IN THE HIGH COURT OF JUDICATURE AT BOMBAY

CIVIL APPELLATE JURISDICTION

CIVIL PUBLIC INTEREST LITIGATION NO. 85 OF 2021

Yohan Tengra ....**Petitioner**

Vs.

State of Maharashtra & Ors. ...**Respondents**

ADDITIONAL AFFIDAVIT ON BEHALF OF PETITIONER

The Petitioner submits as under;

1. I, **Mr. Yohan Tengra**, the petitioner, do hereby state on solemn affirmation that having received, read and understood the Addl. Affidavit, I am filing the present Addl. Affidavit pursuant to the directions of this Hon'ble Court vide Order dated **25.10.2021**, as under:

2. Following questions arose for consideration by this Hon'ble Court:

Sr. Nos.	Particulars	Para Nos	Page Nos
1.	Whether National Authority permits for discrimination of any citizen or putting any restriction on the basis of his vaccination status?	3	952
2.	Judgements of various High Courts after referring the abovesaid information under RTI and the stand taken in parliament, that	4	955

	no state can bring any rule or circular which discriminates a person on the basis of his vaccination status.		
3.	Malafides of few State Authorities and admission of their mistakes by the Hon'ble Health Minister Shri Rajesh Tope.	**5**	**961**
4.	When National Authority has clarified that there cannot be any prohibition or discrimination on the basis of person's vaccination status, then State Authority cannot formulate guidelines in violation of National Authority. It is an offence under section 51 (b) & 55 of Disaster Management Act, 2005	**6**	**962**
5.	The Orders, SOP & rules formulated by the state authorities which discriminates between vaccinated and unvaccinated people is not based on the *"intelligent differentia"* and it does not pass the scrutiny of Article 14, 19, & 21 of the Constitution of India.	**7**	**967**
6.	Studies which show that vaccinated people have as much as, or more viral load than the unvaccinated.	**8**	**968**
7.	Malafides of the State authorities in bringing rules by ignoring the data of prohibited category of person, death causing side effects of vaccines and higher	**9**	**970**

	number of deaths in vaccinated than unvaccinated.		
8.	Recent court orders across the world which stayed the rules and orders of conditions of fully vaccination.	**10**	**979**
9	It is the duty of the Government to publish the side effects of vaccines before calling the citizens to get vaccinated.	**11**	**986**
10	The liberty of citizen cannot be curtailed on the basis of orders passed by the authority or there is a need of creating a law by the legislation as per Article 19(b) 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 & Madan Mili Vs. UOI 2021 SCC OnLine Gau 1503.	**12**	**987**
11	Act of State authority amounts to an offence under Section 51(b), 55 of Disaster Management Act, 2005 & other provisions of I.P.C.	**13**	**993**
12	The ratio laid down by the Full Bench of Hon'ble Supreme Court in of Manohar Lal Sharma Vs. Union of India 2021 SCC OnLine SC 985. apply to the present case which mandates the state to not to litigate adverbial litigation like and to place all	**14**	**995**

	data available with them when matter pertains to life and liberty of majority of citizen.		
13	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**	**995**
14	Study shows that, giving vaccines to the person with previous Covid-19 infection is causing more harm than the disease itself.	**16**	**997**
15	Vaccinated people are at higher risk	**17**	**998**
16	Cases where vaccine causing more harm than the disease itself.	**18**	**1000**
17	Covishield unable to halt breakthrough Delta infections: Study Fresh evidence on Covishield's inability to halt "breakthrough infections" caused by the Delta variant of SARS-CoV-2 in fully vaccinated individuals emerged on Sunday with a group of Indian researchers reporting an	**19**	**1004**

	unexpectedly large proportion of Covid-19 infections among the vaccine recipients.		
19	Vaccines don't stop transmission, admitted by WHO.	**20**	**1005**
20	State definition of Fully Vaccinated including persons with medical certification of exemption from vaccination is not properly explained and said order is not communicated to the public.	**21**	**1005**

3. Whether National Authority permits for discrimination of any citizen or putting any restriction on the basis of his vaccination status?

3.1. 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.***

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."*

A copy of said affidavit is annexed here with at **Exhibit – "AA1" [Page 1014 to 1019]**

3.2. That in the reply under RTI given by the Health Ministry on **01.03.2021** 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 relevant Question & Answer are reproduced as under;

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?

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।

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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।

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।"

A copy of said reply by Health Ministry is at **Exhibit – "AA2" [Page 1020]**

4. Judgements of various High Courts after referring the abovesaid information under RTI and the stand taken in parliament, that no state can bring any rule or circular which discriminates a person on the basis of his vaccination status.

4.1. In **Madan Milli Vs. UOI 2021 SCC OnLine Gau 1503,** ruled as under;

*"3. The petitioner contends that **as per the RTI Information furnished by the Ministry of Health & Family Welfare,** which is available in the website of the Ministry of Health and Family Welfare, Government of India, Covid-19 vaccination is not a mandatory but a voluntary. A copy of the RTI Information available in the website of the Ministry of Health & Family Welfare, Government of India, has*

been annexed by the petitioner as Annexure 3 to the petition. The petitioner also refers to ***an answer given on 19.03.2021 in the Lok Sabha to an Unstarred Question No. 3976 by the Minister of State in the Ministry of Health & Family Welfare, Government of India (Annexure 4 to the petition) stating that there is no provision of compensation for recipients of Covid-19 Vaccination against any kind of side effects or medical complication that may arise due to inoculation. The Covid-19 Vaccination is entirely voluntary for the beneficiaries.***

