original Wuhan strain's spike protein and they also know the configuration differs substantially to that of the Omicron variant.

While the public is being told they should boost their immune system with the existing injections, they're not being told that there could be grave costs to this, like damaging innate immunity, inducing more severe reactions to disease, enhancing transmission or exposing countless people to unnecessary, potentially debilitating or life-threatening adverse reactions.

Pfizer has already announced it's working on making new injections built specifically for Omicron and these might be 100 days away. The immediate decision to foist the old injections on the public to "boost" immunity with what are probably even more weakly neutralizing antibodies at best is clearly based on political or economic, not medical, expedience.

Where did Omicron come from?

The world's media is typically claiming Botswana or South Africa as the country in which Omicron was first detected. It is true that the largest numbers of cases have been found there, as evidenced by the country submission count on the GISAID variant tracker, as seen in Table 2.

Table 2. Most recent reported occurrences of Omicron variant in different countries.



1698

~~548~~

Country	Total #GR/484A (B.1.1.529)	#GR/484A (B.1.1.529) in past 4 weeks	%GR/484A (B.1.1.529) in past 4 weeks
South Africa	171	171	71
Botswana	19	19	22.4
Portugal	13	13	1.3
Netherlands	12	0	0
United Kingdom	9	9	0
Australia	6	6	0.4
Germany	5	5	0.1
Hong Kong	5	5	20.8
Italy	4	4	0.1
Austria	4	4	4
Canada	2	2	0.3
Brazil	2	2	0.3
Japan	2	2	4.8
Sweden	1	1	0
Belgium	1	1	0
Reunion	1	1	1.2
Israel	1	1	0
Spain	1	1	0.1
Czech Republic	1	1	0.2

Source: GISAID. Downloaded Dec. 2021.

But it's also clear, from the GISAID records, that neither Botswana nor South Africa were the countries in which the earliest detection of Omicron (variant B.1.1.529) occurred.

Collections in Sweden, Israel, Reunion and the UK all appear to precede those from Botswana and South Africa. Check out the table from GISAID below, which is in reverse chronological order.

Table 3. Country submission count to GISAID as of Dec. 10, 2021

1699

~~549~~

Country	Strain Name	Collection Date
Italy	hCoV-19/Italy/CAM-COLLI-COTUGNO-A10117/2021	28/11/2021
Japan	hCoV-19/Japan/IC-2278/2021	28/11/2021
Spain	hCoV-19/Spain/MD-HGUGM-6821169/2021	28/11/2021
Australia	hCoV-19/Australia/NSW-ICPMR-14637/2021	28/11/2021
Austria	hCoV-19/Austria/MUW-0231/2021	28/11/2021
Portugal	hCoV-19/Portugal/PT21719/2021	27/11/2021
Germany	hCoV-19/Germany/BY-MVP-000009711/2021	27/11/2021
Czech Republic	hCoV-19/Czech Republic/KNL_2021-11011914O/2021	26/11/2021
Hong Kong	hCoV-19/Hong Kong/VM21045834/2021	26/11/2021
Brazil	hCoV-19/Brazil/SP-HIAE-ID989/2021	25/11/2021
South Africa	hCoV-19/South Africa/Tygerberg_3072/2021	25/11/2021
Belgium	hCoV-19/Belgium/rega-20174/2021	24/11/2021
Canada	hCoV-19/Canada/ON-NML-249359/2021	23/11/2021
Botswana	hCoV-19/Botswana/R43B70_BHP_4021000195/2021	23/11/2021
United Kingdom	hCoV-19/Scotland/QEUH-2BA64B4/2021	23/11/2021
Reunion	hCoV-19/Reunion/PIMIT_Om1/2021	22/11/2021
Israel	hCoV-19/Israel/SMC-7022600/2021	20/11/2021
Sweden	hCoV-19/Sweden/10190023/2021	19/11/2021

Source: GISAID. Downloaded Dec. 1, 2021.

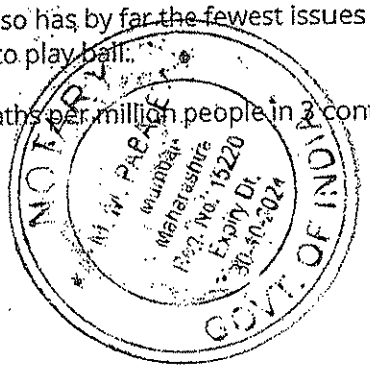
Today we hear that a sample collected in October in Nigeria from an "incoming international traveller" was positive for Omicron.

No doubt a lot more will be revealed in time. For us, currently available information means the jury is absolutely out as to whether Omicron originated in Africa at all.

The origins might well have been a traveler from a highly vaccinated country that imported it to Africa. Dr. Masupu of the Presidential COVID-19 Task Force of the Botswana Government confirmed that the four university students known by the task force to be infected with Omicron were all fully vaccinated.

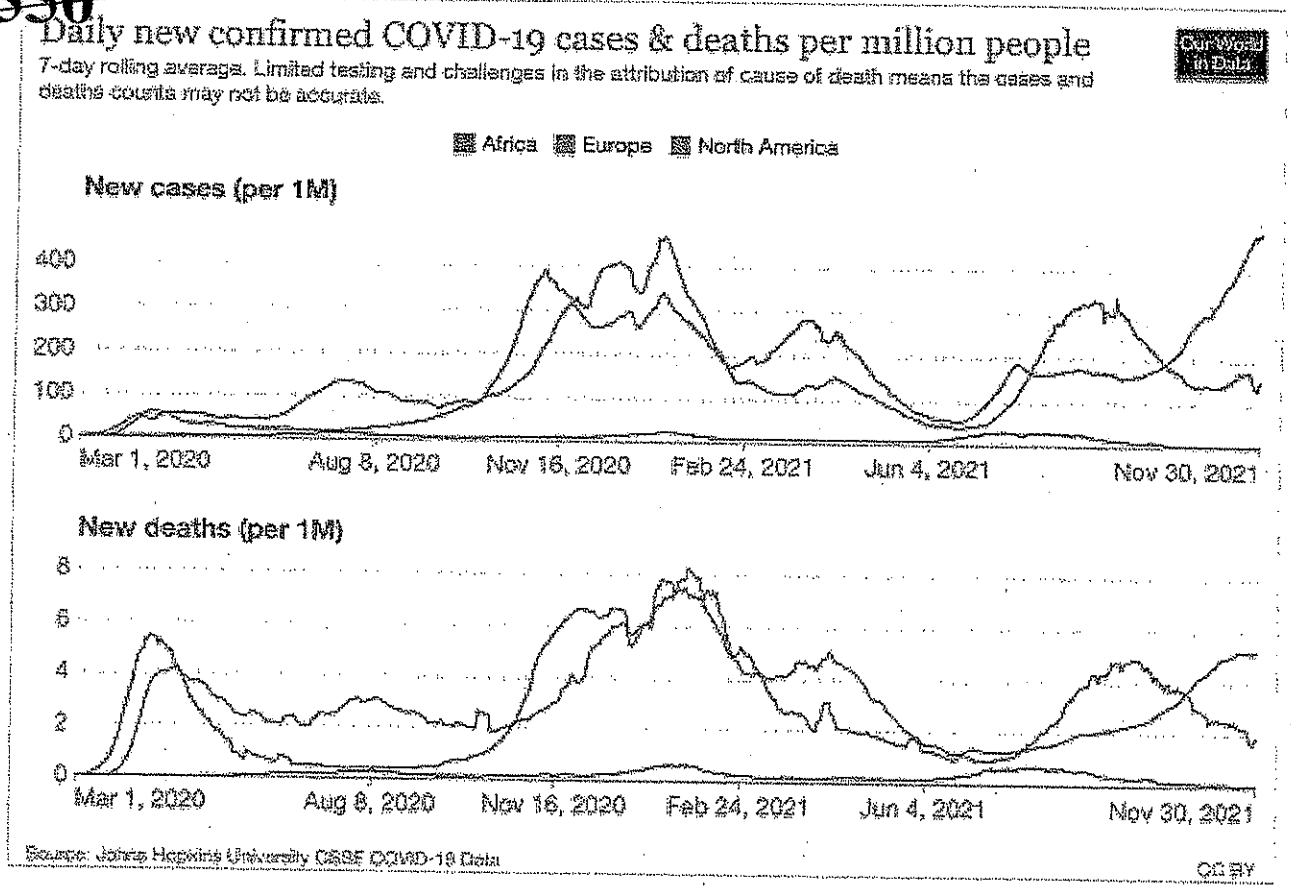
We also know that blaming Omicron on Africa makes sense if there is to be mounting pressure to vaccinate the world's least vaccinated continent, that also has by far the fewest issues with COVID-19 (see Fig. 1). Much of Africa — it seems — doesn't want to play ball.

Figure 1. Daily new confirmed COVID-19 cases and deaths per million people in 3 continents: Africa, Europe and North America.



EG 1700

~~550~~



Source: Our World in Data

What we also know is just after South Africa announced it didn't want to accept more COVID injections from Pfizer or Johnson & Johnson, the Omicron alarm bell was sounded. Coincidence?

Possible consequences of using boosters in an Omicron wave

What we have witnessed since early 2021 when COVID jabs were rolled out across the industrialized world is a gradual loss of synchronicity in the injection efforts.

Different countries had different uptakes, the speed of roll out across successively younger age groups, hesitancy and refusal varied country to country and sometimes even region to region.

All of that loss of synchronicity actually reduces selection pressure — as does having big reservoirs of unvaccinated young people with lively innate immune systems, like in much of the African continent.

Omicron will re-synchronize the injection campaigns. Vast numbers of people will get a top up of the first generation jab, only to be hit yet again when the "must-have" Omicron-specific jab rolls off the production line probably in under 4 months.

More synchronization means that more intense selection pressure will be applied to the spike protein of Omicron, and more replication will occur as the antibodies generated by the injections will not effectively block infection.

This creates the vicious circle that Vanden Bossche has described that we have been caught in already for a year with ever greater risk of more dangerous and more infective mutants being generated.

Higher frequency of exposure also means more insults to the immune system and that means more damage to the innate immunity of our species — our primary weapon against a mutating pathogen.

The conditions are set for escalating risks of antibody-dependent enhancement (ADE) of disease when injected people are exposed to disease, as well as an ever greater toll of adverse events and deaths mediated by autoimmunity, inflammation, neurological and cardiac issues.

The consequences of a bad outcome for humanity are scarcely worth considering — and it seems that's why the politicians, ushered along by a vaccine/biotech/pharma industry with an insatiable appetite for maximizing profitability while avoiding any liability for any damages caused — are going with it.

If vaccine passports and digital IDs for everyone on the planet, as precursors to a new digital currency and the merging of man and machine (transhumanism), are elements of the real end-game, it makes even more sense why global leaders are so up for it. Just don't be fooled that this is about a virus, medicine or science.

Urgent: 3 Ways to Help Stop Biden's Vaccine Mandates

Ominous Omicron

Just as the earlier unscientifically-based decisions to lockdown, mask up and socially isolate populations at the beginning of this pandemic was an ominous signal of the authoritarianism and suppression that was to come, Omicron's arrival is just as ominous.

Once again, it's not the virus we should primarily worry about if we can help our immune systems to be the best versions of themselves, and if we can access early treatments that are variant agnostic.

It is the reaction of governments, health authorities, politicians and business leaders who seem hell bent on continuing this failing, ever more risky endeavor of installing synthetic instructions into our bodies, the consequences of which will not be well known to the public for some years.

Bear in mind that the U.S. Food and Drug Administration asked a federal judge to make the American public wait until 2076 (yes, 55 years!) before all of the data on Pfizer's "genetic vaccine" it relied on for approvals are made public.

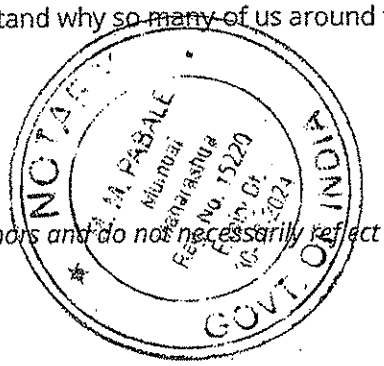
The great news is the judge has just forced Pfizer to release the documents incrementally — the first lot being something of a revelation in terms of the adverse event profile. More on that next week.

Without our trust, one wonders if "they" are beginning to understand why so many of us around the world are conscientious objectors?

Please Digest. Share. Educate.

Originally published by Alliance for Natural Health International.

The views and opinions expressed in this article are those of the authors and do not necessarily reflect the views of Children's Health Defense.



SUGGEST A CORRECTION

1702

~~552~~



Rob Verkerk Ph.D.

Robert Verkerk is an internationally acclaimed expert in health, agricultural and environmental sustainability.

Sign up for free news and updates from Robert F. Kennedy, Jr. and the Children's Health Defense. CHD is planning many strategies, including legal, in an effort to defend the health of our children and obtain justice for those already injured. Your support is essential to CHD's successful mission.

Republishing Guidelines

Children's Health Defense Comment Policy

We welcome relevant and respectful comments. Off-topic comments may be removed. Please read our Comment Policy before commenting.

189 Comments **Children's Health Defense** **Disqus' Privacy Policy** **Login**

Favorite 4 Tweet Share **Sort by Best**

Join the discussion...

LOG IN WITH

OR SIGN UP WITH DISQUS ?

Name

Joopy • a month ago

It's all scripted as part of a globally coordinated conspiracy by the world's ruling classes, including those of US, UK, Europe, Russia, and China. All of it was/is planned in advance and only afterward did/do they manufacture the "pandemic", "cases", "variants", and "waves" to fit the agenda. It has nothing to do with a virus because there is no virus outside of their computer programs and fake test results. It's about killing off large swathes of "useless eaters" and enslaving the survivors. Each new "booster" and new round of restrictions will kill off more people. Those who received the real bullet (poison) rather than the blanks (placebo, which was necessary to give - initially at least - to a large portion in order to limit the damage and therefore the awareness and subsequent outrage) in this real life "game" of Russian roulette-via-syringe have had their health irreparably destroyed and their lives probably drastically shortened, as no one even knows what the long-term effects are.



NOTARY
M. M. PABALE
Mumbai

1703

bioRxiv preprint doi: https://doi.org/10.1101/2021.12.06.471446; this version posted December 9, 2021. The copyright holder for this preprint (which was not certified by peer review) is the author/funder. This article is a US Government work. It is not subject to copyright under 17 USC 105 and is also made available for use under a CC0 license.

EXHIBIT "RA-42" 1553

Minimal cross-over between mutations associated with Omicron variant of SARS-CoV-2 and CD8+ T cell epitopes identified in COVID-19 convalescent individuals

Andrew D Redd[1,2#], Alessandra Nardin[3], Hassen Kared[3], Evan M Bloch[4], Brian Abel[3], Andrew Pekosz[5], Oliver Laeyendecker[1,2], Michael Fehlings[3], Thomas C Quinn[1,2] and Aaron AR Tobian[4]

1- Division of Intramural Research, National Institute of Allergy and Infectious Diseases, National Institutes of Health, Bethesda, MD, USA

2- Department of Medicine, Johns Hopkins University School of Medicine, Baltimore, MD, USA

3- ImmunoScape Pte Ltd, Singapore

4- Department of Pathology, Johns Hopkins University School of Medicine, Baltimore, MD, USA

5- Department of Molecular Microbiology and Immunology, Johns Hopkins Bloomberg School of Public Health, Baltimore, MD, USA

#-Corresponding author: Andrew D. Redd
Rangos 540
851 N Wolfe St, Baltimore MD, 21205
USA
aredd2@jhmi.edu; 410-614-0813

Alternative contact
Aaron AR Tobian
Rangos 540
851 N Wolfe St, Baltimore MD 21205
USA
Atobian1@jhmi.edu; 410-614-0813

Keywords: CD8+ T cell; SARS-CoV-2; COVID-19; Convalescent patients; Omicron

Word count: 1077 (1200 max)

Running Title: CD8 T cell targets Omicron COVID-19 variant



1704

554

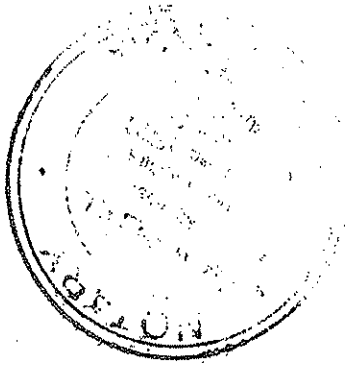
bioRxiv preprint doi: https://doi.org/10.1101/2021.12.06.471446; this version posted December 9, 2021. The copyright holder for this preprint (which was not certified by peer review) is the author/funder. This article is a US Government work. It is not subject to copyright under 17 USC 105 and is also made available for use under a CC0 license.

Abstract

There is a growing concern that ongoing evolution of SARS-CoV-2 could lead to variants of concern (VOC) that are capable of avoiding some or all of the multi-faceted immune response generated by both prior infection or vaccination, with the recently described B.1.1.529 (Omicron) VOC being of particular interest. Peripheral blood mononuclear cell samples from PCR-confirmed, recovered COVID-19 convalescent patients (n=30) infected with SARS-CoV-2 in the United States collected in April and May 2020 who possessed at least one or more of six different HLA haplotypes were selected for examination of their anti-SARS-CoV-2 CD8+ T-cell responses using a multiplexed peptide-MHC tetramer staining approach. This analysis examined if the previously identified viral epitopes targeted by CD8+ T-cells in these individuals (n=52 distinct epitopes) are mutated in the newly described Omicron VOC (n=50 mutations). Within this population, only one low-prevalence epitope from the Spike protein restricted to two HLA alleles and found in 2/30 (7%) individuals contained a single amino acid change associated with the Omicron VOC. These data suggest that virtually all individuals with existing anti-SARS-CoV-2 CD8+ T-cell responses should recognize the Omicron VOC, and that SARS-CoV-2 has not evolved extensive T-cell escape mutations at this time.

Importance:

The newly identified Omicron variant of concern contains more mutations than any of the previous variants described to date. In addition, many of the mutations associated with the Omicron variant are found in areas that are likely bound by neutralizing antibodies, suggesting that the first line of immunological defense against COVID-19 may be compromised. However, both natural infection and vaccination develop T-cell based responses, in addition to antibodies. This study examined if the parts of the virus, or epitopes, targeted by the CD8+ T-cell response in thirty individuals who recovered from COVID-19 in 2020 were mutated in the Omicron variant. Only one of 52 epitopes identified in this population contained an amino acid that was mutated in Omicron. These data suggest that the T-cell immune response in previously infected, and most likely vaccinated individuals, should still be effective against Omicron.



bioRxiv preprint doi: https://doi.org/10.1101/2021.12.06.471446; this version posted December 9, 2021. The copyright holder for this preprint (which was not certified by peer review) is the author/funder. This article is a US Government work. It is not subject to copyright under 17 USC 105 and is also made available for use under a CC0 license.

Introduction

As the global COVID-19 pandemic enters its third year, there is a growing concern that ongoing evolution of SARS-CoV-2 could lead to a variant of the virus that is capable of avoiding the multi-faceted immune response generated by both prior infection or vaccination[1–3]. Several of these variants of concern (VOC) have been identified throughout the pandemic, and have been associated with large scale waves of infection. To date, while several of these VOC have exhibited varying levels of antibody resistance *in vitro*, vaccination, as well as previous infection by SARS-CoV-2, have been shown to maintain a significant level of protection against breakthrough or re-infections, especially in terms of preventing serious disease and mortality[4,5]. However, the recent description of the B.1.1.529 variant, which was later designated as Omicron, contains a greater number of mutations than the previous VOC[6]. If the mutations in the Omicron VOC mediated resistance from any part of the anti-SARC-CoV-2 immune response, either from vaccination or infection, it would have consequences for efforts to contain the COVID-19 pandemic. The variant has also now been identified on every continent except Antarctica, suggesting it has significant transmission potential, similar to other VOC.

The majority of the mutations associated with the Omicron VOC are located in the Spike protein of the virus, presumably due to selection for evasion of antibody responses, and could have significant effects on the ability of pre-existing antibodies to neutralize the virus, although to what extent this is the case has yet to be determined. It is also unknown how these mutations may affect non-neutralizing binding antibody responses. While it is critical to determine the extent that Omicron may or may not be susceptible to existing humoral responses, T-cell associated immunity is in general significantly more difficult for viruses to overcome due to the broad and adaptable response generated in a given individual, as well as the variety of HLA haplotypes between individuals.

A previous analysis by our group of CD8+ T cell responses to the original SARS-CoV-2 variant in convalescent individuals found a broad and varied immune response in virtually all patients examined, even in individuals with relatively low anti-SARS-CoV-2 antibody responses[1]. A subsequent analysis of these data found that mutations associated with the Alpha, Beta, and Gamma VOC had very minimal cross-over with the epitopes identified in this earlier study (1/52 epitopes affected), suggesting that the CD8+ T cell

1706

bioRxiv preprint doi: https://doi.org/10.1101/2021.12.06.471446; this version posted December 9, 2021. The copyright holder for this preprint (which was not certified by peer review) is the author/funder. This article is a US Government work. It is not subject to copyright under 17 USC 105 and is also made available for use under a CC0 license.

556

response from earlier infection would almost certainly still be effective against the new variants[7]. In this study, the mutations associated with Omicron VOC are examined in an identical manner.

Methods:

The detailed methods of the earlier two studies were published previously[1,7]. In short, peripheral blood mononuclear cell (PBMC) samples from PCR-confirmed, recovered COVID-19 convalescent plasma donors collected in April and May 2020 in the Baltimore, MD and Washington DC region who possessed at least one or more of six different HLA haplotypes (HLA-A*01:01, HLA-A*02:01, HLA-A03:01, HLA-A*11:01, HLA-A*24:02 and HLA-B*07:02) were selected for examination of their anti-SARS-CoV-2 CD8+ T cell responses using a multiplexed peptide-MHC tetramer staining approach.

The mutations associated with Omicron VOC (PL: K38R, delta1265, L1266I, A1892T; Nsp4: T492I; 3CL: P132H; Nsp6: delta105-107, I189V; RdRp: P323L; Nsp14:I42V; Spike: A67V, delta69-70, T95I, G142D, delta143-145, N211I; L212V_RE, V213P, R214E, G339D, S371L, S373P, K417N, N440K, G446S, S477N, T478K, E484A, Q493R, G496S, Q498R, T547K, D614G, H655Y, N679K, P681H, N764K, D796Y, N856K, Q954H, N969K, L981F; Envelope: T9I; Matrix: D3G, Q19E, A63T; Nucleocapsid: P13L, delta31-33, R203K, G204R) were mapped to the epitope map developed in the previous analyses, and examined for possible cross-over[8].

Ethics: All study participants provided written informed consent, and this study was approved by the Johns Hopkins Institutional Review Board.

Results:

The individuals examined in this study were primarily male (60%), and the blood samples were collected a median of 42.5 days (interquartile range 37.5-48.0) from initial diagnosis[1]. The patients were selected from the larger study population according to sample availability, and anti-SARS-CoV-2 IgG responses with ten individuals selected from each of three antibody tertiles[1,3]. 132 SARS-CoV-2-specific CD8+ T cell responses were identified in these individuals, which corresponded to 52 unique epitopes found across the viral genome targeting both structural and non-structural proteins.



bioRxiv preprint doi: https://doi.org/10.1101/2021.12.06.471446; this version posted December 9, 2021. The copyright holder for this preprint (which was not certified by peer review) is the author/funder. This article is a US Government work. It is not subject to copyright under 17 USC 105 and is also made available for use under a CC0 license.

Of the mutations associated with the Omicron variant (n=50), only one in the Spike protein (T95I) overlapped with a CD8+ T-cell epitope (GVYFASTEK) identified in this population (Figures 1 and S1). This epitope is restricted to HLA*A03:01 and HLA*A11:01 and a T-cell reactivity was detected in two individuals, typed as HLA:A03:01 and HLA:A03:01/ HLA:A11:01, respectively[9]. Despite the possibility to induce T-cell responses against GVYFASTEK presented on both alleles in one individual, this epitope represented a low-prevalence target in both of these individuals making up 0.1% and a combined 0.4% of all CD8+ T-cell responses in each individual, respectively[1]. In addition, this epitope was 1 of 5 and 1 of 13 of the anti-SARS-CoV-2 epitopes targeted by the two individuals, respectively.

Discussion:

This study demonstrates that despite the substantial number of mutations in the Omicron VOC, in this population only one low-prevalence CD8+ T-cell epitope from the Spike protein contained a single amino acid change. No other mutations were associated with our previously identified epitopes. These data suggest that virtually all individuals with existing anti-SARS-CoV-2 CD8+ T-cell responses should recognize the Omicron VOC, and that SARS-CoV-2 has not evolved extensive T-cell escape mutations at this point.

There are several limitations for this analysis. The results are based on a relatively small samples size of individuals who were all from the United States. Additionally, we examined the CD8+ T-cell responses in previously infected but not vaccinated individuals, and it is possible that the T-cell responses in this later group are more limited and therefore more susceptible to escape. However, work examining T-cell responses from vaccinees has demonstrated a strong CD4+ and CD8+ T-cell responses in these individuals, suggesting that similar trends should be seen in this population as well[2, 10].

While it is unknown what specific immune response, or more likely combination of responses, provides optimum protection against SARS-CoV-2 infection and COVID-19, it almost certainly includes a broad and robust CD8+ T-cell response. These data build on the previous analysis of the initial VOC, and confirm that while SARS-CoV-2 has demonstrated a continued pattern of ongoing evolution this has not resulted in any meaningful accumulation of CD8+ T-cell escape mutations[7]. These data also suggest that existing CD8+ T-cell responses from a previous SARS-CoV-2 infection, and most likely from vaccination as well, will still recognize the Omicron VOC and should provide a significant level of protection against COVID-19.

1708

bioRxiv preprint doi: https://doi.org/10.1101/2021.12.06.471446; this version posted December 9, 2021. The copyright holder for this preprint (which was not certified by peer review) is the author/funder. This article is a US Government work. It is not subject to copyright under 17 USC 105 and is also made available for use under a CC0 license.

558

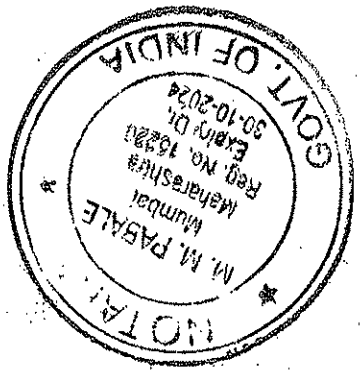
Acknowledgements: The authors would like to thank the CCP study and laboratory teams, and all the convalescent plasma donors for the generous participation in the study.

Funding: This work was supported in part by the National Institute of Allergy and Infectious Diseases (NIAID) R01AI120938, R01AI120938S1 and R01AI128779 (A.A.R.T); the Division of Intramural Research, NIAID, NIH (O.L., A.R., T.Q.); and National Heart Lung and Blood Institute 1K23HL151826-01 (E.M.B).

Potential conflicts of interest: H.K., B.A., A.N., and M.F. are shareholders and/or employees of ImmunoScape Pte Ltd. A.N. is a Board Director of ImmunoScape Pte Ltd.

Figure Legend

Figure 1: SARS-CoV-2 Wuhan variant protein amino acid sequence for Spike protein with CD8+ T cell epitopes highlighted (green) and all mutations and deletions (slash) sites indicated in large blue letters.



bioRxiv preprint doi: https://doi.org/10.1101/2021.12.06.471446; this version posted December 9, 2021. The copyright holder for this preprint (which was not certified by peer review) is the author/funder. This article is a US Government work. It is not subject to copyright under 17 USC 105 and is also made available for use under a CC0 license.

References

1. Kared H, Redd AD, Bloch EM, et al. SARS-CoV-2-specific CD8+ T cell responses in convalescent COVID-19 individuals. J Clin Invest. American Society for Clinical Investigation; **2021**; 131(5).
2. Woldemeskel BA, Garliss CC, Blankson JN. SARS-CoV-2 mRNA vaccines induce broad CD4+ T cell responses that recognize SARS-CoV-2 variants and HCoV-NL63. J Clin Invest [Internet]. American Society for Clinical Investigation; **2021** [cited 2021 Nov 30]; 131(10). Available from: https://doi.org/10.1172/JCI149335DS1
3. Klein SL, Pekosz A, Park HS, et al. Sex, age, and hospitalization drive antibody responses in a COVID-19 convalescent plasma donor population. J Clin Invest [Internet]. American Society for Clinical Investigation; **2020** [cited 2021 Feb 5]; 130(11):6141–6150. Available from: https://doi.org/10.1172/JCI142004.
4. Lopez Bernal J, Andrews N, Gower C, et al. Effectiveness of Covid-19 Vaccines against the B.1.617.2 (Delta) Variant. N Engl J Med [Internet]. N Engl J Med; **2021** [cited 2021 Dec 1]; 385(7):585–594. Available from: https://pubmed.ncbi.nlm.nih.gov/34289274/
5. Tang P, Hasan MR, Chemaitelly H, et al. BNT162b2 and mRNA-1273 COVID-19 vaccine effectiveness against the SARS-CoV-2 Delta variant in Qatar. Nat Med [Internet]. Nat Med; **2021** [cited 2021 Dec 1]; . Available from: https://pubmed.ncbi.nlm.nih.gov/34728831/
6. WHO. Classification of Omicron (B.1.1.529): SARS-CoV-2 Variant of Concern [Internet]. 2021 [cited 2021 Nov 30]. Available from: https://www.who.int/news/item/26-11-2021-classification-of-omicron-(b.1.1.529)-sars-cov-2-variant-of-concern
7. Redd AD, Nardin A, Kared H, et al. CD8+ T-Cell Responses in COVID-19 Convalescent Individuals Target Conserved Epitopes From Multiple Prominent SARS-CoV-2 Circulating Variants. Open Forum Infect Dis [Internet]. Oxford Academic; **2021** [cited 2021 Aug 25]; 8(7). Available from: https://academic.oup.com/ofid/article/8/7/ofab143/6189113
8. GISAID. GISAID [Internet]. [cited 2021 Dec 1]. Available from: https://www.gisaid.org/
9. Grifoni A, Weiskopf D, Ramirez SI, et al. Targets of T Cell Responses to SARS-CoV-2 Coronavirus in Humans with COVID-19 Disease and Unexposed Individuals. Cell [Internet]. Cell; **2020** [cited 2021 Dec 1]; 181(7):1489-1501.e15. Available from: https://pubmed.ncbi.nlm.nih.gov/32473127/
10. Oberhardt V, Luxenburger H, Kemming J, et al. Rapid and stable mobilization of CD8+ T cells by SARS-CoV-2 mRNA vaccine. Nat 2021 5977875 [Internet]. Nature Publishing Group; **2021** [cited

1710

bioRxiv preprint doi: https://doi.org/10.1101/2021.12.06.471446; this version posted December 9, 2021. The copyright holder for this preprint (which was not certified by peer review) is the author/funder. This article is a US Government work. It is not subject to copyright under 17 USC 105 and is also made available for use under a CC0 license.

560

2021 Nov 30]; 597(7875):268–273. Available from: https://www.nature.com/articles/s41586-021-03841-4



bioRxiv preprint doi: https://doi.org/10.1101/2021.12.06.471446; this version posted December 9, 2021. The copyright holder for this preprint (which was not certified by peer review) is the author/funder. This article is a US Government work. It is not subject to copyright under 17 USC 105 and is also made available for use under a CC0 license.

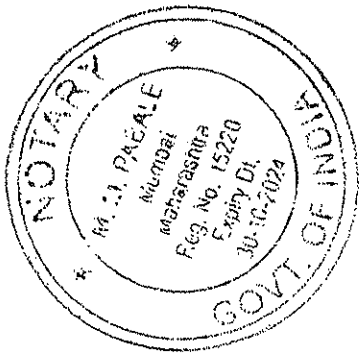
1711

~~561~~

Figure 1:

Spike

MFVFLVLLPLVSSQCVNLTTRTQLPPAYTNSFTRGVYYPDKVFRSSVLHSTQDLFLPFFSNVTWFHAIHVSGTN
GTKRFDNPVLPFNDGVYFASTEKSNIIRGWIFGTTLDSKTQSLLIVNNATNVVIKVCEFQFCNDPFLGVYYHK
NNKSWMESEFRVYSSANNCTFEYVSQPFLMDLEGKQGNFKNLREFVFKNIDGYFKIYSKHTPINLVRDLPQG
FSALEPLVDLPIGINITRFQTLLALHRSYLTPGDSSSGWTAGAAAYYVGYLQPRTFLLKYNENGTITDAVDCALDP
LSETKCTLKSFTVEKGIYQTSNFRVQPTESIVRFPNITNLCPFGEVFNATRFASVYAWNRKRISNCVADYSVLYNS
ASFSTFKCYGVSPTKLNDLCFTNVYADSFVIRGDEVRQIAPGQTGKIADYNYKLPDDFTGCVIAWNSNNLDSK
VGGNYNYLYRLFRKSNLKPFERDISTEIYQAGSTPCNGVEGFNCYFPLQSYGFQPTNGVGYQPYRVVVLSFEL
LHAPATVCGPKKSTNLVKNKCVNFNFNGLTGTGVLTESNKKFLPFQQFGRDIADTTDAVRDPQTLEILDITPCSF
GGVSVITPGTNTSNQVAVLYQDVNCTEVPVAIHADQLTPTWRVYSTGSNVFQTRAGCLIGAEHVNNSYECDI
PIGAGICASYQTQTNSPRRARSVASQSIIAYTMSLGAENSVAYSNNSIAIPTNFTISVTTEILPVSMTKTSVDCTM
YICGDSTECSNLLLQYGSFCTQLNRALTGIAVEQDKNTQEVFAQVKQIYKTPPIKDFGGFNFSQILPDPSKPSKR
SFIEDLLFNKVTLADAGFIKQYGDCLGDIAARDLICAQKFNGLTVLPPLLTDEMIAQYTSALLAGTITSGWTFGA
GAALQIPFAMQMAYRFNGIGVTQNVLYENQKLIANQFNSAIGKIQDSLSSTASALGKLQDVVNQNAQALNTL
VKQLSSNFGAISSVLNDILSRLDKVEAEVQIDRLITGRLQSLQTYVTQQLIRAAEIRASANLAATKMSECVLGQS
KRVDFCGKGYHLMSFPQSAPHGVVFLHVTYVPAQEKNFTTAPAICHDGKAHFPREGVFVSNGTHWFVTQRN
FYEPQIITTDNTFVSGNCDVVIGIVNNTVYDPLQPELDSFKEELDKYFKNHTSPDVDLGDISGINASVVNIQKEI
DRLNEVAKNLNESLIDLQELGKYEQYIKWPWYIWLGFIAGLIAIVMVTIMLCCMTSCCSCLKGCCSCGSCCKFD
EDDSEPVLKGVKLHYT



1712
~~562~~

EXHIBIT "RA-43"

Natural Immunity 75% effective against Omicron variant, Vaccine Immunity only 33%

Investigative Journalist Jeremy Hammond reports on a study out of Africa which sought to determine how effective natural immunity was against Omicron.

"What these numbers mean is that immunity from prior infection was 85% effective at preventing suspected reinfection with the originally predominant variant, 88% effective against the Beta variant, 91% effective against the Delta variant, and 75% effective against the Omicron variant.

To ensure that this understanding of the reported hazard ratios is correct, I contacted the lead author, who is also listed as the corresponding author, and was helpfully put in touch with the second author listed on the paper, Dr. Cari Van Schalwyk, who confirmed that this is a correct interpretation of their study's findings.

The finding that Omicron does escape natural immunity to some extent is certainly important, but it is hardly a cause for alarm. Even if someone's immune defenses fail to prevent infection with this variant, it does not necessarily mean that they will develop COVID-19, much less severe disease. As acknowledged by the New York Times, the available data are also reassuring that, when reinfections (or primary infections) do occur, most individuals remain asymptomatic or experience only mild illness."

Study:https://www.medrxiv.org/content/10.1101/2021.11.11.21266068v2

Source:https://www.jeremyrhammond.com/2021/12/18/fact-check-does-natural-immunity-offer-little-protection-against-

GOVT. OF INDIA
NOTARY

omicron/?utm_source=ActiveCampaign&utm_medium=email&utm_content=Does+Natural+Immunity+Offer+%22Little%22+Protection+Against+Omicron%3F&utm_campaign=Does+Natural+Immunity+Offer+%22Little%22+Protection+Against+Omicron%3F&vgo_ee=rJAOKBoUZmLEn12V6fz%2BaRwUnRnlmwiuCIJkd9A7F3A%3D

A study by researchers from South Africa's largest private health insurer, Discovery Health, and the South African Medical Research Council found that two doses of the Pfizer-BioNTech vaccine is just 33% effective at preventing infection during the continuing wave characterized by the spread of the Omicron variant.

Source:https://www.discovery.co.za/corporate/news-room#/pressreleases/discovery-health-south-africas-largest-private-health-insurance-administrator-releases-at-scale-real-world-analysis-of-omicron-outbreak-based-dot-dot-dot-3150697

Adrian Gore, the founder and chief executive of Discovery Limited, which is the controlling company of the insurance group, similarly published an article on December 15 stating that, "while Omicron seems to be more transmissible than previous variants, with a higher rate of reinfection following prior infection, its severity relative to prior variants seems less (fewer hospital admissions and a lower proportion of high care and ICU admissions compared to previous waves)."

Source:https://www.linkedin.com/pulse/discovery-health-releases-critical-insights-omicron-adrian-gore/

1714
~~564~~

EXHIBIT "RA-44"

Examples of Immunity that lasts for decades in other viral respiratory infections like Sars & the 1918 Flu

People who recovered from the 2003 SARS infection demonstrated robust T-Cell responses seventeen years later

Source:https://www.nature.com/articles/s41586-020-2550-z

Survivors of the 1918 Flu epidemic were tested for their immunity to the 1918 influenza virus 90 years after, and still demonstrated immunity

Source:https://www.nationalgeographic.com/science/article/flu-survivors-still-immune-after-90-years
https://www.nature.com/articles/nature07231

The wide-spread prevalence of high cross-immunity – gained from past common cold infections – further demonstrates the resilience of natural immunity for coronaviruses.

From the study : "Importantly, we detected SARS-CoV-2-reactive CD4+ T cells in ~40%–60% of unexposed individuals, suggesting cross-reactive T cell recognition between circulating "common cold" coronaviruses and SARS-CoV-2."

Source:https://www.sciencedirect.com/science/article/pii/S0092867420306103
https://insight.jci.org/articles/view/146316
https://www.nature.com/articles/s41423-021-00700-0



EXHIBIT "RA-45"

Safety and efficacy of the ChAdOx1 nCoV-19 vaccine (AZD1222) against SARS-CoV-2: an interim analysis of four randomised controlled trials in Brazil, South Africa, and the UK

Merryn Voysey, Sue Ann Costa Clemens*, Shabir A Madhi*, Lily Y Weckx*, Pedro M Folegatti*, Parvinder K Aley, Brian Angus, Vicky L Baillie, Shaun L Barnabas, Qasim E Bhorat, Sagida Bibi, Carmen Briner, Paola Cicconi, Andrea M Collins, Rachel Colin-Jones, Clare L Cutland, Thomas C Darton, Keertan Dheda, Christopher J A Duncan, Katherine R W Emary, Katie J Ewer, Lee Fairlie, Saul N Faust, Shuo Feng, Daniela M Ferreira, Adam Finn, Anna L Goodman, Catherine M Green, Christopher A Green, Paul T Heath, Catherine Hill, Helen Hill, Ian Hirsch, Susanne H C Hodgson, Alane Izu, Susan Jackson, Daniel Jenkin, Carina C D Joe, Simon Kerridge, Anthonet Koen, Gaurav Kwatra, Rajeka Lazarus, Alison M Lawrie, Alice Lelliott, Vincenzo Libri, Patrick J Lillie, Raburn Mallory, Ana V A Mendes, Eveline P Milan, Angela M Minassian, Alastair McGregor, Hazel Morrison, Yama F Mujadidi, Anusha Nana, Peter J O'Reilly, Sherman D Padayachee, Ana Pittella, Emma Plested, Katrina M Pollock, Maheshi N Ramasamy, Sarah Rhead, Alexandre V Schwarzbold, Nisha Singh, Andrew Smith, Rinn Song, Matthew D Snape, Eduardo Sprinz, Rebecca K Sutherland, Richard Tarrant, Emma C Thomson, M Estée Török, Mark Toshner, David P J Turner, Johan Vekemans, Tonya L Villafana, Marion E E Watson, Christopher J Williams, Alexander D Douglas*, Adrian V S Hill*, Teresa Lambe*, Sarah C Gilbert*, Andrew J Pollard* on behalf of the Oxford COVID Vaccine Trial Group†*

NOTARY PUBLIC
Adv. M. PASALE
Mumbai
Maharashtra
Reg. No. 15220
Expiry Dt. 30-10-2024
COURT OF INDIA

Summary

Background A safe and efficacious vaccine against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), if deployed with high coverage, could contribute to the control of the COVID-19 pandemic. We evaluated the safety and efficacy of the ChAdOx1 nCoV-19 vaccine in a pooled interim analysis of four trials.

Methods This analysis includes data from four ongoing blinded, randomised, controlled trials done across the UK, Brazil, and South Africa. Participants aged 18 years and older were randomly assigned (1:1) to ChAdOx1 nCoV-19 vaccine or control (meningococcal group A, C, W, and Y conjugate vaccine or saline). Participants in the ChAdOx1 nCoV-19 group received two doses containing 5×10^{10} viral particles (standard dose; SD/SD cohort); a subset in the UK trial received a half dose as their first dose (low dose) and a standard dose as their second dose (LD/SD cohort). The primary efficacy analysis included symptomatic COVID-19 in seronegative participants with a nucleic acid amplification test-positive swab more than 14 days after a second dose of vaccine. Participants were analysed according to treatment received, with data cutoff on Nov 4, 2020. Vaccine efficacy was calculated as 1–relative risk derived from a robust Poisson regression model adjusted for age. Studies are registered at ISRCTN89951424 and ClinicalTrials.gov, NCT04324606, NCT04400838, and NCT04444674.

Findings Between April 23 and Nov 4, 2020, 23 848 participants were enrolled and 11 636 participants (7548 in the UK, 4088 in Brazil) were included in the interim primary efficacy analysis. In participants who received two standard doses, vaccine efficacy was 62·1% (95% CI 41·0–75·7; 27 [0·6%] of 4440 in the ChAdOx1 nCoV-19 group *vs* 71 [1·6%] of 4455 in the control group) and in participants who received a low dose followed by a standard dose, efficacy was 90·0% (67·4–97·0; three [0·2%] of 1367 *vs* 30 [2·2%] of 1374; $p_{interaction}$=0·010). Overall vaccine efficacy across both groups was 70·4% (95·8% CI 54·8–80·6; 30 [0·5%] of 5807 *vs* 101 [1·7%] of 5829). From 21 days after the first dose, there were ten cases hospitalised for COVID-19, all in the control arm; two were classified as severe COVID-19, including one death. There were 74 341 person-months of safety follow-up (median 3·4 months, IQR 1·3–4·8): 175 severe adverse events occurred in 168 participants, 84 events in the ChAdOx1 nCoV-19 group and 91 in the control group. Three events were classified as possibly related to a vaccine: one in the ChAdOx1 nCoV-19 group, one in the control group, and one in a participant who remains masked to group allocation.

Interpretation ChAdOx1 nCoV-19 has an acceptable safety profile and has been found to be efficacious against symptomatic COVID-19 in this interim analysis of ongoing clinical trials.

Funding UK Research and Innovation, National Institutes for Health Research (NIHR), Coalition for Epidemic Preparedness Innovations, Bill & Melinda Gates Foundation, Lemann Foundation, Rede D'Or, Brava and Telles Foundation, NIHR Oxford Biomedical Research Centre, Thames Valley and South Midland's NIHR Clinical Research Network, and AstraZeneca.

Copyright © 2020 The Author(s). Published by Elsevier Ltd. This is an Open Access article under the CC BY 4.0 license.

Lancet 2021; 397: 99–111
Published Online December 8, 2020 https://doi.org/10.1016/S0140-6736(20)32661-1

This online publication has been corrected. The corrected version first appeared at thelancet.com on January 7, 2021

See Comment page 72

*Contributed equally

†Members are listed in appendix 1 (pp 21–44)

Oxford Vaccine Group, Department of Paediatrics, University of Oxford, Oxford, UK (M Voysey DPhil, P K Aley PhD, S Bibi PhD, R Colin-Jones MSc, K R W Emary BM BCh, S Feng PhD, S Kerridge MSc, A Lelliott BMBS, Y F Mujadidi MSc, P J O'Reilly MBChBAO, E Plested, M N Ramasamy DPhil, S Rhead MBChB, N Singh DPhil, R Song MD, M D Snape MD, A J Pollard FMedSci); Jenner Institute, Nuffield Department of Medicine, University of Oxford, UK (P M Folegatti MD, B Angus MD, P Cicconi PhD, K J Ewer PhD, S H C Hodgson DPhil, S Jackson MRCP, D Jenkin MRCP, C C D Joe PhD, A M Lawrie PhD, A M Minassian DPhil, H Morrison MRCP, M E E Watson PhD, A D Douglas DPhil, A V S Hill FMedSci, T Lambe PhD, S C Gilbert PhD); Institute of Global Health, University of Siena, Siena, Brazil; (S A C Clemens PhD);

1716

Department of Paediatrics (S A C Clemens) and Clinical BioManufacturing Facility (C M Green PhD, R Tarrant PhD), University of Oxford, Oxford, UK; MRC Vaccines and Infectious Diseases Analytics Research Unit, Johannesburg, South Africa (S A Madhi PhD); Department of Pediatrics, Universidade Federal de São Paulo, São Paulo, Brazil (L Y Weckx PhD); Respiratory and Meningeal Pathogens Research Unit, University of the Witwatersrand, Johannesburg, South Africa (V Baillie PhD, C L Cutland PhD); Family Centre for Research with Ubuntu, Department of Paediatrics, University of Stellenbosch, Cape Town, South Africa (S L Barnabas PhD); Soweto Clinical Trials Centre, Soweto, South Africa (Q E Bhorat MSc); Perinatal HIV Research Unit (C Briner MBBCh, A Nana MPharm) and Wits Reproductive Health and HIV Institute (L Fairlie FCPaeds, C Hill BSc, G Kwatra PhD), Faculty of Health Sciences, University of the Witwatersrand, Johannesburg, South Africa; Department of Clinical Sciences, Liverpool School of Tropical Medicine and Liverpool University Hospitals NHS Foundation Trust, Liverpool, UK (A M Collins PhD, D M Ferreira PhD, H Hill PhD); Department of Infection, Immunity and Cardiovascular Disease, University of Sheffield, Sheffield, UK (T C Darton DPhil); Department of Infection and Tropical Medicine, Sheffield Teaching Hospitals NHS Foundation Trust, Sheffield, UK (T C Darton); Division of Pulmonology, Groote Schuur Hospital and the University of Cape Town, South Africa (K Dheda FRCPCH); Faculty of Infectious and Tropical Diseases, Department of Immunology and Infection, London School of Hygiene & Tropical Medicine, London, UK (K Dheda); Department of Infection and Tropical Medicine, Newcastle upon Tyne Hospitals NHS Foundation Trust, Newcastle upon Tyne, UK (C J A Duncan DPhil); Translational and Clinical Research Institute, Immunity and Inflammation Theme, Newcastle University, Newcastle upon Tyne, UK (C J A Duncan); NIHR

Research in context

Evidence before this study

We searched PubMed for research articles published from database inception until Nov 23, 2020, with no language restrictions, using the terms "SARS-CoV-2", "vaccine", "clinical trial", and "efficacy". There were no peer-reviewed publications available on efficacy of any severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccines in development and, at the time of the search, there were no licensed vaccines against SARS-CoV-2. Three vaccine developers recently reported initial efficacy results from phase 3 trials in the media (Pfizer/BioNTech, Moderna, and the Gamaleya National Research Center). Pfizer/BioNTech and Moderna, both developing mRNA vaccines, have reported initial efficacy results of 95% in their primary analysis (Pfizer/BioNTech) and 94·5% in an interim analysis (Moderna). We have previously published safety and immunogenicity results of ChAdOx1 nCoV-19 (AZD1222) for different age groups in phase 1/2 and 2/3 trials.