4. *By referring to the fact that the Covid-19 Vaccination is entirely a voluntary exercise at the choice of an individual as indicated in the RTI answer and the answer given in the Lok Sabha by the Minister of State in the Ministry of Health and Family Welfare, Government of India, as referred to hereinabove, the learned counsel for the petitioner has contended that provision under Clause 11 of the Order dated 30.06.2021, issued by the Chief Secretary cum Chairperson-State Executive Committee, Government of Arunachal Pradesh, vide Memo No. SEOC/DRR&DM/01/2011-12, allowing temporary permits to be issued for developmental works in both public and private sector to only those persons who are vaccinated for Covid-19, have interfered with the rights of the citizens provided under Article 19 (1) (d) of the Constitution of India to move freely throughout*

the territory of India. The learned counsel for the petitioner, therefore, has argued that since the Clause 11 of the Order dated 30.06.2021, issued by the Chief Secretary cum Chairperson-State Executive Committee, Government of Arunachal Pradesh, vide Memo No. SEOC/DRR&DM/01/2011-12, by allowing to issue temporary permits for developmental works in both public and private sector only to persons who have vaccinated for Covid-19 Virus, have interfered with the fundamental rights granted under Article 19 (1) (d) of the Constitution of India and the same may be struck down by this Court in exercise of power under Article 226 of the Constitution of India.

***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-*

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vaccinated persons would have to follow the covid proper behavior protocols as per the SOP, there is no justification for discrimination."

***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."*

4.2. **<u>In Re: Dinthar Incident Aizawl Vs. State of Mizoram 2021 SCC OnLine Gau 1313,</u>** the Division Bench of Hon'ble Gauhati High Court vide its order dated **02.07.2021**, has categorically held 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."*

4.3. In **Osbert Khaling Vs. State of Manipur and Ors. 2021 SCC OnLine Mani 234,** it is ruled as under;

"8.... Restraining people who are yet to get vaccinated from opening institutions, organizations, factories, shops, etc., or ***denying them their livelihood by linking their employment****, be it NREGA job card holders or workers in Government or private projects,* ***to their getting vaccinated would be illegal on the part of the State, if not unconstitutional. Such a measure would also trample upon the freedom of the individual to get vaccinated or choose not to do so."***

4.4. That, the above judgments are passed after hearing the Counsel for Union India and the judgment is regarding the interpretation of constitutional provisions, therefore they are binding on all the authorities in India.

4.5. Hon'ble Supreme Court in the case of **Pradip J. Mehta Vs. commissioner of Income-Tax, Ahmedabad (2008) 14 SCC 283** has ruled that the judgments of other High Court should be appreciated. It is ruled as under;

> ***"Precedent - View taken by other High Court though not but should be referred and appreciated - 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. Thus, the judgment of the other High Court, though not binding, have persuasive value which should be taken note of and dissented from by recording its own reasons. (Para 24)"***

4.6. This Hon'ble High Court in the case of **In Maharashtra Govt., through G. B. Gore, Food Inspector, Nanded Vs. Rajaram Digamber Padamwar & Anr. 2011 SCC OnLine Bom 2021** made it clear that, the authorities in Maharashtra including Subordinate Judges cannot refuse to follow the judgments of other High Court. If Any authority does not then appropriate action will be taken against the said authorities.

Copy of Judgement marked and attached herewith **Exhibit "AA3" [Page 1021 to1036]**

5. Malafides of few State Authorities and admission of their mistakes by the Hon'ble Health Minister Shri Rajesh Tope.

5.1. That, despite having knowledge of the pendency of the present petition before this Hon'ble Court and despite having been served with the copy of the petition. The Respondent No. 3 Iqbal Chahal, Municipal

Commissioner of BMC, Shri Suresh Kakani, Additional Municipal Commissioner, Mumbai Respondent No. 5 Sitaram Kunte, Chief Secretary of Maharashtra, did not mend their ways but kept on committing the offences.

5.2. The shocking part was that another officer viz. Shri Sunil Chavhan, Collector, Aurangabad, brought some harsh prohibition upon the poor unvaccinated citizens that they should not be given their monthly ration. He also put directions for not giving petrol, cooking gas et.al facilities to the unvaccinated people.

A copy of the said unlawful order passed by Collector Aurangabad is annexed herewith at **Exhibit -"AA4" [Page 1037 to 1039]**

5.3. However, after strong opposition from public the State's Health Minister Shri. Rajesh Tope intervened and warned **Respondent No. 5** Sitaram Kunte that it is illegal and no authority can bring any rule which discriminate between the vaccinated and unvaccinated.

A copy of news published in Daily Deshonnati is annexed at **Exhibit "AA5" [Page 1040]**

5.4. Hence, it is ex-facie clear that the rule brought by **Respondent No. 5** and all the officers in Maharashtra were highly illegal and unconstitutional.

6. When National Authority has clarified that there cannot be any prohibition or discrimination on the basis of person's vaccination status, then State Authority cannot formulate guidelines in violation of National Authority. It is an offence under section 51 (b) & 55 of Disaster Management Act, 2005:-

6.1. That, as per **section 38(1) and 39 of Disaster Management Act, 2005** the State Authority or District Authority cannot take any decision against the guidelines and directions given by the National Authority. If any State or District Authority takes any decision by disobeying the guidelines of the National Authority then such person and all Government Officers of the office will be guilty of the offences under **section 55, 51(b) of Disaster Management Act, 2005.**

Section **38(1), 39(a)** of the Act reads thus;

> ***"Section 38(1) in the Disaster Management Act, 2005***
>
> ***38. State Government to take measures.*** *-*
>
> *(1) 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.*
>
> ***Section 39(a) in the Disaster Management Act, 2005***
>
> ***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.***"

Section **51(b), 55** of the Act reads thus;

"Section 51 in the Disaster Management Act, 2005

51. Punishment for obstruction, etc.-

Whosoever,

(b) *refuses to comply with any direction given by or on behalf of the Central Government or the State Government or the National Executive Committee or the State Executive Committee or the District Authority under this Act, shall on conviction be punishable with imprisonment for a term which may extend to one year or with fine, or with both, and if such obstruction or refusal to comply with directions results in loss of lives or imminent danger thereof, shall on conviction be punishable with imprisonment for a term which may extend to two years. notes on clauses Clauses 51 to 58 (Secs. 51 to 58) seeks to lay down what will constitute an offence in terms of obstruction of the functions under the Act, false claim for relief, misappropriation of relief material or funds, issuance of false warning, failure of an officer to perform the duty imposed on him under the Act without due permission or lawful excuse, or his connivance at contravention of the provisions of the*

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Act. The clauses also provide for penalties for these offences.

Section 55 in the Disaster Management Act, 2005

55. Offences by Departments of the Government.-

(1) Where an offence under this Act has been committed by any Department of the Government, the head of the Department shall be deemed to be guilty of the offence and shall be liable to be proceeded against and punished accordingly unless he proves that the offence was committed without his knowledge or that he exercised all due diligence to prevent the commission of such offence. (1) Where an offence under this Act has been committed by any Department of the Government, the head of the Department shall be deemed to be guilty of the offence and shall be liable to be proceeded against and punished accordingly unless he proves that the offence was committed without his knowledge or that he exercised all due diligence to prevent the commission of such offence."

(2) Notwithstanding anything contained in sub-section (1), where an offence under this Act has been committed by a Department of the Government and it is proved that the offence has been committed with the consent or connivance of, or is attributable to any neglect on the part of, any officer, other than the head

of the Department, such officer shall be deemed to be guilty of that offence and shall be liable to be proceeded against and punished accordingly.

6.2. That earlier few Districts authorities and State Governments including authorities of State of Maharashtra put some restrictions on intra state and inter-state movements. Since said restrictions were against the guidelines issued by MHA therefore on **22th Aug 2020**, Home Secretary Sh. Ajay Bhalla, vide his letter outward D. O. No. **40-3 /2020/DM-I(A)** warned Chief secretary of all states as under;

"D.O. No. 40-3/2020-DM-I(A)

Dear Chief Secretary,

Please refer to Ministry of Home Affairs' Order of even number dated 29.07.2020 whereby Guidelines for Unlock-3 have been issued.

2. I would like to draw your kind attention to para-5 of these guidelines which clearly state that ***there shall be no restriction on inter-State and Intra-State movement of persons and goods. No separate permission, approval/e-permit will be required for such movements.*** *This includes movement of persons & goods for cross land border trade under Treaties with neighboring countries.*

3. It has, however, been reported that local level restrictions on movement are being imposed by various districts/States. Such restrictions are creating

problems in inter-State movement of goods and services and are impacting the supply chain, resulting in disruption of economic activities and employment, besides affecting supply of goods and services.

4. ***Such restrictions at local level imposed by the District Administration or by the State Government, amount to violation of the guidelines issued by MHA under the provisions of Disaster Management Act, 2005****.*

5. I would, therefore, request that no restrictions may be imposed on inter-State and intra State movement of persons and goods and services and instructions issued to ensure that MHA guidelines mentioned above are strictly followed."

A copy of the said letter is annexed herewith at **Exhibit -"AA6" [Page 1041]**

7. The Orders, SOP & rules formulated by the state authorities which discriminates between vaccinated and unvaccinated people is not based on the *"intelligent differentia"* and it does not pass the scrutiny of Article 14, 19, & 21 of the Constitution of India.

7.1. That, the decision taken by the State authorities is not taken in good faith but is actuated with ulterior purposes and malafide intention.

7.2. That, the above said decision is taken by ignoring the scientific data and advisory of National Authority and is based on the false assumption that the vaccinated people are completely protected and

unvaccinated people are not protected and therefore they can spread infection.

7.3. That, as per the empirical data available and decision taken by the National authority and judgments given by the various High Courts it is clear that there is no difference between vaccinated and unvaccinated person with regard to possibility of spreading infection.

Vaccinated people can be a Super Spreader. Therefore they are also required to follow the Covid appropriated behavior.

7.4. The aspect of intelligent differentia between vaccinated and non-vaccinated person is considered by the Division Bench of Hon'ble Gauhati High Court in the Case of **Re: Dinthar Incident Aizawl Vs. State of Mizoram 2021 SCC OnLine Gau 1313** where it is ruled that there cannot be any discrimination of the non-vaccinated people because vaccinated people can also be a Super Spreader.

On the issue of intelligent differentia, the **Paras are 12, 13 & 14** are relevant.

8. Studies which show that vaccinated people have as much as, or more viral load than the unvaccinated:

8.1. "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

8.2. "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

8.3. "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

8.4. "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

8.5. 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/

8.6. 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

8.7. 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

8.8. 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

9. Malafides of the State authorities in bringing rules by ignoring the data of prohibited category of person, death causing side effects of vaccines and higher number of deaths in vaccinated than unvaccinated: -

9.1. That, a young **Dr. Snehal Lunawat died due to side effects of 'Covishield'** vaccines. The committee of Adverse Events Following

Immunization (AEFI) in its letter dated **02 October, 2021** admitted that her death was due to side effects of Covishield.