Added value of this study

We report on the first clinical efficacy results of ChAdOx1 nCoV-19 in a pooled analysis of phase 2/3 trials in the UK and Brazil, and safety data from more than 20 000 participants enrolled across four clinical trials in the UK, Brazil, and South Africa. ChAdOx1 nCoV-19 has an acceptable safety profile and is efficacious against symptomatic COVID-19, with no hospital admissions or severe cases reported in the ChAdOx1 nCoV-19 arm. The vaccine can be stored and distributed at 2–8°C, making it particularly suitable for global distribution.

Implications of all the available evidence

The development of safe, effective, affordable, and deployable vaccines against COVID-19 remains paramount in solving the pandemic crisis and re-establishing normality. The positive results presented here support regulatory submissions for conditional or emergency use of ChAdOx1 nCoV-19.

Introduction

As the COVID-19 pandemic, caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), continues to unfold, there has been widespread impact on health, including substantial mortality among older adults and those with pre-existing health conditions,[1,2] and repercussions for the global economy, caused by physical distancing measures, with the greatest consequences for the most vulnerable in society.

Despite global spread of the virus, a large proportion of the population in many countries is thought to have thus far escaped infection and remains non-immune to SARS-CoV-2.[3] Vaccines could play an important role in increasing population immunity, preventing severe disease, and reducing the ongoing health crisis. In response, rapid global efforts to develop and test vaccines against SARS-CoV-2 have led to an unprecedented number of candidate vaccines starting clinical trials during 2020. Currently, 48 vaccines are under clinical evaluation.[4] Several of these have shown good safety and immunogenicity, and 11 of these are currently being evaluated in phase 3 clinical efficacy studies.

The ChAdOx1 nCoV-19 vaccine (AZD1222) was developed at Oxford University and consists of a replication-deficient chimpanzee adenoviral vector ChAdOx1, containing the SARS-CoV-2 structural surface glycoprotein antigen (spike protein; nCoV-19) gene.

Following initiation of a phase 1 clinical trial in the UK (COV001) on April 23, 2020, three further randomised controlled trials of the candidate vaccine were initiated across the UK (COV002), Brazil (COV003), and South Africa (COV005). A further phase 1/2 trial has recently been initiated in Kenya and is not reported here. The immunogenicity results from the phase 1/2 UK study, COV001, in 1077 healthy adults aged 18–55 years,[5] and a phase 2 cohort in COV002 in older adults (≥56 years)[6] have been published and show an acceptable safety profile for the vaccine with induction of binding and neutralising antibodies as well as generation of interferon-γ enzyme-linked immunospot responses, with higher antibody titres after a second dose of vaccine.[5–7]

The phase 1 study (COV001) included an efficacy cohort and the phase 2 and 3 studies (COV002, COV003, and COV005) expanded enrolment to a wider population of participants with higher likelihood of exposure to the virus, such as health-care workers. Exclusion criteria were reduced for phase 3 trials, so that older adults and individuals with a range of comorbidities were also enrolled.

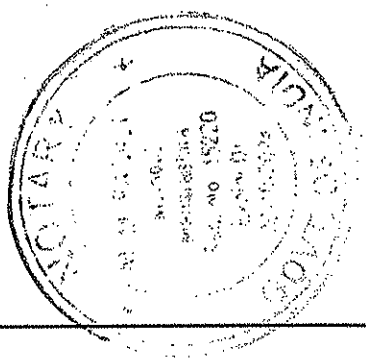
All studies have completed enrolment of their respective efficacy cohorts and are in the follow-up phase. Paediatric studies have not yet been initiated.

Here, we present the combined interim analysis of efficacy and safety from randomised controlled trials of ChAdOx1 nCoV-19.

Methods

Overview

This interim analysis of the efficacy and safety of the ChAdOx1 nCoV-19 vaccine includes data from four ongoing blinded, randomised, controlled trials done across three countries: COV001 (phase 1/2; UK), COV002 (phase 2/3; UK), COV003 (phase 3; Brazil), and COV005 (phase 1/2; South Africa). The interim efficacy is being assessed by a prespecified global pooled analysis combining data from COV002 and COV003. The safety of the vaccine is being assessed using data from all four studies (appendix 1 pp 3–4). Three of the studies are single-blind and one is double blind (COV005). Primary efficacy was assessed in participants who received



two doses of the vaccine. All four studies included participants who received two doses, with a booster dose incorporated into the three trials[6] that were initially designed to assess a single-dose of ChAdOx1 nCoV-19 compared with control (COV001, COV002, and COV003) after review of the antibody response data from COV001.

Despite minor differences across the studies, there is sufficient consistency to justify the proposal for pooled analysis of data, which will provide greater precision for both efficacy and safety outcomes than can be achieved in individual studies and provides a broader understanding of the use of the vaccine in different populations. Once the studies were underway, a statistical analysis plan for the global pooled analysis of these studies was developed before data lock on Nov 4, 2020, and analysis, and was finalised with extensive feedback from national and international regulators (including the Medicines and Healthcare Products Regulatory Agency [UK] and the European Medicines Agency [EU]), including justification for including groups receiving different vaccine doses in the analysis (see statistical analysis plan for further details; appendix 2 pp 2–73). All participants in the four trials provided written informed consent.

Details of amendments to the four trial protocols and the statistical analysis plan are included in appendix 2 (pp 9, 178–182, 327–335, 438–441, 548–550).

Study design and participants

COV001 (UK)

COV001 is a continuing single-blind phase 1/2 clinical trial in five sites in the UK, which began on April 23, 2020, and enrolled 1077 healthy volunteers aged 18–55 years, as previously described.[5] Briefly, healthy adult participants were enrolled after screening to exclude those with pre-existing health conditions. Participants were randomly assigned 1:1 to receive ChAdOx1 nCoV-19 at a dose of 5×10^{10} viral particles (standard dose), measured using spectrophotometry, or meningococcal group A, C, W, and Y conjugate vaccine (MenACWY) as control. An open-label non-randomised subgroup of ten participants were given two doses of ChAdOx1 nCoV-19 28 days apart, as previously reported.[5] This study was originally planned as a single-dose study and 88 participants in the phase 1 part of the study remain recipients of a single dose. However, the protocol was modified to a two-dose regime, following an amendment on July 30, 2020 (version 9.0; appendix 2 pp 180–181), for the remaining phase 2 cohorts as a result of robust booster responses identified in the evaluation of the early immunogenicity cohorts, with the booster dose given at the earliest possible time.[5]

COV002 (UK)

COV002 is a continuing single-blind phase 2/3 study in the UK that began on May 28, 2020, and enrolled participants in 19 study sites in England, Wales, and Scotland. Enrolment particularly targeted individuals working in professions with high possible exposure to SARS-CoV-2, such as health and social care settings.

Two dosage groups were included in COV002: participants who received a low dose of the vaccine ($2\cdot2\times10^{10}$ viral particles) as their first dose and were boosted with a standard dose (in the LD/SD group), and subsequent cohorts who were vaccinated with two standard-dose vaccines (SD/SD group). Initial dosing in COV002 was with a batch manufactured at a contract manufacturing organisation using chromatographic purification. During quality control of this second batch, differences were observed between the quantification methods (spectrophotometry and quantitative PCR [qPCR]) prioritised by different manufacturing sites. In consultation with the national regulator (Medicines and Healthcare products Regulatory Agency), we selected a dose of 5×10^{10} viral particles by spectrophotometer ($2\cdot2\times10^{10}$ viral particles by qPCR), in order to be consistent with the use of spectrophotometry in the phase 1 study (COV001),[5] and to ensure the dose was within a safe and immunogenic range according to measurements by both methods. A lower-than-anticipated reactogenicity profile was noted in the trial, and unexpected interference of an excipient with the spectrophotometry assay was identified. After review and approval by the regulator, it was concluded that the qPCR (low-dose) reading was more accurate and further doses were adjusted to the standard dose (5×10^{10} viral particles) using a qPCR assay. The protocol was amended on June 5, 2020, resulting in enrolment of two distinct groups with different dosing regimens with no pause in enrolment (version 6.0; appendix 2 p 330). A suite of assays has now been developed for characterisation of concentration (which confirmed the low and standard dosing), and future batches are all released with a specification dose of $3\cdot5–6\cdot5\times10^{10}$ viral particles, and this was used for the booster doses in the efficacy analysis presented here.

The LD/SD cohort (aged 18–55 years) was enrolled over 11 days between May 31 and June 10, 2020. The SD/SD cohort (aged 18–55 years) was enrolled from June 9 to July 20, 2020. Subsequently, enrolment of older age cohorts began (from Aug 8, 2020, for participants aged 56–69 years and from Aug 13, 2020, for participants aged ≥70 years), all of whom were assigned to two standard doses (SD/SD cohort). Each site implemented the protocol amendment before changing from low-dose administration to standard-dose administration, and therefore there was no overlap in enrolment of participants in these cohorts.

The 18–55-year-old cohorts were originally planned as single-dose efficacy cohorts. However, the protocol was modified on July 20, 2020, to offer a second dose to the participants in these cohorts as a result of robust booster responses identified in the evaluation of the early immunogenicity cohorts (version 9.0; appendix 2 pp 331–332).[5] Boosting began on Aug 3, 2020, resulting

Southampton Clinical Research Facility and Biomedical Research Centre, University Hospital Southampton NHS Foundation Trust, Southampton, UK (S N Faust PhD); Faculty of Medicine and Institute for Life Sciences, University of Southampton, Southampton, UK (S N Faust); School of Population Health Sciences, University of Bristol and University Hospitals Bristol and Weston NHS Foundation Trust, Bristol, UK (A Finn PhD); Department of Infection, Guy's and St Thomas' NHS Foundation Trust, St Thomas' Hospital, London, UK (A L Goodman FRCP); MRC Clinical Trials Unit, University College London, London, UK (A L Goodman); NIHR/Wellcome Trust Clinical Research Facility, University Hospitals Birmingham NHS Foundation Trust, Birmingham, UK (C A Green DPhil); St George's Vaccine Institute, St George's, University of London, London, UK (P T Heath FRCPCH); AstraZeneca BioPharmaceuticals, Cambridge, UK (I Hirsch PhD, R Mallory MD, J Vekemans MD, T L Villafana PhD); VIDA—Vaccines and Infectious Diseases Analytical Research Unit, Johannesburg, South Africa (A Izu PhD, A Koen MBChB); Severn Pathology, North Bristol NHS Trust, Bristol, UK (R Lazarus DPhil); NIHR UCLH Clinical Research Facility and NIHR UCLH Biomedical Research Centre, London, UK (V Libri MD FRCP); Department of Infection, Hull University Teaching Hospitals NHS Trust, UK (P J Lillie PhD); Escola Bahiana de Medicina e Saúde Pública, Salvador, Braziland Hospital São Rafael, Salvador, Brazil (A V A Mendes MD); Instituto D'Or, Salvador, Brazil (A V A Mendes); Department of Infectious Diseases, Universidade Federal do Rio Grande do Norte, Natal, Brazil (E P Milan MD); London Northwest University Healthcare, Harrow, UK (A C McGregor FRCPath); Setshaba Research Centre, Pretoria, South Africa (S D Payadachee MBChB); Department of Internal Medicine, Hospital Quinta D'Or, Rio de Janeiro, Brazil

1718

(A Pittella MD); Instituto D'Or de Pesquisa e Ensino (IDOR), Rio de Janeiro, Brazil (A Pittella); Department of Internal Medicine, Universidade UNIGRANRIO, Rio de Janeiro, Brazil (A Pittella MD); NIHR Imperial Clinical Research Facility and NIHR Imperial Biomedical Research Centre, London, UK (K M Pollock PhD); Clinical Research Unit, Department of Clinical Medicine, Universidade Federal de Santa Maria, Santa Maria, Brazil (A V Schwarzbold PhD); College of Medical, Veterinary & Life Sciences, Glasgow Dental Hospital & School, University of Glasgow, Glasgow, UK (A Smith FRCPath); Division of Infectious Diseases, Boston Children's Hospital, Boston, MA, USA (R Song); Infectious Diseases Service, Hospital de Clinicas de Porto Alegre, Universidade Federal do Rio Grande do Sul, Porto Alegre, Brazil (E Sprinz MD); Clinical Infection Research Group, Regional Infectious Diseases Unit, Western General Hospital, Edinburgh, UK (R K Sutherland FRCP); MRC-University of Glasgow Centre for Virus Research & Department of Infectious Diseases, Queen Elizabeth University Hospital, Glasgow, UK (E C Thomson FRCP PhD); Department of Medicine, University of Cambridge, UK (M E Török FRCP); Cambridge University Hospitals NHS Foundation Trust, Cambridge, UK (M E Török); Heart Lung Research Institute, Department of Medicine, University of Cambridge and Royal Papworth Hospital NHS Foundation Trust, Cambridge, UK (M Toshner MD); University of Nottingham and Nottingham University Hospitals NHS Trust, UK (D P J Turner PhD); Public Health Wales, Cardiff, Wales (C J Williams FFPH); Aneurin Bevan University Health Board, Newport, UK (C J Williams)

Correspondence to:
Prof Andrew J Pollard, Department of Paediatrics, University of Oxford, Oxford, OX3 9DU, UK
andrew.pollard@paediatrics.ox.ac.uk

See Online for appendix 1

See Online for appendix 2

in a longer gap between prime and booster vaccines in these cohorts than for those aged 55–69 years and those aged 70 years or older, as these participants were enrolled into two-dose groups from the start.

Results for participants enrolled into immunogenicity subgroups have been previously published, including a small subset who received a low-dose boost.[6] Full details are available in the study protocol (appendix 2 pp 184–342) and the procedures have been previously described.[6]

COV003 (Brazil)

COV003 is a continuing single-blind phase 3 study in Brazil that began on June 23, 2020. The focus of recruitment was targeted at those at high risk of exposure to the virus, including health-care workers at six sites across Brazil. Participants were aged 18 years or older, and this trial included individuals with stable pre-existing health conditions. All participants were offered two doses of the vaccine at a dose of $3 \cdot 5–6 \cdot 5 \times 10^{10}$ viral particles with administration up to 12 weeks apart (target 4 weeks), following a protocol amendment on July 28, 2020, to include booster groups (version 4.0; appendix 2 pp 438–439). Full details are available in the study protocol (appendix 2 pp 343–441).

COV005 (South Africa)

COV005 is a continuing double-blind phase 1/2 study in South Africa in healthy adults aged 18–65 years living without HIV that began on June 28, 2020. An additional immunogenicity cohort of those living with HIV was also enrolled but are not included in this interim analysis. All participants were offered two doses of the vaccine at a dose of $3 \cdot 5–6 \cdot 5 \times 10^{10}$ viral particles, with doses administered 4 weeks apart. A small subgroup of 44 participants received a half-dose vaccine (21 as their first dose and 23 as their second dose) as a result of variability in the release assay, before the adoption of new methods for characterisation of concentration. Adjustment in dose was discussed with and approved by the national regulator. Full details are available in the study protocol (appendix 2 pp 442–559).

A combined independent data safety monitoring board reviews safety data from all four trials on a regular basis.

Randomisation and masking

In efficacy cohorts for all studies, participants were randomised 1:1 to receive ChAdOx1 nCoV-19 or a control product. In COV002, MenACWY was chosen as the control group vaccine to minimise the chance of accidental participant unmasking due to local or systemic reactions to the vaccine. COV003 used MenACWY as the control for the first dose and saline for the second dose. In COV005, participants randomly assigned to the control group were administered saline solution. Randomisation lists were prepared by the study statistician (MV) using block randomisation, stratified by study site and study group, and uploaded into to the secure web platform used for the study electronic case report form (REDCap version 9.5.22) for COV001, COV002, and COV003. In COV005, the randomisation list was held by the unmasked study pharmacist who prepared the vaccines for administration, with all other trial staff masked to group allocation. The trial staff administering the vaccine prepared vaccines out of sight of the participants and syringes were covered with an opaque material until ready for administration to ensure masking of participants.

Procedures

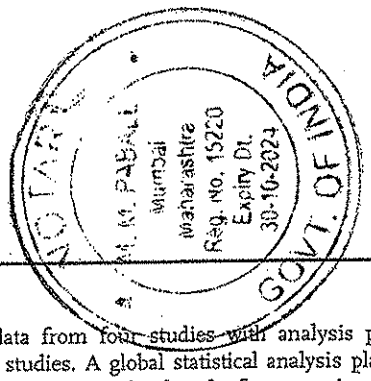
The recombinant adenovirus for ChAdOx1 nCoV-19 was manufactured and vialed by Advent (Pomezia, Italy), and additional batches produced by COBRA Biologics (Keele, UK) and vialed by Symbiosis (Sterling, UK). Both were manufactured according to Good Manufacturing Practice and approved by the regulatory agency in the UK, the Medicines and Healthcare products Regulatory Agency.

Baseline assessments included review of inclusion and exclusion criteria, medical history, vital signs measurement, history-directed clinical examination, and collection of serum for SARS-CoV-2 serology.

Participants across all four trials were asked to contact the study site if they experienced specific symptoms associated with COVID-19 and received regular reminders to do so. Those who met symptomatic criteria had a clinical assessment, a swab taken for a nucleic acid amplification test (NAAT), and blood samples taken for safety and immunogenicity. In the UK and Brazil, the list of qualifying symptoms for swabbing included any one of the following: fever of at least 37·8°C, cough, shortness of breath, and anosmia or ageusia. In South Africa, the list of qualifying symptoms for swabbing was broader, and additionally included myalgia, chills, sore throat, headache, nasal congestion, diarrhoea, runny nose, fatigue, nausea, vomiting, and loss of appetite.

In all studies, if participants were tested outside of the trial, either in their workplace if a health-care worker or by private providers, these results were recorded and assessed by a masked independent endpoint review committee. The source of each swab was recorded plus the details of the test kit where available.

To test for asymptomatic infections, participants in COV002 in the UK were asked to provide a weekly self-administered nose and throat swab for NAAT testing from 1 week after first vaccination using kits provided by the UK Department of Health and Social Care (DHSC). Participants were given home test kits provided by the DHSC that included step-by-step instructions on how to do a self-swab and a link to a demonstration video. The site trial team provided support with logistics of packaging and returning test kits and tracking swab results to participants if required. Swabs were taken by participants in their homes and posted to dedicated DHSC testing laboratories for processing. Participants were directly informed of their results by text or email from the National Health Service (NHS). Swab results



from participants in England and Wales were provided to the trial statistician on a daily basis by the NHS and matched to individuals based on personal identification data (name, date of birth, NHS number, and postcode). Swab results from participants in Scotland were unavailable to the study team at the time of the data cutoff for this analysis, but will be included in future analyses. Any swab results that were not able to be matched to a study participant using at least two pieces of personal data were not added to the study database.

In Brazil, there was no testing plan for asymptomatic infections. In South Africa, asymptomatic infections were detected from swabs obtained at study visits attended, but are not summarised here as there were only a small number of timepoints for detection of these cases.

All cases of COVID-19 were reviewed by two members of a masked independent clinical review team who assessed clinical details, including medical history, symptoms, adverse events, and swab results, and assigned severity scores according to the WHO clinical progression scale.[8]

For symptomatic participants in COV002 in the UK, weekly swabbing continued both before and after participants reported symptoms to the study site. Thus, a participant who reported symptoms and was clinically assessed might also have had additional swabs return positive results through the asymptomatic testing process for several weeks. In addition, due to the large number of health-care workers enrolled in these studies, some participants were tested according to their workplace testing policies and these results were also entered into the database for review by the masked endpoint evaluation committee. Further exploratory assessment of the length of time participants remained NAAT-positive, and the sources of information used for case detection will be done in future analyses.

Outcomes

The primary objective was to evaluate the efficacy of ChAdOx1 nCoV-19 vaccine against NAAT-confirmed COVID-19. The primary outcome was virologically confirmed, symptomatic COVID-19, defined as a NAAT-positive swab combined with at least one qualifying symptom (fever ≥37·8°C, cough, shortness of breath, or anosmia or ageusia).

All participants were given an emergency 24-h telephone number to contact the on-call study physician for the duration of the study to report any illnesses. Serious adverse events were recorded throughout the study and reviewed at each study visit, with causality assigned by the site investigator. Events were clinically coded according to the Medical Dictionary for Regulatory Activities.

Statistical analysis

The plan for assessing efficacy and safety for the ChAdOx1 nCoV-19 vaccine is based on global analyses using all available data from four studies with analysis pooled across the studies. A global statistical analysis plan for pooling study data was developed, after extensive advice from regulators, to prespecify the analyses that would contribute to the assessment of efficacy and this was signed off before any data analysis was conducted.

Randomised participants who received at least one dose in all studies are included in the safety analysis. However, each study had to meet prespecified criteria of having at least five cases eligible for inclusion in the primary outcome before a study was included in efficacy analyses. Neither COV001 or COV005 met these criteria and so are not included in the efficacy assessment for this interim analysis. It is expected that they will be included in efficacy assessments in future analyses once more cases have accrued. Additionally, only efficacy groups for COV002 (ie, groups 4, 6, 9, and 10) were included.

Vaccine efficacy was calculated as 1– adjusted relative risk (ChAdOx1 nCoV-19 *vs* control groups) computed using a Poisson regression model with robust variance.[9] The model contained terms for study, treatment group, and age group (18–55, 56–69, and ≥70 years) at randomisation. A reduced model that did not contain a term for age was used for models affected by convergence issues due to having few cases in the older age groups. The logarithm of the period at risk for the primary endpoint for pooled analysis was used as an offset variable in the model to adjust for volunteers having different follow-up times during which the events occurred. Cumulative incidence is presented using the Kaplan-Meier method.

The global pooled analysis plan allowed for an interim and a final efficacy analysis with α adjusted between the two analyses using a flexible gamma α-spending function, with significance being declared if the lower bound of the $(1-\alpha)$% CI is greater than 20%. Evidence of efficacy at the time of the interim analysis was not considered reason to stop the trials and all trials are continuing to accrue further data that will be included in future analyses.

The first interim analysis was planned to be triggered when at least 53 cases in participants who had received two standard-dose vaccines (SD/SD) had accrued that met the primary outcome definition more than 14 days after the second dose. This analysis provides 77% power for the 20% threshold to assume a true vaccine efficacy of 70%. Although the number of cases in the SD/SD cohort was used as the trigger for the interim analysis, the prespecified primary analysis included both SD/SD and LD/SD recipients. Due to the rapid increase in incidence of COVID-19 in the UK in October, more than 53 cases had accrued by the time of data lock for this interim analysis. There were 98 cases available for inclusion in the SD/SD cohorts. Based on these numbers, the α level calculated using the gamma α-spending function for this analysis is 4·16%.

Participants were excluded from the primary efficacy analysis if they were seropositive at baseline or had no baseline result. Other exclusions included those with NAAT-positive swabs within 14 days after the second vaccination, or those who discontinued from the study before having met the primary efficacy endpoint with a follow-up time of less than 15 days after the second vaccination. All reasons for exclusion are shown in appendix 1 (pp 5–8).

An analysis of efficacy after the first standard-dose vaccine in those who only received standard-dose vaccines was undertaken as a secondary analysis. Individuals were excluded if they had a NAAT-positive swab within 21 days after their first standard-dose vaccine.

Participants were analysed according to the vaccines they received. Sensitivity analyses included those who were seropositive at baseline and an intention-to-treat analysis. Safety analyses include all randomised participants who received at least one dose of any vaccine in any study.

Prespecified subgroup analyses are not included in this report but will be presented in future analyses when a larger dataset is available. However, in response to reviewer and editorial comments, a small number of exploratory subgroup comparisons has been included to explore differences in efficacy in the LD/SD and SD/SD groups and potential confounder variables. The LD/SD cohort in the UK comprised participants aged 18–55 years who received their second dose after a substantial gap. Age and the time difference between vaccines were therefore potential confounders and were explored further in subgroup analyses, restricted to those aged 18–55 years, those with more than 8 weeks' interval between vaccine doses, and a comparison of those in the SD/SD cohort receiving vaccines at short (<6 weeks) or long (≥6 weeks) intervals. Subgroup comparisons were done by incorporating the treatment-by-subgroup interaction term in the model and reporting the p value for the interaction term.

Data analysis was done using R (version 3.6.1 or later). Robust Poisson models were fitted using the PROC GENMOD function in SAS (version 9.4). The α level for the analysis was calculated using the gsDesign function in R. The cutoff date for inclusion in the analysis was Nov 4, 2020, and the data lock date was Nov 21, 2020.

The four trials are registered at ISRCTN89951424 (COV003) and ClinicalTrials.gov, NCT04324606 (COV001), NCT04400838 (COV002), and NCT04444674 (COV005).

Role of the funding source

AstraZeneca reviewed the data from the study and the final manuscript before submission, but the academic authors

	COV002 (UK; LD/SD; N=2741)		COV002 (UK; SD/SD; N=4807)		COV003 (Brazil; all SD/SD; N=4088)	
	ChAdOx1 nCoV-19 (n=1367)	MenACWY (n=1374)	ChAdOx1 nCoV-19 (n=2377)	MenACWY (n=2430)	ChAdOx1 nCoV-19 (n=2063)	MenACWY plus saline (n=2025)
Age, years						
18–55	1367 (100·0%)	1374 (100·0%)	1879 (79·0%)	1922 (79·1%)	1843 (89·3%)	1833 (90·5%)
56–69	0	0	285 (12·0%)	293 (12·1%)	209 (10·1%)	187 (9·2%)
≥70	0	0	213 (9·0%)	215 (8·8%)	11 (0·5%)	5 (0·2%)
Sex						
Female	886 (64·8%)	927 (67·5%)	1378 (58·0%)	1437 (59·1%)	1261 (61·1%)	1156 (57·1%)
Male	481 (35·2%)	447 (32·5%)	999 (42·0%)	993 (40·9%)	802 (38·9%)	869 (42·9%)
BMI, kg/m²	25·2 (22·8–28·7)	25·3 (22·7–28·8)	25·4 (23·9–28·7)	25·5 (22·9–29·1)	25·6 (22·8–29·1)	25·6 (23·1–29·0)
Ethnicity						
White	1257 (92·0%)	1278 (93·0%)	2153 (90·6%)	2214 (91·1%)	1357 (65·8%)	1366 (67·5%)
Black	6 (0·4%)	2 (0·1%)	17 (0·7%)	14 (0·6%)	230 (11·1%)	210 (10·4%)
Asian	76 (5·6%)	59 (4·3%)	137 (5·8%)	138 (5·7%)	54 (2·6%)	53 (2·6%)
Mixed	19 (1·4%)	22 (1·6%)	48 (2·0%)	42 (1·7%)	410 (19·9%)	386 (19·1%)
Other	9 (0·7%)	13 (0·9%)	22 (0·9%)	22 (0·9%)	12 (0·6%)	10 (0·5%)
Health and social care setting workers	1236 (90·4%)	1253 (91·2%)	1441 (60·6%)	1513 (62·3%)	1833 (88·9%)	1775 (87·7%)
Comorbidities						
Cardiovascular disease	104 (7·6%)	92 (6·7%)	264 (11·1%)	266 (10·9%)	271 (13·1%)	244 (12·0%)
Respiratory disease	158 (11·6%)	176 (12·8%)	285 (12·0%)	316 (13·0%)	215 (10·4%)	210 (10·4%)
Diabetes	18 (1·3%)	15 (1·1%)	58 (2·4%)	60 (2·5%)	[illegible]	60 (3·0%)

Data are n (%) or median (IQR). The primary efficacy population (LD/SD and SD/SD) includes randomly assigned participants who were seronegative at baseline and received LD/SD or SD/SD vaccine in the corresponding control group, and remained on study more than 14 days after their second dose without having had a previous virologically confirmed severe acute respiratory syndrome coronavirus 2 infection. In addition, for groups in COV002, only efficacy groups (ie, groups 4, 6, 9, and 10) are included. LD/SD=low-dose prime plus standard-dose boost. SD/SD=two standard-dose vaccines given. MenACWY=meningococcal group A, C, W, and Y conjugate vaccine. BMI=body-mass index.

Table 1: Baseline characteristics of participants included in the primary efficacy population, by study and dosing strategy

NOTARY PUBLIC SALE Mumbai Reg No 15220 Expiry Dt [illegible] GOVT OF INDIA

	Total number of cases	ChAdOx1 nCoV-19		Control		Vaccine efficacy (CI*)
		n/N (%)	Incidence rate per 1000 person-years (person-days of follow-up)	n/N (%)	Incidence rate per 1000 person-years (person-days of follow-up)	
All LD/SD and SD/SD recipients	131	30/5807 (0·5%)	44·1 (248 299)	101/5829 (1·7%)	149·2 (247 228)	70·4% (54·8 to 80·6)†
COV002 (UK)	86	18/3744 (0·5%)	38·6 (170 369)	68/3804 (1·8%)	145·7 (170 448)	73·5% (58·5 to 84·7)
LD/SD recipients	33	3/1367 (0·2%)	34·9 (73 313)	30/1374 (2·2%)	150·2 (72 949)	90·0% (67·4 to 97·0)†§
SD/SD recipients	53	15/2377 (0·6%)	56·4 (97 056)	38/2430 (1·6%)	142·4 (97 499)	60·3% (28·0 to 78·2)
COV003 (Brazil; all SD/SD)	45	12/2063 (0·6%)	56·2 (77 930)	33/2025 (1·6%)	157·0 (76 780)	64·2% (30·7 to 81·5)‡
All SD/SD recipients	98	27/4440 (0·6%)	56·4 (174 986)	71/4455 (1·6%)	148·8 (174 279)	62·1% (41·0 to 75·7)
Other non-primary symptomatic COVID-19 disease¶	18	7/5807 (0·1%)	10·3 (248 299)	11/5829 (0·2%)	16·3 (247 228)	36·4% (−63·8 to 75·3)‡
Any symptomatic COVID-19 disease	149	37/5807 (0·6%)	54·4 (248 299)	112/5829 (1·9%)	165·5 (247 228)	67·1% (52·3 to 77·3)
Asymptomatic or symptoms unknown (COV002)	69	29/3288 (0·9%)	69·8 (151 673)	40/3350 (1·2%)	96·0 (152 138)	27·3% (−17·2 to 54·9)
LD/SD recipients	24	7/1120 (0·6%)	41·4 (61 782)	17/1127 (1·5%)	100·6 (61 730)	58·9% (1·0 to 82·9)‡
SD/SD recipients	45	22/2168 (1·0%)	89·4 (89 891)	23/2223 (1·0%)	92·9 (90 408)	3·8% (−72·4 to 46·3)
Any NAAT-positive swab	221	68/5807 (1·2%)	100·0 (248 299)	153/5829 (2·6%)	226·0 (247 228)	55·7% (41·1 to 66·7)

Vaccine efficacy was calculated from the robust Poisson model. The primary efficacy population (LD/SD and SD/SD) includes randomly assigned participants who were seronegative at baseline and received LD/SD or SD/SD or were in a corresponding control group, and remained on study more than 14 days after their second dose without having had a previous virologically confirmed SARS-CoV-2 infection. In addition, for groups in COV002, only efficacy groups (ie, groups 4, 6, 9, and 10) are included. SARS-CoV-2=severe acute respiratory syndrome coronavirus 2. LD/SD=low-dose prime plus standard-dose boost. SD/SD=two standard-dose vaccines given. NAAT=nucleic acid amplification test. *CIs are 95% unless indicated otherwise. †95·8% CI used for primary analysis. ‡Vaccine efficacy calculated from a reduced robust Poisson model that was not adjusted for age. All other models included an adjustment for age. §p value for interaction term comparing LD/SD with SD/SD is p=0·010. ¶Other non-primary symptomatic COVID-19 disease includes cases who have symptoms other than the five main symptoms that are required for inclusion in the primary analysis (eg, a participant who has diarrhoea and malaise but no fever, cough, shortness of breath, anosmia, or ageusia).

Table 2: Efficacy against SARS-CoV-2 more than 14 days after a second dose of ChAdOx1 nCoV-19 vaccine in the primary efficacy population

retained editorial control. All other funders of the study had no role in the study design, data collection, data analysis, data interpretation, or writing of the report. All authors had full access to all the data in the study and had final responsibility for the decision to submit for publication.

Results

Between April 23 and Nov 4, 2020, 23 848 participants were recruited and vaccinated across the four studies: 1077 in COV001 (UK), 10 673 in COV002 (UK), 10 002 in COV003 (Brazil), and 2096 in COV005 (South Africa). 11 636 participants in COV002 and COV003 met the inclusion criteria for the primary analysis, 5807 of whom received two doses of ChAdOx1 nCoV-19 and 5829 of whom received two doses of control product. A trial profile and reasons for exclusion from the primary analysis are shown in appendix 1 (pp 5–7). Here, we provide safety data on 74 341 person-months of follow-up after first dose (median 3·4 months, IQR 1·3–4·8) and 29 060 person-months of follow-up after two doses (median 2·0, 1·3–2·3).

Of the participants in COV002 and COV003 included in the primary efficacy analyses, the majority were aged 18–55 years (6542 [86·7%] of 7548 in the UK and 3676 [89·9%] of 4088 in Brazil; table 1). Those aged 56 years or older were recruited later and contributed 12·2% of the total cohort in the current analysis (1006 [13·3%] in the UK and 412 [10·1%] in Brazil). 7045 (60·5%) participants were female. 6902 (91·4%) participants in the UK and 2723 (66·6%) participants in Brazil were white (table 1). Baseline participants of the safety population are shown in appendix 1 (pp 9–10).

The timing of priming and booster vaccine administration varied between studies. As protocol amendments to add a booster dose took place when the trials were underway, and owing to the time taken to manufacture and release a new batch of vaccine, doses could not be administered at a 4-week interval. 1459 (53·2%) of 2741 participants in COV002 in the LD/SD group received a second dose at least 12 weeks after the first (median 84 days, IQR 77–91) and only 22 (0·8%) received a second dose within 8 weeks of the first. The median interval between doses for the SD/SD group in COV002 was 69 days (50–86). Conversely, the majority of participants in COV003 in the SD/SD group (2493 [61·0%] of 4088) received a second dose within 6 weeks of the first (median 36 days, 32–58; appendix 1 p 11).

1722

GOVT. OF INDIA
NOT A VALID PAPER
M.A. Mumbai Maharashtra
Regn. No. 15220
Expiry Dt. 30-10-2024

A small proportion of participants were seropositive at baseline (138 [1·3%] of 10 673 in the UK and 235 [2·3%] of 10 002 in Brazil). Three participants seropositive at baseline had subsequent NAAT-positive swabs. One participant had an asymptomatic infection 3 weeks after a first dose of ChAdOx1 nCoV-19. Two other participants in the control group had symptomatic infections 8 weeks and 21 weeks after their baseline sample was taken.

There were 131 cases of symptomatic COVID-19 in LD/SD or SD/SD recipients who were eligible for inclusion in the primary efficacy analysis more than 14 days after the second dose of vaccine (table 2). There were 30 (0·5%) cases among 5807 participants in the vaccine arm and 101 (1·7%) cases among 5829 participants in the control group, resulting in vaccine efficacy of 70·4% (95·8% CI 54·8–80·6; table 2; figure). In participants who received two standard-dose vaccines, vaccine efficacy was 62·1% (95% CI 41·0–75·7), whereas in those who received a low dose as their first dose of vaccine, efficacy was higher at 90·0% (67·4–97·0; $p_{interaction}$=0·010; table 2; appendix 1 pp 12–13).

In England and Wales, 129 529 weekly self-swabs were processed by the DHSC, of which 126 324 (97·5%) were matched to study participants. There were 435 positive swabs, of which 354 (81·4%) were matched. Symptoms in these participants were not routinely assessed as swabs were done at home and sent for testing through the post. Asymptomatic infections or those with unreported symptoms were detected in 69 participants (table 2). Vaccine efficacy in the 24 LD/SD recipients was 58·9% (95% CI 1·0 to 82·9), whereas it was 3·8% (–72·4 to 46·3) in the 45 participants receiving SD/SD (table 2).

Results from sensitivity analyses, including participants who were seropositive at baseline and by intention to treat, were very similar to main results (data not shown).

Results from the subgroup comparisons presented in this analysis were similar to overall results (table 3). In the SD/SD UK cohort who were aged 18–55 years, 49 cases were available for inclusion in the analysis and vaccine efficacy was 59·3% (95% CI 25·1 to 77·9; $p_{interaction}$=0·019; table 3). When further restricted to those who received their vaccines more than 8 weeks apart, 33 cases were included in the SD/SD analysis and vaccine efficacy was 65·6% (24·5 to 84·4; $p_{interaction}$=0·082; table 3; appendix 1 pp 12–13). In the SD/SD cohorts in the UK and Brazil, vaccine efficacy was similar when analysed in subgroups according to time between

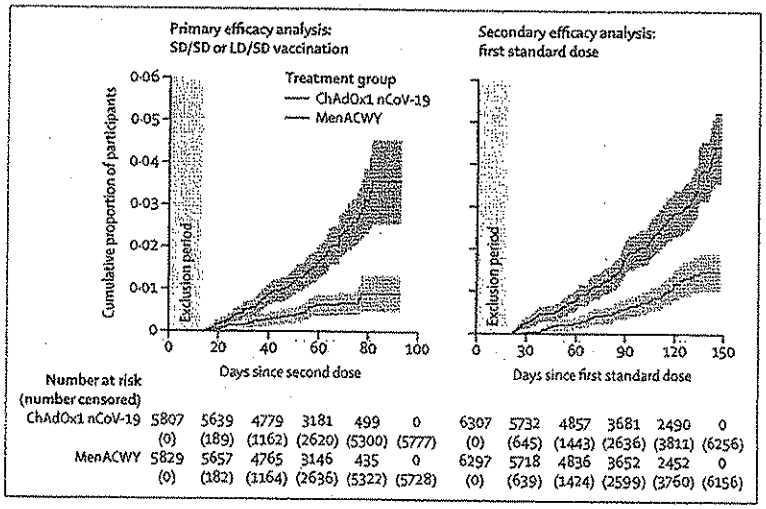


Figure: Kaplan-Meier cumulative incidence of primary symptomatic, NAAT-positive COVID-19
Cumulative incidence of symptomatic COVID-19 after two doses (left) or after first standard dose in participants receiving only standard-dose vaccines (right). Grey shaded areas show the exclusion period after each dose in which cases were excluded from the analysis. Blue and red shaded areas show 95% CIs. LD/SD=low-dose prime plus standard-dose boost. MenACWY=meningococcal group A, C, W, and Y conjugate vaccine. NAAT=nucleic acid amplification test. SD/SD=two standard-dose vaccines given.

	Total number of cases	ChAdOx1 nCoV-19	Control	Vaccine efficacy (95% CI)	p value for interaction
COV002 (UK), age 18–55 years*					0·019
LD/SD recipients	33	3/1367 (0·2%)	30/1374 (2·2%)	90·0% (67·3 to 97·0)	
SD/SD recipients	49	14/1879 (0·7%)	35/1922 (1·8%)	59·3% (25·1 to 77·9)	
COV002 (UK), age 18–55 years with >8 weeks' interval between vaccine doses*					0·082
LD/SD recipients	33	3/1357 (0·2%)	30/1362 (2·2%)	90·0% (67·3 to 97·0)	
SD/SD recipients	34	8/1407 (0·6%)	26/1512 (1·7%)	65·6% (24·5 to 84·4)	
All SD/SD (UK and Brazil)†					0·557
<6 weeks' interval between vaccine doses	28	9/1702 (0·5%)	19/1698 (1·1%)	53·4% (–2·5 to 78·8)	
≥6 weeks' interval between vaccine doses	70	18/2738 (0·7%)	52/2757 (1·9%)	65·4% (41·1 to 79·6)	

Cohorts are all subsets of the primary efficacy population. SARS-CoV-2=severe acute respiratory syndrome coronavirus 2. LD/SD=low-dose prime plus standard-dose boost. SD/SD=two standard-dose vaccines given. BMI=body-mass index. *Models adjusted for BMI (<30 vs ≥30 kg/m²), health-care worker status (yes vs no), and ethnicity (white vs non-white). †Model adjusted for BMI (<30 vs ≥30 kg/m²), health-care worker status (yes vs no), ethnicity (white vs non-white), age (<56 years vs ≥56 years), and study (COV002 vs COV003).

Table 3: Subgroup comparisons of efficacy against SARS-CoV-2 more than 14 days after a second dose of ChAdOx1 nCoV-19 vaccine in the primary efficacy population

	Total number of cases	ChAdOx1 nCoV-19		Control		Vaccine efficacy (95% CI)
		n/N (%)	Incidence per 1000 person-years (person-days of follow-up)	n/N (%)	Incidence per 1000 person-years (person-days of follow-up)	
COV002 (UK)	90	28/3060 (0·9%)	35·4 (288 955)	62/3064 (2·0%)	78·5 (288 395)	55·0% (29·7 to 71·1)
COV003 (Brazil)	102	23/3247 (0·7%)	46·7 (179 743)	79/3233 (2·4%)	162·4 (177 693)	71·2% (54·2 to 81·9)
Primary symptomatic COVID-19*	192	51/6307 (0·8%)	39·7 (468 698)	141/6297 (2·2%)	110·5 (466 088)	64·1% (50·5 to 73·9)
Other non-primary symptomatic COVID-19†	21	12/6307 (0·2%)	9·4 (468 698)	9/6297 (0·1%)	7·1 (466 088)	−32·8% (−214·8 to 44·0)‡
Any symptomatic COVID-19	213	63/6307 (1·0%)	49·1 (468 698)	150/6297 (2·4%)	117·5 (466 088)	58·3% (44·0 to 68·9)
Asymptomatic or symptoms unknown (COV002)	71	34/2751 (1·2%)	46·8 (265 142)	37/2760 (1·3%)	51·0 (264 994)	7·8% (−46·7 to 42·1)
Any NAAT-positive swab	291	102/6307 (1·6%)	79·5 (468 698)	189/6297 (3·0%)	148·1 (466 088)	46·3% (31·8 to 57·8)

Vaccine efficacy was calculated from the robust Poisson model. The first-standard-dose efficacy population includes participants seronegative at baseline who received only standard dose vaccines or were in the corresponding control group, and remained on study 22 days after their first dose without having had a previous virologically confirmed SARS-CoV-2 infection. In addition, for groups in COV002, only efficacy groups (ie, groups 4, 6, 9, and 10) are included. SARS-CoV-2=severe acute respiratory syndrome coronavirus 2. NAAT=nucleic acid amplification test. *NAAT-positive swab plus at least one of cough, shortness of breath, fever higher than 37·8°C, anosmia, or ageusia. †Other non-primary symptomatic COVID-19 disease includes cases that have symptoms other than the five main symptoms required for inclusion in the primary analysis (eg, a participant who has diarrhoea and malaise but no fever, cough, shortness of breath, anosmia, or ageusia). ‡Vaccine efficacy was calculated from a reduced robust Poisson model (excluding the age group category due to the full model failing to converge). Participants with a low dose prime were excluded.

Table 4: Efficacy against SARS-CoV-2 more than 21 days after the first standard dose in seronegative participants who received only standard doses

vaccines, at 53·4% (−2·5 to 78·8) in participants with less than 6 weeks' interval between doses and 65·4% (41·1 to 79·6) in participants with at least 6 weeks' interval ($p_{interaction}$=0·56; table 3).

For our secondary analysis of cases occurring more than 21 days after the first standard dose in participants who received only standard doses, there were 192 included cases with a vaccine efficacy of 64·1% (95% CI 50·5–73·9; table 4; figure)

More than 21 days after their first dose, ten participants were hospitalised due to COVID-19 (defined as WHO clinical progression score ≥4), two of whom were assessed as having severe COVID-19 (WHO score ≥6), including one fatal case. All ten cases were in the control group (table 5).

Five cases included in the primary analysis occurred in those participants older than 55 years of age. Vaccine efficacy in older age groups could not be assessed but will be determined, if sufficient data are available, in a future analysis after more cases have accrued.

Across all four studies, the vaccine had a good safety profile with serious adverse events and adverse events of special interest balanced across the study arms. Serious adverse events occurred in 168 participants, 79 of whom received ChAdOx1 nCoV-19 and 89 of whom received MenACWY or saline control (appendix 1 pp 15–18). There were 175 events (84 in the ChAdOx1 nCoV-19 group and 91 in the control group), three of which were considered possibly related to either the experimental or a control vaccine. A case of haemolytic anaemia in the control group in the UK phase 1/2 study occurring 10 days after MenACWY vaccine was considered possibly related to the intervention and has been previously described.[5] A case of transverse myelitis was reported

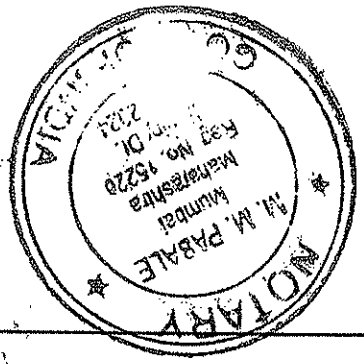
	ChAdOx1 nCoV-19 (n=12 021)	MenACWY or saline control (n=11 724)
Hospitalisation (WHO clinical progression score ≥4)		
≤21 days after the first dose	2*	6
>21 days after the first dose and ≤14 days after the second dose	0	5
>14 days after the second dose	0	5
Severe COVID-19 (WHO clinical progression score ≥6)		
≤21 days after the first dose	0	0
>21 days after the first dose and ≤14 days after the second dose	0	1
>14 days after the second dose	0	1

The safety population includes all randomisation participants who received at least one dose of vaccine. Severe COVID-19 (WHO score ≥6) is a subset of hospitalisations (WHO score ≥4). Cases were eligible for inclusion in efficacy if the first symptom or first NAAT-positive result was on or before the data cutoff date (Nov 4, 2020). Two cases appear in this table that do not appear in the table for serious adverse events in appendix 1 (pp 15–20) as the adverse event reporting date was after the data cutoff date. MenACWY=meningococcal group A, C, W, and Y conjugate vaccine. NAAT=nucleic acid amplification test. *One case on the day of the first vaccination and one case 10 days after the first dose.

Table 5: Hospitalisation for COVID-19 and severe COVID-19 in the safety population

14 days after ChAdOx1 nCoV-19 booster vaccination as being possibly related to vaccination, with the independent neurological committee considering the most likely diagnosis to be of an idiopathic, short segment, spinal cord demyelination. A potentially vaccine-related serious adverse event was reported 2 days after vaccination in South Africa in an individual who recorded fever higher than 40°C, but who recovered

NOT VALID FOR INDIA



rapidly without an alternative diagnosis and was not admitted to hospital. The participant remains masked to group allocation, continues in the trial, and received a second dose of the allocated vaccine without a similar reaction.

There were two additional cases of transverse myelitis that were originally reported as potentially related but later determined to be unlikely to be related to vaccination by an independent committee of neurological experts. One case that occurred 10 days after a first vaccination with ChAdOx1 nCoV-19 was initially assessed as possibly related, but later considered unlikely to be related by the site investigator when further investigation revealed pre-existing, but previously unrecognised, multiple sclerosis. The second case was reported 68 days after MenACWY vaccination. While considered possibly related by the site investigator at the time of reporting, an independent panel of neurological experts considered this to be unlikely. All trial participants have recovered, or are in a stable or improving condition.

There were four non-COVID-19 deaths reported across the studies (three in the control arm and one in the ChAdOx1 nCoV-19 arm) that were all considered unrelated to the vaccine, with cause of death assessed as road traffic accident, blunt force trauma, homicide, and fungal pneumonia.

Discussion

Here, we present the first interim safety and efficacy data for a viral vector coronavirus vaccine, ChAdOx1 nCoV-19, evaluated in four trials across three continents, showing significant vaccine efficacy of 70·4% after two doses and protection of 64·1% after at least one standard dose, against symptomatic disease, with no safety concerns.