A copy of the letter issued by AEFI Committee is at **Exhibit "AA7" [Page 1042 to 1043]**

9.2. That, as per vaccine companies own fact sheet certain category of people are excluded from being vaccinated. Those people include the person with allergies to the contents of vaccine et.al.

9.3. 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. **[Exhibit "AA8" [Page 1044 to 1046]**

Link:
https://www.newindianexpress.com/states/kerala/2021/aug/20/half-of-indias-87k-breakthrough-covid-cases-in-kerala-2347145.html

9.4. 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.

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

9.5. In a recently published study **(30th September 2021)** in the European Journal of Epidemiology, the authors looked at statistical

correlation between vaccination level in a population and the weekly average of Covid cases in that population. They found no significant correlation; in fact the correlation was a weak positive, i.e. **higher vaccination level resulted in a slightly higher level of Covid cases. The study looked at data from 68 countries as well as nearly 3000 counties in the USA.**

"Findings

At the country-level, there appears to be no discernible relationship between percentage of population fully vaccinated and new COVID-19 cases in the last 7 days (Fig. l). 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 I 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 COVID19 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-l9 cases per 1 million people than countries such as Vietnam and South Africa that have around l0% of their population fully vaccinated."

(A copy of the Paper titled "Increases in COVID-19 are unrelated to levels of vaccination across 68 countries and 2947 counties in the united States", published 30 Sep 2021 is annexed as **Exhibit -"AA9" [Page 1047 to 1050]**

9.6. A recent study published in the MedRxiv, found no significant difference in viral load between vaccinated and unvaccinated, asymptomatic and symptomatic groups when Infected with SARS-CoV-2 Delta Variant. The study states:

> *"In our study, mean viral loads as measured by Ct-value were similar for large numbers of asymptomatic and symptomatic individuals infected with SARSCov-2 during the Delta surge, regardless of vaccine status, age, or gender. This contrasts with a large ongoing UK community cohort in which the median Ct-value was higher for vaccinated individuals (27.6) than for unvaccinated individuals (23.1) (5). Also, a study from San Francisco reported that l0 fully vaccinated asymptomatic individuals had significantly lower viral loads than 28 symptomatic, vaccinated individuals [6]. Our study is consistent with other recent reports showing similar viral loads among vaccinated and unvaccinated individuals in settings with transmission of the Delta variant. In a Wisconsin study, Ct-values were similar and culture positivity was not different in a subset of analyses between l1 vaccinated and 24 unvaccinated cases [4]. In both Massachusetts and Singapore, individuals with vaccination breakthroughs caused by the Delta variant had similar Ct-values as unvaccinated individuals [3, l0]. Our findings are supported by consistency across large sample sets using different assays from two distinct locations.*
>
> *A substantial proportion of asymptomatic, fully vaccinated individuals in our study had low Ct-values, indicative of high viral loads. Given that low Ct-values are indicative of high*

levels of virus, culfure positivity, and increased transmission [11], our detection of low Ct-values in asymptomatic, fully vaccinated individuals is consistent with the potential for transmission from breakthrough infections prior to any emergence of symptoms."

A copy of the study titled "No Significant Difference in Viral Load Between Vaccinated and Unvaccinated, Asymptomatic and Symptomatic Groups When Infected with SARS-CoV-2 Delta Variant" posted on 5th October 2021 is annexed as **Exhibit -"AA10" [Page 1051 to 1059]**

9.7. In Gibraltar, despite 100 % vaccination there is surge in Covid cases. The relevant news dated 16th November, 2021 Published in RT Live is at **Exhibit "AA11" [Page 1060 to 1061]**

Link: https://www.rt.com/news/540442-gibraltar-cancels-christmas-covid/

9.8. There have been several instances of covid outbreaks in highly vaccinated college populations in the USA:

a) Harvard University had an outbreak of Covid cases in early September despite having over 90% of its staff and students fully vaccinated:

Link: https://www.thecrimson.com/article/2021/9/3/harvard-hikes-testing-requirements/

b) In the same week, Cornell University had nearly 400 Covid cases although nearly all students were fully vaccinated on campus:

Link: https://cornellsun.com/2021/09/06/as-cornell-reports-record-cases-students-miss-first-classes-bear-burdens-of-covid-policies/

c) Brown University had a similar outbreak in mid September in spite of having nearly 100% of its students and staff fully vaccinated:

Link: https://boston.cbslocal.com/2021/09/15/brown-university-covid-dining-stduents-gathering/

(A copy of the news articles related to these university outbreaks is annexed as **Exhibit -"AA12" [Page 1062 to 1063]**

9.9. Even at the level of a country, vaccination does not reduce Covid cases. 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."