The prespecified analysis population, which was determined following feedback from national and international regulators before unblinding of the study, included a pooled analysis from several countries to improve generalisability, and inclusion of two dose subgroups within the UK trial. This pooling strategy was authorised by the chief investigator (AJP) and study statistician (MV), with no concerns about pooling different control groups, and was accepted by regulators involved in the discussions. There had been initial concern that the LD/SD regimen might have lower efficacy than SD/SD, and the regulatory authority acceptance of the inclusion of the two trial regimens (LD/SD and SD/SD) in analysis was based on the observation that these regimens generated similar levels of binding antibody, and would therefore increase the sample size available for analysis without compromising efficacy. The discussion about pooling and inclusion of LD/SD was made at a time when disease rates were low in the UK and, in the face of the pandemic, it was agreed that pooling could provide the earliest possible read on efficacy that could contribute to public health.

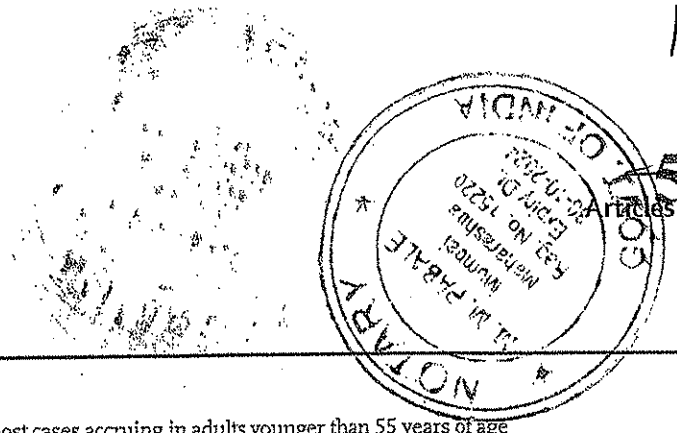
No previous trials have been published on the efficacy of a viral-vectored coronavirus vaccine and so this study provides the first peer-reviewed evidence that induction of immune responses against spike protein using viral vectors provides protection against the disease in humans, as has been seen in animal models.

In participants who received two standard doses, efficacy against primary symptomatic COVID-19 was consistent in both the UK (60·3% efficacy) and Brazil (64·2% efficacy), indicating these results are generalisable across two diverse settings with different timings for the booster dose (with most participants in the UK receiving the booster dose more than 12 weeks after the first dose and most participants in Brazil receiving their second dose within 6 weeks of the first). Exploratory subgroup analyses included at the request of reviewers and editors also showed no significant difference in efficacy estimates when comparing those with a short time window between doses (<6 weeks) and those with longer (≥6 weeks), although further detailed exploration of the timing of doses might be warranted.

Efficacy of 90·0% seen in those who received a low dose as prime in the UK was intriguingly high compared with the other findings in the study. Although there is a possibility that chance might play a part in such divergent results, a similar contrast in efficacy between the LD/SD and SD/SD recipients with asymptomatic infections provides support for the observation (58·9% [95% CI 1·0 to 82·9] *vs* 3·8% [−72·4 to 46·3]). Exploratory subgroup analyses, included at the request of reviewers and editors, that were restricted to participants aged 18–55 years, or aligned (>8 weeks) intervals between doses, showed similar findings. Use of a low dose for priming could provide substantially more vaccine for distribution at a time of constrained supply, and these data imply that this would not compromise protection. While a vaccine that could prevent COVID-19 would have a substantial public health benefit, prevention of asymptomatic infection could reduce viral transmission and protect those with underlying health conditions who do not respond to vaccination, those who cannot be vaccinated for health reasons, and those who will not or cannot access a vaccine, providing wider benefit for society. However, the wide CIs around our estimates show that further data are needed to confirm these preliminary findings, which will be done in future analyses of the data accruing in these ongoing trials.

Similar results have been seen for other vaccines where a reduced number or type of priming dose in infancy can lead to higher responses to a booster vaccine.[10] Further work is needed to determine the mechanism of the increased efficacy with a LD/SD regimen, which might be due to higher levels of neutralising antibody, lower levels of anti-vector immunity with lower vector-derived antigen content of the first dose, or differential antibody functionality or cellular immunity, including altered avidity or immunodominance.

1725



Other coronavirus vaccine developers have released preliminary high-level results in public statements, including more than 90% efficacy reported for the lipid nanoparticle mRNA vaccine BNT162b2,[11] 92% efficacy for the Sputnik V vaccine (developed at the National Research Centre for Epidemiology and Microbiology),[12] and 94·5% for the Moderna lipid nanoparticle mRNA-1273 vaccine.[13] The possibility that more than one efficacious vaccine against COVID-19 might be approved for use in the near future is encouraging. However, control of pandemic coronavirus will only be achieved if the licensure, manufacturing, and distribution of these vaccines can be achieved at an unprecedented scale and vaccination is rolled out to all those who are vulnerable.

The US Food and Drug Administration's guidelines indicate that they would license a vaccine against the pandemic virus that showed at least 50% efficacy[14] and WHO have indicated a minimum efficacy of 50% in its target product profile.[15] A modelling study found that a vaccine with efficacy of 60–80% could allow reduction in physical distancing measures, but this would still require high coverage.[16] The findings here indicate that the efficacy of ChAdOx1 nCoV-19 exceeds these thresholds and has the potential to have a public health impact.

Much consideration has been given to the statistical confidence in vaccine efficacy estimates, given the size of the global population who might be vaccinated. To ensure that point estimates of efficacy in clinical trials are sufficiently robust, some regulatory authorities consider that the lower bound of the CI for efficacy should be higher than 20% (personal communication), with other authorities more stringent and anticipating a lower bound of 30% for licensure.[14] Here, we present data that exceed both these thresholds in the pooled analysis, which we had agreed with regulators before unblinding of the study, and also meet the thresholds set in the individual analyses of trials by country and by study arm.

We designed our studies early in the pandemic and fixed our primary symptomatic disease endpoint on the basis of expert analysis and guidelines from Public Health England and WHO as the first wave of disease spread around the world, although these have now been substantially updated.[17,18] We have used a restricted definition of symptomatic disease, since many other symptoms that are associated with COVID-19 disease are non-specific. Since endpoints in protocols for different vaccines are not well aligned, we recognise that it will be difficult to compare efficacy across programmes. However, we have also included hospital admissions and severe disease as an endpoint in the current study, which might be easier to assess in comparison with other vaccines, and found that in the ten cases available for analysis more than 21 days after the first dose, there was complete protection against hospitalisation for COVID-19.

While the data presented here show that ChAdOx1 nCov-19 is efficacious against symptomatic disease, with most cases accruing in adults younger than 55 years of age so far, an important public health consideration is the morbidity and mortality of the disease in an older adult population and thus the potential efficacy in this age group. We have reported immunogenicity data showing similar immune responses following vaccination with two doses of ChAdOx1 nCov-19 in older adults, including those older than 70 years of age, when compared with those younger than 55 years.[6] As older age groups were recruited later than younger age groups, there has been less time for cases to accrue and as a result, efficacy data in these cohorts are currently limited by the small number of cases, but additional data will be available in future analyses.

These trials, conducted on three different continents, enrolled geographically and ethnically diverse populations. Severe COVID-19 has been seen to disproportionately affect people of non-white ethnicity, as well as those who are male, overweight, and the elderly.[19,20]

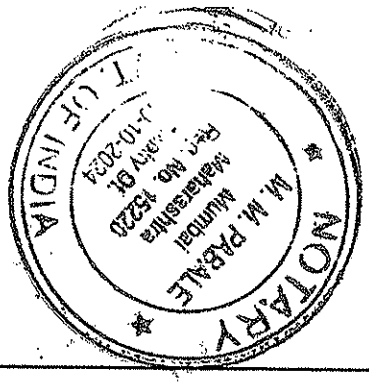
In our studies, the demographic characteristics of those enrolled varied between countries. In the UK, the enrolled population was predominantly white and, in younger age groups, included more female participants due to the focus on enrolment of health-care workers. This is a typically lower risk population for severe COVID-19. The demographic profile combined with the weekly self-swabbing for asymptomatic infection in the UK results in a milder case-severity profile. In Brazil, there was a larger proportion of non-white ethnicities, and again the majority of those enrolled were health-care workers.

We have previously reported on the local and systemic reactogenicity of ChAdOx1 nCoV-19 and shown that it is tolerated and that the side-effects are less both in intensity and number in older adults, with lower doses, and after the second dose. Although there were many serious adverse events reported in the study in view of the size and health status of the population included, there was no pattern of these events that provided a safety signal in the study. Three cases of transverse myelitis were initially reported as suspected unexpected serious adverse reactions, with two in the ChAdOx1 nCoV-19 vaccine study arm, triggering a study pause for careful review in each case. Independent clinical review of these cases has indicated that one in the experimental group and one in the control group are unlikely to be related to study interventions, but a relationship remained possible in the third case. Careful monitoring of safety, including neurological events, continues in the trials. All safety data will be provided to regulators for review.

In this interim analysis, we have not been able to assess duration of protection, since the first trials were initiated in April, 2020, such that all disease episodes have accrued within 6 months of the first dose being administered. Further evidence will be required to determine duration of protection and the need for additional booster doses of vaccine.

The results presented in this Article constitute the key findings from the first interim analysis, which are

1726



provided for rapid review by the public and policy makers. In future analyses with additional data included as they accrue, we will investigate differences in key subgroups such as older cohorts, ethnicity, dose regimen, and timing of booster vaccines, and we will search for correlates of protection.

Until widespread immunity halts the spread of SARS-CoV-2, physical distancing measures and novel therapies are needed to control COVID-19. In the meantime, an efficacious vaccine has the potential to have a major impact on the pandemic if used in populations at risk of severe disease. Here, we have shown for the first time that a viral vector vaccine, ChAdOx1 nCoV-19, is efficacious and could contribute to control of the disease in this pandemic.

Contributors

AJP and SCG conceived the trial and AJP is the chief investigator. AJP, PMF, DJ, MV, and TL contributed to the protocol and design of the study. SACC, SAM, LYW, AVSH, ALG, VLB, SLB, QEB, AMC, MT, AS, KD, CJW, CJAD, PJL, ECT, LF, SNF, CAG, RL, TCD, PTH, HH, DMF, VL, AM, AI, AF, CB, GK, MET, AP, EPM, AVS, AVAM, CLC, ALG, AN, SDP, KMP, ES, RKS, RT, and DPJT are study site principal investigators. PKA, EP, DJ, PMF, SB, AMM, AML, KRWE, MNR, BA, PC, SK, KJE, AL, AF, SR, PJO, SHCH, SJ, HM, JV, IH, RM, YFM, NS, RS, MDS, MEEW, TLV, RC-J, and CH contributed to the implementation of the study or data collection. MV and SF did the statistical analysis. CMG, ADD, CCDJ and RT were responsible for vaccine manufacturing. MV and AJP contributed to the preparation of the report. All authors critically reviewed and approved the final version.

Declaration of interests

Oxford University has entered into a partnership with AstraZeneca for further development of ChAdOx1 nCoV-19. SCG is co-founder of Vaccitech (collaborators in the early development of this vaccine candidate) and named as an inventor on a patent covering use of ChAdOx1-vectored vaccines and a patent application covering this SARS-CoV-2 vaccine (PCT/GB2012/000467). TL is named as an inventor on a patent application covering this SARS-CoV-2 vaccine and was a consultant to Vaccitech for an unrelated project, during the conduct of the study. PMF is a consultant to Vaccitech during the conduct of the study. AJP is chair of the UK Department of Health and Social Care's (DHSC) Joint Committee on Vaccination & Immunisation (JCVI), but does not participate in discussions on COVID-19 vaccines, and is a member of WHO's SAGE. AJP is a National Institute for Health Research (NIHR) Senior Investigator. The views expressed in this Article do not necessarily represent the views of the DHSC, JCVI, NIHR, or WHO. AVSH reports personal fees from Vaccitech, outside of the submitted work, and has a patent on ChAdOx1 licensed to Vaccitech (PCT/GB2012/000467), and might benefit from royalty income to the University of Oxford from sales of this vaccine by AstraZeneca and sublicensees. MS reports grants from NIHR and non-financial support from AstraZeneca, during the conduct of the study; and grants from Janssen, GlaxoSmithKline, Medimmune, Novavax, and MCM and grants and non-financial support from Pfizer, outside of the submitted work. CG reports personal fees from the Duke Human Vaccine Institute, outside of the submitted work. ADD reports grants and personal fees from AstraZeneca, outside of the submitted work. AF is a member of the JCVI and chair of the WHO European Technical Advisory Group of Experts. AF declares research grants from Pfizer, GlaxoSmithKline, Sanofi, Merck Sharp & Dohme, and Valneva, outside of the submitted work. JV, TLV, and IH are employees of AstraZeneca. The other authors declare no competing interests.

Data sharing

Anonymised participant data will be made available when the trials are complete, upon requests directed to the corresponding author. Proposals will be reviewed and approved by the sponsor, investigator, and collaborators on the basis of scientific merit. After approval of a proposal, data can be shared through a secure online platform after signing a data access agreement. All data will be made available for a minimum of 5 years from the end of the trial.

Acknowledgments

This Article was funded by UK Research and Innovation, NIHR, Coalition for Epidemic Preparedness Innovations, the Bill & Melinda Gates Foundation, the Lemann Foundation, Rede D'Or, the Brava and Telles Foundation, NIHR Oxford Biomedical Research Centre, Thames Valley and South Midland's NIHR Clinical Research Network, and AstraZeneca. The authors dedicate this paper to the many healthcare workers who have lost their lives during the pandemic. This report is independent research funded by the UK National Institute for Health Research, UK Research and Innovation, the Bill & Melinda Gates Foundation, the Lemann Foundation, Rede D'OR, the Brava and Telles Foundation, and the South African Medical Research Council. We are grateful to the NIHR infrastructure provided through the NIHR Biomedical Research Centres and the NIHR Clinical Research Network at the UK study sites. The views expressed in this publication are those of the author(s) and not necessarily those of the National Institute for Health Research or the Department of Health and Social Care. PMF received funding from the Coordenacao de Aperfeicoamento de Pessoal de Nivel Superior, Brazil (finance code 001). The authors are grateful to the volunteers who participated in this study. The authors are grateful to the senior management at AstraZeneca for facilitating and funding the manufacture of the AZD1222 vaccine candidate and for financial support for expansion of the Oxford sponsored clinical trials in Brazil. AstraZeneca reviewed the data from the study and the final manuscript prior to submission, but the authors retained editorial control.

References

1 WHO. WHO coronavirus disease (COVID-19) dashboard. 2020. https://covid19.who.int (accessed Nov 8, 2020).
2 Zhou F, Yu T, Du R, et al. Clinical course and risk factors for mortality of adult inpatients with COVID-19 in Wuhan, China: a retrospective cohort study. *Lancet* 2020; 395: 1054–62.
3 Stringhini S, Wisniak A, Piumatti G, et al. Seroprevalence of anti-SARS-CoV-2 IgG antibodies in Geneva, Switzerland (SEROCoV-POP): a population-based study. *Lancet* 2020; 396: 313–19.
4 WHO. DRAFT landscape of COVID-19 candidate vaccines—20 March 2020. 2020. https://www.who.int/blueprint/priority-diseases/key-action/novel-coronavirus-landscape-ncov.pdf?ua=1 (accessed Nov 8, 2020).
5 Folegatti PM, Ewer KJ, Aley PK, et al. Safety and immunogenicity of the ChAdOx1 nCoV-19 vaccine against SARS-CoV-2: a preliminary report of a phase 1/2, single-blind, randomised controlled trial. *Lancet* 2020; 396: 467–78.
6 Ramasamy M, Minassian AM. Safety and immunogenicity of ChAdOx1 nCoV-19 (AZD1222) vaccine administered in a prime-boost regimen in older adults (COV002): a phase 2/3 single blind, randomised controlled trial. *Lancet* 2020; published online Nov 18. https://doi.org/10·1016/S0140–6736(20)32466–1.
7 Barrett JR, Belij-Rammerstorfer S. Phase 1/2 trial of SARS-CoV-2 vaccine ChAdOx1 nCoV-19 with a booster dose induces multifunctional antibody responses. *Nat Med* (in press).
8 Marshall JC, Murthy S, Diaz J, et al. A minimal common outcome measure set for COVID-19 clinical research. *Lancet Infect Dis* 2020; 20: e192–97.
9 Zou G. A modified Poisson regression approach to prospective studies with binary data. *Am J Epidemiol* 2004; 159: 702–06.
10 Pace D, Khatami A, McKenna J, et al. Immunogenicity of reduced dose priming schedules of serogroup C meningococcal conjugate vaccine followed by booster at 12 months in infants: open label randomised controlled trial. *BMJ* 2015; 350: h1554.
11 Pfizer. Pfizer and BioNTech announce vaccine candidate against COVID-19 achieved success in first interim analysis from phase 3 study. Nov 9, 2020. https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-announce-vaccine-candidate-against (accessed Nov 15, 2020).
12 The Gamaleya National Centre. The first interim data analysis of the Sputnik V vaccine against COVID-19 phase III clinical trials in the Russian Federation demonstrated 92% efficacy. Nov 11, 2020. https://sputnikvaccine.com/newsroom/pressreleases/the-first-interim-data-analysis-of-the-sputnik-v-vaccine-against-covid-19-phase-iii-clinical-trials-/ (accessed Nov 15, 2020).

1727
5
Articles

13 Moderna. Moderna's COVID-19 vaccine candidate meets its primary efficacy endpoint in the first interim analysis of the phase 3 COVE study. Nov 16, 2020. https://investors.modernatx.com/news-releases/news-release-details/modernas-covid-19-vaccine-candidate-meets-its-primary-efficacy (accessed Nov 17, 2020).

14 Center for Biologics Evaluation and Research. Development and licensure of vaccines to prevent COVID-19. June, 2020. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/development-and-licensure-vaccines-prevent-covid-19 (accessed Nov 8, 2020).

15 WHO. WHO target product profiles for COVID-19 vaccines. April 9, 2020. https://www.who.int/publications/m/item/who-target-product-profiles-for-covid-19-vaccines (accessed Nov 8, 2020).

16 Bartsch SM, O'Shea KJ, Ferguson MC, et al. Vaccine efficacy needed for a COVID-19 coronavirus vaccine to prevent or stop an epidemic as the sole intervention. *Am J Prev Med* 2020; 59: 493–503.

17 WHO. WHO COVID-19 case definition. Aug 7, 2020. https://www.who.int/publications/i/item/WHO-2019-nCoV-Surveillance_Case_Definition-2020.1 (accessed Nov 8, 2020).

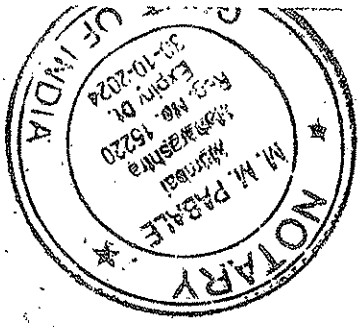
18 Public Health England. COVID-19: investigation and initial clinical management of possible cases. Oct 2, 2020. https://www.gov.uk/government/publications/wuhan-novel-coronavirus-initial-investigation-of-possible-cases/investigation-and-initial-clinical-management-of-possible-cases-of-wuhan-novel-coronavirus-wn-cov-infection#criteria (accessed Nov 8, 2020).

19 Richards-Belle A, Orzechowska I, Gould DW, et al. COVID-19 in critical care: epidemiology of the first epidemic wave across England, Wales and Northern Ireland. *Intensive Care Med* 2020; 46: 2035–47.

20 Sze S, Pan D, Gray LJ, et al. Ethnicity and clinical outcomes in COVID-19: a systematic Review and Meta-analysis. *EClinicalMedicine* 2020; published online Nov 12. https://doi.org/10.1016/j.eclinm.2020.100630.

1728

578



Safety and immunogenicity of ChAdOx1 nCoV-19 vaccine administered in a prime-boost regimen in young and old adults (COV002): a single-blind, randomised, controlled, phase 2/3 trial

Maheshi N Ramasamy, Angela M Minassian*, Katie J Ewer*, Amy L Flaxman*, Pedro M Folegatti*, Daniel R Owens*, Merryn Voysey*, Parvinder K Aley, Brian Angus, Gavin Babbage, Sandra Belij-Rammerstorfer, Lisa Berry, Sagida Bibi, Mustapha Bittaye, Katrina Cathie, Harry Chappell, Sue Charlton, Paola Cicconi, Elizabeth A Clutterbuck, Rachel Colin-Jones, Christina Dold, Katherine R W Emary, Sofiya Fedosyuk, Michelle Fuskova, Diane Gbesemete, Catherine Green, Bassam Hallis, Mimi M Hou, Daniel Jenkin, Carina C D Joe, Elizabeth J Kelly, Simon Kerridge, Alison M Lawrie, Alice Lelliott, May N Lwin, Rebecca Makinson, Natalie G Marchevsky, Yama Mujadidi, Alasdair P S Munro, Mihaela Pacurar, Emma Plested, Jade Rand, Thomas Rawlinson, Sarah Rhead, Hannah Robinson, Adam J Ritchie, Amy L Ross-Russell, Stephen Saich, Nisha Singh, Catherine C Smith, Matthew D Snape, Rinn Song, Richard Tarrant, Yrene Themistocleous, Kelly M Thomas, Tonya L Villafana, Sarah C Warren, Marion E E Watson, Alexander D Douglas*, Adrian V S Hill*, Teresa Lambe*, Sarah C Gilbert*, Saul N Faust*, Andrew J Pollard*, and the Oxford COVID Vaccine Trial Group*

Summary

Background Older adults (aged ≥70 years) are at increased risk of severe disease and death if they develop COVID-19 and are therefore a priority for immunisation should an efficacious vaccine be developed. Immunogenicity of vaccines is often worse in older adults as a result of immunosenescence. We have reported the immunogenicity of a novel chimpanzee adenovirus-vectored vaccine, ChAdOx1 nCoV-19 (AZD1222), in young adults, and now describe the safety and immunogenicity of this vaccine in a wider range of participants, including adults aged 70 years and older.

Methods In this report of the phase 2 component of a single-blind, randomised, controlled, phase 2/3 trial (COV002), healthy adults aged 18 years and older were enrolled at two UK clinical research facilities, in an age-escalation manner, into 18–55 years, 56–69 years, and 70 years and older immunogenicity subgroups. Participants were eligible if they did not have severe or uncontrolled medical comorbidities or a high frailty score (if aged ≥65 years). First, participants were recruited to a low-dose cohort, and within each age group, participants were randomly assigned to receive either intramuscular ChAdOx1 nCoV-19 ($2·2\times10^{10}$ virus particles) or a control vaccine, MenACWY, using block randomisation and stratified by age and dose group and study site, using the following ratios: in the 18–55 years group, 1:1 to either two doses of ChAdOx1 nCoV-19 or two doses of MenACWY; in the 56–69 years group, 3:1:3:1 to one dose of ChAdOx1 nCoV-19, one dose of MenACWY, two doses of ChAdOx1 nCoV-19, or two doses of MenACWY; and in the 70 years and older, 5:1:5:1 to one dose of ChAdOx1 nCoV-19, one dose of MenACWY, two doses of ChAdOx1 nCoV-19, or two doses of MenACWY. Prime-booster regimens were given 28 days apart. Participants were then recruited to the standard-dose cohort ($3·5–6·5\times10^{10}$ virus particles of ChAdOx1 nCoV-19) and the same randomisation procedures were followed, except the 18–55 years group was assigned in a 5:1 ratio to two doses of ChAdOx1 nCoV-19 or two doses of MenACWY. Participants and investigators, but not staff administering the vaccine, were masked to vaccine allocation. The specific objectives of this report were to assess the safety and humoral and cellular immunogenicity of a single-dose and two-dose schedule in adults older than 55 years. Humoral responses at baseline and after each vaccination until 1 year after the booster were assessed using an in-house standardised ELISA, a multiplex immunoassay, and a live severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) microneutralisation assay (MNA_{80}). Cellular responses were assessed using an ex-vivo IFN-γ enzyme-linked immunospot assay. The coprimary outcomes of the trial were efficacy, as measured by the number of cases of symptomatic, virologically confirmed COVID-19, and safety, as measured by the occurrence of serious adverse events. Analyses were by group allocation in participants who received the vaccine. Here, we report the preliminary findings on safety, reactogenicity, and cellular and humoral immune responses. This study is ongoing and is registered with ClinicalTrials.gov, NCT04400838, and ISRCTN, 15281137.

Findings Between May 30 and Aug 8, 2020, 560 participants were enrolled: 160 aged 18–55 years (100 assigned to ChAdOx1 nCoV-19, 60 assigned to MenACWY), 160 aged 56–69 years (120 assigned to ChAdOx1 nCoV-19: 40 assigned to MenACWY), and 240 aged 70 years and older (200 assigned to ChAdOx1 nCoV-19: 40 assigned to MenACWY). Seven participants did not receive the boost dose of their assigned two-dose regimen, one participant received the incorrect vaccine, and three were excluded from immunogenicity analyses due to incorrectly labelled samples. 280 (50%) of 552 analysable participants were female. Local and systemic reactions were more common in participants given ChAdOx1 nCoV-19 than in those given the control vaccine, and similar in nature to those previously reported

Lancet 2020; 396: 1979–93

Published Online November 19, 2020 https://doi.org/10.1016/S0140-6736(20)32466-1

This online publication has been corrected. The corrected version first appeared at thelancet.com on December 17, 2020, and further corrections have been made on April 8, 2021

See Comment page 1942

*Contributed equally

Oxford Vaccine Group, Department of Paediatrics (M N Ramasamy DPhil, M Voysey DPhil, P K Aley PhD, S Bibi PhD, E A Clutterbuck PhD, R Colin-Jones MSc, C Dold PhD, K R W Emary BM BCh, S Kerridge MSc, A Lelliott BMBS, N G Marchevsky MSc, Y Mujadidi MSc, E Plested, S Rhead MBChB, N Singh DPhil, C C Smith PhD, M D Snape MD, R Song MD, Prof A J Pollard FMedSci), The Jenner Institute (A M Minassian DPhil, K J Ewer PhD, A L Flaxman DPhil, P M Folegatti MD, B Angus MD, G Babbage MPhil, S Belij-Rammerstorfer PhD, M Bittaye PhD, P Cicconi PhD, S Fedosyuk PhD, M Fuskova MSc, M M Hou MRCPCH, D Jenkin MRCP, C C D Joe PhD, A M Lawrie PhD, R Makinson MBiol, T Rawlinson DPhil, A J Ritchie PhD, Y Themistocleous MBChB, M E E Watson PhD, A D Douglas DPhil, Prof A V S Hill FMedSci, T Lambe PhD, Prof S C Gilbert PhD), and Clinical

1729
579

Biomanufacturing Facility (C Green PhD, R Tarrant PhD), Nuffield Department of Medicine, and Oxford Centre for Clinical Tropical Medicine and Global Health (H Robinson DipHE), University of Oxford, Oxford, UK; NIHR Clinical Research Facility, University Hospital Southampton NHS Trust, Southampton, UK (D R Owens MRCPCH, L Berry BSc, H Chappell MBBS, D Gbesemete MRCPCH, M N Lwin MSc, A P S Munro MRCPCH, M Pacurar MD, J Rand BA, A L Ross-Russell MA, S Saich BA, S C Warren MBBC); Paediatric Medicine, University of Southampton, Southampton, UK (K Cathie MD); National Infection Service, Public Health England, Porton Down, Salisbury, UK (S Charlton PhD, B Hallis PhD, K M Thomas PhD); NIHR Oxford Biomedical Research Centre, Oxford, UK (E A Clutterbuck, C Dold, S Rhead, H Robinson, A D Douglas, Prof A V S Hill, T Lambe, Prof S C Gilbert, Prof A J Pollard); AstraZeneca BioPharmaceuticals Research and Development, Washington, DC, USA (E J Kelly PhD); AstraZeneca BioPharmaceuticals Research and Development, Bethesda, MA, USA (T L Villafana PhD); Division of Infectious Diseases, Boston Children's Hospital, Boston, MA, USA (R Song); and NIHR Southampton Clinical Research Facility and Biomedical Research Centre, University Hospital Southampton NHS Trust and Faculty of Medicine and Institute for Life Sciences, University of Southampton, Southampton, UK (Prof S N Faust FRCPCH)

Correspondence to:
Dr Maheshi N Ramasamy, Department of Paediatrics, University of Oxford, Oxford OX3 9DU, UK
maheshi.ramasamy@paediatrics.ox.ac.uk

(injection-site pain, feeling feverish, muscle ache, headache), but were less common in older adults (aged ≥56 years) than younger adults. In those receiving two standard doses of ChAdOx1 nCoV-19, after the prime vaccination local reactions were reported in 43 (88%) of 49 participants in the 18–55 years group, 22 (73%) of 30 in the 56–69 years group, and 30 (61%) of 49 in the 70 years and older group, and systemic reactions in 42 (86%) participants in the 18–55 years group, 23 (77%) in the 56–69 years group, and 32 (65%) in the 70 years and older group. As of Oct 26, 2020, 13 serious adverse events occurred during the study period, none of which were considered to be related to either study vaccine. In participants who received two doses of vaccine, median anti-spike SARS-CoV-2 IgG responses 28 days after the boost dose were similar across the three age cohorts (standard-dose groups: 18–55 years, 20713 arbitrary units [AU]/mL [IQR 13898–33550], n=39; 56–69 years, 16170 AU/mL [10233–40353], n=26; and ≥70 years 17561 AU/mL [9705–37796], n=47; p=0·68). Neutralising antibody titres after a boost dose were similar across all age groups (median MNA_{80} at day 42 in the standard-dose groups: 18–55 years, 193 [IQR 113–238], n=39; 56–69 years, 144 [119–347], n=20; and ≥70 years, 161 [73–323], n=47; p=0·40). By 14 days after the boost dose, 208 (>99%) of 209 boosted participants had neutralising antibody responses. T-cell responses peaked at day 14 after a single standard dose of ChAdOx1 nCoV-19 (18–55 years: median 1187 spot-forming cells [SFCs] per million peripheral blood mononuclear cells [IQR 841–2428], n=24; 56–69 years: 797 SFCs [383–1817], n=29; and ≥70 years: 977 SFCs [458–1914], n=48).

Interpretation ChAdOx1 nCoV-19 appears to be better tolerated in older adults than in younger adults and has similar immunogenicity across all age groups after a boost dose. Further assessment of the efficacy of this vaccine is warranted in all age groups and individuals with comorbidities.

Funding UK Research and Innovation, National Institutes for Health Research (NIHR), Coalition for Epidemic Preparedness Innovations, NIHR Oxford Biomedical Research Centre, Thames Valley and South Midlands NIHR Clinical Research Network, and AstraZeneca.

Copyright © 2020 The Author(s). Published by Elsevier Ltd. This is an Open Access article under the CC BY-NC-ND 4.0 license.

Introduction

As of Nov 13, 2020, over 52 million people have been diagnosed with COVID-19 worldwide, with over 1·2 million confirmed deaths.[1] Severe COVID-19 is more common in adults aged 70 years and older and in individuals with comorbidities such as hypertension, diabetes, cardiovascular disease, and chronic respiratory disease.[2] A safe and effective vaccine against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) will be an important tool in controlling the global COVID-19 pandemic. Although there are no licensed vaccines against COVID-19, 48 potential vaccine candidates based on a variety of platforms including lipid nanoparticle mRNA, DNA, adjuvanted protein, inactivated virus particles, and non-replicating viral vectors are in clinical trials (of which 11 candidates are in phase 3 trials) and a further 164 candidates are in preclinical testing.[3]

The WHO global target product profile of critical characteristics for prequalification of a COVID-19 vaccine requires candidates to be targeted at the most at-risk groups, including older adults; have a favourable safety profile; provide efficacy as measured by prevention of virologically confirmed disease or transmission, or both; and to provide at least 6 months of protection for individuals at ongoing risk of exposure to SARS-CoV-2.[4] On Sept 25, 2020, the UK Joint Committee on Vaccination and Immunisation (JCVI) gave interim recommendations for the national prioritisation of COVID-19 vaccines.[5] The following groups were provisionally prioritised: first, older adults living in residential care homes and residential care home workers; second, all adults aged 80 years or older and health-care and social-care workers; and third, all adults aged 75 years and older. However, the JCVI acknowledged that this priority ranking could change substantially if the first available vaccines were not considered safe or effective in older adults. Similar recommendations have also been made by the US Advisory Committee on Immunization Practices.[6]

Immunosenescence refers to the gradual deterioration and decline of the immune system brought on by ageing. Age-dependent differences in the functionality and availability of T-cell and B-cell populations are thought to have a key role in the decrease of immune response.[7] There has been a drive to develop vaccines and adjuvant formulations tailored for older adults to overcome this diminished immune response after vaccination. Assessment of immune responses in older adults is therefore essential in the development of COVID-19 vaccines that could protect this susceptible population.

The spike protein of SARS-CoV-2 binds to ACE2 receptors on target cells during viral entry. Analysis of convalescent patients suggests that the spike protein is an immunodominant antigen, eliciting both antibody and T-cell responses.[8] Most COVID-19 candidate vaccines have been developed to induce anti-spike protein immune responses. Clinical trials using several different vaccine platforms including mRNA,[9,10] adenoviral vectored vaccines,[11,12] inactivated virus,[13,14] and adjuvanted

1730

~~580~~

NOTARY M. M. PABALE Mumbai Maharashtra Reg. No. 1528 Exp. 31-10-2024 GOVT. OF INDIA

Research in context

Evidence before this study

We searched PubMed for research articles published from database inception until Nov 13, 2020, with no language restrictions, using the terms "SARS-CoV-2", "vaccine" AND "clinical trial". We identified published clinical trial data on eight other vaccine candidates. Two recombinant viral vectored vaccines have been tested in clinical trials. A single dose adenovirus (Ad) 5 vector-based vaccine (CanSino Biological/Beijing Institute of Biotechnology, China) elicited neutralising antibodies and T-cell responses in a dose-dependent manner, but was less immunogenic in individuals older than 55 years. A heterologous prime-boost Ad5/Ad26-vectored vaccine schedule (Gamaleya Research Institute, Russia) generated neutralising antibody and cellular responses in adults younger than 60 years. Two nucleoside-modified mRNA vaccine candidates using a two-dose regimen were tested in adults aged 18–55 years and 65–85 years, and generated neutralising antibodies in both age groups in a dose-dependent manner, although immunogenicity decreased with age (Pfizer/BioNTech, USA). Another mRNA vaccine (Moderna, USA) was given to adults older than 56 years. The vaccine was tolerated, with neutralising antibodies induced in a dose-dependent manner, which increased after a second dose. Neutralising antibody responses with this mRNA vaccine appeared to be similar in adults older than 56 years to those aged 18–55 years who also received the vaccine. Two inactivated viral vaccines have also shown neutralising antibody responses in a dose-dependent manner in adults aged 18–59 years (Wuhan Institute Biological Products/SinoPharm, China) or adults aged 18–59 and 60 years and older (Beijing Institute Biological products/SinoPharm, China), with the second showing lower neutralising antibody titres in older adults after two doses. Finally, a clinical trial of a nanoparticle vaccine composed of adjuvanted trimeric severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) spike glycoproteins (Novavax, USA) reported results of a two-dose schedule given 3 weeks apart in healthy adults younger than 60 years. This vaccine was well tolerated and induced neutralisation responses that exceeded those measured in serum samples from convalescent symptomatic patients.

Added value of this study

This study is the fifth published clinical trial of a vaccine against SARS-CoV-2 tested in an older adult population (aged 18–55 years, 56–69 years, and ≥70 years). The vaccine was safe and well tolerated, with reduced reactogenicity in older adults. Antibody responses against the SARS-CoV-2 spike protein were induced in all age groups and were boosted and maintained at 28 days after booster vaccination, including in the 70 years and older group. Cellular immune responses were also induced in all age and dose groups, peaking at day 14 after vaccination.

Implications of all the available evidence

The populations at greatest risk of serious COVID-19 include people with coexisting health conditions and older adults. The immune correlates of protection against SARS-CoV-2 have not yet been determined, but neutralising antibodies are thought to be associated with protection; and in a COVID-19 non-human primate challenge model, neutralising antibody responses correlated with protection. These findings have led to the use of neutralisation assays to assess immune responses in recent human COVID-19 vaccine trials. Immunisation with ChAdOx1 nCoV-19 results in development of neutralising antibodies against SARS-CoV-2 in almost 100% of participants including older adults without severe comorbidities, with higher levels in boosted compared with non-boosted groups. Further assessment of the efficacy of this vaccine is warranted in all age groups and individuals with comorbidities.

spike glycoprotein[15] have shown neutralising antibody responses after immunisation.

Replication-deficient adenovirus vectors containing a pathogen-specific transgene have been used as novel vaccines because of their ability to induce strong humoral and cellular responses.[16] However, pre-existing immunity might reduce the immunogenicity of vectors derived from human viruses; hence, use of simian adenoviruses might be preferable. ChAdOx1 nCoV-19 (AZD1222) is a replication-defective chimpanzee adenovirus-vectored vaccine expressing the full-length SARS-CoV-2 spike glycoprotein gene (GenBank accession number MN908947). Vaccination of rhesus macaques with a single dose of ChAdOx1 nCoV-19 generates humoral and cellular immune responses and protects from lower respiratory infection after subsequent challenge with SARS-CoV-2.[17] Preliminary results of a phase 1/2 clinical trial of ChAdOx1 nCoV-19 in adults aged 18–55 years show that the vaccine is well tolerated and generates robust neutralising antibody and cellular immune responses against the spike glycoprotein.[18] Here we present the safety and immunogenicity results of a phase 2 component of a phase 2/3 multicentre study using ChAdOx1 nCoV-19 at two different doses, in adults including those aged 56–69 years and 70 years and older, and in a one-dose or two-dose regimen.

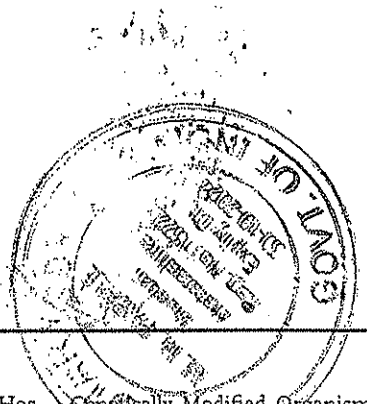
Methods

Study design and participants

In this continuing single-blind, multicentre, randomised, controlled, phase 2/3 trial, the safety and efficacy of the ChAdOx1 nCoV-19 vaccine is being assessed, with sequential age-escalation immunogenicity substudies being done in older age groups. The study is being run at 20 centres in the UK (listed in the appendix [pp 84–87]). Here we report selected results from the phase 2 component of the trial and for which participants were enrolled at two sites in the UK: the Oxford Vaccine Centre, Centre for Clinical Vaccinology and Tropical Medicine, University of Oxford (Oxford) and the NIHR

See Online for appendix

1731
581



Southampton Clinical Research Facility, University Hospital Southampton NHS Foundation Trust (Southampton). Data on the participants from the phase 3 component will be published elsewhere.

We recruited participants in an age-escalation manner. We recruited adults aged 18–55 years, then adults aged 56–69 years, and then adults aged 70 years and older, without severe or uncontrolled medical comorbidities, as defined in the clinical study plan (appendix pp 48–54), through local advertisements. Participants aged 65 years and older with a Dalhousie Clinical Frailty Score of 4 or higher were excluded.[19]

Participants were enrolled into one of ten different groups. Recruitment was sequential with low-dose groups recruited first and standard-dose cohorts recruited after a protocol amendment was approved on June 5, 2020, that incorporated the new higher dose level. For the first stage of recruitment, participants aged 18–55 years were recruited to the low-dose group. Subsequently we recruited participants aged 56–69 years, and further extension to recruit those aged 70 years and older only occurred after safety review by the independent Data Safety Monitoring Board (DSMB). A minimum of 2 weeks of safety and immunogenicity data were reviewed by the DSMB before recruitment to each successive age cohort. The 18–55 years groups received two doses of vaccine and were randomly assigned to receive either the experimental vaccine or the control vaccine. The 56–69 years and 70 years and older groups were randomly assigned to receive either one dose or two doses of vaccine and were then randomly assigned to receive the experimental vaccine or the control vaccine. The same process was repeated with recruitment and randomisation for the standard-dose cohorts after review by the DSMB. All participants underwent a screening visit in which a full medical history, targeted examination, blood test for SARS-CoV-2 exposure, and a urinary pregnancy test in women of childbearing potential were done. Volunteers who were seropositive to SARS-CoV-2 before enrolment were excluded from participating in all groups, apart from those in the 18–55 years standard-dose cohort. Additionally, all participants included in this phase 2 component of the study, apart from those in the 18–55 years low-dose group, had additional safety tests (blood tests for HIV, hepatitis B and C serology, full blood count, and kidney and liver function tests). Full details of eligibility criteria are in the trial protocol (appendix pp 135–38).

Written informed consent was obtained from all participants, and the trial is being done in accordance with the principles of the Declaration of Helsinki and Good Clinical Practice. The study was sponsored by the University of Oxford (Oxford, UK) and approved in the UK by the Medicines and Healthcare products Regulatory Agency (reference 21584/0428/001-0001) and the South-Central Berkshire Research Ethics Committee (reference 20/SC/0179). Vaccine use was authorised by Genetically Modified Organisms Safety Committees at each participating site. An independent DSMB reviewed all interim safety reports. A copy of the protocol is included in the appendix (pp 83–212).

Randomisation and masking

Participants were randomly assigned to receive either the ChAdOx1 nCoV-19 vaccine or the quadrivalent MenACWY protein-polysaccharide conjugate vaccine. MenACWY was used as a comparator vaccine rather than a saline placebo to maintain masking of participants who had local or systemic reactions. Participants aged 18–55 years were randomly assigned (1:1) in the low-dose cohort and (5:1) in the standard-dose cohort to receive either ChAdOx1 nCoV-19 or MenACWY. For both 18–55 years cohorts, participants were given two doses of study vaccine. Participants aged 56–69 years were randomly assigned (3:1:3:1) to one dose of ChAdOx1 nCoV-19, one dose of MenACWY, two doses of ChAdOx1 nCoV-19, or two doses of MenACWY. Participants aged 70 years or older were randomly assigned (5:1:5:1) to one dose of ChAdOx1 nCoV-19, one dose of MenACWY, two doses of ChAdOx1 nCoV-19, or two doses of MenACWY.

Randomisation lists, using block randomisation stratified by age and dose group and study site, were generated by the study statistician (MV). Block sizes were chosen to align with the age group and dose group sizes. Computer randomisation was done with full allocation concealment within the secure web platform used for the study electronic case report form (REDCap version 9.5.22). The trial staff administering the vaccine prepared vaccines out of sight of the participants and syringes were covered with an opaque material until ready for administration to ensure masking of participants. Participants, clinical investigators, and the laboratory team remained masked to group allocation for the duration of the study. However, trial staff administering the vaccine were unmasked.

Procedures

In the previous phase 1/2 study,[18] a single standard dose of 5×10^{10} virus particles of ChAdOx1 nCoV-19 was used, based on previous experience with a ChAdOx1 Middle East respiratory syndrome (MERS) construct. In this study, we assessed a lower dose of $2\cdot2\times10^{10}$ virus particles and a standard dose of $3\cdot5$–$6\cdot5\times10^{10}$ virus particles in adults of different age cohorts. Due to the need to rapidly produce large numbers of doses of vaccine manufactured using Good Manufacturing Practice to allow timely enrolment into the phase 2/3 clinical trial, two different batches of vaccine were used in this study: one manufactured and vialed by Advent (Pomezia, Italy), and one manufactured by COBRA Biologics (Keele, UK) and vialed by Symbiosis (Stirling, UK). Both were manufactured according to Good Manufacturing Practice and approved by the regulatory agency in the UK, the Medicines and Healthcare

1732
582



products Regulatory Agency. The 18–55 years standard-dose cohort received vaccine manufactured by COBRA Biologics for both first (ie, prime) and second (ie, boost) doses and all other cohorts received prime and boost doses, as randomised, manufactured by Advent. Analytical assessment of the batches indicates that the batches are comparable. Formal batch-to-batch comparison studies are ongoing and results will be reported when available.

ChAdOx1 nCoV-19 was administered as a single-dose or two-dose regimen (28 days apart) at either the low dose ($2·2\times10^{10}$ virus particles) or the standard dose ($3·5–6·5\times10^{10}$ virus particles). It was administered as a single intramuscular injection into the deltoid, according to specific study standard operating procedures. The MenACWY vaccine was provided by the UK Department of Health and Social Care and administered as per summary of product characteristics at the standard dose.[20] Depending on the batch used for vaccination, the injection volume for the low dose of ChAdOx1 nCoV-19 was either 0·22 mL or 0·5 mL. The injection volume used for the standard dose of ChAdOx1 nCoV-19 and MenACWY was 0·5 mL.

Safety data from animal studies and our previous phase 1/2 clinical trial[18] of ChAdOx1 nCoV-19 were reviewed before recruitment of participants. Volunteers were considered enrolled into the trial at the point of vaccination. Participants were observed in the clinic for a minimum of 15 min after the vaccination procedure in case of any immediate adverse events.

Participants from each group were instructed to complete a diary card to record solicited local and systemic adverse reactions for 7 days after each dose. Protocol-defined solicited local adverse events included injection-site pain, tenderness, warmth, redness, swelling, induration, and itch, and solicited systemic adverse events included malaise, muscle ache, joint pain, fatigue, nausea, headache, chills, feverishness (ie, a self-reported feeling of having a fever), and objective fever (defined as an oral temperature of 38°C or higher). All participants were given an emergency 24-h telephone number to contact the on-call study physician as required. Serious adverse events will be recorded throughout the follow-up period of 1 year after the last dose of vaccine.

Severity of adverse events was graded with the following criteria: mild (transient or mild discomfort for <48 h, no interference with activity, and no medical intervention or therapy required), moderate (mild-to-moderate limitation in activity, and no or minimal medical intervention or therapy required), severe (substantial limitation in activity and medical intervention or therapy required), or potentially life-threatening (requires assessment in emergency department or admission to hospital). All participants in the 56–69 years and 70 years and older groups and participants in the 18–55 years standard-dose group had clinical and immunogenicity assessments at 0, 7, 14, and 28 days after their prime and booster vaccinations. Participants in the 18–55 years low-dose group had clinical and immunogenicity assessments at baseline, immediately before the boost dose, and at 14 and 28 days after their booster vaccination.

Humoral responses at baseline and after vaccination were assessed using Meso Scale Discovery multiplexed immunoassay against spike and receptor binding domain [RBD], a standardised total IgG ELISA against trimeric SARS-CoV-2 spike protein, and a live SARS-CoV-2 microneutralisation assay MNA_{80}, which was done at Public Health England (Porton Down, UK), as described previously.[18] Cellular responses were assessed using an ex-vivo IFN-γ enzyme-linked immunospot (ELISpot) assay to enumerate antigen-specific T cells.[18] Neutralising antibodies to the ChAdOx1 vector were measured using a secreted embryonic alkaline phosphatase (SEAP)-reporter assay, which measures the reciprocal of the serum dilution required to reduce in-vitro expression of vector-expressed SEAP by 50%, 24 h after transduction.[21] Due to the labour-intensive nature of neutralisation assays, we prioritised analysis of samples from the ChAdOx1 nCoV-19 groups, randomly selecting more samples from ChAdOx1 nCoV-19 participants than control samples to be sent for blinded analysis.

Outcomes

The coprimary outcomes of the trial are to assess efficacy as measured by the number of cases of symptomatic, virologically confirmed COVID-19 and safety of the vaccine as measured by the occurrence of serious adverse events. Secondary outcomes include safety, reactogenicity, and immunogenicity profiles of ChAdOx1 nCoV-19 in older adults (aged 56–69 years and ≥70 years), efficacy against severe and non-severe COVID-19, death, and seroconversion against non-spike proteins. A full list of secondary and tertiary outcomes is in the protocol (pp 118–24).