A copy of the article in The Times of Israel titled "Health Ministry chief says coronavirus spread reaching record heights" dated **14 Sep 2021** is annexed as **Exhibit -"AA13" [Page 1064 to 1065]**

8.10. Cases where country stop use of AstraZeneca (Covi-Shield) vaccines due to its side effects:-

9.10.1. <u>AstraZeneca (Covishield) related risks</u>:

a) The UK's yellow card system has reported adverse events at the rate of about I in 106 doses for the AstraZeneca vaccine (Covishield). https://www.gov.uk/government/publications/coronavirus-covid-19-vaccine-adverse-reactions/coronavirus-vaccine-summary-of-yellow-card-reporting

b) In March 2021 about 16 European countries banned the use of Astra Zeneca's Covid Vaccine over concerns of blood clotting among receipts of the vaccine. In Apr 2021, various European countries such as Spain, Belgium, Italy, restricted the AstraZeneca vaccine to older people:

> "Italy, Spain and Belgium have joined other European countries in limiting the use of the Oxford/AstraZeneca vaccine to older age groups as the EU struggles to agree common guidelines to counter expected public hesitancy. The European Medicines Agency (EMA) on Wednesday found a possible link between the vaccine and very rare cases of blood clots, although it said its benefits far outweighed the risks and did not announce any restrictions. In Britain, the government's joint committee on vaccines and immunisation said healthy people aged rB to 24 who were not at high risk of covid should have the option of a different jab if one was available in their area."

(A copy of the article in The Guardian titled "Spain, Belgium and Italy restrict AstraZeneca covid vaccine to older people" dated 8th April 2021 is at **Exhibit <u>"AA14" [Page 1066 to 1067]</u>**

c) As recently as last month, the NIH (USA) ordered a study on the Covid-19 vaccines impact menstrual cycle.

(A copy of an article in the New York Post titled 'NIH orders $1.67M study on how COVID-19 vaccine impacts menstrual cycle" dated 7th September 2021 is at Exhibit **"AA15" [Page 1068 to 1069]**

9.10.2. Moderna related risks:

d) Toward the end of Sep 2021, based on an understanding of myocarditis (heart inflammation) risk among young people, Ontario (Canada) restricted the Moderna vaccine to only those above age 24.

(A copy of the article in the Toronto Sun tiled "Ontario now recommending against Moderna vaccine for men 18-24 years old" dated 29th September 2021, is at Exhibit **"AA16" [Page 1070]**

e) In the first week of October 2021, various European countries followed suit with Sweden and Denmark pausing Moderna COVID-l9 vaccine for younger age groups after reports of rare cardiovascular side effects.

(A copy of an article in Reuters titled "Sweden, Denmark pause Moderna Covid19 vaccine for younger age groups" dated 6th October 2021 is at Exhibit **"AA17" [Page 1071 to 1073]**

f) Following this Finland limited the use of the Moderna vaccine.

(A copy of the article titled "Finland joins Sweden and Denmark in limiting Moderna COVID-I9 vaccine" dated 07 Oct 2021 is at **Exhibit "AA18" [Page 1074]**

g) The Chief Epidemiologist in Iceland decided to stop the use of Moderna vaccine against Covid 19 while further information is obtained on safety of the vaccine during booster vaccinations. (A copy of the report titled "Stop the use of the Moderna vaccine in Iceland in the light of new data" dated 08 Oct 2021 is at Exhibit **"AA19" [Page 1076]**

9.11. Various countries have been meticulously tracking vaccine side-effects and correcting course during their vaccination campaign, after noticing adverse side-effects. An article published in the American Thinker states:

"This vast Phase 3 clinical trial of mRNA vaccines in which Americans are participating mostly out of fear is not going well. It is abundantly clear for anyone advocating for public health that the vaccination program should be stopped. Iceland has just stopped giving the Moderna vaccine to anyone which is a good step in the right direction. Sweden, Denmark, and Finland have banned the Moderna vaccine for anyone under the age of 30.

VAERS, our vaccine adverse effect reporting system, showed at the beginning of this week 16,000 deaths, 23,000 disabilities, 10,000 MI/myocarditis, 87,000 urgent care visits, 75,000 hospital stays, and 775,000 total adverse events. The VAERS system is widely known to under-report events, with an estimated 90 to 9970 ofevents going unreported there.

Eudravigilance, the European reporting system now associates 26,000 deaths in close proximity to administration of the vaccine. Whistleblower data from the CMS system (Medicare charts) showed close to 50,000 deaths in the Medicare group shortly after the vaccine.

An AI-powered tracking program called Project Salus also follows the Medicare population and shows vaccinated Medicare recipients are having worse outcomes week by week of the type consistent with Antibody Dependent Enhancement. This occurs when the vaccine antibodies actually accelerate the infection leading to worsening COVID-19 infection outcomes. Antibody Dependent Enhancement has occurred previously with trials of other coronavirus vaccines in animals. The CDC and the FDA are suppressing this data and no one who receives the vaccine has true informed consent."

A copy of the article published in the American Thinker titled, "The Unvaccinated Are Looking Smarter Every Week" dated **16th October 2021** is annexed as **Exhibit - "AA20" [Page 1077]**

10. Recent court orders across the world which stayed the rules and orders of conditions of fully vaccination:-

10.1. Many State in USA and private individuals filed as case before the court against vaccination conditions.

10.2. **United States Court of Appeal** for the fifth Circuit, considering the seriousness of the issue vide its order dated **6th November,2021** granted interim stay at first hearing.