Here we report preliminary results for selected secondary endpoints, comparing local and systemic reactogenicity and cellular and humoral immunogenicity of ChAdOx1 nCoV-19 between different age groups, after one or two doses and at low or standard dose. Efficacy analyses are not included in this report.

Statistical analysis

We present safety endpoints as frequencies (%) with 95% binomial exact CIs. We present immunological endpoints as medians and IQR. Analyses were by group allocation in participants who received the vaccine.

We did comparisons across the three age groups (aged 18–55 years, aged 56–69 years, and aged ≥70 years) using Kruskal-Wallis tests within each dose level of the vaccine (low dose or standard dose) for antibody responses or unadjusted analysis of variance applied to log-transformed values for neutralisation titres. We did comparisons between low-dose and standard-dose groups using Wilcoxon rank sum tests (antibody

1733
583

response) or independent samples Student's *t* test applied to log-transformed values for neutralisation titres. We present unadjusted p values for a small number of statistical comparisons to avoid issues of multiplicity. To assess the association between responses on different assays, we used unadjusted linear regression to analyse log-transformed values after baseline.

Sample sizes were nominal for these immunogenicity subgroups and no power calculations were done.

We did all statistical analyses using SAS version 9.4 and R version 3.6.1 or later. This study is registered with ClinicalTrials.gov, NCT04400838, and with ISRCTN, 15281137.

Role of the funding source

AstraZeneca reviewed the data from the study and the final manuscript before submission, but the authors retained editorial control. All other funders of the study had no role in the study design, data collection, data analysis, data interpretation, or writing of the report. All authors had full access to all the data in the study and had final responsibility for the decision to submit for publication.

Results

Between May 30 and Aug 8, 2020, 560 participants were enrolled in the study and randomly assigned to the experimental vaccine or control vaccine group: 160 participants aged 18–55 years (100 assigned to ChAdOx1 nCoV-19, 60 assigned to MenACWY), 160 aged 56–69 years (120 assigned to ChAdOx1 nCoV-19, 40 assigned to MenACWY), and 240 aged 70 years and older (200 assigned to ChAdOx1 nCoV-19, 40 assigned to MenACWY). Full details on randomisation are in figure 1. All participants randomly assigned to treatment were vaccinated. One participant (in the 18–55 years low-dose group) received the incorrect vaccine after randomisation and was excluded from analysis. Seven participants randomly assigned to receive two doses of vaccine chose not to continue with the boost dose and were excluded from further analyses. Three participants were excluded from immunology analyses due to incorrectly labelled samples (either incorrect participant identification numbers or incorrect timepoints noted on the label, or both; figure 1). The baseline characteristics of the participants eligible for inclusion in the analysis in each group are shown in the table. Participants 70 years and older were recruited from the NIHR Southampton Clinical Research Facility, University Hospital Southampton NHS Foundation Trust. All other participants were recruited at the Oxford Vaccine Centre, Centre for Clinical Vaccinology and Tropical Medicine, University of Oxford. Among the analysed population, 280 (50%) of 552 participants were female. 524 (95%) of 552 participants identified as white, and 540 (98%) were non-smokers. A large proportion of health-care workers who were predominantly female were enrolled in the 18–55 years and 56–69 years age groups. The median age in the 18–55 years group was 43·0 years (IQR 33·6–48·0), in the 56–69 years group was 60·0 years (57·5–63·0) and in the 70 years and older group was 73·0 years (71·0–76·0). The median age in the 70 years and older groups ranged from 73 years to 74 years across dosing groups, with the oldest participants aged 83 years.

The following results for local and systemic adverse reactions are all for participants who were randomly assigned to receive two doses of vaccine. Injection-site pain and tenderness were the most common solicited local adverse reactions and occurred most frequently in the first 48 h after vaccination (data for standard-dose regimen shown in figure 2; data for the low-dose groups and control groups are shown in the appendix [pp 7, 9, 19–21]). In those aged 56 years or older, a standard dose of ChAdOx1 nCoV-19, whether the prime or boost vaccination, elicited a greater number of local or systemic reactions than did MenACWY. The difference was less clear with the low-dose vaccine in the 56–69 years and 70 years and older groups, and the number of participants in the control groups was small (appendix p 30). At least one local symptom was reported after the prime vaccination with standard-dose ChAdOx1 nCoV-19 by 43 (88%) of 49 participants in the 18–55 years group, 22 (73%) of 30 in the 56–69 years group, and 30 (61%) of 49 in the 70 years and older group (appendix p 29). Similar proportions of local symptoms were reported after the boost vaccination with the standard dose of ChAdOx1 nCoV-19, with 37 (76%) of 49 participants in the 18–55 years group, 21 (72%) of 29 in the 56–69 years group, and 27 (55%) of 49 in the 70 years and older group reporting at least one local symptom. A similar pattern was seen across the age groups in participants after their prime vaccination with low-dose ChAdOx1 nCoV-19 and after the boost vaccination with the low-dose vaccine, but with fewer total adverse reactions than in the standard-dose groups (appendix pp 7, 9, 19–21). No severe local symptoms were reported by recipients of ChAdOx1 nCoV-19. In the two-dose control groups, across both the low-dose and standard-dose cohorts, local symptoms were reported by 33 (57%) of 58 participants in the 18–55 years group, five (25%) of 20 in the 56–69 years group, and seven (35%) of 20 in the 70 years and older group after the prime vaccination with MenACWY, and by 50 (86%) of 58 in the 18–55 years group, seven (37%) of 19 in the 56–69 years group, and four (20%) of 20 in the 70 years and older group after the boost vaccination with MenACWY (appendix p 29). Data for participants randomly assigned to receive only one dose of vaccine were similar to the data after a prime dose of vaccine in the two-dose groups (data not shown).

Fatigue, headache, feverishness, and myalgia were the most commonly solicited systemic adverse reactions (data for the standard-dose groups are shown in figure 3; data for the low-dose groups and control groups are shown in the appendix [pp 8, 10, 19–21]). At least one systemic symptom was reported after the prime

1734
584

vaccination with the standard dose of ChAdOx1 nCoV-19 by 42 (86%) of 49 participants in the 18–55 years group, 23 (77%) of 30 in the 56–69 years group, and 32 (65%) of 49 in the 70 years and older group (appendix p 29). The severity of symptoms reported in the standard-dose groups was reduced after the boost vaccination, with only one (1%) of 127 participants reporting a severe reaction compared with seven (5%) of 128 participants after the prime vaccination. At least one systemic adverse reaction after the boost vaccination of standard dose of ChAdOx1

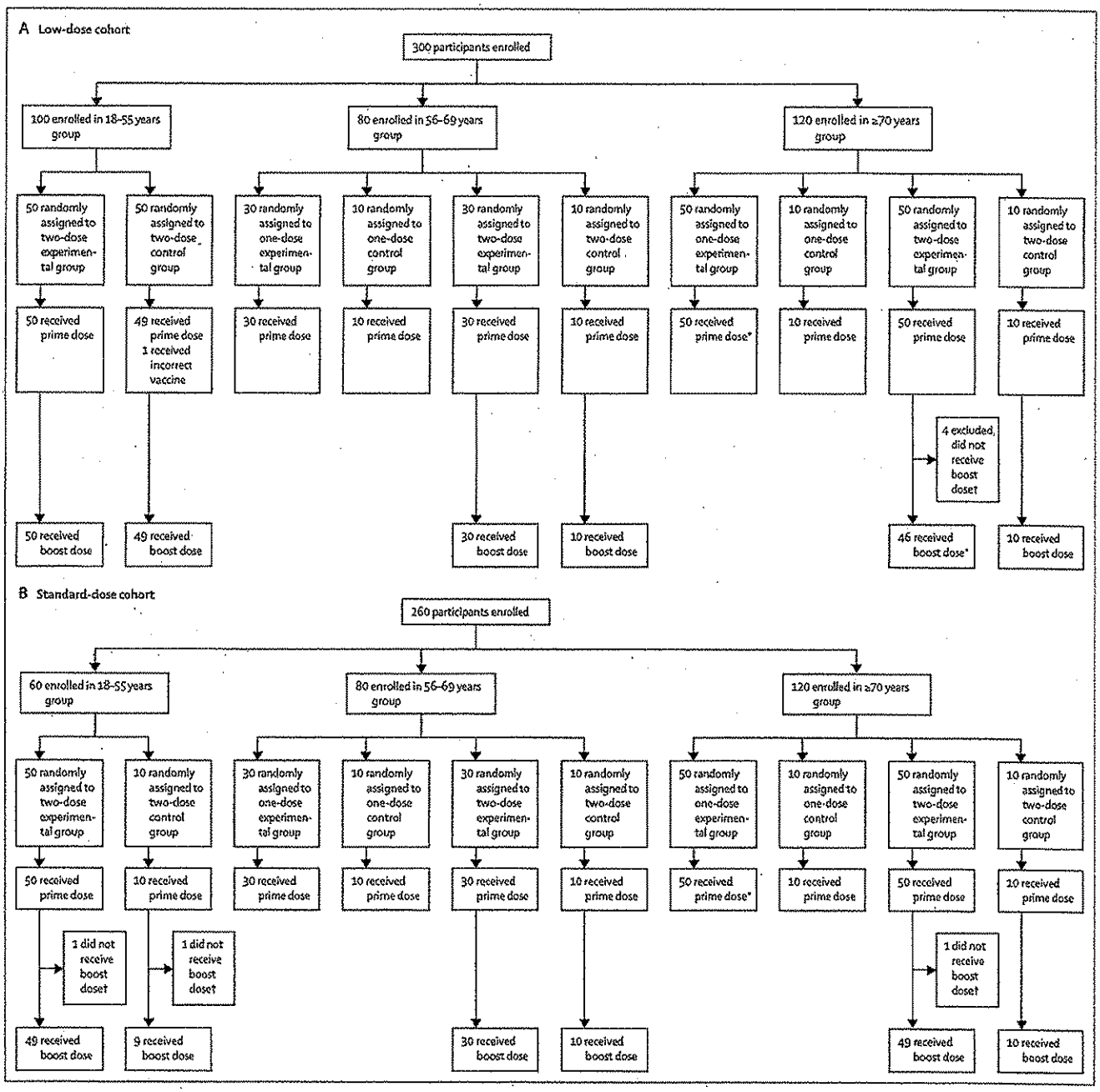


Figure 1: Study profile for the low-dose (A) and standard-dose (B) cohorts
*One participant excluded from immunogenicity analyses, due to mislabelling of laboratory sample. †Reasons for not receiving boost dose included that the participant moved away or was unavailable for visits, delay in receiving boost dose, or withdrawal of consent.

1735
585

	Age 18–55 years		Age 56–69 years				Age ≥70 years			
	ChAdOx1 nCoV-19, two doses	MenACWY, two doses	ChAdOx1 nCoV-19, one dose	MenACWY, one dose	ChAdOx1 nCoV-19, two doses	MenACWY, two doses	ChAdOx1 nCoV-19, one dose	MenACWY, one dose	ChAdOx1 nCoV-19, two doses	MenACWY, two doses
Low dose										
Number enrolled	50	49	30	10	30	10	50	10	46	10
Sex										
Female	35 (70%)	28 (57%)	19 (63%)	4 (40%)	10 (33%)	8 (80%)	24 (48%)	6 (60%)	16 (35%)	6 (60%)
Male	15 (30%)	21 (43%)	11 (37%)	6 (60%)	20 (67%)	2 (20%)	26 (52%)	4 (40%)	30 (65%)	4 (40%)
Age, years, median (IQR, range)	44·5 (39·0–51·0, 22·0–54·0)	42·0 (32·0–48·0, 23·0–55·0)	60·0 (58·9–62·3, 56·0–69·0)	57·8 (56·3–60·8, 56·0–68·0)	60·4 (57·8–66·0, 56·0–69·4)	60·5 (58·3–63·9, 56·7–69·0)	73·5 (71·0–76·0, 69·0–83·0)	73·0 (70·0–74·0, 70·0–81·0)	73·0 (71·0–75·0, 70·0–82·0)	73·0 (71·2–74·0, 70·0–76·0)
BMI, kg/m², median (IQR, range)	24·6 (22·9–28·9, 19·4–45·1)	24·8 (21·6–27·7, 18·0–37·2)	25·0 (23·2–27·3, 20·2–37·6)	25·5 (22·5–27·3, 20·9–34·4)	25·9 (24·0–28·8, 21·3–36·6)	24·0 (23·2–26·0, 22·2–33·2)	26·0 (23·8–28·0, 20·0–36·0)	24·9 (22·3–26·9, 19·3–32·5)	26·0 (23·4–27·7, 19·4–42·1)	26·8 (24·3–29·5, 19·2–35·3)
Smoker	3 (6%)	1 (2%)	0	1 (10%)	2 (7%)	0	1 (2%)	0	1 (2%)	0
Alcohol drinker	44 (88%)	42 (86%)	28 (93%)	9 (90%)	26 (87%)	8 (80%)	43 (86%)	10 (100%)	43 (94%)	9 (90%)
Health-care worker	35 (70%)	26 (53%)	17 (57%)	7 (70%)	12 (40%)	4 (40%)	0	0	0	1 (10%)
Race or ethnicity										
White	48 (96%)	45 (92%)	30 (100%)	9 (90%)	27 (90%)	10 (100%)	50 (100%)	10 (100%)	45 (98%)	10 (100%)
Black or Black British	0	0	0	0	0	0	0	0	0	0
Asian or Asian British	2 (4%)	1 (2%)	0	0	2 (7%)	0	0	0	0	0
Mixed race or ethnicity	0	3 (6%)	0	0	0	0	0	0	1 (2%)	0
Other race or ethnicity*	0	0	0	1 (10%)	1 (3%)	0	0	0	0	0
Comorbidities										
Cardiovascular disease	4 (8%)	10 (20%)	5 (17%)	0	11 (37%)	0	14 (28%)	3 (30%)	16 (35%)	2 (20%)
Respiratory disease	12 (24%)	9 (18%)	7 (23%)	0	7 (23%)	0	6 (12%)	2 (20%)	6 (13%)	1 (10%)
Diabetes	0	0	0	0	0	1 (10%)	1 (2%)	0	2 (4%)	0
Standard dose										
Number enrolled	49	9	30	10	30	10	50	10	49	10
Sex										
Female	23 (47%)	7 (78%)	16 (53%)	3 (30%)	16 (53%)	5 (50%)	25 (50%)	1 (10%)	21 (43%)	2 (20%)
Male	26 (53%)	2 (22%)	14 (47%)	7 (70%)	14 (47%)	5 (50%)	25 (50%)	9 (90%)	28 (57%)	8 (80%)
Age, years, median (IQR, range)	39·0 (30·0–45·0, 19·0–55·0)	43·0 (35·8–50·0, 32·0–54·0)	59·0 (58·0–61·0, 56·0–69·0)	61·5 (57·5–63·8, 57·0–66·0)	59·5 (57·0–61·0, 56·0–67·0)	60·5 (57·9–61·0, 56·0–64·0)	74·0 (72·0–76·0, 70·0–80·0)	74·0 (71·0–75·5, 70·0–78·0)	73·0 (71·0–75·0, 70·0–83·0)	73·5 (72·2–74·8, 71·0–81·0)
BMI, kg/m², median (IQR, range)	26·9 (24·6–30·9, 20·2–39·7)	24·1 (23·8–25·6, 18·6–39·0)	26·7 (25·2–30·0, 18·6–36·8)	28·9 (25·6–30·2, 21·7–31·9)	24·0 (22·4–27·1, 19·9–33·5)	26·1 (23·6–27·7, 20·5–30·2)	25·1 (23·7–28·5, 17·5–32·6)	26·8 (25·8–28·5, 23·0–31·7)	27·1 (24·2–29·2, 20·3–40·2)	25·6 (24·1–29·3, 18·9–32·5)
Smoker	1 (2%)	0	0	0	0	1 (10%)	1 (2%)	0	0	0
Alcohol drinker	45 (92%)	6 (67%)	29 (97%)	10 (100%)	29 (97%)	10 (100%)	39 (78%)	9 (90%)	42 (86%)	9 (90·0%)
Health-care worker	13 (27%)	5 (56%)	10 (33%)	2 (20%)	12 (40%)	5 (50%)	2 (4%)	0	0	0
Race or ethnicity										
White	40 (82%)	7 (78%)	29 (97%)	10 (100%)	26 (87%)	9 (90%)	50 (100%)	10 (100%)	49 (100%)	10 (100%)
Black or Black British	1 (2%)	0	0	0	0	0	0	0	0	0
Asian or Asian British	7 (14%)	2 (22%)	0	0	4 (13%)	1 (10%)	0	0	0	0
Mixed race or ethnicity	0	0	0	0	0	0	0	0	0	0
Other race or ethnicity*	1 (2%)	0	1 (3%)	0	0	0	0	0	0	0
Comorbidities										
Cardiovascular disease	6 (12%)	0	4 (13%)	3 (30%)	4 (13%)	1 (10%)	20 (40%)	3 (30%)	13 (27%)	4 (40%)
Respiratory disease	10 (20%)	1 (11%)	4 (13%)	1 (10%)	3 (10%)	3 (30%)	3 (6%)	0	4 (8%)	0
Diabetes	2 (4%)	0	2 (7%)	2 (20%)	0	0	0	1 (10%)	3 (6%)	1 (10%)

Data are n (%) unless otherwise specified. BMI=body-mass index. *Included Hispanic-Columbian, Indian, Japanese, and White Irish/English.

Table: Baseline characteristits of prime-boost participants included in the analysis

1736
586

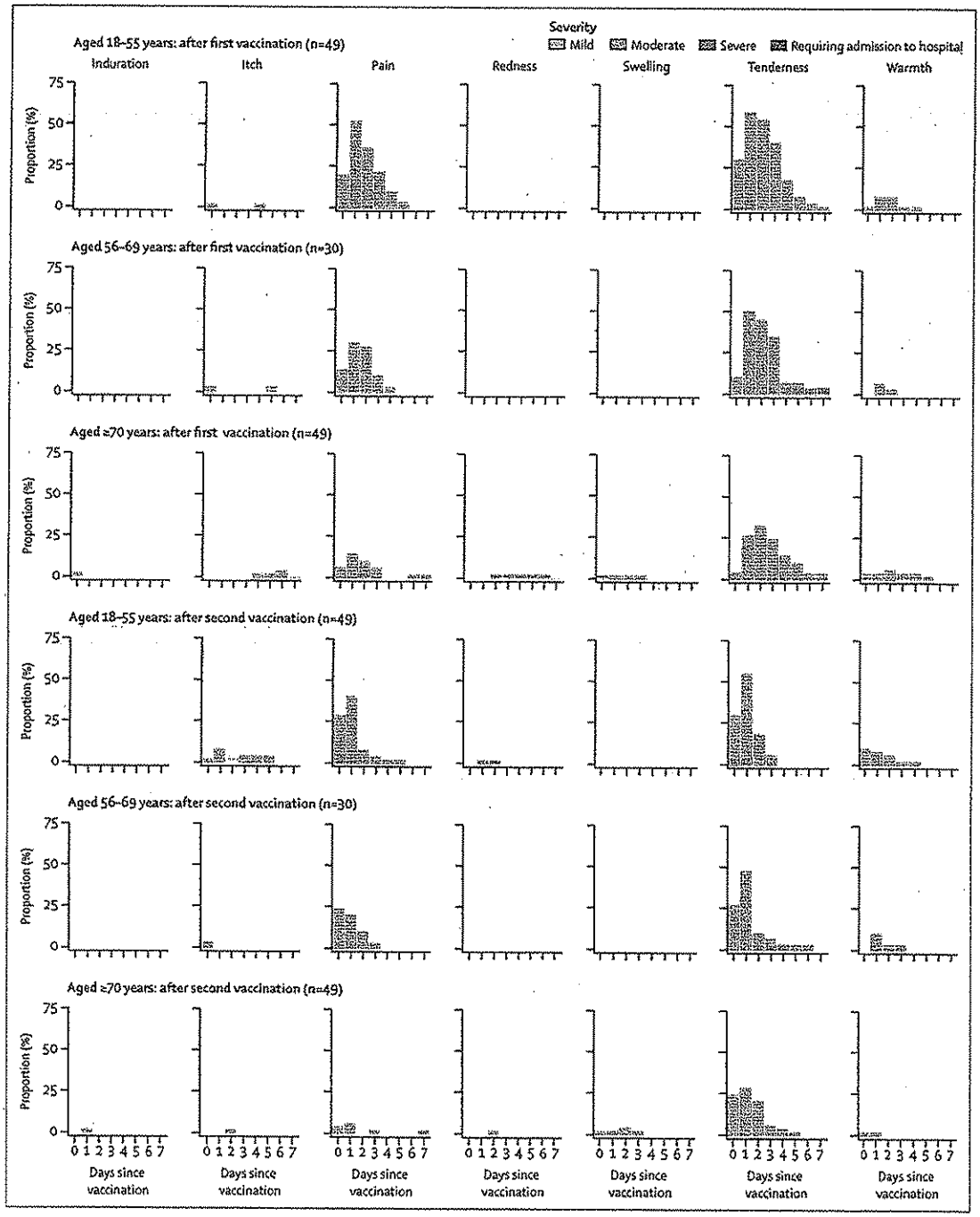


Figure 2: Solicited local adverse reactions in the 7 days after prime and boost doses of standard-dose vaccine, by age
Day 0 is the day of vaccination. Participants shown are those randomly assigned to receive two doses, and data are only shown for participants who received both doses of vaccine.

nCoV-19 was reported by 32 (65%) of 49 participants in the 18–55 years group, 21 (72%) of 29 in the 56–69 years group, and 21 (43%) of 49 in the 70 years and older group (appendix p 29). Within 7 days after the prime vaccination with ChAdOx1 nCoV-19, the incidence of objectively measured fever was low in the 18–55 years standard-dose

1737
587

group (12 [24%] of 49), and no fevers were recorded in either the 56–69 years or 70 years and older standard-dose groups (appendix pp 16–18). No participants of any age who received the standard dose of ChAdOx1 nCoV-19 had objective fever after the boost vaccination. A similar pattern of decreasing reactogenicity with increasing age

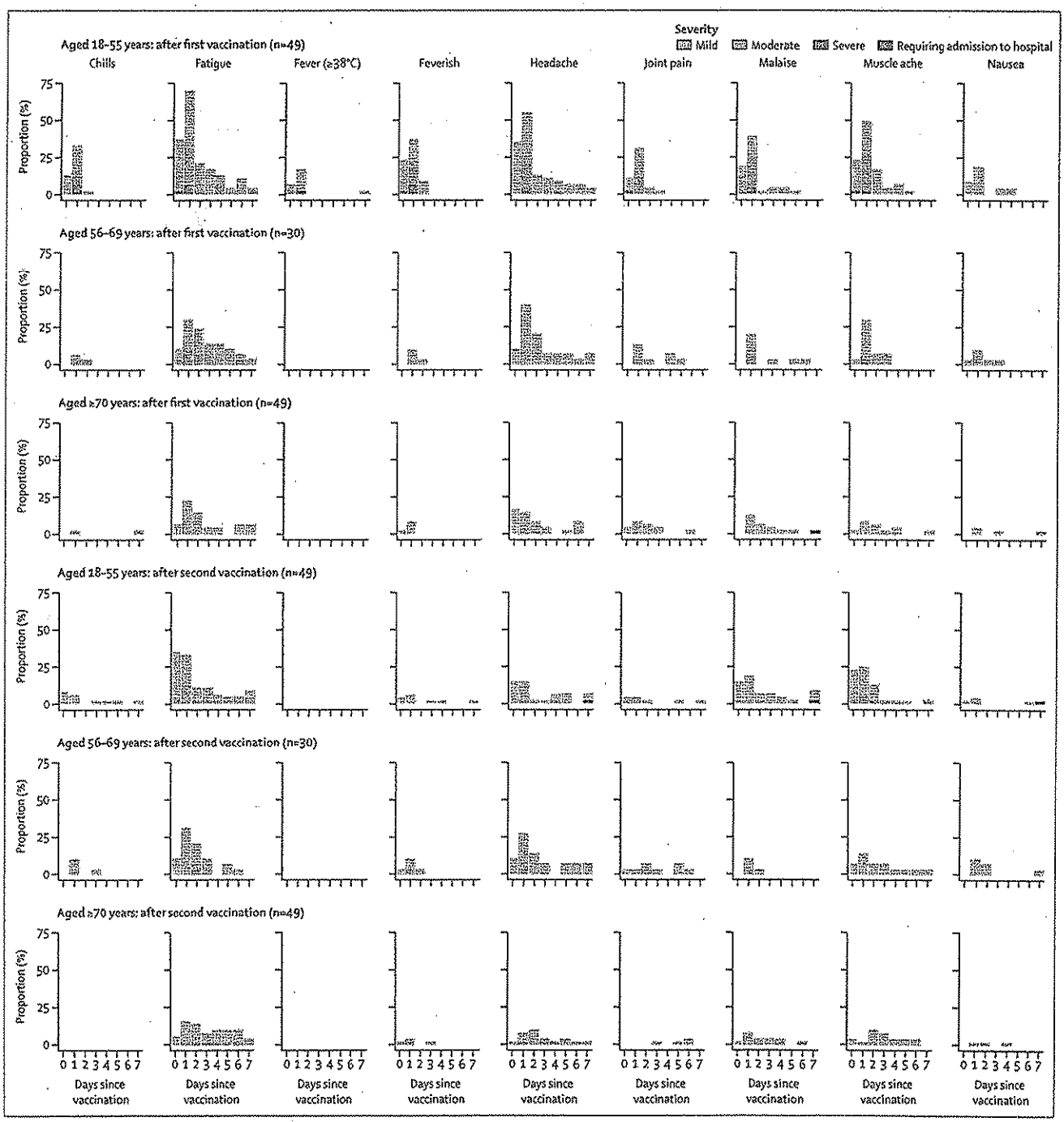


Figure 3: Solicited systemic adverse reactions in the 7 days after prime and boost doses of standard-dose vaccine, by age
Day 0 is the day of vaccination. Feverish is self-reported feeling of feverishness, whereas fever is an objective fever measurement (mild: 38·0 to <38·5°C, moderate: 38·5 to <39·0°C, severe: ≥39·0°C). Participants shown are those randomly assigned to receive two doses, and data are only shown for participants who received both doses of vaccine.

1738
588

GOVT. OF INDIA
M. M. PARALE
Mumbai
Maharashtra
Reg. No. 15226
Expiry Dt.
30-10-2024

was seen in the low-dose groups (appendix pp 7–8, 19–21). Similar results after the first dose were seen in those who were randomly assigned to receive only one dose of vaccine (data not shown). Data for the control groups are in the appendix (p 10).

As of Oct 26, 2020, 13 serious adverse events have occurred (across all age and vaccine groups), none of which are considered related to either study vaccine as assessed by the investigators (appendix p 31).

Using a multiplex immunoassay that detected total IgG against RBD and trimeric spike protein, we observed that participants who received the prime vaccination of standard-dose ChAdOx1 nCoV-19 had similar anti-spike antibody titres by day 28 after their prime vaccination as those who received a low dose (p=0·12 adjusted for age; figure 4; appendix p 12). At both dose levels, and for all dose groups combined, anti-spike IgG responses at day 28 decreased with increasing age (low-dose groups: 18–55 years, median 6439 arbitrary units [AU]/mL [IQR 4338–10 640], n=49; 56–69 years, 4553 AU/mL [2657–12 462], n=60; ≥70 years, 3565 AU/mL [1507–6345], n=93; p=0·0037; standard-dose groups: 18–55 years, median 9807 AU/mL [IQR 5847–17 220], n=43; 56–69 years, 5496 AU/mL [2548–12 061], n=55; ≥70 years, 4156 [2122–12 595], n=97; p=0·0044). By 28 days after the boost vaccination, similar antibody titres were seen across all two-dose groups, regardless of age or vaccine dose (eg, standard-dose groups: 18–55 years, median 20 713 AU/mL [IQR 13 898–33 550], n=39; 56–69 years, 16 170 AU/mL [10 233–40 353], n=26; and ≥70 years, 17 561 AU/mL [9705–37 796], n=47; p=0·68), and were higher than for those who did not receive a boost vaccination (appendix p 13). Similar results were seen with anti-RBD antibodies (figure 4; appendix p 12) and with an in-house standardised ELISA (appendix pp 12–13). Data for the control group are in the appendix (pp 12–13).

In a live SARS-CoV-2 microneutralisation assay (MNA_{80}), median titres peaked by day 42 in most groups that received two vaccinations (figure 5). There were no significant differences in normalised titres between age groups at day 42 (low-dose groups: 18–55 years, median 161 [IQR 99–233], n=41; 56–69 years, 143 [79–220], n=28; ≥70 years, 150 [103–255], n=34; p=0·90; standard-dose groups: 18–55 years, median 193 [IQR 113–238], n=39; 56–69 years, 144 [119–347], n=20; and ≥70 years, 161 [73–323], n=47; p=0·40). Within each age group, no significant differences were seen in neutralisation titres between low-dose and standard-dose vaccine recipients at the same timepoint (18–55 years p=0·33, 56–69 years p=0·12, ≥70 years p=0·62; figure 5; appendix p 14). Neutralising titres were achieved by 14 days after the boost vaccination in 208 (>99%) of 209 recipients of a boost vaccination. The one participant with a non-neutralising level was in the 70 years and older two-dose low-dose group.

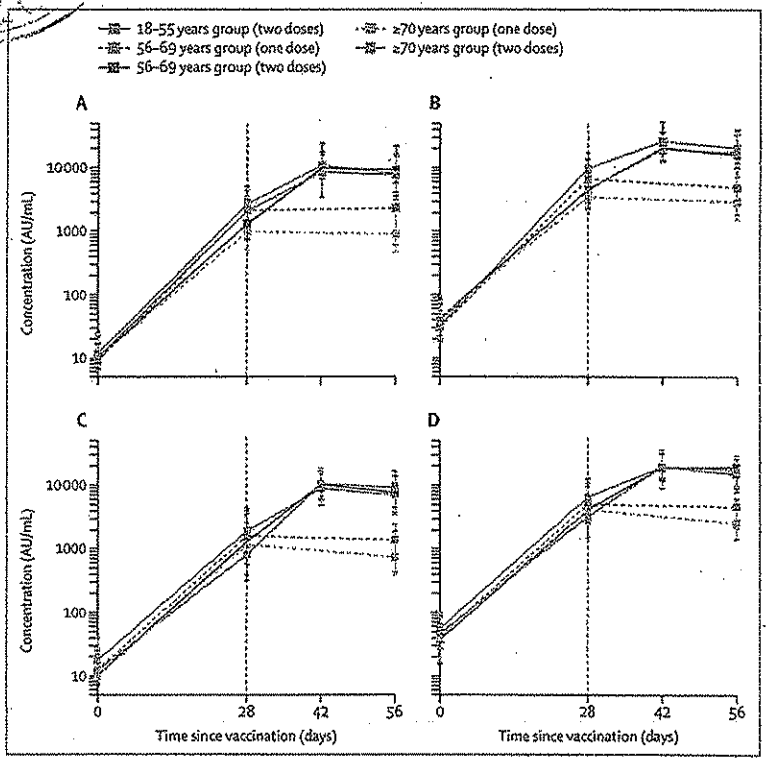


Figure 4: SARS-CoV-2 IgG response to the receptor binding domain in the standard-dose groups (A) and low-dose groups (C) and the spike protein in the standard-dose groups (B) and the low-dose groups (D), by age

Datapoints are medians, with whiskers showing the IQRs. Solid lines show participants who were randomly assigned to and received two doses of vaccine and dashed lines indicate participants who were randomly assigned to receive one dose. The vertical black line indicates when participants who received two doses received their boost dose. Data for the control groups are shown in the appendix (p 12). AU=arbitrary units. SARS-CoV-2=severe acute respiratory syndrome coronavirus 2.

Anti-spike IgG levels after vaccination across all timepoints in those who received two doses of vaccine were highly correlated with neutralising titres in all age groups and for both low-dose and standard-dose vaccines (r^2 from linear regression 0·42–0·75, all p<0·0001; appendix p 32).

IFN-γ ELISpot responses against SARS-CoV-2 spike protein peaked 14 days after the prime vaccination (standard-dose groups: 18–55 years, median 1187 spot-forming cells [SFCs] per million peripheral blood mononuclear cells [PBMCs; IQR 841–2428], n=24; 56–69 years, 797 SFCs [383–1817], n=29; and ≥70 years, 977 SFCs [458–1914], n=48; appendix p 16) and did not increase significantly after the boost vaccination (p=0·46 from paired Student's *t* test of day 28 *vs* day 42; figure 6). ELISpot data were unavailable for the 18–55 years low-dose group because PBMCs were not collected in this group. In those who received two standard doses of vaccine, a significant difference was seen across age groups with those aged 56–69 years having higher responses at day 42 than other age groups receiving the

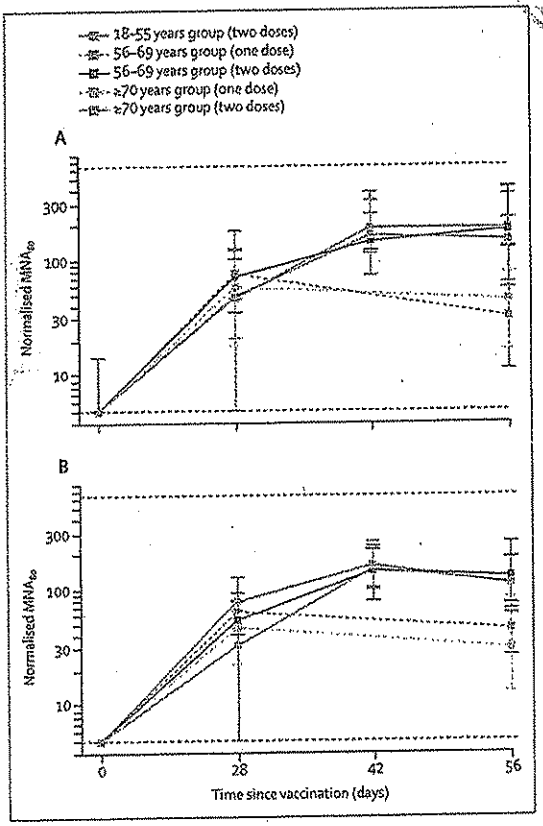


Figure 5: Neutralising antibody titres measured using a live SARS-CoV-2 microneutralisation assay (MNA_{80}) after prime and boost doses of vaccine in standard-dose groups (A) and low-dose groups (B), by age
Datapoints are medians, with whiskers showing the IQR. Solid lines show participants who were randomly assigned to and received two doses of vaccine and dashed lines indicate participants who were randomly assigned to receive one dose. Horizontal dotted lines show upper and lower limits of assay (values outside this range set to 640 beyond the upper limit and 5 beyond the lower limit). Data for the control groups are shown in the appendix (p 14).
To normalise data across assay runs, a reference sample was included in all assay runs and test samples normalised to this value by generating log_{10} ratios.
SARS-CoV-2=severe acute respiratory syndrome coronavirus 2.

same vaccine regimen (18–55 years, median 413 SFCs per million PBMCs [IQR 245–675], n=23; 56–69 years, 798 SFCs [462–1186], n=28; and ≥70 years, 307 SFCs [161–516], n=47; p<0·0001; appendix p 15).

Anti-ChAdOx1 neutralising antibody titres across different age and dose groups are shown in figure 7. Titres increased with the prime vaccination with ChAdOx1 nCoV-19 in all groups to similar levels, but were not increased further after a boost dose of vaccine at day 28. This observation was in contrast with the anti-SARS-CoV-2 spike protein antibody levels, which were increased 28 days after the boost vaccination (figure 4). Anti-ChAdOx1 neutralising titres immediately before the boost vaccination were negatively correlated with standardised ELISA values 28 days after the boost vaccination (p=0·037; figure 7), but no significant

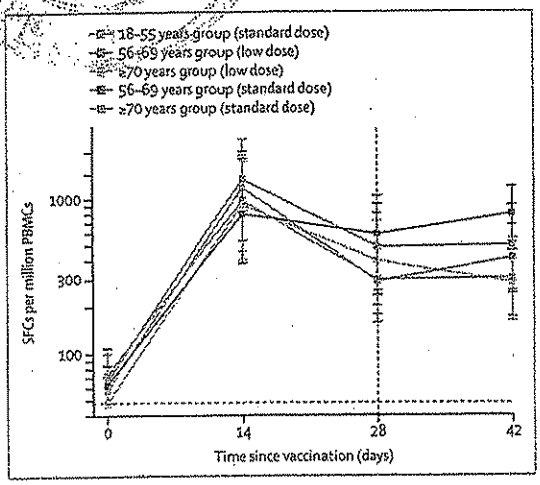


Figure 6: IFN-γ ELISpot response to peptides spanning the SARS-CoV-2 spike insert after prime and boost doses of vaccine for all participants who were given two doses of vaccine, by age group and vaccine dose
ELISpot data were unavailable for the 18–55 years low-dose group because PBMCs were not collected in this group. Datapoints are medians, with whiskers showing the IQR. The lower limit of detection is 48 SFCs per million PBMCs (horizontal dotted line). Day 42 samples are from participants who received the boost dose at day 28 (vertical dotted line). Data for both one-dose and two-dose groups, with numbers analysed at each timepoint, are in the appendix (p 15).
ELISpot=enzyme-linked immunospot. PBMC=peripheral blood mononuclear cells. SARS-CoV-2=severe acute respiratory syndrome coronavirus 2. SFC=spot-forming cells.

correlation was seen between anti-ChAdOx1 neutralising titres immediately before the boost vaccination and ELISpot responses 14 days after the boost vaccination (p=0·22; figure 7).

Discussion

Our findings show that the ChAdOx1 nCoV-19 vaccine was safe and well tolerated with a lower reactogenicity profile in older adults than in younger adults. Immunogenicity was similar across age groups after a boost vaccination. If these responses correlate with protection in humans, these findings are encouraging because older individuals are at disproportionate risk of severe COVID-19 and so any vaccine adopted for use against SARS-CoV-2 must be effective in older adults.

Most of the reported local and systemic adverse events were mild to moderate in severity, in line with our previous phase 1 study of the ChAdOx1 nCoV-19 vaccine[18] and previously reported studies of ChAdOx1-vectored vaccines.[22–26] Fewer adverse events were reported after the boost vaccination than after the prime vaccination and reactogenicity reduced with increasing age. The lower dose of vaccine was less reactogenic than the standard dose of vaccine across all age groups.

The serious adverse events observed during the trial in these study groups were judged to be unrelated to the study vaccines and occurred at frequencies expected for these conditions in the general population. None of the participants included in this report had any suspected

1740
590

unexpected serious adverse reactions. In the phase 3 component of the trial, suspected unexpected serious adverse reactions occurred in other groups, and will be reported in detail in a subsequent publication. We carefully monitored suspected unexpected serious adverse reactions and other adverse events to ensure that no pattern of unexplained illnesses emerged that could indicate a safety concern. Independent assessments have led to the recommendation that the trial is safe to continue.

The ChAdOx1 nCoV-19 vaccine induced a specific antibody response to the SARS-CoV-2 spike glycoprotein and RBD at 28 days after a single dose across all age groups, including adults aged 70 years and older. A clear effect of a boost vaccination on antibody titres at day 56 was seen that was unrelated to dose regimen or age group. Similar patterns were observed with neutralising antibody responses, with no difference in the magnitude of the response at day 28 after the prime vaccine regardless of age or vaccine dose, but a booster effect was observed in individuals who received a second dose of vaccine.

Other clinical trials have also assessed safety, tolerability, and immunogenicity of SARS-CoV-2 vaccines in older adults. An adenovirus 5 vector-based vaccine also had reduced reactogenicity in adults aged 55 years and older compared with adults aged 18–54 years after a single dose of vaccine, although immunogenicity was concurrently reduced in this older age group.[11] A two-dose mRNA vaccine has also been shown to be immunogenic in adults older than 56 years with dose-dependent immune responses and similar neutralising antibody titres and cellular immune responses to younger adults.[9] Another two-dose mRNA vaccine has shown immunogenicity in older adults, but absolute neutralising antibody responses in adults aged 65–85 years were lower than in those aged 18–55 years.[10] By contrast with our observations, in both these studies, reactogenicity was more common after the second dose of an mRNA vaccine. A two-dose inactivated virus vaccine has also shown lower absolute neutralising antibody titres in adults aged 60 years and older than in adults aged 18–59 years, but reactogenicity was not formally compared between the first and second doses in this study.[13]

T-cell responses are important in controlling disease in natural infection[6] and therefore generation of a robust cellular immune response is a desirable attribute for a vaccine against SARS-CoV-2. Here, we found that spike-specific T-cell responses measured with ELISpot peaked at 14 days after the prime vaccination, consistent with previous studies of simian adenovirus-vectored vaccines,[25] and were similar in all groups regardless of age and vaccine dose. Spike protein T-cell responses measured with ELISpot have also been reported in studies with other adenovirus-vectored vaccines against SARS-CoV-2,[12] including in adults older than 55 years.[11] Theoretical concerns about vaccine-enhanced disease have led to a view that a type 1 T-helper (Th1)-biased CD4 response is a preferred coronavirus vaccine characteristic.[26] An adjuvanted nanoparticle vaccine has been shown to induce spike-specific CD4 T-cell cytokine responses with a predominantly Th1 profile,[15] as has an mRNA vaccine in small numbers of adults aged 56–70 years and 71 years and older.[9] More detailed investigations of antigen-specific T-cell responses in our study participants are ongoing.

The robust humoral and cellular immune responses obtained in our older adult population were encouraging given that a number of studies have shown that decreasing immune function with age leads to decreased immune responses to vaccines. This fact holds true for vaccines such as for influenza, for which pre-existing

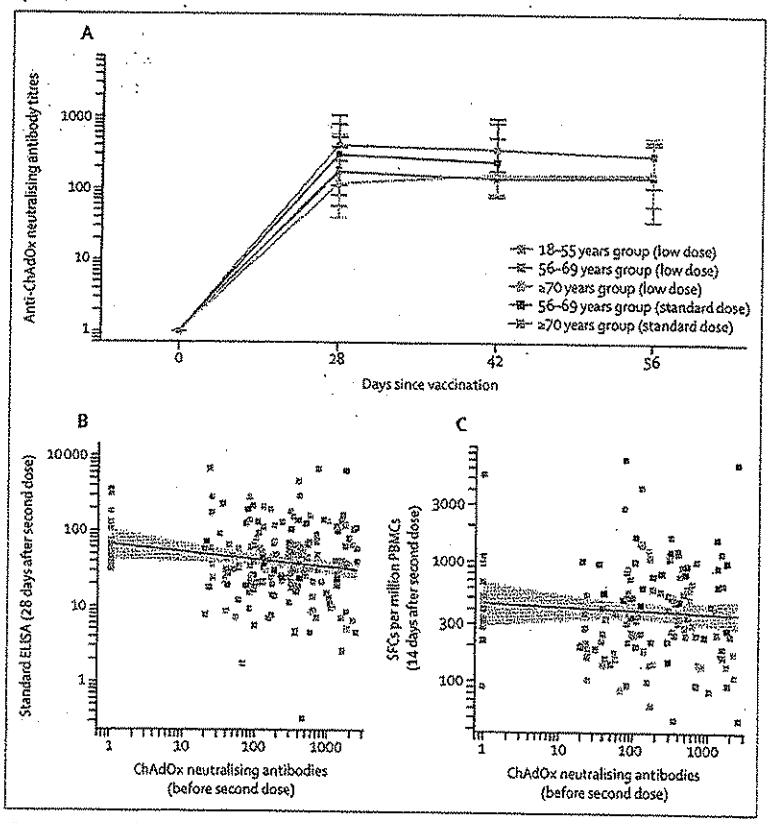


Figure 7: **Anti-ChAdOx1 vector neutralising titres after prime and boost doses of vaccine, by age and vaccine dose, and the correlation between pre-boost dose anti-ChAdOx1 neutralising antibodies and 28 days after boost dose antibody and T-cell responses**

(A) Anti-ChAdOx1 neutralising antibody titres in participants who received ChAdOx1 nCoV-19 vaccine by age and dose: datapoints are medians, with whiskers showing the IQR. Values below the limit of detection were assigned a value of 1. (B) Anti-ChAdOx1 neutralising antibody titre immediately before boost dose of vaccine versus standardised IgG ELISA against SARS-CoV-2 spike 28 days after the boost dose of vaccine with linear regression of logged values (p=0·037). (C) Anti-ChAdOx1 neutralising antibody titres immediately before boost dose of vaccine versus SARS-CoV-2 spike specific T cells measured by IFN-γ ELISpot on day 14 after the boost dose of vaccine with linear regression of logged values (p=0·22). In B and C, each datapoint is one participant and the solid line shows the linear regression, with the shaded area showing the 95% CI from an unadjusted linear regression of anti-vector neutralisation titres against logged ELISA (in B) or ELISpot (in C) response. Data were unavailable at day 56 for the 56–69 years standard-dose group. ELISpot=enzyme-linked immunospot. PBMC=peripheral blood mononuclear cells. SARS-CoV-2=severe acute respiratory syndrome coronavirus 2. SFC=spot-forming cells.

1741
591

immune memory exists,[27] and vaccines that induce primary immune responses, such as hepatitis B.[28] Other adenovirus-vector platforms against SARS-CoV-2 have either shown reduced immunogenicity in an older age group[11] (although this study was of a single-dose regimen and so not directly comparable with our prime-boost regimen) or have not yet been tested in an older population.[12]

However, our results are consistent with previous studies of adenovirus-vector-based vaccines against respiratory pathogens that evoke humoral and T-cell responses in older adults, including a human adenovirus-vectored respiratory syncytial virus (RSV) vaccine[29] and a simian adenovirus-vectored RSV vaccine.[30] Our results with ChAdOx1 nCoV-19 are also consistent with those of a ChAdOx1-vectored vaccine against influenza that showed good immunogenicity in adults older than 50 years.[22]

Notably, the anti-spike antibody responses in our study increased after a boost vaccination at an interval of 1 month but the neutralising anti-vector antibody responses did not. There was also no difference in anti-vector immunity by age. We observed a small negative correlation between anti-vector antibody titres and anti-spike total IgG, but not T-cell ELISpot responses. Further work is needed to investigate if homologous boosting with adenovirus-vectored vaccines can be done without loss of immunogenicity to the pathogen-specific transgene.

In the absence of a clear serological correlate of protection against SARS-CoV-2, clinical studies have focused on measuring neutralising antibodies because these have been shown to confer protection from challenge in animal models.[9–15] Live virus neutralisation assays are labour intensive and can only be done in specialist laboratories under category 3 biological safety conditions. We found here that anti-spike IgG levels correlate with neutralising antibody titres for all age groups. This finding suggests that, should neutralising antibodies be shown to be protective in humans, routine serological assays could be used for the standardised evaluation of functional antibody by vaccine candidates in clinical trials.

A limitation of this study is its single-blind design. However, all laboratory analyses and clinical assessments reported in this manuscript were done in a blinded fashion. A further limitation is possible variation of severity of local reactions due to the difference in injection volumes between different batches of vaccine in the low-dose group. Ongoing studies in larger groups will investigate the reactogenicity of a booster dose in more detail. Finally, the selection of participants aged 70 years and older, with a median age of 73–74 years between dose groups and with few comorbidities, might not be representative of the general older population, including those living in residential care settings or older than 80 years. Early phase studies in older adults require healthy volunteers to be enrolled for safety assessments, and recruitment to the study occurred during a period of national lockdown when more susceptible individuals were advised by Public Health England to self-isolate. Therefore, we excluded volunteers with substantial comorbidities or clinical frailty. Larger studies are now underway to assess immunogenicity, safety, and efficacy in older adults with a wider range of comorbidities.

Ultimately, licensure of a vaccine relies on the demonstration of efficacy in preventing COVID-19 and safety. Phase 3 studies with ChAdOx1 nCoV-19 are ongoing in the UK, Brazil, and the USA to assess vaccine efficacy and safety. Here we found similar safety and immunogenicity of ChAdOx1 nCoV-19 in older adults compared with younger adults, which could support the use of this vaccine in this older age group, if it is shown to be protective in phase 3 trials.

Contributors

AJP and SCG conceived and designed the trial and AJP is the chief investigator. AJP, AMM, HR, MNR, MV, and PMF contributed to the protocol and design of the study. AVSH and SNF were the study site principal investigators. ALF, CD, EAC, KJE, RM, and TL were responsible for laboratory testing and assay development. MV and NGM did the statistical analysis. SCG and TL were responsible for vaccine development. ADD, CG, and RT were responsible for vaccine manufacture. AJP, AMM, MNR, MV, NGM, and TL contributed to the preparation of the report. AMM, DRO, HR, KJE, MNR, PKA, and PMF contributed to the implementation of the study. All other authors contributed to the implementation of the study and data collection. All authors critically reviewed and approved the final version.

Declaration of interests

Oxford University has entered into a partnership with AstraZeneca for further development of ChAdOx1 nCoV-19 (AZD1222). AstraZeneca reviewed the data from the study and the final manuscript before submission, but the authors retained editorial control. SCG is cofounder of Vaccitech (a collaborator in the early development of this vaccine candidate) and named as an inventor on a patent covering use of ChAdOx1-vectored vaccines (PCT/GB2012/000467) and a patent application covering this SARS-CoV-2 vaccine. TL is named as an inventor on a patent application covering this SARS-CoV-2 vaccine and was consultant to Vaccitech. PMF is a consultant to Vaccitech. AJP is Chair of the UK Department of Health and Social Care's JCVI, but does not participate in policy advice on coronavirus vaccines, and is a member of the WHO Strategic Advisory Group of Experts (SAGE). AVSH is a cofounder of and consultant to Vaccitech and is named as an inventor on a patent covering design and use of ChAdOx1-vectored vaccines (PCT/GB2012/000467). MDS reports grants from Janssen, GlaxoSmithKline, MedImmune, Novavax, and MCM Vaccine and grants and non-financial support from Pfizer outside of the submitted work. CG reports personal fees from the Duke Human Vaccine Institute outside of the submitted work. ADD reports grants and personal fees from AstraZeneca outside of the submitted work. All other authors declare no competing interests.

Data sharing

The study protocol and clinical study plan are provided in the appendix (pp 45–212). Anonymised participant data will be made available when the trial is complete, upon requests directed to the corresponding author. Proposals will be reviewed and approved by the sponsor, investigator, and collaborators on the basis of scientific merit. After approval of a proposal, data can be shared through a secure online platform after signing a data access agreement. All data will be made available for a minimum of 5 years from the end of the trial.

Acknowledgments

This Article reports independent research funded by UK Research and Innovation (MC_PC_19055), Engineering and Physical Sciences Research Council (EP/R013756/1), Coalition for Epidemic Preparedness

1742
592



Innovations, and the National Institute for Health Research (NIHR). We acknowledge support from Thames Valley and South Midland's NIHR Clinical Research Network and the staff and resources of NIHR Southampton Clinical Research Facility, and the NIHR Oxford Health Biomedical Research Centre. PMF received funding from the Coordenacao de Aperfeicoamento de Pessoal de Nivel Superior, Brazil (finance code 001). ALF was supported by the Chinese Academy of Medical Sciences Innovation Fund for Medical Science, China (grant number: 2018-I2M-2-002). KJE is an NIHR Biomedical Research Centre Senior Research Fellow. AJP and SNF are NIHR senior investigators. The views expressed in this publication are those of the authors and not necessarily those of the NIHR or the UK Department of Health and Social Care. We thank the senior management at AstraZeneca for facilitating and funding the Mesoscale antibody assay included in this manuscript. We also thank the volunteers who participated in this study.

References

1 WHO. Coronavirus disease (COVID-19) dashboard. Geneva: World Health Organization, Nov 13, 2020. https://covid19.who.int (accessed Nov 13, 2020).
2 Wu Z, McGoogan JM. Characteristics of and important lessons from the coronavirus disease 2019 (COVID-19) outbreak in China: summary of a report of 72 314 cases From the Chinese Center for Disease Control and Prevention. *JAMA* 2020; 323: 1239–42.
3 WHO. Draft landscape of COVID-19 vaccine candidates. Geneva: World Health Organization, Nov 12, 2020. https://www.who.int/publications/m/item/draft-landscape-of-covid-19-candidate-vaccines (accessed Nov 13, 2020).
4 WHO. WHO target product profiles for COVID-19 vaccines: version 3. Geneva: World Health Organization, April 29, 2020. https://www.who.int/docs/default-source/blue-print/who-target-product-profiles-for-covid-19-vaccines.pdf?sfvrsn=1d5da7ca_5 (accessed Oct 26, 2020).
5 Joint Committee on Vaccination and Immunisation. Priority groups for coronavirus (COVID-19) vaccination: advice from the JCVI, 25 September 2020. UK Government, Sept 25, 2020. https://www.gov.uk/government/publications/priority-groups-for-coronavirus-covid-19-vaccination-advice-from-the-jcvi-25-september-2020 (accessed Oct 26, 2020).
6 US Centers for Disease Control and Prevention. The COVID-19 vaccination program interim operational guidance for jurisdictions playbook. Nov 5, 2020. https://www.cdc.gov/vaccines/covid-19/covid19-vaccination-guidance.html (accessed Nov 16, 2020).
7 Aw D, Silva AB, Palmer DB. Immunosenescence: emerging challenges for an ageing population. *Immunology* 2007; 120: 435–46.
8 Peng Y, Mentzer AJ, Liu G, et al. Broad and strong memory $CD4^+$ and $CD8^+$ T cells induced by SARS-CoV-2 in UK convalescent individuals following COVID-19. *Nat Immunol* 2020; 21: 1336–45.
9 Anderson EJ, Rouphael NG, Widge AT, et al. Safety and immunogenicity of SARS-CoV-2 mRNA-1273 vaccine in older adults. *N Engl J Med* 2020; published online Sept 29. https://doi.org/10.1056/NEJMoa2028436.
10 Walsh EE, Frenck RW Jr, Falsey AR, et al. Safety and immunogenicity of two RNA-based COVID-19 vaccine candidates. *N Engl J Med* 2020; published online Oct 14. https://doi.org/10.1056/NEJMoa2027906.
11 Zhu FC, Guan XH, Li YH, et al. Immunogenicity and safety of a recombinant adenovirus type-5-vectored COVID-19 vaccine in healthy adults aged 18 years or older: a randomised, double-blind, placebo-controlled, phase 2 trial. *Lancet* 2020; 396: 479–88.
12 Logunov DY, Dolzhikova IV, Zubkova OV, et al. Safety and immunogenicity of an rAd26 and rAd5 vector-based heterologous prime-boost COVID-19 vaccine in two formulations: two open, non-randomised phase 1/2 studies from Russia. *Lancet* 2020; 396: 887–97.
13 Xia S, Zhang Y, Wang Y, et al. Safety and immunogenicity of an inactivated SARS-CoV-2 vaccine, BBIBP-CorV: a randomised, double-blind, placebo-controlled, phase 1/2 trial. *Lancet Infect Dis* 2020; published online Oct 15. https://doi.org/10.1016/S1473-3099(20)30831-8.
14 Xia S, Duan K, Zhang Y, et al. Effect of an inactivated vaccine against SARS-CoV-2 on safety and immunogenicity outcomes: interim analysis of 2 randomized clinical trials. *JAMA* 2020; 324: 951–60.
15 Keech C, Albert G, Cho I, et al. Phase 1-2 Trial of a SARS-CoV-2 recombinant spike protein nanoparticle vaccine. *N Engl J Med* 2020; published online Sept 2. https://doi.org/10.1056/NEJMoa2026920.
16 Milligan ID, Gibani MM, Sewell R, et al. Safety and immunogenicity of novel adenovirus type 26- and modified vaccinia Ankara-vectored Ebola vaccines: a randomized clinical trial. *JAMA* 2016; 315: 1610–23.
17 van Doremalen N, Lambe T, Spencer A, et al. ChAdOx1 nCoV-19 vaccine prevents SARS-CoV-2 pneumonia in rhesus macaques. *Nature* 2020; 586: 578–82.
18 Folegatti PM, Ewer KJ, Aley PK, et al. Safety and immunogenicity of the ChAdOx1 nCoV-19 vaccine against SARS-CoV-2: a preliminary report of a phase 1/2, single-blind, randomised controlled trial. *Lancet* 2020; 396: 467–78.
19 Rockwood K, Song X, MacKnight C, et al. A global clinical measure of fitness and frailty in elderly people. *CMAJ* 2005; 173: 489–95.
20 Nimenrix: summary of medicinal product characteristics. Oct 28, 2020. https://www.medicines.org.uk/emc/medicine/26514#gref (accessed Oct 29, 2020).
21 Dicks MD, Spencer AJ, Edwards NJ, et al. A novel chimpanzee adenovirus vector with low human seroprevalence: improved systems for vector derivation and comparative immunogenicity. *PLoS One* 2012; 7: e40385.
22 Coughlan L, Sridhar S, Payne R, et al. Heterologous two-dose vaccination with simian adenovirus and poxvirus vectors elicits long-lasting cellular immunity to influenza virus A in healthy adults. *EBioMedicine* 2018; 29: 146–54.
23 Tapia MD, Sow SO, Mbaye KD, et al. Safety, reactogenicity, and immunogenicity of a chimpanzee adenovirus vectored Ebola vaccine in children in Africa: a randomised, observer-blind, placebo-controlled, phase 2 trial. *Lancet Infect Dis* 2020; 20: 719–30.
24 Wilkie M, Satti I, Minhinnick A, et al. A phase 1 trial evaluating the safety and immunogenicity of a candidate tuberculosis vaccination regimen, ChAdOx1 85A prime - MVA85A boost in healthy UK adults. *Vaccine* 2020; 38: 779–89.
25 Ewer K, Rampling T, Venkatraman N, et al. A monovalent chimpanzee adenovirus Ebola vaccine boosted with MVA. *N Engl J Med* 2016; 374: 1635–46.
26 Lambert PH, Ambrosino DM, Andersen SR, et al. Consensus summary report for CEPI/BC March 12–13, 2020 meeting: assessment of risk of disease enhancement with COVID-19 vaccines. *Vaccine* 2020; 38: 4783–91.
27 Goodwin K, Viboud C, Simonsen L. Antibody response to influenza vaccination in the elderly: a quantitative review. *Vaccine* 2006; 24: 1159–69.
28 Denis F, Mounier M, Hessel L, et al. Hepatitis-B vaccination in the elderly. *J Infect Dis* 1984; 149: 1019.
29 Williams K, Bastian AR, Feldman RA, et al. Phase 1 safety and immunogenicity study of a respiratory syncytial virus vaccine with an adenovirus 26 vector encoding prefusion F (Ad26.RSV.preF) in adults aged ≥60 years. *J Infect Dis* 2020; 222: 979–88.
30 Green CA, Sande CJ, Scarselli E, et al. Novel genetically-modified chimpanzee adenovirus and MVA-vectored respiratory syncytial virus vaccine safely boosts humoral and cellular immunity in healthy older adults. *J Infect* 2019; 78: 382–92.

1748

EXHIBIT "RA-46"

~~593~~

भारतीय आयुर्विज्ञान अनुसंधान परिषद
स्वास्थ्य अनुसंधान विभाग, स्वास्थ्य और परिवार कल्याण मंत्रालय, भारत सरकार

INDIAN COUNCIL OF MEDICAL RESEARCH

Indian Council of Medical Research
Department of Health Research, Ministry of Health and Family Welfare, Government of India

No. Grievance/2021/ICMR/6033

Dated: 30/09/2021

To
Shri Ambar Koiri
B-1501, Runwal Heights
LBS Road, Mulund West
Mumbai – 400 080

Subject: Application for providing certified copies of documents mentioned - regarding

Sir,

This is with the reference to your three different letters dated 14.09.2021. Please find enclosed herewith the reply received from the Division of Epidemiology and Communicable Diseases (ECD), for your information.

With kind regards,

Yours faithfully,

(Mahesh Chand)
Sr. Administrative Officer
Public Grievance Cell

वी. रामलिंगस्वामी भवन, पोस्ट बॉक्स नं. 4911,
अंसारी नगर, नई दिल्ली - 110 029, भारत

V. Ramalingaswami Bhawan, P.O. Box No. 4911,
Ansari Nagar, New Delhi - 110 029, India

Tel: +91-11-26588695 / 26588980 / 26589794
+91-11-26589336 / 26588707
Fax: +91-11-26588662 | icmrnic.in

1744

594

Following are the replies of three different letters dated 14.09.2021sent by Sh. Ambar Koiri, received at ICMR vide diary No. 608572 dated 21.09.2021 that

1. **I urgently require certified copies of documents relating to regulatory requirements for setting up a lab to conduct RT-PCR/RAT testing.**

The required documents that can be place under public domain have already been uploaded on ICMR COVID-19 Portal under the Tab "Testing Strategy". Ministry of Health and Family Welfare has issued a guideline for COVID-19 testing in private laboratories in India vide order No. Z.28015/23/2020-EMR dated 21.03.2020. The guideline is available in public, the same you can download from the ICMR official website at https://www.icmr.gov.in/pdf/covid/labs/Notification_ICMR_Guidelines_Private_Laboratories.pdf

Besides that, ICMR has published a call for applications from Government & Private Medical Colleges for setting up COVID-19 testing facility on dated 08.04.2020, which includes the requirement for setting up a COVID-19 testing facility. The same is available on ICMR official website https://www.icmr.gov.in/pdf/covid/labs/Invitation_from_Govt_Pvt_Medical_College-COVID19_testingfacility.pdf

2. **I urgently require certified copies of (1)All documents related to the Isolation of SARS-CoV-2 virus in Indian Laboratories, (2) All document s pertaining to studies conducted by Indian scientists in Indian Institutes of repute which have established the infectiousness of the novel virus, together with peer reviewed research, that proves beyond any reasonable doubt, that the SAR-CoC-2 is the sole cause of the disease, Covid-19, (3) Please provide all documents confirming that the Indian Government holds samples of the virus (SARS-Cov-2).**

ICMR guidelines, publications etc. that could be disseminated in public domain have already been uploaded on ICMR website. Please visit "COVID-19 Tupeline" Tab on ICMR COVID-19 Portal.

1) SARS-CoV-2 was first isolated in India by ICMR-National Institute of Virology, Pune. The study was subsequently published in April 2020, and can be accessed at:https://doi.org/10.4103/ijmr.IJMR_1029_20

2) All studies related to COVID-19 undertaken by ICMR may be accessed at: https://www.icmr.gov.in/cpapers.html and

NOTARY M. M. PABALE Mumbai Maharashtra Reg. No. 15220 Expiry Dt. 30-10-2024 GOVT. OF INDIA

17 45
~~595~~

https://niv.co.in/COVID_19_publications_%20from_ICMR_NIV%20.pdf.These research article are available in public domain and article of your interest can be accessed from the respective publishers website.

3) Guidelines for storage of specimens for COVID-19 diagnosis issued by ICMR for Govt. and Pvt. are-

i. A Guidelines for storage of respiratory specimens collected for COVID-19 diagnosis by RT PCR platforms in Government laboratories dated 25/06/2020 available on ICMR official website at https://www.icmr.gov.in/pdf/covid/labs/Govt_labs_sample_retention_advisory_25062020.pdf

ii. A guidelines for positive sample storage by ICMR approved private labs that are doing COVID-19 testing by Real time RT-PCR/CB-NAAT/TrueNat dated 11/06/2020available on ICMR official website athttps://www.icmr.gov.in/pdf/covid/labs/Private_Lab_Advisory_11062020.pdf

3. **I urgently require certified copies of (1) Please provide all peer reviewed scientific evidence used to implement mandatory mask wearing, (2) Please provide all peer reviewed scientific evidence use to implement testing of asymptomatic people, (3) Please provide all peer reviewed scientific evidence used to implement lockdowns and night curfews, (4) Please provide all peer reviewed scientific evidence used to implement Social distancing guidelines, (5) Please provide all documents relating to research undertaken by Central Agencies as proof of asymptomatic transmission of the novel virus.**

As mentioned above, all information that could be available to public have already been uploaded on ICMR website, you may visit on ICMR COVID-19 portal.

1) There are several advisories issued by national and international health organization for use of Mask to reduce the risk of COVID-19 infection.

i. WHO: Coronavirus disease (COVID-19) advice for the public: When and how to use masks. Available at https://www.who.int/emergencies/diseases/novel-coronavirus-2019/advice-for-public/when-and-how-to-use-masks. As per the WHO's guidance on Mask Use in the context of COVID-19 dated 1 December 2020, reviews significant published literature on mask use to prevent COVID-19 and provides guidance. The studies reviewed are listed in the WHO document. The studies were carried out in different settings

1746

~~596~~

(community as well as healthcare settings) and helped formulate the guidance provided by WHO on mask use.

ii. CDC Atlanta: Guidance for Wearing Masks. Available at https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/cloth-face-cover-guidance.html

iii. MoHFW, GoI, New Delhi: Novel Coronavirus Disease 2019 (COVID-19): Guidelines on rational use of Personal Protective Equipment. Available at https://www.mohfw.gov.in/pdf/GuidelinesonrationaluseofPersonalProtectiveEquipment.pdf.

iv. A systematic review and meta-analysis published by Chu et al also advocates physical distancing of at least 1 m (2 m being more effective), use of face masks, and eye protection to prevent the spread of COVID-19. These are available in the public domain, and can be accessed at: https://www.who.int/publications/i/item/advice-on-the-use-of-masks-in-the-community-during-home-care-and-in-healthcare-settings-in-the-context-of-the-novel-coronavirus-(2019-ncov)-outbreakandhttps://doi.org/10.1016/S0140-6736(20)31142-9

2) As per the WHO's Recommendations for SARS-CoV-2 testing strategies and diagnostic capacities: Interim Guidance dated 25 June 2021, states criteria for testing of asymptomatic people based on peer-reviewed articles. This may be accessed at: https://apps.who.int/iris/bitstream/handle/10665/342002/WHO-2019-nCoV-lab-testing-2021.1-eng.pdf?sequence=1&isAllowed=y

3) ICMR has not conducted such study. However, the impact of lockdowns and other interventions in reducing the spread of COVID-19 have been documented in articles which can be accessed at:

i. https://doi.org/10.4103/ijmr.IJMR_4051_20

ii. https://doi.org/10.4103/ijmr.ijmr_1627_210

4) ICMR has not conducted such study. A systematic review and meta-analysis published by Chu et al also advocates physical distancing of at least 1 m (2 m being more effective), use of face masks, and eye protection to prevent the spread of COVID-19. This can be accessed at:https://doi.org/10.1016/S0140-6736(20)31142-9

5) The Indian Council of Medical Research has conducted 4 nationwide sero-prevalence studies. Details of the studies are available at the following links:

i. 1st seroprevalence study results:https://doi.org/10.4103/ijmr.IJMR_3290_20

ii. 2nd seroprevalence study results:https://doi.org/10.1016/S2214-109X(20)30544-1

iii. 3rd seroprevalence study results: https://doi.org/10.1016/j.ijid.2021.05.040

iv. 4th seroprevalence study press release:https://pib.gov.in/PressReleasePage.aspx?PRID=1739902

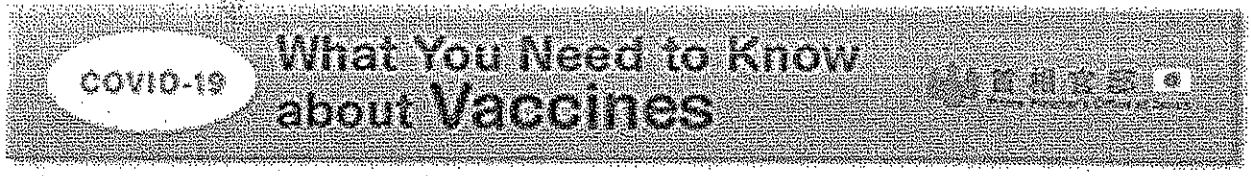
NOTARY M.M. PABALE Mumbai Maharashtra Reg. No. 15220 Expiry Dt. 30-9-2024 GOVT. OF INDIA

1747
~~597~~

EXHIBIT "RA-47"

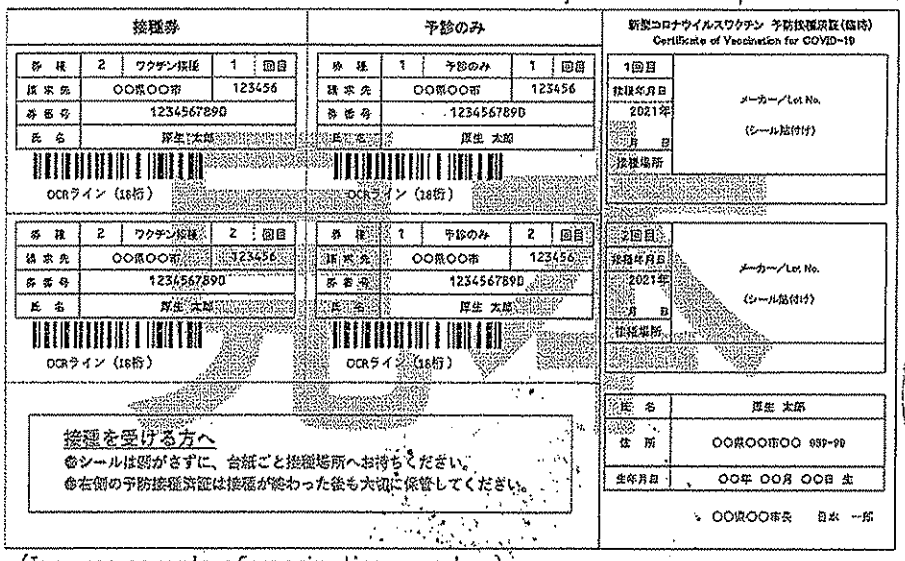
COVID-19 Vaccines

Important Notice

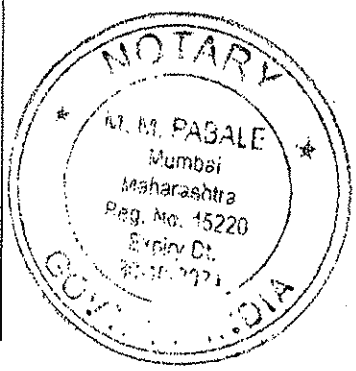


Free of charge to anyone eligible

The costs of vaccination is free for all Japanese citizens and all eligible foreign residents in Japan. The municipality in which you reside will send you a "Vaccination voucher" and a "COVID-19 vaccine notification"*. Vaccines will be supplied gradually, and the eligibility are prioritized based on age and other factors. The vaccine is administered only with the recipient's consent.



(Image: sample of vaccination voucher)



1748

598 sample of vaccination voucher［PDF形式：168KB］

Call Center (Toll Free)

■ **MHLW Call Center: 0120-761-770** (Every day including weekends and holidays)
-English, Chinese, Korean, Portuguese and Spanish: 9:00-21:00 ／ Thai: 9:00-18:00 ／ Vietnamese: 10:00-19:00

■ **FRESC Help Desk: 0120-76-2029** (Monday-Friday 9:00-17:00) PDF
-Vietnamese, Chinese, English, Korean, Spanish, Portuguese, Nepali, Thai, Indonesian, Filipino, Myanmar, Khmer(Cambodian), Mongolian, French, Sinhala, Urdu, Bemgali

Multilingual Information

Translations of Notifications and Prevaccination Screening on Multilingual

Vaccination certificate for/from overseas

【Vaccination certificate for overseas】
The vaccination certificate is issued to those who need to present it at international travel occasions. Learn more

【Vaccination certificate from overseas】
List of coutries and regios that issue vaccination certificates reconized as vaild by Japan. Learn more

Vaccine Q&A

Japanese version

NOTARY M. M. PASALE Mumbai Maharashtra Reg. No. 15220 Expiry Dt. 30-10-2024 GOVT. OF INDIA

ページの先頭へ戻る

How to get vaccinated

Receive a "Vaccination voucher" and a "COVID-19 vaccine notification"

1749

~~599~~

You will receive a "Vaccination voucher" and a "COVID-19 vaccine notification" from the municipalities. Vaccines will be supplied gradually, and the eligibility are prioritized based on age and other factors.

Find available medical institutions and vaccination sites

You may find a medical institution or vaccination site for your COVID-19 vaccine from municipal website, newsletters and "Vaccine Navi" web. Please choose your city of residence, and you can find a medical institution or vaccination site, and check the availability.

Make a reservation for the first dose by phone or online

You will be able to make a reservation for your first vaccination dose by phone or online. "Vaccine Navi" web will help you to find the phone number and the online reservation sites. Please check the availability before making a reservation. Some municipalities and medical institutions might give you an opportunity to schedule for both the first and the second doses at the first contact.

Visit the vaccination site you reserved

Please show your vaccination voucher (without detaching any sticker), and your ID (residence card, driver's license, or health insurance card etc.) at the reception. As you will have the injection to your shoulder muscle, please wear a T-shirt or other clothes that you can show your shoulder easily. Screening questionnaire is available in Japanese. If you are more comfortable with other languages, please refer to the "translations in 17 languages"and check corresponding items in the Japanese form. It is recommended to fill the questionnaire before you visit the vaccination site if possible.

Make a reservation for the second dose

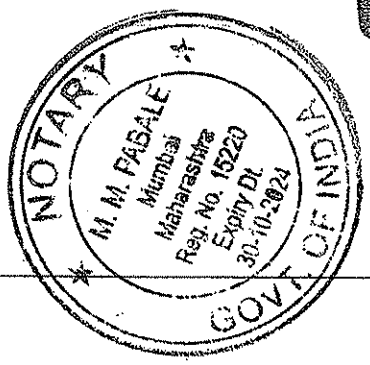
Follow the same reservation process as you did for the first dose. (Some medical institutions may provide reservations for the first and the second doses at the first contact.) It is important that you receive two doses of your COVID-19 vaccine. The interval should be at least three weeks between the two doses if you receive the COVID-19 Pfizer [Comirnaty] vaccine; at least four weeks between the two doses if you receive the Moderna COVID-19 vaccine. If you had Astrazeneca vaccine, the interval between two doses is usually 4-12 weeks. However, in order to ensure maximum efficacy, it is best to leave at least eight weeks. Please get the second vaccination as soon as possible if you have exceeded the period.

NOTARY Mumbai Maharashtra

Video Instruction (in Japanese)

1750
1750
600

新型コロナワクチンを受けるには



ページの先頭へ戻る

Search Vaccination Sites

How to find your local vaccination site

Find the Vaccination site from "Vaccine Navi" web in Japanese, Yasashii-Nihongo, English and Chinese.

ページの先頭へ戻る

About Vaccines

Available Vaccines in Japan

-Pfizer Inc. ※Learn more
Vaccine name: Comirnaty
Pharmaceutical approval: February 14, 2021
Vaccine type: mRNA vaccine
Number of times to administer: twice
Vaccination interval: 21 days

-Takeda Pharmaceutical Company Limited/Moderna Inc. ※Learn more
Vaccine name: Moderna COVID-19 vaccine
Pharmaceutical approval: May 21, 2021
Vaccine type: mRNA vaccine

175)
~~601~~

Number of times to administer: twice
Vaccination interval: 28 days

-AstraZeneca PLC ※Learn more
Vaccine name: Vaxzevria
Pharmaceutical approval: May 21, 2021
Vaccine type: viral vector vaccine
Number of times to administer: twice
Vaccination interval: 28~84 days (56-84 days for maximum efficacy)

Click here for COVID-19 vaccination instruction of Pfizer, Moderna and AstraZeneca in other languages

The Relief System for Injury to Health with Vaccination

Vaccinations may cause health problems (illness or disability). Although this is extremely rare, the risk cannot be eliminated, and a relief system has been established for this reason. In the case of health damage as a result of the vaccine from the COVID-19 vaccine, relief (medical expenses, disability pension benefits, etc.) is also available under the Immunization Act. Please consult with the municipality where your residence is located regarding the procedures required for application.

Consent to vaccination

Although we encourage all citizens to receive the COVID-19 vaccination, it is not compulsory or mandatory. Vaccination will be given only with the consent of the person to be vaccinated after the information provided. Please get vaccinated of your own decision, understanding both the effectiveness in preventing infectious diseases and the risk of side effects. No vaccination will be given without consent. Please do not force anyone in your workplace or those who around you to be vaccinated, and do not discriminate against those who have not been vaccinated.

・Human Rights Counseling in foreign languages

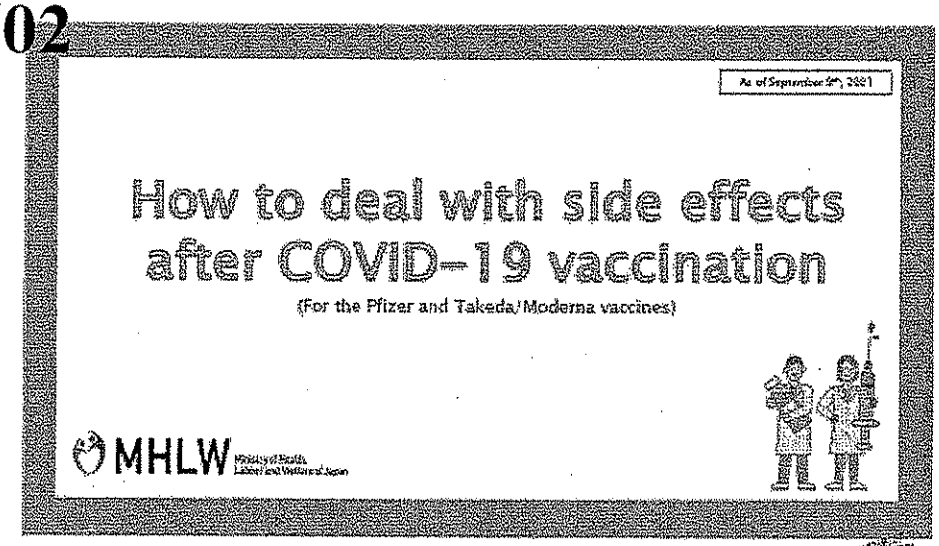
ページの先頭へ戻る

Side Effects after vaccination

NOTARY
M. M. PAGALE
Mumbai
Maharashtra
Reg. No. 15220
Expiry Dt.
30-10-2024
GOVT. OF INDIA

1752

602



How to deal with side effects after COVID-19 vaccination

ページの先頭へ戻る

やさしいにほんごのしりょう

ワクチンを打（う）ってもらうときにあなたに質問（しつもん）すること

新型コロナワクチンを打ってもらうときにあなたに質問することを、やさしいにほんごにしています。質問のこたえを、予診票に書いてわたします。

説明書（せつめいしょ）

新型コロナワクチンを打ってもらうときの説明のための書類です。

- ファイザーという会社のワクチンについて
- モデルナという会社のワクチンについて
- アストラゼネカという会社のワクチンについて

接種（せっしゅ）のおしらせ

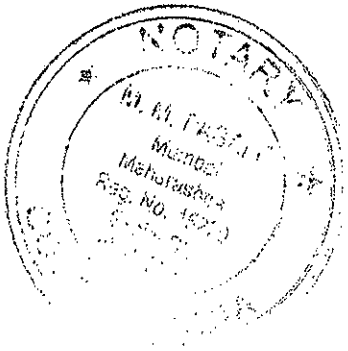
新型コロナワクチンを打ってもらうときのためのおしらせです。

- 外国人の方へ
- 療育手帳（愛の手帳）をおもちの方へ

ページの先頭へ戻る

PDFファイルを見るためには、Adobe Readerというソフトが必要です。Adobe Readerは無料で配布されていますので、こちらからダウンロードしてください。

1753
603



1754
~~604~~

EXHIBIT "RA-48"

Our response to the Affidavit filed by the State Government

On behalf of the state, Dr. Sadhana Tayade has given a response to our petition. Her main arguments can be summarized as follows:

a) Vaccination reduced rates of hospitalization of Covid-19 patients

b) Suggests that there is some evidence that vaccination will make it less likely that we will pass the virus on to others

Our response to these is as follows

a) To support their first point, the respondent has attached a graph on page 953 where the numbers show that the rates of hospitalization have come down as the vaccination rate has increased. This does not prove that the vaccination has reduced the hospitalizations as the hospitalization rate typically peaks at a certain time during the year according to the season, and then declines on its own. This phenomena could be observed in the year 2020 as well, where after the first wave, infections, Covid hospitalizations and deaths declined on their own without any vaccine being developed. Many Indian experts gave statements at that time trying to hypothesize why this phenomena took place, and mentioned many factors like herd immunity, Indians having better immunity, seasonality effect, etc.

In order to make their case that it is vaccines which reduced the hospitalization, the respondent should attach segregated data which shows how many vaccinated vs unvaccinated patients are admitted in the hospitals.

We have attached counter data in the petition above which shows that in Bangalore and Kerala, it is the vaccinated who are taking up more than 50% of the hospital beds. The same phenomena can also be observed in UK , USA & Israel, which is also referenced in our petition.

We have also attached peer reviewed scientific studies above which show that Ivermectin, Omega3 fatty acids, Vitamin D, Black seeds, Nutritional and oxidative therapies, & Arginine have also been proven to reduce covid-19 infections, hospitalizations and deaths. So even if the vaccines are effective in reducing hospitalizations, they are by no means the only tool at our disposal.

B) In their reply, the respondent mentions on page 951 that there is some evidence that the vaccines would reduce the chance of the virus spreading, but have attached no evidence of the same. In contrast to that, we have attached plenty of documented evidence to show that the vaccines do not reduce the chance of infection/transmission. We have attached 8 scientific studies which shows that the viral load of a vaccinated person is same or more than the viral load of an unvaccinated person. We have also attached studies which show that vaccinated people are 13 times more likely to spread the virus compared to those naturally immune according to one study, and 27 times more likely in another study. We have also attached data from Assam, India, which shows that 80% of their total Covid cases have occurred in the vaccinated, and a global study done on 67 countries which shows that the countries with the most number of vaccines administered also had the highest cases.

C) The respondent also supports our point in their own affidavit on page 959 regarding vaccines being voluntary. Relevant portion is referenced below: "Is it mandatory to take the vaccine?

Vaccination for Covid-19 is voluntary"

They also support our point in their affidavit on page 960 regarding vaccines not stopping transmission.

"Do I need to use the mask/other Covid-19 appropriate precautions after receiving the vaccine?

NOTARY
M. M. PAGALE
Mumbai
Maharashtra
Reg. No. 15220
Expiry Dt.

1756
606

Yes, it is absolutely necessary that everyone who has received the Covid-19 vaccine should continue to follow the Covid-19 appropriate behavior i.e. mask, do gaj ki doori and hand sanitization to protect themselves and those around from spreading the infection.

How long will I remain protected after vaccination?

Longevity of immune response in vaccinated individuals is yet to be determined. Hence, continuing the use of masks, handwashing, physical distancing, and other Covid-19 appropriate behaviors is strongly recommended."



EXHIBIT "RA-49"

Natural Immunity vs Vaccine Immunity Table

Sr. No.	Points of concern and comparison	Vaccine Generated Immunity	Immunity developed due to Covid-19 infection i.e. Natural Immunity
1.	Protection from infection	Double Dose of vaccine having no guarantee of person not getting infected or spreading the infection. Vaccinated person is 13-27 times more likely to get infected than a naturally immune person. (Pg No 960 Pt 23 of reply affidavit by State)	Person is fully protected and safest. He is 13-27 times less likely to get infected than a vaccinated person. He is highly unlikely to spread the infection as he is highly unlikely to get infected in the first place.
2.	Longevity of immunity developed	As per reply affidavit filed by the State at Pg. No. 960 Point No. 24, there is no study of longevity of such immunity in vaccinated people. (But dishonest officers try to give the credit of natural immunity to vaccines)	Immunity development due to infection lasts for decades (as witnessed from other viral respiratory illnesses of the past like Sars and spanish influenza).

~~15~~ 1758

~~608~~

3.	A] Expense of public money required B] Who will be benefited	A] Thousand of crores B] Only vaccine companies and corrupt officials will be benefited	A] Free of cost. As it is already developed in the body. Already two third of Indias population is having antibodies. B] Country's money will be saved and economy will grow up as such persons are treated as protected, which they actually are.
4.	Side effects	Serious death causing side effects	No side effects, but if naturally immune person is vaccinated he faces worse side effects compared to someone who is not naturally immune
5.	Public benefits or reasons for recommending.	A] No guaranteed public benefit of protection from infection or death or saving the public money is found. Cannot be recommended over natural immunity or for persons having risks. B] Giving vaccines to	A] Since already more than 2/3rd of the population have developed antibodies therefore herd immunity is developed. Scientists recommends that the persons with natural immunity are the safest and recognizing them

NOTARY M. M. Pandey Mumbai Maharashtra Reg. No. 15220 City Dt. GOVT. OF INDIA

		the person with natural immunity is causing much harm and with no additional benefits. Therefore not recommended for more than two third population	will be helpful for everyone and also for the economy of our country.
6.	Variants	Very less efficacy against variants, as immunity is developed only against the spike protein.	Offers protection against almost all variants, as immunity is developed against all parts of the virus.
7.	Immunity Location	Generates antibodies in the blood, whereas sars-cov-2 infection takes place via the mouth and respiratory tract	Generates immune cells at the point of entry of the virus, to preemptively stop an infection before it happens



1760

~~610~~

EXHIBIT "RA-50"

Will Omicron End The Pandemic? Top Experts Say Omicron May Act As 'Natural Vaccine' For Covid-19

Source: Outlook

Link: https://www.outlookindia.com/website/story/india-news-with-mild-symptoms-omicron-is-probably-natural-vaccine-top-scientists-doctors/406227

Author: Jeevan Prakash Sharma

Published on: 22 Dec 2021,

NOTARY
M. M. PADALE
Mumbai
Maharashtra
Reg. No. 15220
Expiry Dt.
30-10-2024
INDIA

Since the Omicron variant of Coronavirus is spreading much faster and is not impacting the patients much, doctors believe that this might act as a natural vaccine against Covid-19.

Omicron, the new variant of the Covid-19 virus (Sars-Cov-2), has been spreading five times faster than its previous variants globally. However, shreds of evidence available so far show that its symptoms are mild. People who have contracted it are either asymptomatic or have mild symptoms such as cough, stuffy nose or fatigue.

Due to these reasons, a section of top scientists and doctors have played down the fear among people and said that the Omicron might work as a natural vaccine itself.

Noted immunologist, Gobardhan Das, who is Professor of Molecular Medicine at Jawaharlal Nehru University, said, "I believe Omicron is probably the natural vaccine. Omicron is the version of the Delta variant with additional mutation. If you have seen its symptoms, people are not getting hospitalised. It is casing very mild symptoms."

He adds, "So it suggests that over a period of time, this virus has attenuated itself. This is like our vaccine strategy where we make attenuation in the virus and administer it to people."

Considering its high rate of infectivity, which is five times more than the Delta variant, Prof Das is of the view that Omicron is the better vaccine than any available vaccine.

"The whole virus is going inside the body which has multiple mutations. So the more the body fight against the virus, the better is the immune response. This will produce a better response. It is happening for good as it will produce a better immune response," Prof Das said.

Another noted immunologist Dr. N K Mehra, former dean of AIIMS and honorary emeritus scientist, Indian Council of Medical Research, says, "I fully support this view because as of now it is very mild and it can prove to be a boon in disguise. Two international studies have shown that it grows ten times slower than the Delta variant in the lungs which is a very good sign. We need to see the data for another few weeks to find out if it behaves in a similar way in all the countries."

"Having said that, I will also advise people not to lower their guards because if the numbers will go exponentially high, then people will rush towards hospitals, not due to severity but out of panic, and health infrastructure will be overwhelmed. There is also a possibility that treatment may cause more harm. Hence, we need to keep all the precautions on."

Dr. Sandeep Budhiraja, Group Medical Director of Max Healthcare & Senior Director, Institute of Internal Medicine seconds with both Prof Das and Dr. Mehra on the basis of the current data.

"The data which is available so far and what we have seen so far from our experience of Omicron is that this is going to work as a live attenuated vaccine. Since it is highly infectious and spread very fast but hopefully it is going to cause mild illness for most people, it will act as a booster dose for those who are vaccinated and a vaccine dose for those who are unvaccinated," Dr. Budhiraja said.

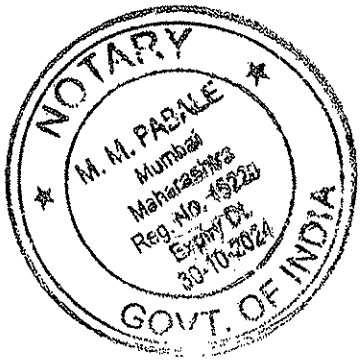
He says that this is good for poor countries like those in Africa where vaccine uptake is very low and so this virus may act as a natural vaccine and give additional protection to the people.

"If that be the case then this is one way by which this pandemic actually can come to an end. Although I think it is too early and we need to wait about a few more weeks," Dr. Budhiraja said.

He added, "Right now the data that we have is mainly coming from South Africa. That data may or may not be applicable or replicable for all other countries because of the population, seroprevalence, etc so we will have to wait and watch the data especially one that is coming from the UK for the next two weeks. But if it turns out to be mild I do agree that this actually would be more of a blessing and can help overcome this pandemic."

Dr. Amitav Banerjee, Head, Department of Community Medicine, Dr. DY Patil Medical College Pune, agrees that viruses mutate to adapt themselves so that they can survive and which according to him is Darwin's Law.

"We also call it Nature's Law of adaptation. The new mutant, according to the available data and report, is causing very mild and self-limiting symptoms," Dr. Banerjee added.



Dr. Banerjee is of the view that a deadly virus dies with the person whom it infects but a variant that causes a very mild infection survives and spreads fast. This is so because it is so mild that most of the time people remain asymptomatic and don't even isolate themselves.

He added, "In this wild goose chase for mutating viruses we may end up chasing a version of the common cold! We should ask whether it is worth the effort? We should weigh the collateral harm which will ensue. To mitigate the impact of mutants, if any, we should resort to focused protection including vaccination of high risk groups while the young & healthy can lead normal lives."



1764
~~614~~

EXHIBIT "RA-51"

माझा देश, माझी जबाबदारी

मानव अधिकार सुरक्षा परिषद, पुसद तर्फे जनहितार्थ प्रकाशित

(नमुना अर्ज)

प्रति,

जिल्हाधिकारी/जिल्हा न्यायदंडाधिकारी,

यवतमाळ तथा अध्यक्ष जिल्हा आपत्ति

व्यवस्थापन प्राधिकरण,

जिल्हाधिकारी कार्यालय, यवतमाळ

लॉक-डाऊन व इतर निर्बंधनामुळे क्षती झालेल्या अर्जदारास आपत्ति व्यवस्थापन कायद्यातिल नियम १२ (एफ) व साथरोग अधिनियम, १८९७ चे कलम २ नुसार नुकसान भरपाई देणेबाबत विनंती अर्ज.

१. नाव : [illegible]

२. वय : [illegible]

३. पत्ता : [illegible]

[illegible]

४. धंदा : व्यावसाईक/शेतकरी/इतर.

शेत मजुरी

NOTARY
M. M. PABALE
Mumbai
Maharashtra
Reg. No. 15220
Expiry Dt.
30-10-2021
GOVT. OF INDIA

Dispatcher
Dispatch
S.D.O. Office, Pusad.

५. क्षतीचे विवरण: लॉक-डाउन व प्रतिबंधक योजनांचा कालावधी माहे एप्रिल २०२० ते सप्टेंबर

अंदाजे ५०,०५० लाख/कोटी रुपये. (एकूण नुकसानाच्या दुप्पट रक्कम

६. व्यवसायाचे व नुकसानीचे विवरण: करिता संबंधित पत्रे/घोषणापत्रे/प्रतिज्ञालेख/छायाप्रती/

विडिओ/स्वत:च्या/मित्रांच्या /इति बँक खात्याचे

विवरण इ.

७. वित्तीय स्थिति: (i) आपत्ति व्यवस्थापन कायदा, २००५ चे नियम १२ पुढीलप्रमाणे;

"१२. क्षतिपूर्ती च्या किमान मापदंडाकरिता मार्गर्शक तत्वे – "राष्ट्रीय प्राधिकरण, आपत्तीमुळे प्रभावित झालेल्या व्यक्तिंना मदत करण्याच्या किमान मानकांसाठी मार्गर्शिक तत्त्ववांची शिफारस करेल, ज्यात समाविष्ट–

(i) मदत शिबिरांमध्ये निवारा, अन्न, पिण्याचे पाणी, वैद्यकीय सुविधा आणि स्वच्छतेसाठी पुरवल्या जाणाऱ्या किमान आवश्यकता;

(ii) विधवा आणि अनाथांसाठी करण्यात येणाऱ्या विशेष तरतुदी;

(iii) जीवित हानी आणि घरांच्या नुकसानीच्या विरूद्ध सहाय्य आणि उपजीविकेच्या साधने पुनर्संचयीत करण्यासाठी सहाय्य;

(iv) आवश्यक असणारी इतर मदत.

(ii) साथरोग अधिनियम, १८९७ चे नियम २ पुढीलप्रमाणे;

"२. अशा प्रादुर्भावास किंवा प्रसारास प्रतिबंध करण्यासाठी [त्यास] आवश्यक वाटतील त्या उपाययोजना स्वतः करू शकेल किंवा एखाद्या व्यक्तीस तसे करण्यास फर्मावू शकेल अगर तिला तसे करण्याची शक्ती देऊ शकेल आणि जाहीर नोटिशीद्वारे, आवश्यक वाटतील असे तात्पुरते निर्बंध विहित

1766
616

करून, जनतेने किंवा कोणत्याही वर्गातील व्यक्तीने त्यांचे पालन केले पाहिजे असे फर्मावू शकेल, आणि तसेच, झालेला खर्च (भरपाईची रक्कम जसेल तर अशी रक्कम धरून) कशा रीतीने व कोणाकडून भागवण्यात येईल ते ठरवून देऊ शकेल."

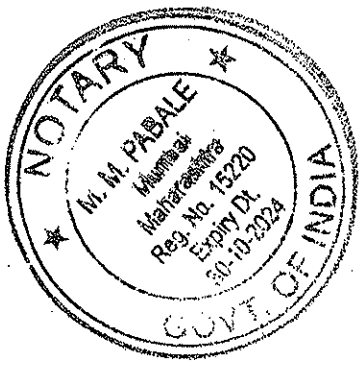
८. **विनंती:** तरी अर्जदारास त्वरीत नुकसान भरपाई रु. 50,000 देण्यात यावी.

सही

[redacted]

नाव शे सलीम शे मजहर

पत्ता मुलतानवाडी - पुसद



फोन [redacted]

pH.37LK14a

NOTARY
M. M. PABALE
Mumbai
Maharashtra
Reg. No. 15220
Expiry Dt.
30-10-2024
GOVT. OF INDIA

९. **अतिरिक्त:**

अर्जदारासारख्या पिडीत नागरिकांना नुकसान भरपाईची रक्कम देण्यास टाळा-टाळ करण्यासाठी सरकारला कोणतेही निमित्त उपलब्ध नाही, कारण सरकार सर्व सरकारी अधिकारी/कर्मचारी/लोकप्रतिनिधि/आमदार/खासदार इतर यांना पूर्ण पगार देत आहे.

सर्व सामान्य माणसाचे उदरनिर्वाह वगळता सर्व काही सुरळीत सुरू आहे.

म्हणूनच, सामान्य माणसाला नुकसान भरपाई न देण्यामागे सरकारकडे कोणतेही संयुक्तीक कारण नाही. न्यायालयात सरकारला कोणताही बचाव घेता येणार नाही.

खरं तर, ही सर्व मुख्यमंत्र्यांची जबाबदारी आहे आणि हे त्यांचे प्रथम कर्तव्य आहे.