Said order reads thus;

> *In the Hon'ble Court of United States* ***BST Holdings Vs. Occupational Safety And Health Administration Order Dated 6th Nov, 2021*** *, it is ruled as under;*
>
> *Before the court is the petitioners'[1] emergency motion to stay enforcement of the Occupational Safety and Health Administration's November 5, 2021 Emergency Temporary Standard[2] (the "Mandate") pending expedited judicial review.*
>
> *Because the petitions give cause to believe there are grave statutory and constitutional issues with the Mandate, the Mandate is hereby STAYED pending further action by this court.*
>
> *The Government shall respond to the petitioners' motion for a permanent injunction by 5:00 PM on Monday, November 8.*
>
> *The petitioners shall file any reply by 5:00 PM on Tuesday, November 9.*

A copy of the judgment is at **Exhibit"AA21" [Page 1081]**

10.3. Thereafter vide its detail order dated **12th November ,2021** the United States Court confirm the interim stay.

A copy of the judgment is at **Exhibit "AA22" [Page 1084]**

10.4. The Slovenia Constitutional Court has blocked the government plan to make coronavirus vaccines mandatory for public employees, hours before it was due to come into force.

> *"In its decision the court said that "despite the very serious epidemic situation", it considered that "implementing the potentially unconstitutional (measure) ... would have worse consequences than delaying implementation".*

(A copy of the article titled "Vaccine mandate for public employees in Slovenia blocked", dated 30 Sep 2021 is annexed as **Exhibit - "AA23" [Page 1016]**

10.5. In New York, a federal appeals court blocked New York City's coronavirus vaccine mandate days before the mandate goes into effect. "The 2nd circuit Court of Appeals granted an expedited injunction on Friday blocking the city from mandating that all public school employees submit proof of their first coronavirus vaccine dose by Monday."

A copy of the article in The Hill tilled "Federal appeals court blocks NYC teacher vaccine mandate" dated **25 Sep 2021** is annexed as **Exhibit - "AA24" [Page 1111]**

10.6. In Gainesville, Florida a lower court has issued an injuction against vaccine mandates for employees.

> *"A Circuit Court judge has issued a temporary injunction preventing the City of Gainesville from requiring a COVID- 19 vaccine for employees or terminating employees that do not get the vaccine."*

A copy of the news report titled "BREAKING: Judge grants temporary injunction preventing vaccine mandates for city employees" dated 23 Sep 2021 is annexed as **Exhibit -"AA25" [Page 1112]**

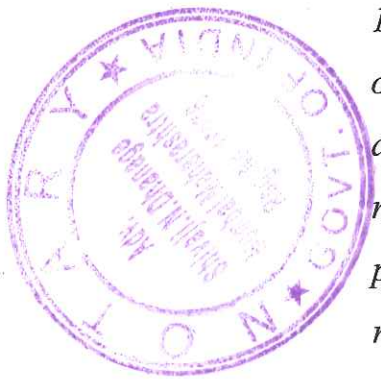
10.7. The governor of Texas has barred all Covid-19 vaccine mandates in state and termed the vaccine mandates as bullying by the administration. The order states:

> *"WHEREAS, I issued Executive Orders GA-35, GA-38, and GA-39 to prohibit governmental entities and certain others from imposing COVID- 19 vaccine mandates or requiring vaccine passports; and WHEREAS, in yet another instance of federal overreach, the Biden Administration is now bullying many private entities into imposing COVIDl9 vaccine mandates, causing workforce disruptions that threaten Texas' s continued recovery from the COVID- 19 disaster; and*
>
> *WHEREAS, countless Texans fear losing their livelihoods because they object to receiving a COVID-19 vaccination for reasons of personal conscience, based on a religious belief, or for medical reasons' including prior recovery from COVID-19; and*
>
> ...
>
> *WHEREAS, the legislature has taken care to provide exemptions that allow people to opt out of being forced to take a vaccine for reasons of conscience or medical reasons; and*

....

NOW, THEREFORE, I, Greg Abbott, Governor of Texas, by virtue of the power and authority vested in me by the Constitution and laws of the State of Texas, do hereby order the following on a statewide basis effective immediately:

1. No entity in Texas can compel receipt of a COVID-19 vaccine by any individual, including an employee or a consumer, who objects to such vaccination for any reason of personal conscience, based on a religious belief, or for medical reasons, including prior recovery from COVID-I9. I hereby suspend all relevant statutes to the extent necessary to enforce this prohibition.



2. The maximum fine allowed under Section 4 1 8. 173 of the Texas Government Code and the State's emergency management plan shall apply to any "failure to comply with" this executive order. Confinement in jail is not an available penalty for violating this executive order."

A copy of the executive order of the Governor of Texas, USA dated **11th October 2021** is annexed as **Exhibit - "AA26" [Page 1113]**

10.8. The UK Parliamentary Committee report dated **09 Sep 2021** held that the Covid passport policy lacks scientific evidence base and must be done away with. Based on this report the government decided not to issue any vaccine mandates. The report stated:

"The Committee's report demanded that the Government provide scientific evidence backing-up its claims that requiring Covid passports was necessary to reopening the economy and society if it pressed ahead with plans to implement them. Doing so through the publication of the public health case, cost-benefit analyses, and modeling of the potential impacts would be essential to public understanding and acceptance of the system, the report said. The Government failed to give any such evidence in its response. Added to this, the latest analysis by Public Health England (PHE) found that although being fully vaccinated protects against infection and severe symptoms, it unlikely to do much to stop the spread of the virus if people become infected. Jabbed and unjabbed individuals carry similar amounts of the virus. Researchers call this having a similar viral load. Concerns over viral load of the Delta variant appeared in Sage meeting minutes from 22 July. Sage, the Government's scientific advisory panel, warned that there is 'limited vaccine effect against onward transmission' of the variant. Civen that this meeting was held before the Government: responded to the Committee's report, the Committee has severe concerns about the way in which this policy has been developed and kept under consideration."