1767
~~617~~

टीप:

यापूर्वी १८९६ ते १९१८ या कालावधीत पुणे प्लेगमध्ये झालेल्या हाणीचे ब्रिटिश सरकारने याच नियमांतर्गत उपाययोजना करीत पीडित नागरिकांना नुकसानीची भरपाई दिली होती.

https://indianexpress.com/article/research/how-oppressive-containment-measures-during-poona-plague-led-to-assassination-of-british-officer-6450775

सही

नाव शेख लक्ष्मीय शे. महजर

पत्ता मुलतान वाडी - पुसद

फोन नं. 8378960404

प्रतिलिपी,

१) मा. उपविभागीय दंडाधिकारी साहेब, पुसद जि. यवतमाळ

२) मा. मुख्यमंत्री साहेब, महाराष्ट्र राज्य मुंबई - ३२

NOTARY
M. M. PABALE
Mumbai
Maharashtra
Reg. No. 15220
Expiry Dt.
GOVT. OF INDIA

1768

618

भारत सरकार
GOVERNMENT OF INDIA



शेख तस्लीम शेख मज़हर
Shaikh Taslim Shaikh
Mazhar
[illegible] DOB: 01/01/1996
पुरुष/MALE

8349 5783 1292

भारतीय विशिष्ट पहचान प्राधिकरण
[illegible] OF INDIA

पत्ता:
मूल्तानवाडी कवडीपुर,
[illegible],
कावडीपूर, यवतमाळ,
महाराष्ट्र-445215

Address:
Multanwadi kawadipur,
Post.Pardi Tq.Pusad,
Kawadipur, Yavatmal,
Maharashtra -445215

8349 5783 1292

NOTARY
M. M. PABALE
Mumbai
Maharashtra
Reg. No. 15220
Expiry Dt.
30-10-2024
GOVT. OF INDIA

1769

~~619~~

SBI-KIOSK BANKING

Identity Card

CIF Number:	[illegible]
Account Number:	[illegible]
IFSC Code:	SBIN0000459
First Name:	SHAIKH
Middle Name:	YASIN
Last Name:	SHAIKH
Address:	MULTANWADI KAWADIPUR PARDI DIST-YAVATMAL
Village Name:	PUSAD
PinCode:	445215
KNO Name:	SUDHAKAR SANDE
KIOSK Location:	PALODI



NOTARY

M. M. PABALE

Mumbai

Maharashtra

Reg. No. 15220

Expiry Dt.

GOVT. OF INDIA

1770

~~620~~

EXHIBIT "RA-52"

REPORT NO.
72

सत्यमेव जयते

PARLIAMENT OF INDIA
RAJYA SABHA

DEPARTMENT-RELATED PARLIAMENTARY STANDING COMMITTEE
ON HEALTH AND FAMILY WELFARE

SEVENTY SECOND REPORT

Alleged Irregularities in the Conduct of Studies using Human Papilloma Virus (HPV) Vaccine by Path in India (Department of Health Research, Ministry of Health and Family Welfare)

(Presented to the Rajya Sabha on 30th August, 2013)
(Laid on the Table of Lok Sabha on 30th August, 2013)

NOTARY M. M. PARAB Mumbai Maharashtra No. 15220 GOVT. OF INDIA

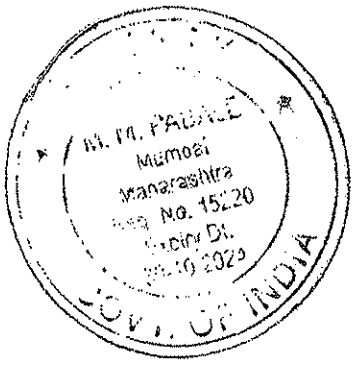
भारतीय संसद, राज्य सभा
PARLIAMENT OF INDIA, RAJYA SABHA

Rajya Sabha Secretariat, New Delhi
August, 2013/Bhadra, 1935 (Saka)

1771

~~621~~

M. M. PABALE
Mumbai
Maharashtra
Reg. No. 15220
Expiry Dt.
30-10-2024
GOVT. OF INDIA



Website:http://rajyasabha.nic.in
E-mail:rs-chfw@sansad.nic.in

1772
622

Hindi version of this publication is also available

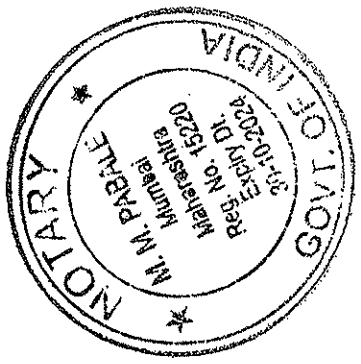
PARLIAMENT OF INDIA
RAJYA SABHA

DEPARTMENT-RELATED PARLIAMENTARY STANDING COMMITTEE ON HEALTH AND FAMILY WELFARE

SEVENTY SECOND REPORT

Alleged Irregularities in the Conduct of Studies using Human Papilloma Virus (HPV) Vaccine by Path in India (Department of Health Research, Ministry of Health and Family Welfare)

(*Presented to the Rajya Sabha on* 30*th August,* 2013)
(*Laid on the Table of Lok Sabha on* 30*th August,* 2013)





Rajya Sabha Secretariat, New Delhi
August, 2013/Bhadra, 1935 (Saka)

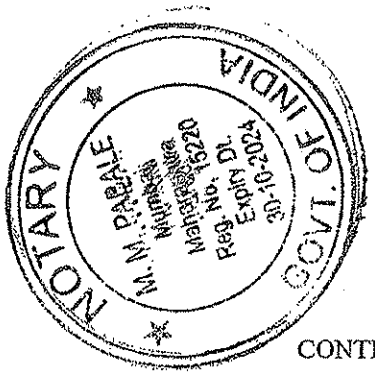
1773

~~623~~

NOTARY
M. M. PABALE
Mumbai
Maharashtra
Reg. No. 15220
Expiry Dt.
31-10-2024
GOVT. OF INDIA

1774

624

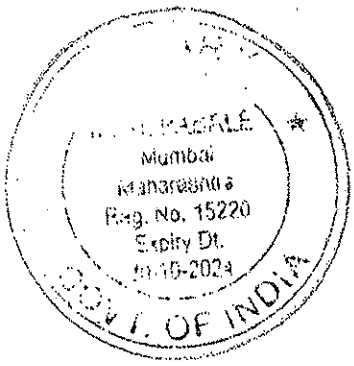


CONTENTS

		Pages
1.	Composition of the Committee	(i)-(vi)
	Composition of the Committee (2009-10)	(i)
	Composition of the Committee (2010-11)	(ii)
	Composition of the Committee (2011-12)	(iii)-(iv)
	Composition of the Committee (2012-13)	(v)-(vi)
2.	Preface	(vii)-(viii)
3.	Acronyms	(ix)-(x)
4.	Report	1—19
	(I) Background	1—3
	(II) Nature of Project	3—4
	(III) Role of Department of Health Research/ICMR	4—7
	(IV) Role of Drug Controller General of India	7—8
	(V) Marketing Approval to HPV Vaccine in India	8—9
	(VI) Inquiry Committee	9—16
	(a) Composition and Terms of Reference	9
	(b) Conflict of Interest	9—10
	(c) Adverse Events Reporting	10
	(d) Informed Consent	11—13
	(e) Role of Ethics Committees	13
	(f) Use of Official Machinery	13—14
	(g) Action taken on the Inquiry Committee Report	14—16
	(VII) Programmes for Appropriate Technology in Health (PATH)	16—19
5.	Observations/Recommendations — At a Glance	20—24
6.	Minutes	25—34
7.	Annexures	35—41

1775

~~625~~



1776

626

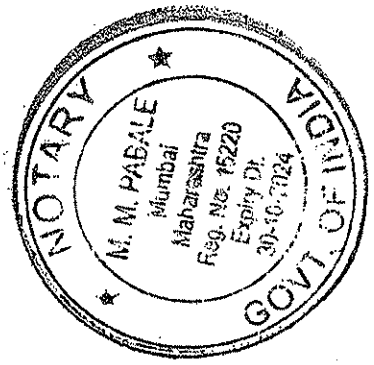
COMPOSITION OF THE COMMITTEE
(2009-10)

RAJYA SABHA

1. Shri Amar Singh — *Chairman*
2. Shrimati Viplove Thakur
#3. Dr. Radhakant Nayak
4. Shri Janardan Dwivedi
5. Shri Balbir Punj
6. Dr. Prabhakar Kore
7. Shrimati Brinda Karat
8. Shrimati Vasanthi Stanley.
@9. Dr. M.A.M. Ramaswamy
10. Dr. Anbumani Ramadoss

LOK SABHA

11. Shri J. M. Aaron Rashid
12. Shri Ashok Argal
13. Shrimati Sarika Devendra Singh Baghel
14. Shri Vijay Bahuguna
15. Dr. Chinta Mohan
16. Shrimati Tabassum Hasan
17. Dr. Sanjay Jaiswal
18. Shri S. R. Jeyadurai
19. Dr. (Shrimati) Kruparani Killi
20. Shri N. Kristappa
21. Dr. Tarun Mandal
22. Shri Datta Meghe
23. Dr. Jyoti Mirdha
24. Shrimati Jayshreeben Patel
25. Shri R.K. Singh Patel
26. Shri M. K Raghavan
27. Dr. Anup Kumar Saha
28. Shrimati Meena Singh
29. Dr. Arvind Kumar Sharma
30. Shri Pradeep Kumar Singh
31. Shri Ratan Singh



SECRETARIAT

Shrimati Vandana Garg, *Additional Secretary*
Shri R. B. Gupta, *Director*
Shrimati Arpana Mendiratta, *Joint Director*
Shri Dinesh Singh, *Assistant Director*
Shri Satis Mesra, *Committee Officer*

Ceased to be a Member *w.e.f.* 1st July, 2010.
@ Ceased to be a Member *w.e.f.* 30th June, 2010.

1777
627

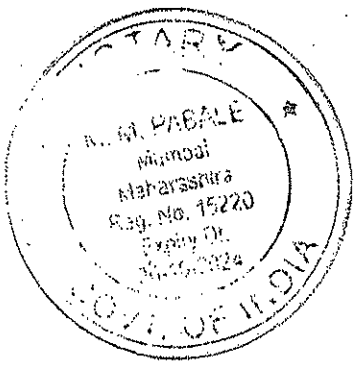
COMPOSITION OF THE COMMITTEE
(2010-11)

RAJYA SABHA

1. Shri Brajesh Pathak — *Chairman*
2. Shri Janardan Dwivedi
3. Shrimati Viplove Thakur
4. Dr. Vijaylaxmi Sadho
5. Shri Balbir Punj
6. Dr. Prabhakar Kore
@7. Shrimati Brinda Karat
8. Shrimati Vasanthi Stanley
9. Shri Rasheed Masood
*10. Shrimati B. Jayashree

LOK SABHA

11. Shri Ashok Argal
12. Shrimati Sarika Devendra Singh Baghel
13. Shri Vijay Bahuguna
14. Shrimati Tabassum Hasan
15. Dr. Sanjay Jaiswal
16. Shri S. R. Jeyadurai
17. Dr. Kruparani Killi
18. Shri Nimmala Kristappa
19. Dr. Tarun Mandal
20. Shri Datta Meghe
21. Dr. Jyoti Mirdha
22. Dr. Chinta Mohan
23. Shrimati Jayshreeben Patel
24. Shri R.K. Singh Patel
25. Shri M. K Raghavan
26. Shri J. M. Aaron Rashid
27. Dr. Anup Kumar Saha
28. Dr. Arvind Kumar Sharma
29. Shrimati Meena Singh
30. Shri Pradeep Kumar Singh
31. Shri Ratan Singh



SECRETARIAT

Shrimati Vandana Garg, *Additional Secretary*
Shri R.B. Gupta, *Director*
Shrimati Arpana Mendiratta, *Joint Director*
Shri Dinesh Singh, *Assistant Director*
Shri Satis Mesra, *Committee Officer*

---

* Ceased to be a Member *w.e.f.* 18th August, 2011.
@ Nominated to the Committee *w.e.f.* 21st September, 2010.

1778

628

COMPOSITION OF THE COMMITTEE
(2011-12)

RAJYA SABHA

1. Shri Brajesh Pathak — *Chairman*
*2. Shri Janardhan Dwivedi
%3. Shrimati Viplove Thakur
4. Dr. Vijaylaxmi Sadho
5. Shri Balbir Punj
6. Dr. Prabhakar Kore
7. Shrimati Vasanthi Stanley
^8. Shri Rasheed Masood
9. Shrimati B. Jayashree
10. Shri Derek O'Brien

LOK SABHA

11. Shri Ashok Argal
&12. Shrimati Harsimrat Kaur Badal
@13. Shri Vijay Bahuguna
14. Shrimati Raj Kumari Chauhan
15. Shrimati Bhavana Gawali
16. Dr. Sucharu Ranjan Haldar
17. Dr. Monazir Hassan
18. Dr. Sanjay Jaiswal
19. Shri S. R. Jeyadurai
20. Shri P. Lingam
21. Shri Datta Meghe
22. Dr. Jyoti Mirdha
23. Dr. Chinta Mohan
24. Shri Sidhant Mohapatra
25. Shrimati Jayshreeben Kanubhai Patel
26. Shri M. K. Raghavan
27. Shri J. M. Aaron Rashid
28. Dr. Arvind Kumar Sharma
29. Shri Radhe Mohan Singh
30. Shri Ratan Singh
31. Dr. Kirit Premjibhai Solanki

NOTARY GOVT. OF INDIA Adv. M. PARALE Mumbai Maharashtra Reg. No. 15220 Expiry Dt. 30-10-2024

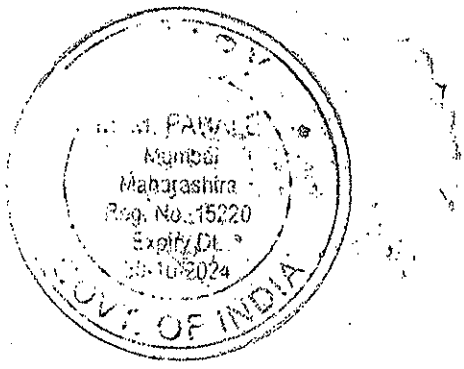
---

* ceased to be a Member *w.e.f.* 27th January, 2012 and re-nominated to the Committee on 2nd February, 2012.
% Vacant *vide* resignation *w.e.f.* 2nd April, 2012.
^ Vacant *vide* resignation *w.e.f.* 9th March, 2012 and renominated as Member *w.e.f.* 04th May, 2012.
& ceased to be a Member *w.e.f.* 29th June, 2012.
@ vacant *vide* resignation *w.e.f.* 30th April, 2012.

17 79
~~629~~

SECRETARIAT

Shrimati Vandana Garg, *Joint Secretary*
Shri R. B. Gupta, *Director*
Shrimati Arpana Mendiratta, *Joint Director*
Shri Dinesh Singh, *Deputy Director*



1780

~~630~~

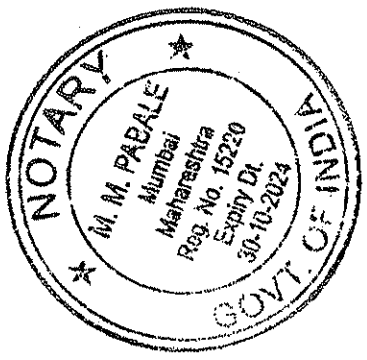
COMPOSITION OF THE COMMITTEE
(2012-13)

RAJYA SABHA

1. Shri Brajesh Pathak — *Chairman*
2. Dr. Vijaylaxmi Sadho
*3. Dr. K. Chiranjeevi
4. Shri Rasheed Masood
5. Dr. Prabhakar Kore
6. Shri Jagat Prakash Nadda
7. Shri Arvind Kumar Singh
&8. Shri D. Raja
9. Shri H. K. Dua
10. Shrimati B. Jayashree
^11. Shri Mohd. Ali Khan
%12. Shri Rajkumar Dhoot

LOK SABHA

@13. Shri Ashok Argal
14. Shri Kirti Azad
15. Shri Mohd. Azharuddin
16. Shrimati Sarika Devendra Singh Baghel
17. Shri Kuvarjibhai M. Bavalia
18. Shrimati Priya Dutt
19. Dr. Sucharu Ranjan Haldar
20. Mohd. Asrarul Haque
21. Dr. Monazir Hassan
22. Dr. Sanjay Jaiswal
23. Dr. Tarun Mandal
24. Shri Mahabal Mishra
25. Shri Zafar Ali Naqvi
26. Shrimati Jayshreeben Patel
27. Shri Harin Pathak
28. Shri Ramkishun
29. Dr. Anup Kumar Saha
30. Dr. Arvind Kumar Sharma
31. Dr. Raghuvansh Prasad Singh
32. Shri P.T. Thomas
#33. Shri Chowdhury Mohan Jatua



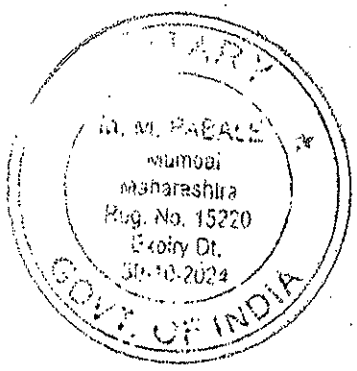
---

* Ceased to be Member of the Committee *w.e.f.* 28th October, 2012.
& Ceased to be Member of the Committee *w.e.f.* 24th July, 2013.
^ Nominated as a Member to the Committee *w.e.f.* 27th August, 2013.
% Nominated as a Member to the Committee *w.e.f.* 27th August, 2013.
@ Ceased to be Member of the Committee *w.e.f.* 9th January, 2013.
# Nominated as a Member to the Committee *w.e.f.* 14th December, 2012.

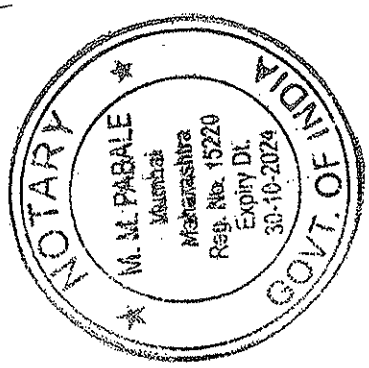
1781
~~631~~

SECRETARIAT

Shri P.P.K. Ramacharyulu, *Joint Secretary*
Shri R. B. Gupta, *Director*
Shrimati Arpana Mendiratta, *Joint Director*
Shri Dinesh Singh, *Deputy Director*
Shri Pratap Shenoy, *Committee Officer*



1782
632



PREFACE

I, the Chairman of the Department-related Parliamentary Standing Committee on Health and Family Welfare, having been authorized by the Committee to present the Report on its behalf, do hereby present this Seventy Second Report of the Committee on the "Alleged Irregularities in the Conduct of Studies Using Human Papilloma Virus (HPV) Vaccine" by Programme for Appropriate Technology in Health (PATH) in India.

2. The Committee first took up the issue about the trial of HPV vaccine on the children in Khammam district of Andhra Pradesh and Vadodra district of Gujarat and reported deaths of the children therefrom in its meeting held on 06th April, 2010 during the course of examination of Demands for Grants (2010-11) of Department of Health Research and sought exact status in this regard from the Secretary, Department of Health Research. Subsequently, taking serious view of the procedural and ethical lapses on the part of the Ministry, the Committee sought the matter of allowing trial of the vaccine as also the approval for its marketing in the country to be enquired into. The Committee also desired the Ministry to take further appropriate action in the matter and apprise it of the follow-up action taken in this regard at the earliest. As a sequel to the Committee's recommendation, a Committee was appointed by the Government of India to enquire into"Alleged Irregularities in the Conduct of Studies Using Human Papilloma Virus (HPV) Vaccine" by Programme for Appropriate Technology in Health (PATH) in India on 15th April,2010. The Final Report of the Committee appointed by the Government of India to enquire into"Alleged Irregularities in the Conduct of Studies Using Human Papilloma Virus (HPV) Vaccine" by Programme for Appropriate Technology in Health(PATH) in India was made on 15th February,2011.

3. The Committee thereafter deliberated on the subject in its meetings held on 25th July, 2011 and 24th May, 2013.

4. During the course of examination of the subject, the Committee heard the views of the Secretary, Department of Health Research and other officials of the Department on 25th July, 2011 and Secretary, Department of Health Research and Drug Controller General of India (DCGI) on 24th May, 2013.

5. During the finalization of its Report, the Committee relied upon the following documents/ papers:–

(i) Background note received from the Ministry;

(ii) Final Report of the Committee Appointed by the Government of India to enquire into "Alleged Irregularities in the Conduct of Studies Using Human Papilloma Virus (HPV) Vaccine" by Programme for Appropriate Technology in Health (PATH) in India;

(iii) Oral Evidences tendered by Secretary, Department of Health Research and DCGI; and

(iv) Replies to the questionnaires received from the Department of Health Research.

6. The Committee considered the Draft Report and adopted the same in its meeting held on 29th August, 2013.

1783

~~633~~

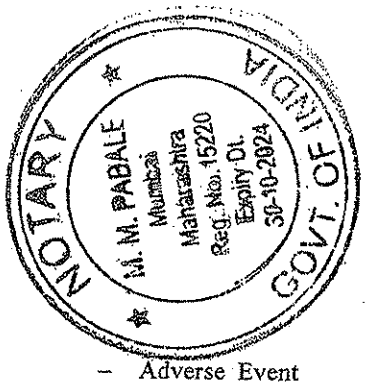
7. For facility of reference and convenience, observations and recommendations of the Committee have been printed in bold letters in the body of the Report.

BRAJESH PATHAK,
Chairman,
Department-related Parliamentary Standing
Committee on Health and Family Welfare

NEW DELHI;
29th August, 2013
Bhadra 7, 1935 (*Saka*)

1784

634



ACRONYMS

1.	AE	– Adverse Event
2.	AEFI	– Adverse Event Following Immunization
3.	ANM	– Auxiliary Nurse Midwife
4.	AP	– Andhra Pradesh
5.	AIIMS	– All India Institute of Medical Sciences
6.	ASHA	– Accredited Social Health Activist
7.	CDSCO	– Central Drugs Standard Control Organisation
8.	CTRI	– Clinical Trials Registry- India
9.	CORT	– Centre for Operations Research and Training
10.	DCGI	– Drug Controller General of India
11.	DGHS	– Director General of Health Services
12.	DHR	– Department of Health Research
13.	DG, ICMR	– Director General, Indian Council of Medical Research
14.	FCRA	– Foreign Currency Regulation Act
15.	FERA	– Foreign Exchange Regulation Act
16.	FEMA	– Foreign Exchange Management Act
17.	GCP	– Good Clinical Practice
18.	GAVI	– Global Alliance for Vaccines and Immunizations
19.	HPV	– Human Papilloma Virus
20.	HMSC	– Health Ministry Screening Committee
21.	HoD	– Head of Department
22.	ICMR	– Indian Council of Medical Research
23.	MEA	– Ministry of External Affairs
24.	MHA	– Ministry of Home Affairs
25.	MoU	– Memorandum of Understanding
26.	MEA	– Ministry of External Affairs
27.	MHA	– Ministry of Home Affairs
28.	NGO	– Non-Governmental Organization
29.	NRHM	– National Rural Health Mission

1785

~~635~~

30. NTAGI	–	National Technical Advisory Group on Immunization
31. O&G	–	Obstetrics and Gynaecology
32, PATH	–	Programme for Appropriate Technology in Health
33. PBC	–	Public Benefit Corporation
34. PPP	–	Public-Private Partnership
35. PSURs	–	Periodic Safety Update Reports
36. RoC	–	Registrar of Companies
37. RBI	–	Reserve Bank of India
38. SAE	–	Serious Adverse Event
39. UIP	–	Universal Immunization Programme
40. USFDA	–	United States Food and Drug Administration
41. WHO	–	World Health Organisation

NOTARY
M. PABALE
Mumbai
Maharashtra
Reg. No. 15220
Expiry Dt.
30-10-2024
GOVT. OF INDIA

1786

636

NOTARY M. M. PABALE Mumbai Maharashtra Reg. No. 15220 Expiry Dt. 30-10-2024 GOVT. OF INDIA

REPORT

I. BACKGROUND

1.1 During March, 2010 the entire world was shocked by the media reports about the deaths of some female children and adolescents in Khammam district of Andhra Pradesh after being administered Human Papilloma Virus (HPV) vaccines. The vaccination trials were carried out by an American agency *viz.* Programme for Appropriate Technology in Health (PATH). The project was reportedly funded by Bill and Melinda Gates Foundation, an American charity.

1.2 Several questions were asked and concerns expressed in the media and well meaning quarters on the role of government agencies including Indian Council of Medical Research (ICMR) and Drugs Controller General of India (DCGI) in approving and facilitating the trials, which was against all laws of the land and even international ethical norms and rules; misuse of government funds, man-power, facilities and infrastructure for a private project of dubious nature; use of logo of National Rural Health Mission (NRHM), an official programme of the Union Government during these vaccination drives to give it respectability and official endorsement; and above all the blatant violation by PATH of all regulatory and ethical norms laid down by the Government of India for the purpose as also possible violations of such norms prescribed and very scrupulously enforced in the Country of its origin *viz.* United States of America.

1.3 Taking cognizance of these reports, the Committee (2009-10) which was examining the Demand for Grants (2010-11) of the Department of Health Research at that point of time sought a detailed clarification from the Government in the matter. In response the Secretary of the Department of Health Research and DG, ICMR informed the Committee that it was a vaccine against the Human Papilloma Virus which causes cervical cancer in women. The Drugs Controller General, India had given approval for marketing of HPV vaccines in India as a vaccine to be prescribed by the clinicians as per schedule 'Y' of the Drugs and Cosmetics Rules and then for a post-marketing surveillance trial. The Committee was informed that the proposal for trial came two years earlier (though later on during the Committee's examination it was proved that it began in 2006) before the ICMR through PATH, an American agency, and the logic for allowing the trial was to see acceptability of this vaccine on Indian population. Besides, these trials were approved by the National Ethical Committee and the State Ethical Committee.

1.4 Attention of the Secretary was drawn to DCGI guidelines wherein Phase III trials cannot be conducted on children until a similar trial was conducted on adults. It was admitted by the Secretary that the DCGI guidelines were not adhered to in the present case but this vaccine is given before the sexual activity begins and then it protects against cancer. That was the reason for allowing trials on girls of the age of 10-14 years. The Committee was assured that State Governments of Andhra Pradesh and Gujarat would be asked to get the ongoing clinical trial stopped immediately.

1.5 Hugely perturbed by these blatant violations, the Committee in its Forty first Report on Demands for Grants (2010-11) of the Department of Health Research made the following recommendations on this issue:

> "Taking serious view of procedural and ethical lapses on the part of the Ministry, the Committee sought the matter of allowing trial of the vaccine as also the approval for its marketing in the country to be enquired into by a premier investigating agency and to take further appropriate follow-up action in the matter. It also asked that findings of the investigating agency and the follow-up action taken in this regard may be furnished to the

1787
637

Committee at the earliest. The Committee, taking a serious view in the matter, recommends to the Department of Health Research that in future all guidelines and norms should be adhered to before allowing trials of any drug including vaccines on Indian population. The Committee also recommends that the DCGI should observe optimum precautions and follow all norms and guidelines while allowing marketing of any drug including the vaccines in the Indian market".

1.6 The Department of Health Research in its Action Taken Note on the above recommendations submitted the following:

> "PATH in partnership with State Governments of Gujarat and Andhra Pradesh was implementing an operational research study related to cancer of cervix prevention in India. ICMR is providing technical support and consultation for development of protocol and plan of monitoring.
>
> The study utilized both the brands of HPV vaccines available in the market (Gardasil by Merck in Andhra Pradesh; and Cervarix by GSK in Gujarat). In view of certain complaints received, the State Governments have been advised not to carry out further vaccination till further orders. To ascertain the facts of the matter, Minister for Health and Family Welfare appointed a Committee comprising of Dr. S.S. Agarwal, former Director, Advanced Centre for Training, Research, Education on Cancer, Dr. S.P. Aggarwal, former DGHS and Dr. Sunita Mittal, HoD, Obstetrics and Gynaecology, AIIMS to investigate ethical issues raised in the matter."

1.7 Not being satisfied with the action taken by the Government on its Recommendations, the Committee in its Forty eighth Report further recommended the following:

> "The Committee observes that as a result of its intervention, the State Governments have been advised by the Department not to carry out HPV vaccinations and a Committee has been appointed to investigate ethical issues raised in the matter. The Committee is not aware about the date of setting up of the Committee. However, the absence of any specific time-line for submission of Report of the Committee in the Action Taken Note given by the Department makes the Committee somewhat apprehensive. Like so many Committees set up by the Government, findings of this Committee, as and when received, may remain on paper only. The Committee, therefore, recommends that every effort should be made to expedite the Report of this Committee so that real facts about the HPV Vaccine trial are made known without any further delay and corrective measures not only in respect of this case but for all such ongoing/proposed clinical trials of drugs/vaccines are taken. The Committee also recommends that the Department should at least now work in close coordination with other concerned departments/organizations to undertake a comprehensive analysis of the process of granting permission to research studies having hazardous effects on health and put in place a fool-proof system for pre-empting unethical research studies."

1.8 Considering the enormity of the wrong doing/criminality involved, and the dilly-dallying attitude of the Government in taking exemplary corrective action, the Committee took it up for detailed examination. The succeeding paragraphs contain the details of the matter, Committee's findings and recommendations.

1.9 Cancer of the cervix (mouth of uterus) popularly called Cervical Cancer has been there ever since the dawn of human race. Over the years, preventive and treatment protocols have been developed by medical experts.

1.10 The Committee was given to understand that on June 1, 2006 the American drug regulator, the U. S. Food and Drug Administration (USFDA) approved the first vaccine to prevent HPV virus

1788
638

NOTARY M. M. PAWALE Mumbai Maharashtra Reg. No. 15220 Expiry Dt. 30-10-2024 GOVT. OF INDIA

that is claimed to cause 70% of cervical cancers, under the brand name of Gardasil by a US drug company namely, Merck.

1.11 In the very same month, an American organization called Program for Appropriate Technology in Health (PATH) embarked upon a large scale, 5-year long (June 2006 to May 2011) project with "the main objective .....to generate and disseminate evidence for informed public sector introduction of HPV vaccines" in four countries, India, Uganda, Peru and Vietnam. Interestingly these four countries have different ethnic populations: India (Indo-Aryans, Dravidians, Tribals etc.), Uganda (Negroid), Peru (Hispanics) and Vietnam (Mongoloids). The Committee has been given to understand that ethnicity is relevant in the determination of safety and efficacy of some drugs. What would be of further interest, as per World Health Organization (WHO) is that all these countries have state-funded national vaccine immunization programs, which if expanded to include Gardasil, would mean tremendous financial benefit to the then sole manufacturer.

1.12 With this background a clinical trial under the title 'Post-licensure observational study of Human Papilloma Virus Vaccination – Demonstration Project' was undertaken by Programme for Appropriate Technology in Health (PATH), an agency of American origin. The Indian Council of Medical Research (ICMR), which is the highest body in the Country for medical research and related matters lent its platform to PATH in an improper and unlawful manner. The State Governments of Andhra Pradesh and Gujarat swayed by the involvement of ICMR followed suit.

II. NATURE OF PROJECT

2.1 Given the controversy surrounding the project, the Committee was keen to know from the Government the exact nature of the project. The Committee noticed that there was fundamental difference between the perceptions of Drugs Controller General of India (DCGI) and Department of Health Research (DHR)/Indian Council of Medical Research (ICMR) on the actual nature of the project. The DCGI was of the opinion that since human subjects, as part of the research, were receiving invasive intervention like vaccines, the clinical trial rules must be enforced. Experts also upheld these views and were very clear about it. However, PATH described the project as an "observational study" since "it did not conform to the definition of clinical trial".

2.2 The Committee found from the information furnished to it that ICMR representative on the Project Advisory Committee not only opposed DCGI but also argued that the nature of the project does not require them to follow the clinical trial rules, including reporting of serious adverse effects within a specific time-frame.

2.3 The Committee in this regard took note of the expert opinion given in the Inquiry Committee report which questioned the PATH description of the project and observed that since "the demonstration project is a study of a pharmaceutical product carried out on humans and since the primary objectives include the study of serious adverse effects, it is clear that clinical trial rules and guidelines should apply".

2.4 In fact, the Inquiry Committee in one of its findings very pointedly stated that the investigators had variously labeled the research project carried out by them as "Observational Study/Demonstrational Study," etc. to establish that the study was not a clinical trial. But, since the project had been carried as research on human participants, it had to follow all the guidelines and statutory requirements applicable for research on human participants.

2.5 **The Committee finds the entire matter very intriguing and fishy. The choice of countries and population groups; the monopolistic nature, at that point of time, of the product being pushed; the unlimited market potential and opportunities in the universal immunization progammes of the respective countries are all pointers to a well planned scheme to commercially exploit a situation. Had PATH been successful in getting the HPV**

vaccine included in the universal immunization programme of the concerned countries, this would have generated windfall profit for the manufacturer(s) by way of automatic sale, year after year, without any promotional or marketing expenses. It is well known that once introduced into the immunization programme it becomes politically impossible to stop any vaccination. To achieve this end effortlessly without going through the arduous and strictly regulated route of clinical trials, PATH resorted to an element of subterfuge by calling the clinical trials as "Observational Studies" or "Demonstration Project" and various such expressions. Thus, the interest, safety and well being of subjects were completely jeopardized by PATH by using self-determined and self-servicing nomenclature which is not only highly deplorable but a serious breach of law of the land. The Committee is not aware about the strategy followed by PATH in the remaining three countries *viz.* Uganda, Vietnam and Peru. The Government should take up the matter with the Governments of these countries through diplomatic channels to know the truth of the matter and take appropriate necessary action, accordingly. The Committee would also like to be apprised of the responses of these countries in the matter.

III. ROLE OF DEPARTMENT OF HEALTH RESEARCH/INDIAN COUNCIL OF MEDICAL RESEARCH

3.1 One of the functions mandated to the Department of Health Research/ICMR is promotion and coordination of basic, applied, clinical and operational research in medical, health and bio-medical field through development of infrastructure, manpower and skills. Uniform Ethical Guidelines for bio-medical Research on human subjects are incorporated in Good Clinical Practice (GCP) and ICMR documents. These guidelines outline the procedure for Ethics Committees review of clinical trials in India using the human beings as participants. All institutions and investigators in the country which carry out any form of biomedical research involving human beings are obliged to follow these guidelines in letter and spirit to protect participants.

3.2 As per the records made available to the Committee, the first documented contact made by PATH with ICMR took place, as early as, on 5th October 2006. An employee of PATH India sent an e-mail to Deputy Director of National AIDS Research Institute, ICMR expressing sorrow that she could not travel to Seattle, United States for "Formative Research Workshop" (on HPV vaccine) scheduled for October 24-26, 2006. Apparently, PATH functionaries were in touch with ICMR officials on an informal basis in the past.

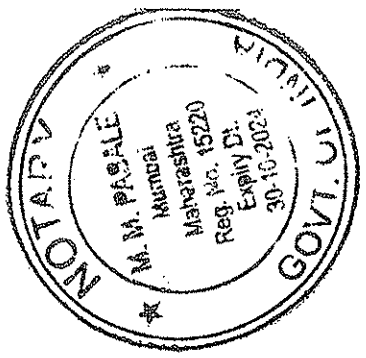
3.3 Within a few days, a meeting took place between PATH and ICMR officials on 13 October, 2006 at PATH office in New Delhi where it was stated that "HPV vaccine, when available (in India), can prevent HPV and cervical cancer." The possibility of Global Alliance for Vaccines and Immunizations (GAVI) subsidizing the cost of vaccine for the first 2 - 4 years was also mentioned. Evidence (on role, utility of vaccine) made available to Government of India and States would "help to decide on public sector (State funded) introduction of the vaccine."

3.4 On 16 November, 2006, a draft Memorandum of Understanding (MoU) between PATH and ICMR was circulated by PATH which stated that "Parties (PATH and ICMR) desiring to explore collaboration to support public sector decision regarding HPV vaccine introduction in India and to generate necessary evidence to allow the possible introduction of HPV vaccine into India's Universal Immunization Programme."

3.5 Thus as early as October-November 2006, it was clear that the main objective of PATH project was to generate evidence that would facilitate the introduction of HPV vaccine Gardasil into government-funded immunization program in India. This appears to be a promotional activity for the benefit of manufacturing company because at that time only one HPV vaccine, Gardasil had been approved abroad, though not in India. Indeed "the key object of the project activities in India

1790

~~640~~



is to gather information and help the government make a decision about the introduction of HPV vaccine". The Country Director of PATH in India emphasized that "this needs to be our consistent message throughout the project." In the formal proposal submitted by PATH to the ICMR on Project Proposals involving Foreign Collaboration/Assistance, the applicant clearly stated under Para 9. Objectives of the Project: ".....Introduction of HPV vaccines into Universal Immunization Program." The Committee found repeated mention of similar objectives at several places in various documents submitted by the Ministry. The Memorandum of Understanding (MoU) was signed by PATH and ICMR on 20 February, 2007. At that time only Gardasil was marketed in some countries in the world though not approved for use in India. The MoU stated that the purpose of the project was:

(i) Increasing understanding of HPV vaccine (*i.e.* Gardasil) introduction.

(ii) To help in decision-making related to the use of HPV (*i.e.* Gardasil) vaccine in the public and private sector.

3.6 The Committee enquired from the Secretary of Department of Health Research (DHR) and DG, ICMR, as to whether the Department or CDSCO, before approving the project had really reviewed its actual design. The Committee highlighted the observations of the experts of the Inquiry Committee who have opined that the design of the project itself was faulty. For instance, in the documents there was no column whatsoever for Serious Adverse Events (SAE) and no diary was to be maintained as part of the protocol.

3.7 Moreover, much before the trials started, many expected side effects including anaphylaxis (severe allergic reaction), syncope, convulsions, asthma, central demyelinating diseases, acute disseminated encephalomyelitis, Idiopathic Thrombopenia Purpura, etc. were known. And astonishingly, as the records stated, while ICMR functionary was worried of bad publicity in case of side effects, PATH did not provide for urgent expert medical attention in case of serious adverse events whether known or unexpected.

3.8 After going through the final report and interactions with the Secretaries of the Department of Health and Family Welfare and the Department of Health Research/ICMR and DCGI, the Committee felt that it needs clarification as to under what category, permission was given to PATH to conduct such study on the Indian people and whether the programme was a clinical trial or promotional activity. The Committee took note of the fact that the Enquiry Committee meeting held on September 27, 2010, noted as under **(Annexure-A):**

> "....Besides the factual information about the terms of reference the Committee was greatly concerned with the aspect of commercial interests of manufacturers influencing the Government policy on this expensive vaccine. The committee observed that the study was initiated by PATH on its own ..... without any reference from the National Technical Advisory Group on Immunization (NTAGI), the official body of the GOI on vaccines.....It is not clear whether the State expenses were funded by PATH or came from their own resources. The monetary contributions of ICMR are also not clear. The Committee therefore felt that it would be in the fitness of the inquiry to document the sources and magnitude of funding of the study".

3.9 In this connection, the Committee also noted that one of the roles assigned to ICMR in the MOU signed by the Director General of the ICMR was "advising on plans for results dissemination to support decision making for use of the HPV vaccine".

3.10 **The Committee is unable to understand as to how ICMR could commit itself to support "the use of the HPV vaccine" in an MOU signed in the year 2007 even before the vaccine was approved for use in the country, which actually happened in 2008. The**

NOTARY M. M. PASALE Mumbai Maharashtra (15220)

Committee also questions the decision of ICMR to commit itself to promote the drug for inclusion in the Universal Immunization Programme (UIP) even before any independent study about its utility and rationale of inclusion in UIP was undertaken.

3.11 The Committee noted that there were many gaps and missing links in the whole episode and enquired as to when ICMR came into contact with PATH. First a vaccine should get the approval from the Government and then only it can be used in UIP. Secretary, Department of Health Research/DG, ICMR while responding to the queries, informed that the first discussion with the PATH was held in 2006 followed by signing of agreement in the year 2007. At that time HPV vaccine had not been approved in India and no study was conducted on it. This was all a preparatory exercise.

3.12 The Committee was informed that the trial was on the two vaccines approved by DCGI. It was also stated that these vaccines had been tested abroad and on a limited number of people in India as per rules following which DCGI had given the approval for their marketing in the country, and then a post-marketing surveillance trial.

3.13 The Committee in this connection took note of the fact that before any drug is tested especially on a large population of 25,000-32,000 children between the age of 10 to 14, then according to the CDSCO guidelines, no such trial can be conducted on children until a similar, prior trial is conducted on adults to determine efficacy and safety.

3.14 The Secretary, Department of Health Research/DG, ICMR while deposing before the Committee in its meeting held on 25th July, 2011, stated that the terms of reference of the Enquiry Committee was to find out any relation between the deaths with the administration of vaccine and any incidents of irregularities in the implementation of the study. He stated that the Enquiry Committee concluded that the deaths reported during trial had no uniform pattern to link them to the administration of vaccines.

3.15 The Committee noted that all the seven deaths were summarily dismissed as unrelated to vaccinations without in-depth investigations. According to Inquiry Committee report, the speculative causes were suicides, accidental drowning in well (why not suicide?), maleria, viral infections, sub-arachnoid haemorrhage (without autopsy) etc. The Committee has been given to understand that suicidal ideation is caused by many drugs. Since then one more death due to suicide in case of Gardasil has been reported in addition to 5 deaths reported during 2009-10. Therefore, HPV vaccine as a possible, if not probable, cause of suicidal ideation cannot be ruled out.

3.16 The Secretary of DHR/DG, ICMR acknowledged that certain irregularities were reported in the implementation of the project. With regard to Informed Consent, he said that though the consent was taken properly in Gujarat, there were gross violations of norms in Andhra Pradesh. He informed the Committee that DCGI, had sought explanation for the incidents of irregularities.

3.17 The Committee took note of Secretary's comments but sought to know as to how ethical it was on the part of ICMR to become a party to a project in the name of Public-Private Partnership (PPP mode). How ICMR, which is mandated to formulate ethical guidelines for researchers, can become a direct party in such a study. The Secretary, Department of Health Research admitted that presence of ICMR in the Project's Advisory Committee-responsible and accountable for various acts of omissions and commissions-clearly indicates Conflict of Interest. Therefore, ICMR owes full moral responsibility for numerous irregularities reportedly committed in the study.

3.18 **The Committee feels that there was serious dereliction of duty by many of the Institutions and individuals involved. The Committee observes that ICMR representatives, instead of ensuring highest levels of ethical standards in research studies, apparently acted at the behest of the PATH in promoting the interests of manufacturers of the HPV Vaccine.**

1792

642

3.19 **It was unwise on the part of ICMR to go in the PPP mode with PATH, as such an involvement gives rise to grave Conflict of Interest. The Committee takes a serious view of the role of ICMR in the entire episode and is constrained to observe that ICMR should have been more responsible in the matter. The Committee strongly recommends that the Ministry may review the activities of ICMR functionaries involved in PATH project.**

3.20 Secretary of Department of Health Research and DG, ICMR in their defense also claimed that the ICMR had fulfilled the written role entrusted to it but the irregularities that took place during the implementation of the study clearly indicate that there were certain micro (ground) level issues requiring more attention. For instance, it was noticed that States were not even capable of monitoring the adverse effects. He stated that this all was a learning exercise.

3.21 It maybe pertinent to mention here that the safety, efficacy and introduction of vaccines in India is handled by National Technical Advisory Group on Immunization (NTAGI). Thus, at the very outset, ICMR should have either referred PATH to NTAGI or at least taken NTAGI on board.

3.22 **The Committee from its examination has found that DHR/ICMR have completely failed to perform their mandated role and responsibility as the apex body for medical research in the Country. Rather, in their over-enthusiasm to act as a willing facilitator to the machinations of PATH they have even transgressed into the domain of other bodies/ agencies which deserves the strongest condemnation and strictest action against them. The Committee fails to understand as to why ICMR took so much interest and initiative in this project when the safety, efficacy and introduction of vaccines in India is handled by National Technical Advisory Group on Immunization (NTAGI). The submissions of the Secretary, DHR/DG, ICMR before the Committee about the commencement of the project, facts of the case and the action taken have also failed to stand scrutiny during the Committee's examination of the matter. The Committee, therefore, reiterates the recommendation made in their Forty-first Report that the matter of allowing trial of the vaccine as also the approval for its marketing in the Country be inquired into by a premier investigating agency and appropriate action be taken thereafter by the Government in the matter. The Committee expects the Government not to procrastinate in this matter any further.**

IV. ROLE OF DRUG CONTROLLER GENERAL, INDIA (DCGI)

4.1 The Committee noted that as per Rule122-DA and Schedule Y of the Drugs and Cosmetics Rules, 1945 made under the Drugs and Cosmetics Act, 1940, no clinical trial on a drug can be conducted except under, and in accordance with the permission in writing, of the Licensing Authority *i.e.* DCGI. All vaccines are deemed to be drugs. Clinical trials of pharmaceutical products are conducted on human subjects in the country to determine or verify safety and/or efficacy. Every permission for conducting clinical trials also, *inter alia*, includes a condition that in event of trial related injury or death, the sponsor will provide complete medical care as well as compensation. Statement to this effect needs to be incorporated in the Informed Consent Form. The details of compensation provided are to be intimated to the office of DCGI.

4.2 The Committee noted from the evidence available that the nature of the PATH project made it Post-marketing Phase IV Clinical Trial under Drugs and Cosmetic Rules. It was on this basis that DCGI approved the clinical trial on 22 April, 2009 and had earlier issued import licenses on 23 December, 2008 though it was incorrect on the part of DCGI to issue import licences on Form 11 under Rule 33 which states:

> *Import of drugs for examination, test or analysis:* Small quantities of drugs the import of which is otherwise prohibited under section 10 of the Act may be imported for the purpose of examination, test or analysis subject to the following conditions:

NOTARY M. H. PABALE Mumbai Maharashtra Regn. No. 15220 Expiry Dt. 30-10-2024 GOVT. OF INDIA

(a) No drug shall be imported for such purpose except under a licence in Form 11;

(b) the licensee shall use the substances imported under the license exclusively for purposes of examination, test or analysis and shall carry on such examination, test or analysis in the place specified in the license, or in such other places as the licensing authority may from time to time authorize.

4.3 Since both Gardasil and Cervarix had received marketing approval from CDSCO on 4 July, 2008 and 10 September, 2008 respectively, DCGI should have issued Import Licenses on Form 10 which is applicable to import of drugs already approved.

4.4 The so called Demonstration Project of PATH has the objectives as follows:

Primary Outcomes:

- Number and percentage of vaccinated girls.
- Number and percentage of vaccinated girls experiencing Serious Adverse Events (SAEs)
- Number and percentage of vaccinated girls experiencing non-Serious Adverse Events.
- Timeliness of reporting SAEs to local, state and national authorities.
- Timeliness of reporting Non-SAEs to local, state and national authorities.

4.5 Thus it is clear that PATH project had two well defined and specific objectives:

(a) The commercial objective of the project was to generate evidence, data and arguments to support inclusion of HPV vaccines into India's state-funded Universal Immunization Program (UIP), and

(b) The scientific purpose was to collect data on serious and non-serious adverse effects. Given that similar projects were launched in Peru, Uganda and Vietnam, the entire exercise would have collected side effect profiles of HPV vaccines in all the ethnic groups that reside in developing countries. Such data would be invaluable to promote the two branded, patented, single source HPV vaccines as safe all over the world.