A copy of the article on the report titled "Covid passport policy lacks scientific evidence base" dated 9 Sep 2021 is annexed as **Exhibit - "AA27" [Page 1116]**

10.9. A court in Galicia, Spain, over tuned regional governments requirement for Covid passports in bars and restaurants.

A copy of the article titled "Galicia courts overtum regional govemment requirement for Covid passports in bars and restaurants" dated **12 Aug 2021** is annexed as **Exhibit -"AA28" [Page 1118]**

10.10. In Andalusia, Spain,

"Andalusian justice rejects the requirement of the covid certificate to enter the nightclubs. The magistrates consider that the measure requested by the Board violates the right to privacy and the principle of non-discrimination and is neither suitable nor necessary."

A copy of the article, "Andalusian justice rejects the requirement of the Covid certificate to enter the nightclubs" dated **12 Aug 2021**, is annexed as **Exhibit -"AA29" [Page 1119]**

10.11. The Scandinavian countries of Sweden, Finland, Norway, Denmark have all done away with all Covid restrictions; Denmark had briefly considered vaccine passports but recently decided to do away with such a system.

A copy of the article in News.com titled "Denmark ditches vaccine passports, its last remaining Covid restriction" dated **10 Sep 2021** is annexed as **Exhibit - "AA30" [Page 1121]**

11. It is the duty of the Government to publish the side effects of vaccines before calling the citizens to get vaccinated.

11.1 In the case **(W.P.(C) 343/2019 & CM Nos.1604 1605/2019) between Master Haridaan Kumar (Minor through Petitioners Anubhav Kumar and Mr. Abhinav Mukherji) Versus Union of India,** & **W.P.(C) 350/2019 & CM Nos. 1642-1644/2019** between **Baby Veda Kalaan & Others Versus Director of Education & Others.**

11.2 Hon'ble High Court of Delhi had observed that the authority is bound to advertise the side effects of the vaccines before getting their consent.

It is ruled as under;

"The contention that indication of the side effects and contraindications in theadvertisement 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 aninformed 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."

The Hon'ble High Court of Delhi thus passed the following orders;

***"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".*

01- Further on the issue of informed consent, the Hon'ble High Court had clearly directed that:

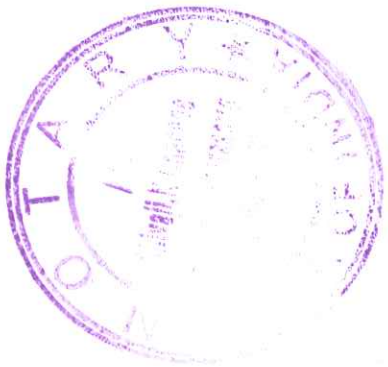
"Directorate of Family Welfare shall issue quarter page advisements in various newspapers as indicated by the respondents... The advertisements shall also indicate that the vaccination shall be administered with Auto Disable Syringes to the eligible children by Auxiliary Nurse Midwifery. The advertisement shall also clearly indicate the side effects and contraindications as may be finalized by the Department of Preventive Medicine, All India Institute of Medical Sciences".

12. The liberty of citizen cannot be curtailed on the basis of orders passed by the authority or there is a need of creating a law by the

legislation as per Article 19(b) 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 & Madan Mili Vs. UOI 2021 SCC OnLine Gau 1503.

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 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.

18. *The SOP provides that vaccinated persons who are employed in shops/stores and to drive transport/commercial vehicles should wear mask and adhere to all proper covid protocols. If an un-vaccinated person is to be made to adhere to the same protocols, there can be no difference in the work of a vaccinated or un-vaccinated person. As such, the restriction placed upon un-vaccinated persons only due to non-vaccination is unreasonable and arbitrary.*

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 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."*

In the case of **Madan Mili Vs. UOI 2021 SCC OnLine Gau 1503,** 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.

15. *For the reasons stated hereinabove, it prima facie appears to this Court that Clause 11 of the Order dated 30.06.2021, issued by the Chief Secretary cum Chairperson-State Executive Committee, Government of Arunachal Pradesh, vide Memo No. SEOC/DRR&DM/01/2011-12, in so far it makes a classification of persons who are Covid-19 vaccinated and persons who are Covid-19 unvaccinated for the purpose of issuance of temporary permits for developmental works in both public and private sector in the State of Arunachal Pradesh violates Articles 14, 19 (1) (d) & 21 of the Constitution of India calling for an interim order in the case. Accordingly, till the returnable date, Clause 11 of the Order dated 30.06.2021, issued by the Chief Secretary cum Chairperson-State Executive Committee, Government of Arunachal Pradesh, vide Memo No. SEOC/DRR &DM/01/2011-12, in so far it discriminates between Covid-19 vaccinated persons and Covid-19 unvaccinated persons for issuance of temporary permits for developmental works in both public and private sector in the State of Arunachal Pradesh, shall remain stayed."*

13. Act of State authority amounts to an offence under Section 51(b), 55 of Disaster Management Act, 2005 & other provisions of I.P.C.