4.6 **The Committee's examination has proved that DCGI has also played a very questionable role in the entire matter. Initially, it took a call that since human subjects, as part of the studies, were receiving invasive intervention like immunization, clinical trial rules must be enforced. However, it remained as a silent spectator thereafter, even when its own rules and regulations were being so flagrantly violated. The approvals of clinical trials, marketing approval and import licenses by DCGI appear to be irregular. Therefore, the role of DCGI in this entire matter should also be inquired into.**

V. MARKETING APPROVAL TO HPV VACCINES IN INDIA

5.1 Before approving any new drug (including new vaccines), under Drugs and Cosmetics Rules, it is mandatory to conduct Phase III clinical trials in India to determine any ethnic differences in the safety and efficacy profiles. As per records made available to the Committee the following clinical trials, albeit, under various names, were conducted:

Gardasil (Merck): Clinical trials were conducted on 108 subjects (girls in the age group of 9-15 years). Several violations took place in the trial: (a) trials should have been conducted in adults first before exposing children to known and unknown side effects, (b) in adolescents and

1794

644

children the trials should have been conducted from "top to bottom" age groups *i.e.* first in adolescents (13-15 years) followed by children (9-12 years). This was not done. Vaccines were administered to children irrespective of age at the same time.

Cervarix (GSK): Clinical trials were conducted on 162 subjects (adults in the age group of 18-35 years). Yet permission was given to use the vaccine in children (10-14 years) in violation of rules.

VI. INQUIRY COMMITTEE

(a) Composition and Terms of Reference

6.1 The Committee was informed that because of the concerns raised at different fora, the study was suspended and an Enquiry Committee was constituted by the Govt. of India vide notification No. V.25011/160/2010-HR dated 15th April, 2010, to enquire into "Alleged irregularities" in the conduct of studies using Human Papilloma Virus (HPV) vaccines by PATH in India.

The inquiry committee consisted of the following:

(1) Dr. S.S. Agarwal, former Director, Advanced Centre for Training, Research, Education on Cancer,

(2) Dr. S.P. Aggarwal, former DGHS, and

(3) Dr. Sunita Mittal, HoD, Obstetrics and Gynaecology, AIIMS

6.2 The terms of reference of the Committee were to enquire into:

(i) Link between the deaths and vaccine, if any, and

(ii) Ethical Issues of subjecting children of marginalized populations to these studies, and investigations in children without appropriate Consent.

6.3 The Committee was assisted by the following experts:

(i) Dr. Rani Kumar, Dean, AIIMS

(ii) Dr. A. K. Dutta, Head of Pediatrics, Kalawati Saran Hospital

(iii) Dr. Y. K. Gupta, Head of Pharmacology, AIIMS

(b) Conflict of Interest

6.4 The Committee sought information from the Ministry of Health and Family Welfare (MoHFW) as to whether members of the Inquiry Committee were asked to file Conflict of Interest declarations. In response the Ministry replied: "No written Conflict of Interest declarations were sought from the core members of the Inquiry Committee as well as experts. It was understood that if there is any conflict, highly learned members will point it out."

6.5 In order to verify the Ministry's claim, the Committee picked just one member *i.e.*, Professor and HoD of the Department of Obstetrics and Gynaecology (O&G) of All India Institute of Medical Sciences (AIIMS). It was found that manufacturers of Gardasil, Merck was sponsoring and funding a trial in the Department of O&G at AIIMS to determine if 2 doses of Gardasil can be used safely and effectively instead of 3 doses. Documents received by the Committee in connection with the examination of AIIMS also revealed that the individual in question availed the hospitality of these very sponsors during the said individual's visit to Seoul to attend a conference.

The FCRA application form was, therefore, deliberately left incomplete to hide this truth. All these speaks of a serious conflict of interest of this member of the Inquiry Committee.

6.6 The Committee also found that the Ministry appointed a senior official of ICMR (described as Resource Person) to assist the Inquiry Committee. The concerned individual was the main link between ICMR and PATH, and had participated actively in all discussions, meetings and helped PATH to carry out the project proactively in every respect right from the beginning in October 2006. As such he had a clear Conflict of Interest and could not be relied upon to give correct information and unbiased opinion. Indeed he should have been summoned as a witness to answer questions and not as an official Resource Person attached to the Enquiry Committee.

(c) Adverse Events Reporting

6.7 The Committee examined the final Report of the Inquiry Committee constituted to enquire into the alleged irregularities in the conduct of studies using HPV vaccines by PATH in India. In its first meeting held on 21-4-2010, the Inquiry Committee sought details on the following core issues:

1. When did PATH approach ICMR for trial runs?
2. With whose permission was MOU signed?
3. Did President of ICMR approve?
4. Whether it had approval of the Screening Committee?
5. Approval of DCGI.
6. Details of reimbursements provided so far by PATH to ICMR
7. Names of beneficiaries.
8. Expenditure incurred by ICMR so far on all items including travel expenses.

6.8 However in its second meeting on 30 April, 2010, no discussion took place on the above crucial issues since the Inquiry Committee wished "to restrict itself to the terms of reference."

6.9 Inexplicably, however, as the records placed before the Committee proved, this decision did not prevent the Inquiry Committee from going into and recommending actions on other matters far beyond the terms of reference.

6.10 The Committee notes that once this matter was taken up by it, the Government appointed an Inquiry Committee on 15 April, 2010 to inquire into 'alleged irregularities in the conduct of the studies using HPV vaccines by PATH in India'. The Committee has noted the serious conflict of interest of members of this Inquiry Committee with the subject matter. The Committee, therefore, strongly deprecates the Government for appointing a committee to inquire into such a serious matter in such a casual manner even without ascertaining as to whether any of the members of the said Inquiry Committee were having any conflict of interest with the subject matter of inquiry.

6.11 The Committee finds it very intriguing as to when the Inquiry Committee after having sought details of some core issues in the very first meeting of the Committee on 21 April, 2007 subsequently chose not to pursue them purportedly because 'it wanted to restrict itself to its terms of reference'. These core issues raised by the Inquiry Committee earlier, if pursued to their logical end, would not only have provided the Inquiry Committee a lot more clarity in unraveling the truth but also the Country would have known the exact details as to what transpired in this sordid incident.

1796

~~646~~

(d) Informed Consent

6.12 Obtaining Informed Consent from study subjects is a core requirement in the conduct of clinical trials and protection of human rights. In case of minors, the Consent has to be signed by parents/guardians. In the case of uneducated signatories, an independent person has to explain and witness the consent process. The Informed Consent document approved by various Ethics Committees on PATH project included the sentence: "I have read the information in this consent form (or it has been read to me). I consent to allow my daughter to receive three doses of HPV vaccines." In the case of Andhra Pradesh 9,543 forms were signed, 1,948 had thumb impressions while hostel warden had signed 2,763 forms. In the case of Gujarat 6,217 forms were signed, 3,944 had thumb impressions and 545 were either signed or carried thumb impression of guardians. The data shows that a very large number of parents/guardians were illiterate and could not even sign in their local language *i.e.* Telugu or Gujarati.

6.13 One of the experts, while going into the question of Informed consent in great detail, in two reports, has pointed out glaring discrepancies. Out of 100 consent forms for AP Project taken for study, it was found that signatures of witnesses were missing in 69 forms. In many forms there were no dates while in others the signature of just one person appeared in seven forms The legality of the Andhra Pradesh State Government circular directing all Headmasters/Wardens in all private/government/ashram schools to sign the consent forms on behalf of parents/guardians was also questionable.

6.14 The Inquiry Committee, while going through the above report, noticed the following irregularities and discrepancies in the study:

(i) The warden/teachers/headmasters were not given written permission by the parents/ guardians to sign on behalf of their girls.

(ii) On many forms witness had not signed and of the forms which are signed, it is not clear whether they are signed by full time government employees, as per rules.

(iii) Neither the photograph nor the photo ID card of parents/guardians/wardens is pasted in consent form.

(iv) On many forms investigator has not signed.

(v) On some forms signature of parents/guardians is not matching with their names.

(vi) The date of vaccination is much earlier than the date of signature of parents/guardian in the consent forms. Apparently they were obtained post-facto.

(vii) In some forms, the name is of the father but signature is of probably mother (lady's name).

6.15 Secretary, DHR and DG, ICMR while deposing before the Committee, reiterated that the regulatory approvals given to the project were in proper order and due attention was paid to the guidelines and formats for seeking consent. However, during the implementation of the project certain irregularities took place. He admitted there were cases of discrepancies in A.P. He admitted that many consent forms were filled up by the Principal on behalf of the students. He admitted to gross violation in the recording of SAEs also. He informed the Committee that keeping all these observations in view the DCGI, besides issuing immediate instructions to stop the study, had sought explanations for irregularities committed during the study.

6.16 **The Committee observes that obtaining informed consent from study subjects is a fundamental requirement in the conduct of clinical trials to ensure that the human rights of the study subjects are ensured. In case of minors it is mandatory that the consent be**

1797

647

signed by parents/guardians. For the uneducated subjects, the law requires an independent person to explain and witness the consent process. The Committee is however deeply shocked to find that in Andhra Pradesh out of the 9543 forms, 1948 forms have thumb impressions while hostel wardens have signed 2763 forms. In Gujarat, out of the 6217 forms 3944 have thumb impressions and 5454 either signed or carried thumb impressions of guardians. The data also revealed that a very large number of parents/guardians are illiterate and could not even write in their local languages viz. Telugu or Gujarati. The Committee is further shocked to find from one of the reports that out of 100 consent forms for Andhra Pradesh project signatures of witnesses were missing in 69 forms. In many forms there were no dates. One particular person had signed seven forms. In fact the legality of Andhra Pradesh State Government directing headmasters in all private/ Government/ashram/schools to sign the consent form on behalf of parents/guardians is highly questionable. The absence of photographs of parents/guardians/wardens on consent forms, the absence of signatures of investigators; the signatures of parents/guardians not matching with their names; the date of vaccination being much earlier than the date of signature of parents/guardian in the consent forms, etc. all speak of grave irregularities.

6.17 The Committee, accordingly, concludes that most, if not all consent forms, were carelessly filled-up and were incomplete and inaccurate. The full explanation, role, usefulness and pros and cons of vaccination had not been properly communicated to the parents/guardians. The Committee observes that there is a gross violation of the consent and legal requirement of consent which had been substantiated by the experts. The Committee takes a serious view of the violations and strongly recommends that on the basis of the above facts, PATH should be made accountable and the Ministry should take appropriate action in the matter including taking legal action against it for breach of various laws of the land and possible violations of laws of the Country of its origin.

6.18 The Committee was informed that the basic aim of the study was to evaluate strategies for introduction and delivery of the vaccines in the public sector. Strangely four of the five primary outcome measures proposed in the study related to evaluation and determination of safety of the vaccines.

6.19 One of the experts has stated that there was lack of rigour in the design regarding reporting and dealing with serious adverse events. He has pointed out absence of preparedness in the event of any such occurrence that would put children at grave risk. The side effects mentioned by the manufacturers themselves were revised several times and now include serious health issues. Since there were contra-indications to the use of the vaccines, the reasons for not ascertaining contra-indications before the girls were vaccinated is clearly an act of willful negligence.. The design of the project neither took the possibility of Serious Adverse Event (SAE) seriously nor was there any attention paid to the need for an independent monitoring agency. Consequently action on investigations into the causes of deaths took an unacceptably long time. A number of discrepancies and gaps in the investigations of the deaths have also been pointed out. There was no diary card based reporting of adverse events for recording minor or major adverse events in the study protocol in such a large study. This resulted in gross under reporting of the adverse events.

6.20 Another expert, while analyzing deaths and Adverse Events Following Immunizations (AEFI) has observed after reviewing all seven deaths (five deaths from AP in the Gardasil group and two deaths in Gujarat from Cervarix group), that there was no common pattern to the deaths that would suggest that these were caused by the vaccine. However, the reporting system as per Government of India surveillance of vaccine preventable disease guidelines notification was not done within time limit in two cases in AP and both the cases in Gujarat. There was no uniformity in the reporting system of AEFI in both the States. The primary end point of the study was to

1798

~~648~~

find out the number of girls having serious and non serious adverse events following vaccination through routine UIP system. He has opined that in this regard first of all routine system of reporting should have been verified in both States.

6.21 Another expert has stated that the reporting of non-serious AEs was grossly under reported and hence the accuracy of SAEs is doubtful as well. It has been observed that delay in reporting and investigations of deaths could have been due to sole dependence on routine UIP protocol. It was a significant lapse in the protocol and execution of the study. While reporting on safety aspects in the study, it has been pointed out that there was absence of preparedness to handle Serious Adverse Events (SAE) like anaphylaxis, cardiac arrest, seizures, etc. occurring at the sites of vaccine administration. Though such serious adverse events might be rare but it was advisable to be well prepared for such an eventuality through adequate training of health workers. Assessment of the immune status of the participants by the ANM, ASHA or the health workers was virtually non-existent. These issues needed to be addressed as prescribing information of the HPV vaccines specifically contra-indicates administration in immune-compromised subjects (such as HIV/AIDS etc.).

6.22 **The Committee, in the light of the observations made by experts, feels that the methodology and implementation of the study at both the places was full of flaws. The Committee is of the view that since the population under study was vulnerable, utmost caution should have been exercised in the implementation of the study. The Committee also recommends that there should be an independent monitoring mechanism in such a study involving human participants so that the accurate recording of AEs and SAEs could be made. The findings of the experts clearly indicate that the safety and rights of the children in this vaccination project were highly compromised and violated. The Committee is also concerned over the fact that there was no insurance cover for the children. The Committee strongly recommends that while allowing any such trial in future, all the lapses pointed out by the experts should be addressed effectively. ICMR and DCGI should ensure strict adherence to the guidelines, methodology and monitoring.**

(e) Role of Ethics Committees

6.23 While examining the role of the Ethics Committees in both the States, one of the experts pointed out that Ethics Committees were supposed to meet periodically to evaluate and monitor the progress of the project and review SAE reports. No such meetings were held by the Committees. Only after reports of deaths appeared in the media, the meetings of these Committees were held.

6.24 **The Committee takes a serious note of the fact that both the Ethics Committees existed only as a formality and they did not play the role they were designated for. This is a clear dereliction of duty on the part of the Ethics Committees. The Committee apart from recommending suitable action in the matter, strongly recommends that there should be a mechanism in place to take appropriate action against such dereliction of duty on the part of the Ethics Committees. There should be specific guidelines for Ethics Committees and the Ethics Committees should strictly follow them. The functioning of Ethics Committees should be regularly monitored.**

(f) Use of Official Machinery

6.25 The Committee has noted that the information/publicity material displayed/distributed at trial sites implied that the Government had started a vaccination programme. Thus, the credibility of the Universal Immunization Programme (UIP) was used to promote private, foreign interests. It has

NOTARY
M. M. P...
Mumbai
Maharashtra
Reg. No. 15...
Expiry Dt.
30-10-2024

1799
649

been found that the funds meant for the NRHM were used, without authorization for monitoring and transportation of the vaccines to the fields for use in the project.

6.26 **The Committee observes that the wrongful use of the NRHM logo for a project implemented by a private, foreign agency as well as the identification of this project with the UIP has adversely affected and damaged the credibility of the programme as well as that of the NRHM. The Committee, therefore, recommends that such practices of diverting public funds for advancing interests of a private agency should never be allowed in future. The Committee strongly recommends that strict action should be taken against those officials responsible for such lapses.**

6.27 Besides, the Committee notes that no information had been provided to Indian authorities about funding of the project except that it was reportedly funded by Bill and Melinda Gates Foundation and that the vaccines had been donated by the manufacturers. The information regarding financial investments of ICMR and State Governments in the project was not provided, though the States clearly provided cold chain and manpower for immunization. **The Committee, accordingly, observes that it might have been more prudent if the National Technical Advisory group on Immunization (NTAGI) had been brought into the picture right in the beginning to review and give its views on the study prior to its approval and implementation.**

6.28 No information is available on the total outlay on the project spent by PATH, ICMR, state governments of Andhra Pradesh and Gujarat (immunization staff, cold chain system, equipment, transportation etc.). According to the documents submitted by PATH to ICMR/Health Ministry Screening Committee, the total outlay by PATH for expenses in India was Rs. 29,76,000. However Centre for Operations Research and Training (CORT), a sub-contractor of PATH had quoted US$ 83,889 (first year) and US$ 96,472 (second year), which is not included in the figure submitted to ICMR/HMSC.

6.29 **Considering the above lapses and irregularities committed by PATH during the course of conducting the trials on hapless tribal children in Andhra Pradesh and Gujarat, the Committee is convinced that the authorities concerned did not exercise due diligence in scrutinizing the publicity material of PATH. Blurring the distinction between the UIP and PATH project due to the involvement of the State Governments in the project and ignoring the financial contribution of ICMR and the State Governments are very serious issues. The Committee, therefore, recommends that the Ministry should investigate into the above acts of omissions and commissions and take necessary action against those who are found responsible for breach of rules and regulations.**

(g) Action taken on the Inquiry Committee Report

6.30 With a view to find out the action taken by the Government on the findings of the Inquiry Committee, the Committee again heard the Secretary, Department of Health Research/DG, ICMR along with DCGI at its meeting held on 24th May, 2013. The Secretary informed the Committee that after the submission of Report by the Inquiry Committee, they were formally called to give explanation in the year 2011. In addition, clarifications were also sought from them in between which were formally answered to. The Committee in the said meeting desired to know whether criminal inquiry, if any, has been initiated against PATH on account of the following irregularities in the conduct of trial as pointed out by the Inquiry Committee:

(i) Irregularities in obtaining consent forms and actual implementation of the consent process;

(ii) Lack of monitoring and preparedness to deal with serious adverse events;

1800

~~650~~

(iii) Inclusion of vulnerable and tribal population groups;

(iv) Blurring of distinction between Universal Immunization Programme and PATH study;

(v) Absence of insurance coverage for the study participants; and

(vi) Inclusion of the statement in the consent form that "you will not be charged for your daughter to receive the vaccine" that could be construed as covert inducement.

6.31 The Committee also sought to know as to whether any compensation was awarded to the families of children for suppression of material information before administering vaccines.

6.32 The Committee also took note of the Action Taken Note submitted by Department of Health Research wherein it was informed that subsequent to findings of the Inquiry Committee following action was taken:

(i) PATH was informed about suggestions made by the Committee;

(ii) Principal Investigators of other suspended studies on HPV vaccines were informed to get their studies re-examined from respective Ethics Committees after addressing the concerns raised by the Inquiry Committee;

(iii) DCG(I) was informed of the suggestions of the Committee for necessary action; and

(iv) Suggestions were forwarded to the relevant authority for inclusion in the Draft bill on Biomedical Research on Human Subjects.

6.33 DCG(I) informed the Committee that subsequent to findings of the Inquiry Committee; the following action was taken:

(i) Both the manufacturers of HPV vaccines have been asked to submit additional data for 4 years on PSURs (Periodic Safety Update Reports), every 6 months for first 2 years, and annually during the subsequent 2 years, and to submit protocol for approval for conducting post marketing surveillance study;

(ii) Proposal to amend the definition of "New Drug" under rule 122-E would be taken up for consideration; and,

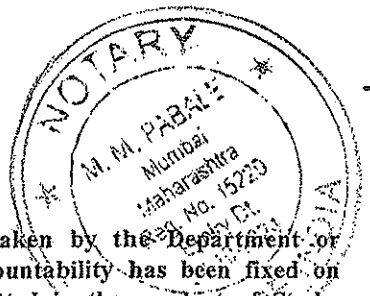
(iii) In future the following steps would be ensured before approving a clinical trial by DCG(I): (a) every clinical trial is to be registered at ICMR's clinical trial registry of India; (b) every approval would include a condition for provision of complete medical care in case of study related injury/death and the statement to this effect is to be included in the informed consent: (c) DCG(I) should be informed about death/injury: (d) Schedule 'Y' would be amended to expand the responsibilities of sponsors, investigators and Ethics Committees; and (e) the consent forms are to be amended to include details of address and occupations of subject giving socio-economic background.

6.34 **The Committee is amazed at the audacity of DCGI to merely repeat various steps which it proposes to take as if they are new, additional measures. All these are already part of the written rules and are supposed to be followed by all sponsors. Except for slight amendment in the Informed Consent Form, there is nothing new in the ATN submitted by DCGI.**

6.35 The Committee observes that the Department has nothing fresh to offer in the status note as the same information was furnished by it in December, 2012 *vide* its updated note on Action Taken after availability of Report of enquiry Committee.

1801

~~651~~



6.36 **The Committee not being convinced with the action taken by the Department or DCGI, feels that the whole issue has been diluted and no accountability has been fixed on the erring Officials/Departments for the gross violations committed in the conduct of Study. The Committee also feels that a very casual approach has been taken by the Department in the matter and their replies lack any concrete action to protect and safeguard the health of our people.**

6.37 **The Committee also noticed lack of firm action on the part of DCGI, to avoid such irregularities in future. One of the actions proposed by the DCGI to check any recurrence of such gross violations was 'proposal to amend the definition of New Drug during the next meeting'. The same assurance was given by DCGI in December, 2012. The Committee, accordingly, observes that response of the Department and DCGI is very casual, bureaucratic and lacks any sense of urgency. The Committee feels that DCGI is not very serious in bringing improvements in the system. It, therefore, desires the Ministry to ensure compliance by DCGI.**

VII. PROGRAMME FOR APPROPRIATE TECHNOLOGY IN HEALTH (PATH)

7.1 The Committee during the course of its present examination sought information from the Government about PATH in order have a better understanding of its legal status and its *locus standi* in carrying out various activities on the Indian soil including the project in question where apparently several laws of India and possibly of its country of origin had been violated.

7.2 The information furnished to the Committee reveals that PATH describes itself as an "International nonprofit, non-government organization based in the United States." Legally, it is a Public Benefit Corporation (PBC) registered (No. 600588751 dated 28th August, 1981) by the Corporation and Charities Division in the State of Washington. For all practical purposes its legal status in US is equivalent to a Registered Society in the Indian context. It is certainly not a commercial company and hence would not be subject to the jurisdiction of Company Law Board or Registrar of Companies in India. Incidentally, Ford Foundation is also a PBC (Registration number 768093 dated 15th January, 1936). Under American laws organizations such as Trusts, Fraternal Societies, Savings and Loan Associations, Municipal Utility Services etc. are all registered as PBCs.

7.3 Under Indian rules, foreign non-commercial organizations such as PATH wanting to set up an office in India are required to obtain (a) permission from the Ministry of External Affairs (MEA) from "political angle" (**Annexure B**) and (b) permission from Ministry of Home Affairs (MHA) from "security angle" (**Annexure C**). In the latter case, application needs to be forwarded through proper channel such as Ministry of Health and Family Welfare for health-related activities, Ministry of Human Resources for education related activities, Ministry of Labour for trade union or workers related activities etc. Once such an approval is accorded, then an office can be setup which should naturally abide by all other laws of the land such as income tax, shop and establishment act, municipal and other applicable laws, just to mention a few.

7.4 The Committee asked the Department to direct PATH to provide details of various mandatory permissions required by foreign agencies, including charities, for and in connection with opening office in India and the date of opening of its office in India. Unbelievably, the exact date of opening the office is not even known to its functionaries in New Delhi. To begin with vide its letter dated 5-3-2012, PATH claimed that "it has a Liaison Office status under Income Tax Rules." Since no such provision exists, after prolonged correspondence it settled for 19th April, 1999 as the date of opening office based on the fact that its PAN card (No. AAFCP2249G) is dated 19th April, 1999. The Committee was intrigued because PAN card is issued just for income tax

1802

652



purposes and nothing else. Income Tax Department does not go about permitting foreign entities to open offices in India. In any case PAN card is not a replacement for Ministry of External Affairs and Ministry of Home Affairs approvals. Besides, the application for issuance of PAN card must have been made much before 19th April 1999 there being no online system of obtaining PAN card instantaneously. It can be safely assumed that the date of opening office has to be much earlier than 19th April, 1999.

7.5 PATH also produced copy of a letter dated 16-3-1999 from PATH office in US to the Exchange Control Department of the Reserve Bank of India along with reply dated 19-4-1999 received by PATH in US on 29-4-1999. It merely stated that since PATH is "not engaged in any commercial, trading or industrial activity," it does not need "RBI permission from foreign exchange angle. *However you may seek necessary approval from the Government of India or other statutory/ regulatory bodies as applicable."* Apparently PATH paid no attention to RBI's sane advice. Even before the letter reached PATH office in the United States on 29-4-1999, it had already opened its office in India.

7.6 The Foreign Exchange Regulation Act (FERA) was replaced with Foreign Exchange Management Act (FEMA) on 1-6-2000. PATH produced post-facto permission from the Reserve Bank of India dated 25-5-2009 which clearly stated:

> *"RBI permission (is) granted from the foreign exchange angle....and should not be construed to convey the approval of any other statutory authority or Government under any other laws/regulations."* Moreover, the Liaison Office is permitted to undertake "solely liaison work for the head office" as mentioned below:
>
> 1. Representing in India the parent company/group companies
> 2. Promoting export, import from/to India.
> 3. Promoting technical/financial collaborations between parent/group companies and companies in India.
> 4. Acting as a communication channel between the parent company and Indian companies.
>
> "The office in India will not render any consultancy or any other services directly/indirectly with or without any consideration."
>
> In addition *"Permission granted by RBI is limited to and for the purpose of the provisions of FEMA-2000 and shall not be construed in any way as regularizing, condoning or in any manner validating any irregularities, contraventions and other lapses, if any, under the provisions of any other law."*

7.7 It is clear that the back dated permission obtained after 10 years of having opened its office in India was merely and exclusively from foreign exchange angle and not a substitute for approval from MEA and MHA.

7.8 Finally and belatedly PATH produced a certificate from the Registrar of Companies (RoC) dated 23-9-2009 stating that PATH, a company originally incorporated in US, had filed documents on 10-09-2009 notifying establishment of place of business in India *w.e.f.* 19.4.1999. The Certificate was apparently issued in violation of its own rules that states that documents must be submitted within 30 days of the establishment of "place of business." In any case such a certificate cannot and does not obviate the need to obtain baseline, mandatory permission from MEA and MHA. Moreover RoC deals with commercial companies, not foreign trusts, foundations and charities.

1803
653

7.9 PATH also claimed that it had received "permission" from the Ministry of Health and Family Welfare to set up an office in India. The *post-facto* letter dated 27-4-2001 (two years after PATH admits having opened the office in India) is not a permission at all but a vague, non-specific statement to say that PATH was "engaged in health care related activities".

7.10 According to the published Annual Report of PATH for the year 2008, it received funding in "excess of US $ 1,000" from many governmental sources including the Ministry of Health and Family Welfare, Government of India. However, in response to Rajya Sabha Question Number 952 on 3.8.2010, the Health Minister denied any Ministry funding to PATH.

7.11 **The Committee is concerned that if PATH can set up an office in India so easily without getting the required mandatory approvals/permissions, then individuals and entities inimical to the interest of the country can do the same. The Committee expresses its concern that paper and shell companies can be easily registered in many jurisdictions and then set up a place of business in India as "Liaison offices" with no questions being asked. It is surprising that security and intelligence agencies did not raise an eyebrow on the way a foreign entity entered India virtually incognito through the backdoor. The Committee desires that such incidents should not be allowed in future. The Government should tighten the rules lest one day foreign citizens, with deep roots in organizations/nations inimical to India, set up offices in the country to engage in anti-national and/or unlawful activities.**

7.12 **It is apparent the PATH has exploited with impunity the loopholes in our system as also the absence of a nodal point or a single window for maintaining a data bank of foreign entities entering the Country for setting up their offices. Given the multiplicity of agencies involved in processing such requests there is a definite need for a nodal agency which would keep a tab on all such existing and aspiring agencies from the point of view of having obtained all necessary clearances/permissions before commencing their operations in India. The Committee strongly recommends that government set up one such umbrella agency which should be linked to all the agencies that are involved in processing such requests. The Committee desires that within three months such an agency should be put in place and start functioning. The proposed nodal agency should be a part of MHA with a well established coordination mechanism with the MEA so that undeserving cases are dealt forthwith through diplomatic channels. All ministries/departments/agencies/state governments/other entities should be required to share details of all requests/proposals from foreign entities for setting up offices in any form with this nodal agency.**

7.13 **Coming to the instant case, it is established that PATH by carrying out the clinical trials for HPV vaccines in Andhra Pradesh and Gujarat under the pretext of observation/ demonstration project has violated all laws and regulations laid down for clinical trials by the Government. While doing so, its sole aim has been to promote the commercial interests of HPV vaccine manufacturers who would have reaped windfall profits had PATH been successful in getting the HPV vaccine included in the UIP of the Country. This is a serious breach of trust by any entity as the project involved life and safety of girl children and adolescents who were mostly unaware of the implications of vaccination. The violation is also a serious breach of medical ethics. This act of PATH is a clear cut violation of the human rights of these girl children and adolescents. It also deems it an established case of child abuse. The Committee, therefore, recommends action by the Government against PATH. The Committee also desires that the National Human Rights Commission and National Commission for Protection of Children Rights may take up this matter from the point of view of the violation of human rights and child abuse. The National Commission for Women should also *suo motu* take cognizance of this case as all the poor and hapless subjects are females.**

1804

654

7.14 **The Ministry of Health and Family Welfare should without wasting time report the violations indulged in by PATH to international bodies like WHO and UNICEF so as to ensure that appropriate remedial action is initiated by these agencies worldwide.**

7.15 **The Committee also desires that the Ministry of Health and Family Welfare may take up the matter through the Ministry of External Affairs with the US Government so as to ensure that appropriate action is taken against PATH under the laws of its country of origin in case of any violations of laws there.**



1805

~~655~~

OBSERVATIONS/RECOMMENDATIONS — AT A GLANCE

II. NATURE OF PROJECT

1. The Committee finds the entire matter very intriguing and fishy. The choice of countries and population groups; the monopolistic nature, at that point of time, of the product being pushed; the unlimited market potential and opportunities in the universal immunization progammes of the respective countries are all pointers to a well planned scheme to commercially exploit a situation. Had PATH been successful in getting the HPV vaccine included in the universal immunization programme of the concerned countries, this would have generated windfall profit for the manufacturer(s) by way of automatic sale, year after year, without any promotional or marketing expenses. It is well known that once introduced into the immunization programme it becomes politically impossible to stop any vaccination. To achieve this end effortlessly without going through the arduous and strictly regulated route of clinical trials, PATH resorted to an element of subterfuge by calling the clinical trials as "Observational Studies" or "Demonstration Project" and various such expressions. Thus, the interest, safety and well being of subjects were completely jeopardized by PATH by using self-determined and self-servicing nomenclature which is not only highly deplorable but a serious breach of law of the land. The Committee is not aware about the strategy followed by PATH in the remaining three countries *viz.* Uganda, Vietnam and Peru. The Government should take up the matter with the Governments of these countries through diplomatic channels to know the truth of the matter and take appropriate necessary action, accordingly. The Committee would also like to be apprised of the responses of these countries in the matter. (Para 2.5)

III. ROLE OF DEPARTMENT OF HEALTH RESEARCH/INDIAN COUNCIL OF MEDICAL RESEARCH

2. The Committee is unable to understand as to how ICMR could commit itself to support "the use of the HPV vaccine" in an MOU signed in the year 2007 even before the vaccine was approved for use in the country, which actually happened in 2008. The Committee also questions the decision of ICMR to commit itself to promote the drug for inclusion in the Universal Immunization Programme (UIP) even before any independent study about its utility and rationale of inclusion in UIP was undertaken. (Para 3.10)

3. The Committee feels that there was serious dereliction of duty by many of the Institutions and individuals involved. The Committee observes that ICMR representatives, instead of ensuring highest levels of ethical standards in research studies, apparently acted at the behest of the PATH in promoting the interests of manufacturers of the HPV Vaccine. (Para 3.18)

4. It was unwise on the part of ICMR to go in the PPP mode with PATH, as such an involvement gives rise to grave Conflict of Interest. The Committee takes a serious view of the role of ICMR in the entire episode and is constrained to observe that ICMR should have been more responsible in the matter. The Committee strongly recommends that the Ministry may review the activities of ICMR functionaries involved in PATH project. (Para 3.19)

180C
656

5. The Committee from its examination has found that DHR/ICMR have completely failed to perform their mandated role and responsibility as the apex body for medical research in the Country. Rather, in their over-enthusiasm to act as a willing facilitator to the machinations of PATH they have even transgressed into the domain of other bodies/ agencies which deserves the strongest condemnation and strictest action against them. The Committee fails to understand as to why ICMR took so much interest and initiative in this project when the safety, efficacy and introduction of vaccines in India is handled by National Technical Advisory Group on Immunization (NTAGI). The submissions of the Secretary, DHR/DG, ICMR before the Committee about the commencement of the project, facts of the case and the action taken have also failed to stand scrutiny during the Committee's examination of the matter. The Committee, therefore, reiterates the recommendation made in their Forty-first Report that the matter of allowing trial of the vaccine as also the approval for its marketing in the Country be inquired into by a premier investigating agency and appropriate action be taken thereafter by the Government in the matter. The Committee expects the Government not to procrastinate in this matter any further. (Para 3.22)

IV. ROLE OF DRUG CONTROLLER GENERAL, INDIA (DCGI)

6. The Committee's examination has proved that DCGI has also played a very questionable role in the entire matter. Initially, it took a call that since human subjects, as part of the studies, were receiving invasive intervention like immunization, clinical trial rules must be enforced. However, it remained as a silent spectator thereafter, even when its own rules and regulations were being so flagrantly violated. The approvals of clinical trials, marketing approval and import licenses by DCGI appear to be irregular. Therefore, the role of DCGI in this entire matter should also be inquired into. (Para 4.6)

VI. INQUIRY COMMITTEE

(c) Adverse Events Reporting

7. The Committee notes that once this matter was taken up by it, the Government appointed an Inquiry Committee on 15 April, 2010 to inquire into 'alleged irregularities in the conduct of the studies using HPV vaccines by PATH in India'. The Committee has noted the serious conflict of interest of members of this Inquiry Committee with the subject matter. The Committee, therefore, strongly deprecates the Government for appointing a committee to inquire into such a serious matter in such a casual manner even without ascertaining as to whether any of the members of the said Inquiry Committee were having any conflict of interest with the subject matter of inquiry. (Para 6.10)

8. The Committee finds it very intriguing as to when the Inquiry Committee after having sought details of some core issues in the very first meeting of the Committee on 21 April, 2007 subsequently chose not to pursue them purportedly because 'it wanted to restrict itself to its terms of reference'. These core issues raised by the Inquiry Committee earlier, if pursued to their logical end, would not only have provided the Inquiry Committee a lot more clarity in unraveling the truth but also the Country would have known the exact details as to what transpired in this sordid incident. (Para 6.11)

(d) Informed Consent

9. The Committee observes that obtaining informed consent from study subjects is a fundamental requirement in the conduct of clinical trials to ensure that the human rights

NOTARY
M. M. PABALE
Mumbai
Maharashtra
Reg. No. 15220
Expiry Dt.
30-10-2020
GOVT. OF INDIA

1807
657

of the study subjects are ensured. In case of minors it is mandatory that the consent be signed by parents/guardians. For the uneducated subjects, the law requires an independent person to explain and witness the consent process. The Committee is however, deeply shocked to find that in Andhra Pradesh out of the 9543 forms, 1948 forms have thumb impressions while hostel wardens have signed 2763 forms. In Gujarat, out of the 6217 forms 3944 have thumb impressions and 5454 either signed or carried thumb impressions of guardians. The data also revealed that a very large number of parents/guardians are illiterate and could not even write in their local languages viz. Telugu or Gujarati. The Committee is further shocked to find from one of the reports that out of 100 consent forms for Andhra Pradesh project signatures of witnesses were missing in 69 forms. In many forms there were no dates. One particular person had signed seven forms. In fact the legality of Andhra Pradesh State Government directing headmasters in all private/ Government/ashram/schools to sign the consent form on behalf of parents/guardians is highly questionable. The absence of photographs of parents/guardians/wardens on consent forms, the absence of signatures of investigators; the signatures of parents/guardians not matching with their names; the date of vaccination being much earlier than the date of signature of parents/guardian in the consent forms, etc. all speak of grave irregularities. (Para 6.16)

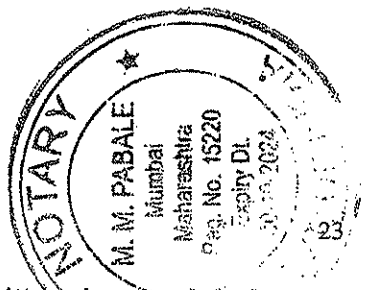
10. The Committee, accordingly, concludes that most, if not all consent forms, were carelessly filled-up and were incomplete and inaccurate. The full explanation, role, usefulness and pros and cons of vaccination had not been properly communicated to the parents/guardians. The Committee observes that there is a gross violation of the concept and legal requirement of consent which had been substantiated by the experts. The Committee takes a serious view of the violations and strongly recommends that on the basis of the above facts, PATH should be made accountable and the Ministry should take appropriate action in the matter including taking legal action against it for breach of various laws of the land and possible violations of laws of the Country of its origin. (Para 6.17)

11. The Committee, in the light of the observations made by experts, feels that the methodology and implementation of the study at both the places was full of flaws. The Committee is of the view that since the population under study was vulnerable, utmost caution should have been exercised in the implementation of the study. The Committee also recommends that there should be an independent monitoring mechanism in such a study involving human participants so that the accurate recording of AEs and SAEs could be made. The findings of the experts clearly indicate that the safety and rights of the children in this vaccination project were highly compromised and violated. The Committee is also concerned over the fact that there was no insurance cover for the children. The Committee strongly recommends that while allowing any such trial in future, all the lapses pointed out by the experts should be addressed effectively. ICMR and DCGI should ensure strict adherence to the guidelines, methodology and monitoring. (Para 6.22)

12. The Committee takes a serious note of the fact that both the Ethics Committees existed only as a formality and they did not play the role they were designated for. This is a clear dereliction of duty on the part of the Ethics Committees. The Committee apart from recommending suitable action in the matter, strongly recommends that there should be a mechanism in place to take appropriate action against such dereliction of duty on the part of the Ethics Committees. There should be specific guidelines for Ethics Committees and the Ethics Committees should strictly follow them. The functioning of Ethics Committees should be regularly monitored. (Para 6.24)

1808

658



13. The Committee observes that the wrongful use of the NRHM logo for a project implemented by a private, foreign agency as well as the identification of this project with the UIP has adversely affected and damaged the credibility of the programme as well as that of the NRHM. The Committee, therefore, recommends that such practices of diverting public funds for advancing interests of a private agency should never be allowed in future. The Committee strongly recommends that strict action should be taken against those officials responsible for such lapses. (Para 6.26)

14. Besides, the Committee notes that no information had been provided to Indian authorities about funding of the project except that it was reportedly funded by Bill and Melinda Gates Foundation and that the vaccines had been donated by the manufacturers. The information regarding financial investments of ICMR and State Governments in the project was not provided, though the States clearly provided cold chain and manpower for immunization. The Committee, accordingly, observes that it might have been more prudent if the National Technical Advisory group on Immunization (NTAGI) had been brought into the picture right in the beginning to review and give its views on the study prior to its approval and implementation. (Para 6.27)

15. Considering the above lapses and irregularities committed by PATH during the course of conducting the trials on hapless tribal children in Andhra Pradesh and Gujarat, the Committee is convinced that the authorities concerned did not exercise due diligence in scrutinizing the publicity material of PATH. Blurring the distinction between the UIP and PATH project due to the involvement of the State Governments in the project and ignoring the financial contribution of ICMR and the State Governments are very serious issues. The Committee, therefore, recommends that the Ministry should investigate into the above acts of omissions and commissions and take necessary action against those who are found responsible for breach of rules and regulations. (Para 6.29)

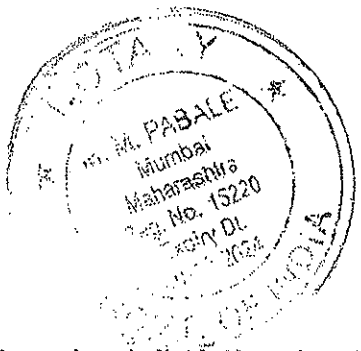
16. The Committee is amazed at the audacity of DCGI to merely repeat various steps which it proposes to take as if they are new, additional measures. All these are already part of the written rules and are supposed to be followed by all sponsors. Except for slight amendment in the Informed Consent Form, there is nothing new in the ATN submitted by DCGI. (Para 6.34)

17. The Committee not being convinced with the action taken by the Department or DCGI, feels that the whole issue has been diluted and no accountability has been fixed on the erring Officials/Departments for the gross violations committed in the conduct of Study. The Committee also feels that a very casual approach has been taken by the Department in the matter and their replies lack any concrete action to protect and safeguard the health of our people. (Para 6.36)

18. The Committee also noticed lack of firm action on the part of DCGI, to avoid such irregularities in future. One of the actions proposed by the DCGI to check any recurrence of such gross violations was 'proposal to amend the definition of New Drug during the next meeting'. The same assurance was given by DCGI in December, 2012. The Committee, accordingly, observes that response of the Department and DCGI is very casual, bureaucratic and lacks any sense of urgency. The Committee feels that DCGI is not very serious in bringing improvements in the system. It, therefore, desires the Ministry to ensure compliance by DCGI. (Para 6.37)

VII. PROGRAMME FOR APPROPRIATE TECHNOLOGY IN HEALTH (PATH)

19. The Committee is concerned that if PATH can set up an office in India so easily



1809
659

without getting the required mandatory approvals/permissions, then individuals and entities inimical to the interest of the country can do the same. The Committee expresses its concern that paper and shell companies can be easily registered in many jurisdictions and then set up a place of business in India as "Liaison offices" with no questions being asked. It is surprising that security and intelligence agencies did not raise an eyebrow on the way a foreign entity entered India virtually incognito through the backdoor. The Committee desires that such incidents should not be allowed in future. The Government should tighten the rules lest one day foreign citizens, with deep roots in organizations/nations inimical to India, set up offices in the country to engage in anti-national and/or unlawful activities. (Para 7.11)

20. It is apparent the PATH has exploited with impunity the loopholes in our system as also the absence of a nodal point or a single window for maintaining a data bank of foreign entities entering the Country for setting up their offices. Given the multiplicity of agencies involved in processing such requests there is a definite need for a nodal agency which would keep a tab on all such existing and aspiring agencies from the point of view of having obtained all necessary clearances/permissions before commencing their operations in India. The Committee strongly recommends that government set up one such umbrella agency which should be linked to all the agencies that are involved in processing such requests. The Committee desires that within three months such an agency should be put in place and start functioning. The proposed nodal agency should be a part of MHA with a well established coordination mechanism with the MEA so that undeserving cases are dealt forthwith through diplomatic channels. All ministries/departments/agencies/state governments/other entities should be required to share details of all requests/proposals from foreign entities for setting up offices in any form with this nodal agency. (Para 7.12)

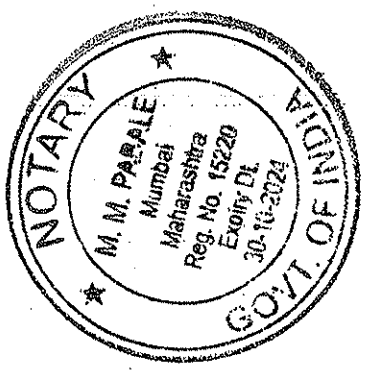
21. Coming to the instant case, it is established that PATH by carrying out the clinical trials for HPV vaccines in Andhra Pradesh and Gujarat under the pretext of observation/ demonstration project has violated all laws and regulations laid down for clinical trials by the Government. While doing so, its sole aim has been to promote the commercial interests of HPV vaccine manufacturers who would have reaped windfall profits had PATH been successful in getting the HPV vaccine included in the UIP of the Country. This is a serious breach of trust by any entity as the project involved life and safety of girl children and adolescents who were mostly unaware of the implications of vaccination. The violation is also a serious breach of medical ethics. This act of PATH is a clear cut violation of the human rights of these girl children and adolescents. It also deems it an established case of child abuse. The Committee, therefore, recommends action by the Government against PATH. The Committee also desires that the National Human Rights Commission and National Commission for Protection of Children Rights may take up this matter from the point of view of the violation of human rights and child abuse. The National Commission for Women should also *suo motu* take cognizance of this case as all the poor and hapless subjects are females. (Para 7.13)

22. The Ministry of Health and Family Welfare should without wasting time report the violations indulged in by PATH to international bodies like WHO and UNICEF so as to ensure that appropriate remedial action is initiated by these agencies worldwide. (Para 7.14)

23. The Committee also desires that the Ministry of Health and Family Welfare may take up the matter through the Ministry of External Affairs with the US Government so as to ensure that appropriate action is taken against PATH under the laws of its country of origin in case of any violations of laws there. (Para 7.15)

1810

660

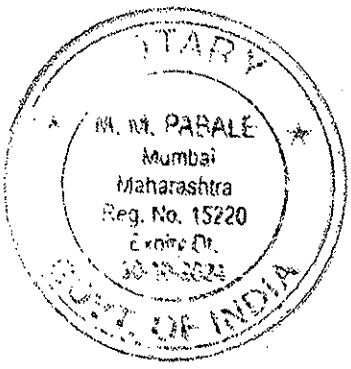


MINUTES

1811

~~661~~

ITARY
M. M. PABALE
Mumbai
Maharashtra
Reg. No. 15220
Expiry Dt.
30-10-2024
GOVT. OF INDIA



1812

662

VIII

EIGHTH MEETING

(2009-10)

The Committee met at 11.00 A.M. on Tuesday, the 6th April, 2010 in Room No. 139, First Floor, Parliament House Annexe, New Delhi.

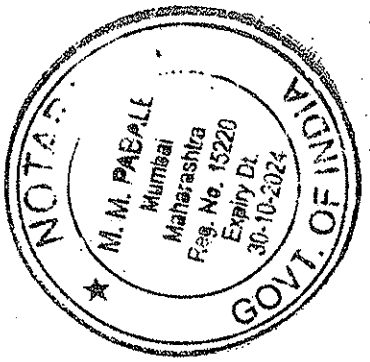
MEMBERS PRESENT

RAJYA SABHA

1. Shri Amar Singh — *Chairman*
2. Shrimati Viplove Thakur
3. Dr. Radhakant Nayak
4. Shri Janardan Dwivedi
5. Shrimati Brinda Karat
6. Shrimati Vasanthi Stanley

LOK SABHA

7. Shri Ashok Argal
8. Shrimati Sarika Devendra Singh Baghel
9. Dr. Chinta Mohan
10. Dr. Sanjay Jaiswal
11. Shri S.R. Jeyadurai
12. Dr. (Shrimati) Kruparani Killi
13. Shri N. Kristappa
14. Dr. Tarun Mandal
15. Dr. Jyoti Mirdha
16. Shri R.K. Singh Patel
17. Dr. Anup Kumar Saha
18. Shrimati Meena Singh
19. Dr. Arvind Kumar Sharma
20. Shri Ratan Singh



SECRETARIAT

Shrimati Vandana Garg, *Additional Secretary*

Shri R. B. Gupta, *Director*

Shrimati Arpana Mendiratta, *Joint Director*

Shri Dinesh Singh, *Assistant Director*

1813

663

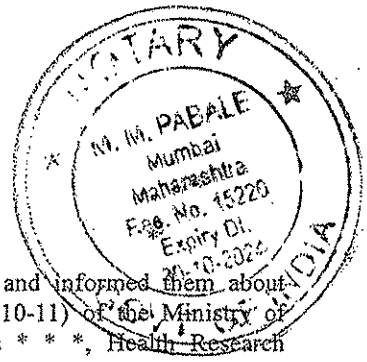
WITNESSES

* * *

Representatives from the Department of Health Research

1. Dr.Vishwa Mohan Katoch, Secretary
2. Ms. Shalini Prasad, Joint Secretary
3. Dr. Vijay Kumar, Scientist
4. Dr. Bela Shah, Head NCD Division
5. Dr. K. Satyanarayana, Head P&I Division
6. Shri Sanjiv Datta, Financial Adviser

* *



2. At the outset, the Chairman welcomed Members to the meeting and informed them about the agenda of the meeting, *i.e.*, examination of Demands for Grants (2010-11) of the Ministry of Health and Family Welfare and taking oral evidence of the Secretaries * * *, Health Research * * * in connection therewith.

3. * * *

4. * * *

5. * * *

6. * * *

7. The Committee then adjourned at 1.30 P.M. for lunch to meet again at 2.30 P.M.

8. * * *

9. During the course of the meeting, Shrimati Brinda Karat, Member of the Committee raised the issue about the trial of HPV vaccine on the children in Khammam district of Andhra Pradesh and reported deaths of the children therefrom and sought exact status in this regard from the Secretary. The Secretary, Department of Health Research informed the Committee that the Drug Controller General of India had given approval for marketing of HPV vaccine in India as per schedule 'Y' of the Drugs and Cosmetics Act and then a post-marketing surveillance. The Committee was informed that the proposal for trial came two years back before the ICMR through PATH, an American NGO. Attention of the Secretary was drawn to DCGI guidelines whereunder third phase trial cannot be conducted on children until a similar trial was conducted on adults. It was admitted by the Secretary that the DCGI guidelines were not adhered to in the present case. The Committee was assured that State Governments of Andhra Pradesh and Gujarat would be asked to get the ongoing clinical trial stopped immediately. Taking serious view of procedural and ethical lapses on the part of the Ministry, the Committee sought the matter of allowing trial of the vaccine as also the approval for its marketing in the country to be enquired into by a premier investigating agency and to take further appropriate action in the matter. It also asked that findings of the investigating agency and the follow-up action taken in this regard may be furnished to the Committee at the earliest.

10. * * *

11. * * *

12. A verbatim record of the proceedings of the meeting was kept.

13. The Committee then adjourned at 5.15 P.M.

---

* Relate to other matters.

1814

~~664~~

XV

FIFTEENTH MEETING

(2010-11)

The Committee met at 11.00 A.M. on Monday, the 25th July, 2011 in Committee Room 'A', Ground Floor, Parliament House Annexe, New Delhi.

MEMBERS PRESENT

RAJYA SABHA

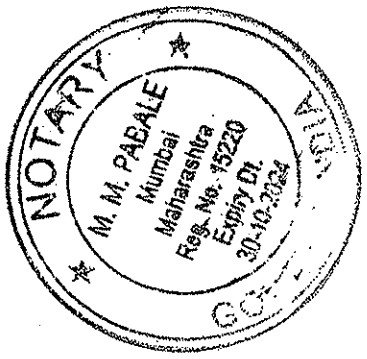
1. Shri Brajesh Pathak — *Chairman*
2. Shri Janardan Dwivedi
3. Shrimati Viplove Thakur
4. Dr. Vijaylaxmi Sadho
5. Shrimati Brinda Karat
6. Shri Rasheed Masood
7. Shrimati B. Jayashree

LOK SABHA

8. Shri Ashok Argal
9. Shrimati Sarika Devendra Singh Baghel
10. Shri Vijay Bahuguna
11. Dr. Sanjay Jaiswal
12. Shri S.R. Jeyadurai
13. Shri N. Kristappa
14. Dr. Tarun Mandal
15. Dr. Jyoti Mirdha
16. Dr. Anup Kumar Saha
17. Shrimati Meena Singh
18. Shri Pradeep Kumar Singh

SECRETARIAT

Shri P.P.K. Ramacharyulu, *Joint Secretary*
Shri R. B. Gupta, *Director*
Shrimati Arpana Mendiratta, *Joint Director*
Shri Dinesh Singh, *Assistant Director*



WITNESSES

* * *

Department of Health Research

1. Dr. V.M. Katoch, Secretary, Health Research
2. Ms. Shalini Prasad, Joint Secretary
3. Shri S.K. Rao, Joint Secretary

---

* Relate to other matters.

2. The Chairman welcomed the Members of the Committee and apprised them of the agenda of the meeting, *i.e.* to hear oral evidence on (i) * * *(ii) * * * and (iii) issues arising out of the final report of the Committee to enquire into "Alleged irregularities in the conduct of studies using Human Papilloma Virus (HPV)" by PATH in the country.

3. * * *

4. * * *

(The Committee adjourned at 12.20 *P.M. to meet again at* 2.30 *P.M.)*

5. In the second half of the meeting, the Committee heard the views of Secretaries of Departments of Health Research and Health and Family Welfare on the issues arising out of the final report of the Committee appointed to enquire into "Alleged irregularities in the conduct of studies using Human Papilloma Virus (HPV) by PATH in the country". The Secretary, Department of Health Research, in his deposition, admitted before the Committee that the trials of the vaccine were not conducted by PATH according to the required protocol/guidelines in Andhra Pradesh. He admitted flaws in ethical procedure in conducting the tests such as lack of proper consent from the parents etc. He further stated that new guidelines are being issued and a moratorium has been imposed on further trials till guidelines are issued. The Members raised some queries like how far it was ethically correct for ICMR to go into Private Public Partnership (PPP) mode, faulty design of project; differences between ICMR and DCGI with respect to the project, action taken against the person involved; sale of this vaccine even before it was tested. The Members also enquired as to why the said enquiry report has not been posted on the website of the Ministry. The Secretary, Department of Health and Family Welfare submitted before the Committee that show cause notice of 15 days has been issued to PATH to seek its written views on the issue and action will be taken within three months after the reply of PATH is received. Members also raised queries like sources and magnitude of funding of this project, compensation to the affected parties and blacklisting of PATH, etc. which were partly answered. The Committee directed the witnesses to furnish written replies to queries which remained unanswered.

6. A verbatim record of the proceedings of the meeting was kept.

7. The Committee then adjourned at 3.30 P.M.

NOTARY
M. M. PABALE
Mumbai
Maharashtra
Reg. No. 15220
Expiry Dt.
INDIA

* Relate to other matters.

1816

~~666~~

XII

TWELFTH MEETING

(2012-13)

The Committee met at 12.00 (NOON) on Friday, the 24th May, 2013 in Committee Room 'A', Ground Floor, Parliament House Annexe, New Delhi.

MEMBERS PRESENT

1. Shri Brajesh Pathak — *Chairman*

RAJYA SABHA

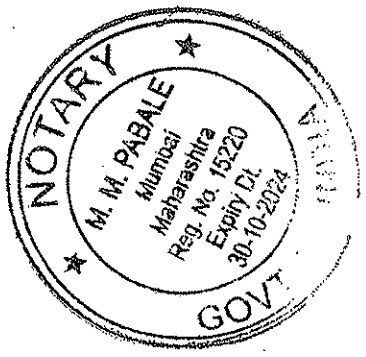
2. Dr. Vijaylaxmi Sadho
3. Shri Rasheed Masood
4. Shri Jagat Prakash Nadda
5. Shri D. Raja
6. Shri H.K. Dua
7. Shrimati B. Jayashree

LOK SABHA

8. Shri Kirti Azad
9. Shri Mohd. Azharuddin
10. Shrimati Sarika Devendra Singh Baghel
11. Dr. Sucharu Ranjan Haldar
12. Dr. Monazir Hassan
13. Dr. Sanjay Jaiswal
14. Shri Tarun Mandal
15. Shrimati Jayshreeben Patel
16. Shri Harin Pathak
17. Dr. Anup Kumar Saha
18. Dr. Raghuvansh Prasad Singh

SECRETARIAT

Shri P.P.K. Ramacharyulu, *Joint Secretary*
Shri R. B. Gupta, *Director*
Shrimati Arpana Mendiratta, *Joint Director*
Shri Pratap Shenoy, *Committee Officer*



WITNESSES

Department of Health Research

1. Dr. V. M. Katoch, Secretary
2. Dr. D. K. Shukla, Scientist-F
3. Dr. Tanveer Kaur, Scientist-D

1817
667

Department of Health and Family Welfare

Dr. G. N. Singh, Drug Controller General of India

I. Opening Remarks

2. At the outset, the Chairman welcomed Members of the Committee and apprised them of the agenda of the meeting, *i.e.*, to hear the Secretary, Department of Health Research along with the Drug Controller General of India (DCGI) on the Action Taken on the final report of the Committee appointed by the Government of India to enquire into "Alleged irregularities in the conduct of studies using Human Papilloma Virus (HPV) vaccine" by PATH in India. * * *

II. Oral Evidence of the Secretary, Department of Health Research and DCGI on the final report of the Committee appointed by the Government of India to enquire into"Alleged irregularities in the conduct of studies using Human Papilloma Virus (HPV) vaccine" by PATH in India

3. Thereafter, the Committee heard the Secretary, Department of Health Research on the Action Taken on the final report of the Committee appointed by the Government of India to enquire into"Alleged irregularities in the conduct of studies using Human Papilloma Virus (HPV) vaccine" by PATH in India. In his deposition, the Secretary, stated that in the year 2007, PATH had applied for licence for trials which was approved in the year 2008 and trails were started on the tribal and non tribal girls of Andhra Pradesh and Gujarat in the year 2009 to see the acceptance of the vaccines. In the year 2010, five deaths in Andhra Pradesh and two deaths in Gujarat were reported. Subsequent to the reported deaths an expert Committee was set up under the Chairmanship of Prof. S.S. Aggarwal, PGIMER, Chandigarh, which in its Report submitted in February, 2011, found the discrepancies in respect of: (i) consent forms and actual implementation of the consent process; (ii) methods of monitoring of adverse effects/serious adverse effects and remedial measure for such events; (iii) inclusion of vulnerable and tribal population groups; (iv) blurring of distinction between National Immunization Programme and Path study; (v) insurance coverage for the study participants; and (vi) convert inducement and indirect coercion etc. The Secretary, apprised the Committee about the remedial action taken pursuant to the findings of the expert Committee. However, members were not satisfied with the action taken by the Department.

4. The Drug Controller General of India, in his deposition, *inter alia* stated that during the future trials for any vaccination, the following safeguards would be adopted: (i) consent form would be transparent; (ii) consent would be in audiovisual format; (iii) clear guidelines have been framed. He also informed the Committee that these guidelines are available on the website of the Ministry. Further, he informed the Committee that in future strict emphasis would be laid on enforcement and patient safety.

5. Thereafter, members raised queries on some issues including conduct of trail without guardian's approval; details of action taken, if any, against officials who had given approval to these trials; absence of complete details of postmortem conducted on the subjects who had died during the said trials; details of use of machinery of State Governments by PATH during the conduct of the trials; whether the said trials were classified as 'clinical trial'; non action on the findings of the Expert Committee, etc. The Chairman directed the witnesses to send comprehensive written replies to queries which remained unanswered, within a week's time.

6. A verbatim record of the proceedings of the meeting was kept.

7. The Committee adjourned at 12.56 P.M.

---

* Relate to other matters.

NOTARY
M. M. PABALE
Mumbai
Maharashtra
Reg. No. 15223
Expiry Dt.
30.10.2013
GOVT. OF INDIA

1819
668

XV

FIFTEENTH MEETING

(2012-13)

The Committee met at 4.00 P.M. on Thursday, the 29th August, 2013 in Committee Room 'A', Ground Floor, Parliament House Annexe, New Delhi.

MEMBERS PRESENT

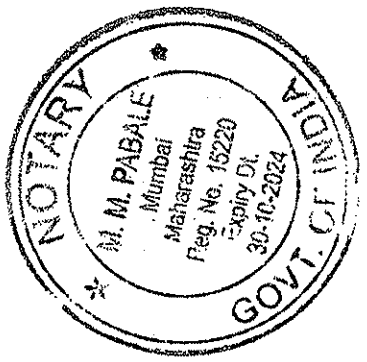
1. Shri Brajesh Pathak — *Chairman*

RAJYA SABHA

2. Shri Jagat Prakash Nadda
3. Shri Mohd. Ali Khan
4. Shri H.K. Dua

LOK SABHA

5. Shri Kuvarjibhai M. Bavalia
6. Dr. Sucharu Ranjan Haldar
7. Mohd. Asrarul Haque
8. Dr. Sanjay Jaiswal
9. Shrimati Jayshreeben Patel
10. Dr. Anup Kumar Saha
11. Shri P. T. Thomas



SECRETARIAT

Shri P.P.K. Ramacharyulu, *Joint Secretary*

Shri R. B. Gupta, *Director*

Shrimati Arpana Mendiratta, *Joint Director*

Shri Dinesh Singh, *Deputy Director*

Shri Pratap Shenoy, *Committee Officer*

* * *

I. Opening Remarks

2. At the outset, the Chairman welcomed the Members of the Committee and apprised them of the agenda of the meeting, *i.e.*, * * * and consider and adopt draft Seventy-second Report on "Alleged irregularities in the conduct of studies using Human Papilloma Virus (HPV) vaccine by PATH in India."

---

* Relates to other matters.

1826

~~669~~

II. Adoption of the Draft Report on "Alleged irregularities in the conduct of studies using Human Papilloma Virus (HPV) vaccine by PATH in India."

3. The Committee then considered and discussed the draft Seventy-second Report on "Alleged irregularities in the conduct of studies using Human Papilloma Virus (HPV) vaccine by PATH in India." The Chairman invited Members to share their specific suggestions for incorporation in the Draft Report. After some discussion, the Committee adopted the Report with some modifications.

4. The Committee, thereafter, decided that the Report may be presented to the Rajya Sabha and laid on the Table of the Lok Sabha on Friday, the 30th August, 2013. The Committee authorized its Chairman and in his absence, Shri Shri H.K. Dua and Shri Jagat Prasad Nadda to present the Report in Rajya Sabha, and Shri Sanjay Jaiswal, and in his absence, Dr. Anup Kumar Saha to lay the Report on the Table of the Lok Sabha.

II. * * *

3. * * *

4. * * *

5. A verbatim record of the proceedings of the meeting was kept.

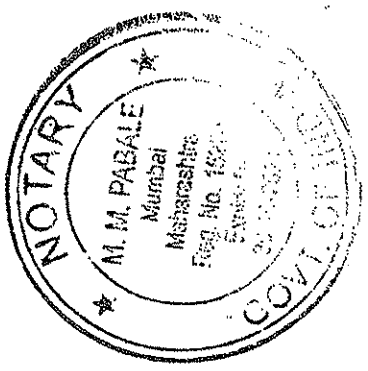
6. The Committee adjourned at 5.00 P.M.

NOTARY
M. M. PABALE
Mumbai
Maharashtra
Reg. No. 15220
Expiry Dt.
30-10-2024
GOVT. OF INDIA

1821

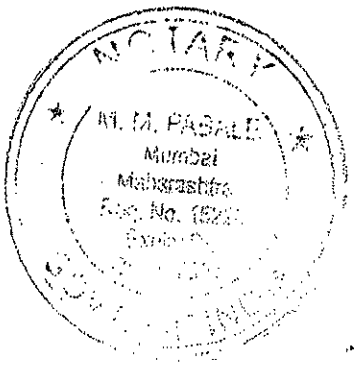
~~670~~

ANNEXURES



1822

~~671~~



1823

672

ANNEXURE-A

Committee to investigate "Alleged irregularities in conduct of studies in India using Human Papilloma Virus (HPV) vaccine"

Minutes of the 5th **Meeting** held on September 27th at the Indian Red Cross Society, (NHO), New Delhi

1. All members of the committee were present. In addition the Experts nominated to assist the committee *vide* GO no. V.250II/160/20IO-HR dated June 30th, 2010 were also invited to attend the meeting.

2. The minutes of the meeting dated June 22nd, 2010 as circulated were adopted.

3. The Experts were requested to present salient findings of their reports and the members discussed with them their findings. A summary of the discussions is as follows:

(a) Dr. Rani Kumar, Dean, AIIMS –

(i) She was requested to carry out numerical analysis of the consent forms – under headings already identified – separately for the AP and Gujarat. (Action: Dr. Rani Kumar)

(ii) She requested the list of members of the two ethics committees at AP and Gujarat. In particular she asked about the membership of a lawyer in the committee. She also asked about the functioning of these committees – the number and dates of meetings, and any monitoring of the PATH study prior to repots in the Press. (Action: Dr. Kishore Chaudhry)

(iii) Opined that the trial in adolescent girls was justified as this is the target group to benefit, but authorization of school authorities by the AP Govt. to give consent on behalf of the girls was not correct. Also, implementation of the procedure of taking consent lacked rigor.

(b) Dr. Y.K. Gupta, HOD Pharmacology, AIIMS – made the following points:

(i) Bridging trials in India, as required under Schedule Y for drugs/vaccines already approved and in use abroad, for licensing in India were carried out as required. One of the studies was in Adults and the other one was in adolescent girls.

(ii) The DCGI has licensed the GSK HPV vaccine Cervarix for " .... females from 10-45 years of age for prevention of cervical cancer. ... ", and MSD vaccine Gardasil for " .. girls and women 9-26 years of age for prevention of cervical cancer ..."

(iii) There is wide international experience, including that in India, regarding use of HPV vaccines in adolescent girls.

(iv) HPV vaccines are quite safe. Millions of doses of HPV vaccines of both types have been used abroad. By the end of May, 2010, there were 16, 410 VARES reports of AE following Gardasil vaccination licensed in the US in 2006. 8% of these have been considered serious, including syncope, GB syndrome, blood clots, and anaphylaxis. A total of 53 deaths have been recorded following vaccination

but they do not seem to be related to the vaccine. The use of the vaccine continues all over the world. Several countries have incorporated it in their national programmes.

(v) Both the GSK and MSD have submitted the required Periodic Safety Update Reports to the DCGI. These are international reports, and not India specific. There has been some delay in submission of these reports. The last six monthly report for 18th November to 17th May, 2010 which should have covered the reports the deaths from India has not been submitted yet.

(vi) A critical analysis of the First Information Reports of SAE/Deaths, Medical records related to these events and the Post-mortem reports do not support the possibility of deaths to be related to vaccine but it can not be ruled out with certainty. This was mainly because the alternate cause of death as listed can not be fully substantiated on the basis of medical records in all the cases. The quality of the medical records was not adequate. The capability of the local staff and preparedness to deal with SAEs/Critical illnesses leading to death is also suspect. Most of the deaths were detected when the ANMs were mobilizing the recipients for the next vaccination. These events were not reported and investigated timely. In most cases the treatment was provided by private medical practitioners and the subjects had to be shifted to a better facility while they died on the way. There was no plan to deal with the crisis as it emerged.

(vii) There is a strong need to strengthen the post-licensing surveillance.

(c) Dr. A.K. Dutta, Head of Pediatrics, Kalavati Saran Hospital, New Delhi –

(i) Dr. Dutta focused on analysis of Deaths and AE, both serious and minor, under the HPV vaccination project carried out in AP and Gujarat, by PATH in collaboration with the respective State Governments.

(ii) Dr. Dutta highlighted that the Primary Outcome measures of the project were:

- Number and percent of eligible girls fully vaccinated, partially vaccinated or not vaccinated at all according to vaccine delivery strategy
- Number and percent of vaccinated girls experiencing serious adverse events, as reported spontaneously through routine mechanisms of UIP programme
- Number and percent of vaccinated girls experiencing non-serious adverse events, as reported spontaneously through routine mechanisms of UIP programme
- Timelines of reporting serious adverse events to local, state and National authorities, as per the usual UIP protocol and
- Timelines of reporting non-serious adverse events to local, state and National authorities, as per the usual UIP protocol

(iii) Since 4 out of the 5 outcome measures related to monitoring and reporting of AE the project should not have totally relied on the existing UIP AEFI reporting system. There should have been a parallel research based monitoring system for AEFI to compare with the State system. Alternatively the effectiveness of the State system should have been pre-verified before initiating the study.

(iv) Dr. Dutta found that 3 of the 7 deaths have occurred within 30 days of last vaccine dose (one in AP and 2 in Gujarat, on days 18,20 and 23), while 4 were after this period (45,49,96,97 days after the vaccine).

Mumbai
Maharashtra
Reg. No. 13220
Expiry Dt.
20-10-2013

1825
674

The ones within 30 days have been attributed to Fever of unknown origin - ? Viral, Malaria and Snake bite. Two of the 4 later deaths were attributed to Pesticide poisoning. In both cases post-mortem has been done and chemical report on record has confirmed presence of the poison in stomach.

In one case there was history of drowning in a pond. The fourth case has died after a brief illness of few hours, probably neurological ? Intracranial hemorrhage/ Intracranial space occupying lesion.

Dr. Dutta's observation was that – 1. There was no specific pattern of illness leading to death, 2. The illnesses can not be explained by expected adverse responses to vaccine, and 3. There was an alternate plausible diagnosis in most cases. Therefore, the deaths were unlikely to be related to the vaccine. However, post-mortem has been carried out only in 2 cases. And the alternate diagnosis is not confirmed in all the cases.

(v) Further a critical analysis of the reporting of other AE and SAE shows the inadequacies of the AEFI reporting system. Dr. Dutta was of the opinion whether it was an observational study or otherwise the vaccine was administered to the subjects and data collected for enerating knowledge. It should have followed all the rigors of the research.

4. The committee deliberated on the reports of the Experts and pertinent data received under various queries raised during previous meetings of the committee. Besides the factual information about the terms of reference the committee was greatly concerned with the aspect of commercial interests of manufacturers influencing the Government policy on this expensive vaccine. The committee observed that the study was initiated by PATH on its own having obtained funds from the Bill and Melinda Gates Foundation and supply of vaccine from the manufacturers – without any reference from the NTAGI, the official body of the GOI on vaccines. It is not clear whether the State expenses were funded by PATH or came from their own resources. The monetary contribution of ICMR is also not clear. The committee therefore felt that it would be in the fitness of the inquiry to document the sources and magnitude of funding of the study. It desired to obtain the following information from the PI, *i.e.* PATH in this case:

   (i) Letter of Sanction of grant form Bill and Melinda Gates foundation for Indian study

   (ii) Letter of donation of vaccine by the manufacturers and the invoice indicating the cost of the vaccine for trial in India

   (iii) Copies of the letters of PATH to ICMR and State Government, including the terms and conditions of collaboration

   (iv) Financial contribution of the 3 parties to the study, *viz.*, the PA TH, ICMR and the State Governments from beginning till date

   Action: Dr. Kishore Chaudhry

5. The committee noted the urgency to submit the report. Since most of the facts have been gathered and analyzed, including the critical input of the experts, it decided to expedite the finalization of the report. Since there was consensus on all issues among the members, the committee authorized the chairman to prepare the draft report which may be circulated to all the members and then finalized in a meeting called for the purpose. In the meantime the additional information as identified above may also be collected. The next meeting could be held in about 2 week time. (Action: Chairman)

1826

~~675~~

ANNEXURE-B

Government of India
Ministry of External Affairs

भारत सरकार
विदेश मंत्रालय, नई दिल्ली

New Delhi the_____200

No.AA/551/1/2011

Dt. 11th June, 2012.

OFFICE MEMORANDUM

Sub: Clinical Trial of HPV Vaccine – regarding

Reference O.M. No. RS.10/2(ii)/2011-Com. (H&FW) dated 4th June, 2012 from the Parliament of India, Rajya Sabha Secretariat, New Delhi, on the subject mentioned above.

2 As per the existing procedure, the clearance of the Ministry of External Affairs from Political angle is required before any foreign organisation/charity/foundation etc. sets up an office/branch in India. The concerned foreign entity may approach this Ministry with a detailed proposal, to be routed through the concerned nodal Ministry in India, for processing and issue of above Political clearance.

Sd/-
(R.K. Nagpal)
Deputy Secretary (Coord)

Parliament of India
Rajya Sabha Secretariat,
[Kind Attn: Ms. Arpana Mendiratta, Joint Director],
Parliament House/Annexe,
New Delhi. Telefax: 23035428
23012007

1827

~~676~~

ANNEXURE-C

No.II/20034/280/2012-IS-II
Government of India
Ministry of Home Affairs
IS-I Division, (IS-II Desk)

New Delhi, the 5th July, 2012

Office Memorandum

Subject:– Parliamentary Standing Committee on Health and Family Welfare – clinical trial of HPV Vaccine and related matters – furnishing of information to the Committee.

The undersigned is direacted to enclose a copy of Rajya Sabha Secretariat O.M No.RS.10/2(ii)/2011-Com.(H&FW) dated 21st June, 2012 along with a copy of earlier D.O. letter dated 4th June, 2012 regarding clinical trial of HPV Vaccine on the subject noted above and to state that Department of Economic Affairs is the concerned Administrative Ministry for "setting up of the Liaison Offices/Branch Offices/Project Offices in India by foreign entities". As such, laying down the procedure/rules/guidelines etc. for setting up of such offices falls within the ambit of DEA.

2. Department of Economic Affairs seeks MHA's comments from security angle on the applications received from various firms for setting up of the Liaison Offices/Branch Offices/Project Offices in India by foreign entities. As such, Ministry of Home Affairs assesses the suitability of the applicant company from security angle.

3. Further, a draft Circular proposed by RBI and forwarded by DEA containing additional reporting feature by foreign entities for implementing additional security safeguards is under consideration in this Ministry.

4. In view of foregoing, the above Rajya Sabha Secretariat O.M. dated 21st June, 2012 along with its enclosures is transferred to Department of Economic Affairs for giving a suitable reply to Rajya Sabha Secretariat, under intimation to this Ministry.

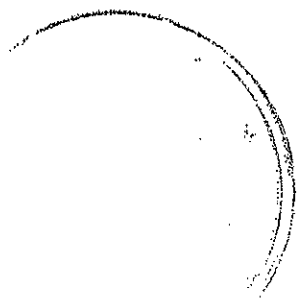
Sd/-
(Rakesh Mittal)
Director (IS-I)

Department of Economic Affairs
(Shri R.K. Sinha, Under Secretary),
North Block, New Delhi.

Copy for information to: Rajya Sabha Secretatiat (Ms. Arpana Mendiratta, Joint Director), Parliament House Annexe, New Delhi-110001.

1828

~~677~~



~~829~~

678



Printed at : Bengal Offset Works, 335, Khajoor Road, Karol Bagh, New Delhi-110005.

AIM Awaken India Movement
awakenindiamovement.com
www.awakenindiamovement.com
mail2aim@protonmail.ch

EXHIBIT "RA-53"

18th October, 2021

To,

Subodh Kumar Jaiswal

Director, Central Bureau of Investigation (CBI)

Subject: **(i) Immediate arrest of mastermind accused Srinath Reddy and other accused members of Public Health Foundation of India (PHFI) who were responsible for misappropriation of around 108 crores of public money.**

(ii) Conducting Narco Analysis, Brain Mapping, Lie Detector and other scientific tests of all accused to bring the complete conspiracy to the surface

NOTARY M. M. PABALE Mumbai Maharashtra Reg. No. 15220 Expiry Dt. 25-10-2021 OF INDIA

Ref: (i) FIR registered by the Economic Offence Wing (EOW) against Srinath Reddy's aide Mr. Anil Pawar.

(ii) Case registered by the Intelligence Bureau and foreign division of health ministry against PHFI

(iii) Law laid down by Hon'ble Supreme Court of India in the case of **Navin Singh Vs. State (2021) 6 SSC 191.**

1830
680

Respected sir,

1. The PHFI has been funded by the government of India.

2. That, Government of India had given an amount of more than rupees 100 crore to PHFI.

3. That, the dishonest trustees of the PHFI hatched a conspiracy to misappropriate the said amount and in furtherance of said conspiracy the mastermind Srinath Reddy, President of PHFI has shown that he had invested the said amount through a person who goes by the name of Anil Pawar.

4. Said person Mr. Anil Pawar, who is brought in picture by Mr. Srinath Reddy is a fraudster and not holding any post in any nationalized Bank. In fact he worked for siphoning of the said amount.

   An amount of around rupees 82 crores was invested through the said fraud person.

5. The dishonesty and malafide intention of the PHFI members is ex-facie clear from the very fact that;

   (i) The amount was given by the Govt. of India for building two public health school campuses but the amount was misappropriated by the accused for unauthorised purposes.

   In an order by Home Ministry and as published in an Article in Economic Times published on 21st April 2017, it is clear that, the members of PHFI are misusing the funds for unauthorised purposes such as **:- to lobby media, parliamentarians and government.** PHFI, according to the home ministry, has bank accounts with credits of Rs 223 crore more than what it had declared to the home ministry.

https://economictimes.indiatimes.com/news/politics-and-nation/mha-order-revoking-license-of-phfi-lists-7-undesirable-activities/articleshow/58294627.cms?from=mdr

(ii) The office of the PHFI is at Delhi but surprisingly they invested the amount of Rs. 82 Crores in Mumbai, The amount is around Rs. 108 Crores, according to a whistleblower working in PHFI who revealed the same to journalist Kapil Bajaj

-https://timesofindia.indiatimes.com/city/mumbai/mumbai-economic-offences-wing-files-four-chargesheets-in-fraud-cases/articleshow/41962416.cms

-https://dragada.com/kbforyou/2018/02/17/phfis-rs-100-crore-scam-and-ensnaring-of-sree-chitra-tirunal-institute-in-a-corrupt-deal-impostors-club-hurtles-from-fraud-to-fraud-updated/

(iv) As published in above article, according to a whistleblower from PHFI, PHFI had redacted its publicly available reports in order to hide the swindle which took place through collusion between scamsters within PHFI and those claiming to represent Dena Bank and Oriental Bank of Commerce (OBC). Head-Finance Amit Chaturvedi, who is directly answerable for the stolen funds, continued to be on the payroll of PHFI while propriety demands he should have been the first to quit or be asked to step down, according to the said whistleblower. The aforementioned swindle took place when PHFI dealt with middlemen of Dena Bank and Oriental Bank of Commerce (OBC) in transferring money into fixed deposits (FDs).

1832
~~682~~

"Funds were transferred to FDs with mere Reddy's authorization, even though in any well governed organization with checks and balances that would have been the job of a committee of the governing board." "Fake FD receipts were issued to PHFI and the money was diverted to the third parties."

https://dragada.com/kbforyou/2018/02/17/phfis-rs-100-crore-scam-and-ensnaring-of-sree-chitra-tirunal-institute-in-a-corrupt-deal-impostors-club-hurtles-from-fraud-to-fraud-updated/

(v) K. Srinath Reddy also forged a document (purportedly a copy of the signed and stamped document setting out the composition of PHFI governing body as on 31 March 2006.) and sent it to journalist Kapil Bajaj as an RTI response. This is an offense under the RTI act.

https://drive.google.com/file/d/1bRHsJbkS4XwEifnMiYtvDBZ4IBBJSC8a/view?usp=sharing

(vi) The accused by name Anil Pawar, through whom amount was invested is not on any responsible post but he is a known fraudster and living in a chawl. This leads to only one inference that Mr. Srinath Reddy is hand in glove with that accused.

(vii) The founder and ex-chairman of PHFI, Rajat Gupta was sentenced to two years in prison and ordered to pay a $5-million fine by a US judge who termed Indian-American's **insider trading crimes** as "disgusting" and a **"terrible breach of trust"**. Gupta, 63 was also ordered by US District Judge Jed Rakoff to serve a year of supervised release after the end of his prison term.

Link: https://www.thehindubusinessline.com/markets/rajat-gupta-gets-2-years-in-jail-for-insider-trading/article23084253.ece

6. That, law about duty and responsibility and liability of trustees regarding investment of trust money is very clear. It can be seen from the provisions of the **section 20** of the Indian Trust Act.

The three Judge Queen's Bench in the case of **Jonathan Ingham Learoyd And William Edwin Carter And Elizabeth Whiteley [L.R.] 12 App. Cas. 727** in a similar case hold such trustee as guilty of breach of trust and ordered him to pay the amount from his own. It is ruled as under;

> *"The trustees had not acted with ordinary prudence, and were liable to make good by paying the money with interest at 4 per cent. From the date of the last payment.*
>
> *Business men of ordinary prudence may, select investments which are more or less of a speculative character; but it is the duty of a trustee to confine himself to the class of investments which are permitted by the trust, and likewise to avoid all investments of that class which are attended with hazard.*
>
> *In these circumstances, I think it has been established that, at the time of taking the security, the appellants altogether failed to exercise that ordinary amount of care which the law required of them. An improper and unauthorized investment.*
>
> *Bacon V.C. held the trustees liable to make good the £3000 with interest at 4 per cent. from August 1884[3], and this decision was affirmed by the Court of Appeal.*

1834
684

7. That, Three-Judge Bench in the case of **Chapman Vs. Browne (1902)1 Ch. 785** had ruled that, the it was case where trustee invested the trust's money in an improper way without taking proper precaution and legal advice. Case filed against said trustee. Court declared that the investment was a breach of trust. Court further ordered that the defaulting trustee should deposit the said amount in Court. The appeal filed by the defaulter trustee was dismissed with Cost.

8. That the, accused Srinath Reddy is guilty of criminal breach of trust and therefore, liable to be punished u/s 409 of IPC and other provisions of Corruption Act. As per law he is liable to pay the of swindled amount of around Rs. 108 Crore from his pocket. His all movable and immovable properties which are gained out of proceeds of crime is liable to be confiscated, seized and attached.

9. In fact, the concern authority under **Indian Trust Act** or **Members Of Ministry Health And Family Welfare** were bound to initiate proceedings against Mr. Shrinath Reddy for recovery of said amount of Rupees 108 Crores.

But they failed to act promptly. Therefore, their inaction also needs to be enquired as per provisions of Section 218 of IPC.

10. That, section 409 of Indian Penal Code is an offence punishable with life imprisonment for breach of trust. It reads thus;

> ***"409. Criminal breach of trust by public servant, or by banker, merchant or agent.***—*Whoever, being in any manner entrusted with property, or with any dominion over property in his capacity of a public servant or in the way of his business as a banker, merchant, factor, broker, attorney or agent, commits criminal breach of trust in respect of that property, shall be punished with*

1[imprisonment for life], or with imprisonment of either description for a term which may extend to ten years, and shall also be liable to fine."

11. That, **section 52** of Indian Penal Code says that, when no care and caution is taken while doing any act, then it is to be presumed that the act is done in bad faith.

In **Noor Mohamed Mohd. Shah R. Patel Vs. Nadirshah Ismailshah Patel 2003 SCC OnLine Bom 1233**, it is ruled as under;

"It has to be kept in mind that nothing can be said to be done in good faith which is not done with due care and caution. If these ingredients are indicated by the complaint, the Magistrate is obliged to take the cognizance of the complaint so presented before him."

NOTARY PARAS Mumbai Maharashtra Reg. No. 15220 Expiry Dt. 30-10-2024 GOVT. OF INDIA

12. Criminal liability of other members of PHFI:

12.1. That Hon'ble Supreme Court and various High Courts in India have ruled that, when a **body/society/trust** commits an offense of misappropriation of public money then the members in the **trust/society/body** who did not oppose the proposal or ant act of unlawful siphoning of the money are also accused as that of main accused. Hon'ble Supreme Court further Said that if other members were innocent then they should have opposed the unlawful act and criminal activities of main accused, here Mr. Srinanth Reddy. Hon'ble Supreme Court observed that, such accused members should not be protected from the rest they don't deserve bail. They needs to be arrested and subjected to custodial interrogation.

12.2. In **Rajendra Ramdas Chaudhari Vs The State of Maharashtra and The Superintendent of Police MANU/MH/0111/2009**, Hon'ble High Court rejected the bail of such accused and observed as under;

1836
~~686~~

"Misappropriation of public fund. - offenses under section Sections 34, 120-B, 201, 406, 408, 409, 420, 465, 468 and 471 of Indian Penal Code, 1860 (IPC).

The present applicant should have opposed such proposals during the meetings, if he was really innocent. Not only that the applicant has attended the number of meetings and signed the proceedings of the meetings. *The argument of the learned A.P.P. that the present applicant is vicariously liable for all the bogus loans, sanctioned during his period, has considerable substance and said the contention cannot be rejected at outright.*

The present applicant has not opposed any of the bogus loan cases during the meetings in which he attended and signed the proceedings.

If the arguments of the learned A.P.P. are carefully perused, various instances have been cited by the A.P.P. to show that how the loans are advanced illegally to the persons contrary to the Rules and Regulations of R.B.I., provisions of Maharashtra Co-operative Societies Act and Rules there under and relevant directions issued by the Government from time to time.

Nobody made any attempt to verify whether the borrowers were eligible, whether the proper procedure was followed, whether the sufficient securities were obtained and whether such huge loans were likely to be recovered.

15. The Supreme Court in the case of Narinderjit Singh Sahni and Anr. v. Union of India and Ors. reported in MANU/SC/0644/2001 : AIR2001SC3810 has observed that if accused facing a charge under Sections 406, 409, 420 and 120-B is ordinarily not entitled to invoke the provisions of

www.awakenindiamovement.com mail2aim@protonmail.ch

Section 438 of the Criminal Procedure Code unless it is established that such criminal accusation is not a bona fide one.

16. In the case of Ram Narain Poply v. Central Bureau of Investigation with Pramod Kumar Monocha v. Central Bureau of Investigation with Vinayak Narayan Deosthali reported in MANU/SC/0017/2003 : 2003CriLJ4801 the Supreme Court has observed thus: 382. The cause of the community deserves better treatment at the hands of the Court in the discharge of its judicial functions. The Community or the State is not a persona non granta whose cause may be treated with disdain. The entire community is aggrieved if economic offenders who ruin the economy of the State are not brought to book. A murder maybe committed in the heat of moment upon passions being aroused. An economic offences is committed with cool calculation and deliberate design with an eye on personal profit regardless of the consequence to the Community. A disregard for the interest of the community can be manifested only at the cost of forfeiting the trust and faith of the community in the system to administer justice in an even handed manner without fear of criticism from the quarters which view white collar crimes with a permissive eye unmindful of the damage done to the national Economy and National Interest, as was aptly stated in State of Gujrat v. Mahanlal Jitamalji Porwal and Anr. A.I.R. 1987 1321.

18. The Supreme Court in the case of Himanshu Chandravadan Desai and Ors. v. State of Gujrat reported in 2006 Cri. L.J. 136 while considering bail application of the applicants therein has observed thus:

Accused a Director of Bank and others involved in Bank Scam - Siphoned off funds of Bank worth crores by bogus loans and

fictitious letters of credit in name of their friends, relatives etc. Offence is very serious Evidence showing their prima facie involvement in offence - Having regard to huge amounts involved there is danger of accused absconding, if released on bail, or attempting to tamper with evidence by pressurizing witnesses Refusal of bail is proper."

12.3. That, the other members who were not present in the meeting **or** who were added as a new member **or** who were not directly concerned can also liable to be made as accused as none of them had made any complaint against the main accused i.e. Mr. Srikanth Reddy but they tried to cover up his fraud by way of their act of commission and omission.

Therefore, as per section 201, 202, 120(B) & 34 of IPC they all are liable for prosecution.

Section 202 of The Indian Penal Code reads thus;

"202. Intentional omission to give information of offence by person bound to inform. - Whoever, knowing or having reason to believe that an offence has been committed, intentionally omits to give any information respecting that offence which he is legally bound to give, shall be punished with imprisonment of either description for a term which may extend to six months, or with fine, or with both."

12.5. Hon'ble Supreme Court in the case of **Raman Lal 2001 Cr. L. J. 800** had ruled as under;

"Conspiracy – I.P.C. Sec. 120 (B) – Apex court made it clear that an inference of conspiracy has to be drawn on the basis of circumstantial evidence only because it becomes difficult to get direct evidence on such issue – The offence can only be proved largely from the inference drawn from acts or illegal ommission

committed by them in furtherance of a common design – Once such a conspiracy is proved, act of one conspirator becomes the act of the others – A Co-conspirator who joins subsequently and commits overt acts in furtherance of the conspiracy must also be held liable – Proceeding against accused cannot be quashed."

[Also see: **CBI VS Bhupendra Champaklal Dalal 2019 SCC OnLine Bom 140.]**

13. Enquiry & action against other public servant under section 218, 120(B) Etc. of IPC sitting at who are at the office of PHFI

13.1. That, many public servants of Union of India (UOI) are or were involved in the meetings at PHFI office. Those in bold are sitting as of 2020.

The details are as under;

Mr. Lav Agarwal, Joint Secretary of MOHFW

Balram Bhargava (DG – ICMR)

Prof Dr. Sunil Kumar (DGHS, MOHFW)

Dr Sanjay Tyagi (Ex Director General of Health Services, MOHFW)

Dr. Soumya Swaminathan (Ex Director General, ICMR)

Prof K Vijayraghavan (Ex Secretary, Department of Biotechnology)

Prasanna Hota (Ex Secretary MOHFW)

1848

~~690~~

Nirmal Ganguly (Ex DG, ICMR)

Vishwa Katoch (Ex Director General ICMR)

TKA Nair (Former Advisor to PMO)

Dr. Montek Singh Ahluwallia (Former Deputy Chair of Planning Commission)

Mr Bhanu Pratap Sharma (Ex Secretary, MOHFW)

Dr Jagdish Prasad (Ex DGHS, MOHFW)

13.2. That, public servants and members involved in the affairs of PHFI were bound to report the frauds committed by Mr Srinath Reddy and other fraudster members of PHFI. But they failed to perform their duty and therefore they are liable for prosecution u/s 201,202, 218,120(B) & 34 Etc. of IPC. The members of PHFI are also in the category of Public Servant as they are getting their salary from funds received by the Govt.

13.3. The section 218 of IPC is concerned with bringing erring public servants to book for falsifying the public records in their charge. The essence of the offence under section 218 is intent to cause loss or injury to any public or person or thereby save any person from legal punishment or save any property from forfeiture or any other charge, **Biraja Prosad Rao Vs. Nagendra Nath, (1985) 1 Crimes 446 (Ori.)**

13.4. The law makes it clear that for punishment under sec 218 of IPC the Actual commission of offence by main accused Srinath Reddy is different and to punish the public servants doing their acts of commission and omission to save accused is sufficient to punish those public servants:-

(i) The actual guilt or innocence of the alleged offender is immaterial if the accused believes him guilty and intends to screen him. **Hurdut Surma, (1967) 8 WR (Cr.) 68.**

(ii) For the purpose of an offence punishable under section 218 the actual guilt or otherwise of the offender alleged as sought to be screened from punishment is immaterial. It is quite sufficient that the commission of a congnizable offence has been brought to the notice of the accused officially and that in order to screen the offender that accused prepared the record in a manner which he knew to be incorrect, **Moti Ram Vs. Emperor, AIR 1925 Lah 461**.

(iii) Where it was proved that the accused's intention in making a false report was to stave off the discovery of the previous fraud and save himself or the actual perpetrator of that fraud from legal punishment, it was held that he was guilty of this offence, **Girdhari Lal,(1886) 8 All 633**.

(iv) Where the accused increased the marks of particular persons for pecuniary benefits during the course of preparing final record for appointment as physical education teacher, it was held that the offence alleged is clearly made out, **Rakesh Kumar Chhabra Vs. State of H.P., 2012 CrLJ 354(HP)**

14. **History of fraudster chairman of PHFI:-**

14.1. That, Mr. Rajat Gupta was founder & Chairman of PHFI.

14.2. That, Mr. Rajat Gupta was arrested, prosecuted and sentenced for fraud.

Link: https://www.thehindubusinessline.com/markets/rajat-gupta-gets-2-years-in-jail-for-insider-trading/article23084253.ece

1842
692

15. Earlier prosecution of PHFI by Home Ministry and Intelligence Bureau:-

15.1. That, PHFI were also prosecuted by the Intelligence Bureau for their frauds of foreign funds.

15.2. That, in an order by Home Ministry and as published in an Article in Economic Times published on 21st April 2017, it is clear that, the members of PHFI are misusing the funds for unauthorised purposes :

15.3. The seven violations cited by the home ministry against PHFI, which has been receiving a significant chunk of its foreign funding from Bill and Melinda Gates Foundation, include using foreign contributions to lobby media, parliamentarians and government on tobacco control policy issues, "which is prohibited under FCRA". PHFI, according to the home ministry, has bank accounts with credits of Rs 223 crore more than what it had declared to the home ministry.

15.4. Also, it is alleged to have wrongfully declared Rs 43 crore received for anti-tobacco lobbying when foreign funding during 2009-10 and 2012-13 was received seeking permission of the home ministry for the purpose `research' and `establishment of corpus fund'.

15.5. Another charge against PHFI includes making remit tances of Rs 22 crore to foreign countries from its FCRA account and Rs 10.75 crore to BBC World Services Trust, UK "for unknown purpose".

15.6. The revision order, issued under Section 22 of FCRA, states that PHFI declared only six of its 151 bank accounts to MHA. Of the 151 accounts, 22 are saving or current accounts while 128 are FD accounts. Two bank accounts were used as `transit' accounts for unknown reasons, violating provisions of FCRA and FCRR, 2011, according to the home ministry .

15.7. PHFI was also found to be having more than one PAN identity for opening accounts and FDs, in violation of the Income Tax Act, 1961. Besides, the NGO failed to declare foreign receipts of Rs 1.19 crore from GlaxoSmithKline in 2014-

https://economictimes.indiatimes.com/news/politics-and-nation/mha-order-revoking-license-of-phfi-lists-7-undesirable-activities/articleshow/58294627.cms?from=mdr

15.8. The Union health ministry is also said to have taken up the matter with Gauba. His predecessor, Rajiv Mehrishi, who was part of the decision to crack down on PHFI, had refused a review after **both the Intelligence Bureau and the foreigners division of the home ministry said they had made a watertight case against PHFI. Intelligence Bureau officers said they would not buckle under pressure, for the charges hold ground.**

https://www.theweek.in/theweek/current/foreign-bug.html

16. That, the PHFI and their dishonest members are influencing the policy of Indian Health ministry in such a way that the ultimate benefit will go to the pharma mafia and wrongful loss will be of Govt. of India and 135 Crore citizen. A detailed article exposing the PHFI members and their modus oprandi and their acts of commission and omission to play with the life of Indians to give undeserving benefits to the pharma mafia is published by renowned researcher and scientist Sh. Yohan Tengra.

Link: **India's Covid-19 Task Force & "Experts" Exposed : Conflicts of Interest in Our Public Health System** (An expose by Yohan Tengra.) https://awakenindiamovement.com/indias-covid-19-task-force-experts-exposed-conflicts-of-interest-in-our-public-health-system/

17. A detailed complaint cum notice under sec 80 of CPC is already sent to Hon'ble Health Minister on 23.09.2021. In the said complaint the entire

1844
694

corruption of the members of PHFI is explained in detail. A copy of said complaint cum notice dated 23.09.2021 is available at following link;

Link:

17. That, the earlier investigation against the arrested accused Anil Pawar is incomplete as the proofs and other aspects given in the present complaint were neither available nor considered by the then Investigating officer. Therefore it is necessary to conduct a thorough investigation to unearth the larger conspiracy to cause a loss of lakhs of Crores to Govt of India with sole intention of giving wrongful gain to pharma mafia and further to play with the life of 135 Crore Indians.

17. Under these circumstances it is just and necessary to;

(i) Immediately arrest Mr. Srinath Reddy and other present and ex-members of PHFI responsible for misappropriation of public money of around 108 Crores and thereby committing offences u/s 409, 201, 202, 120 (B) & 34 of Indian Penal Code and other provisions of Prevention of Corruption Act;

GOVT. OF INDIA NOTARY M. M. PABALE Mumbai Maharashtra Reg. No. 15211

(ii) Recover the misappropriated amount from Mr. Srinath Reddy as per the law laid down by Hon'ble Full Bench and as mentioned in para 6 & 7 of this complaint;

(iii) Direct confiscation, seizure and attachment of all the moveable and immoveable properties and bank accounts of mastermind Srinath Reddy and other accused members of PFHI, Which is earned by them out of the proceeds of crime;

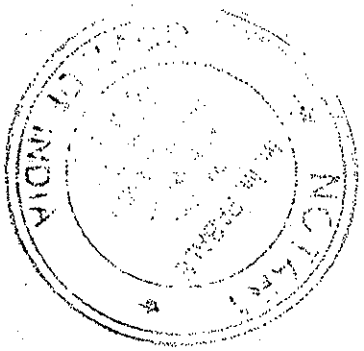
(iv) Conduct the scientific test of accused members of PHFI such as Narco Analysis Test, Lie Detector Test, Brain Mapping Test etc.., to bring out the complete truth to the public and to prevent

their anti-national activities to kill Indians and to give profits to the pharma mafia and their Kingpin Bill Gates.

Sincerely

Ambar H. Koiri
B – 1501, Runwal Hts.
L.B.S. Marg, Mulund (W)
Mumbai – 400 080.




INDIA
NOTARY


INDIA
NOTARY