Section **51(b), 55** of the Act reads thus;

"Section 51 in the Disaster Management Act, 2005

51. Punishment for obstruction, etc.-

Whosoever,

(b) *refuses to comply with any direction given by or on behalf of the Central Government or the State Government or the National Executive Committee or the State Executive Committee or the District Authority under this Act, shall on conviction be punishable with imprisonment for a term which may extend to one year or with fine, or with both, and if such obstruction or refusal to comply with directions results in loss of lives or imminent danger thereof, shall on conviction be punishable with imprisonment for a term which may extend to two years. notes on clauses Clauses 51 to 58 (Secs. 51 to 58) seeks to lay down what will constitute an offence in terms of obstruction of the functions under the Act, false claim for relief, misappropriation of relief material or funds, issuance of false warning, failure of an officer to perform the duty imposed on him under the Act without due permission or lawful excuse, or his connivance at contravention of the provisions of the*

Act. The clauses also provide for penalties for these offences.

Section 55 in the Disaster Management Act, 2005

55. Offences by Departments of the Government.-

(1) Where an offence under this Act has been committed by any Department of the Government, the head of the Department shall be deemed to be guilty of the offence and shall be liable to be proceeded against and punished accordingly unless he proves that the offence was committed without his knowledge or that he exercised all due diligence to prevent the commission of such offence. (1) Where an offence under this Act has been committed by any Department of the Government, the head of the Department shall be deemed to be guilty of the offence and shall be liable to be proceeded against and punished accordingly unless he proves that the offence was committed without his knowledge or that he exercised all due diligence to prevent the commission of such offence."

(2) Notwithstanding anything contained in sub-section (1), where an offence under this Act has been committed by a Department of the Government and it is proved that the offence has been committed with the consent or connivance of, or is attributable to any neglect on the part of, any officer, other than the head

of the Department, such officer shall be deemed to be guilty of that offence and shall be liable to be proceeded against and punished accordingly.

14. The ratio laid down by the Full Bench of Hon'ble Supreme Court in of Manohar Lal Sharma Vs. Union of India 2021 SCC OnLine SC 985. apply to the present case which mandates the state to not to litigate adverbial litigation like and to place all data available with them when matter pertains to life and liberty of majority of citizen.

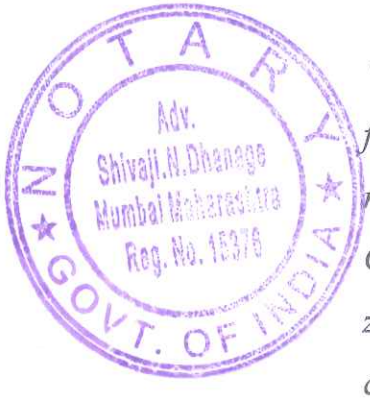
15. The decision taken by the authority apart from its legality also amounts to an offence of misappropriation of thousands of crores of public money for giving vaccine to the persons with natural immunity when from the suggestions given by the domain experts and research proved that the natural immunity 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"

15.2 "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 Science Mag: 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.

"Vaccines 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.

"This study demonstrated that natural immunity confers longer lasting and stronger protection against infection, symptomatic disease and hospitalization caused by the Delta variant of SARS-CoV-2, compared to the BNT162b2 two-dose vaccine-induced immunity,' study authors said.

Link: https://www.medrxiv.org/content/10.1101/2021.08.24.21262415v1

15.3. The Brownstone Institute lists 81 of the highest-quality, complete, most robust scientific studies and evidence reports/position statements on natural immunity as compared to the COVID-19 vaccine-induced immunity.

Link: https://childrenshealthdefense.org/defender/research-natural-immunity-covid-brownstone-institute/

16. Study shows that, giving vaccines to the person with previous Covid-19 infection is causing more harm than the disease itself.

16.1. An international survey21 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

17. Vaccinated people are at higher risk:-

17.1. "A majority of gravely ill patients in Israel are double vaccinated. A majority of deaths over 50 in England are also double vaccinated. **[Exhibit]**

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

17.2. A study published Sept. 30, in the peer-reviewed European Journal of Epidemiology Vaccines found "no discernible relationship" between the percentage of population fully vaccinated and new COVID cases.

In fact, the study found the most fully vaccinated nations had the highest number of new COVID cases, based on the researchers' analysis of emerging data during a seven-day period in September.

The authors said the sole reliance on vaccination as a primary strategy to mitigate COVID-19 and its adverse consequences "needs to be re-examined," especially considering the Delta (B.1.617.2) variant and the likelihood of future variants.

They wrote:

> "Other pharmacological and non-pharmacological interventions may need to be put in place alongside increasing vaccination rates. Such course correction, especially with regards to the policy narrative, becomes paramount with emerging scientific evidence on real-world effectiveness of the vaccines."

As part of the study, researchers investigated the relationship between the percentage of population fully vaccinated and new COVID cases across 68 countries and 2,947 U.S. counties that had second dose vaccine, and available COVID case data.

Link: https://link.springer.com/article/10.1007/s10654-021-00808-7

17.3 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).

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

18. Cases where vaccine causing more harm than the disease itself:

18.1 Healthy boys may be more likely to be admitted to the hospital with heart inflammation from the Pfizer-BioNTech COVID vaccine than with COVID itself, according to a new pre-print study.

U.S. researchers found boys between the ages of 12 and 15, with no underlying medical conditions, were four to six times more likely to be diagnosed with vaccine-related myocarditis than they were to be hospitalized with COVID.

Link: https://www.medrxiv.org/content/10.1101/2021.08.30.21262866v1

18.2. Many countries banned the use of Covi-Shield vaccines due to its side effects:

11 European countries banned the use of AstraZeneca (Covishield) vaccines for deaths of their citizens due to side effects of Said Vaccine.

Link: **https://www.aljazeera.com/news/2021/3/15/which-countries-have-halted-use-of-astrazenecas-covid-vaccine**

18.3. Majority of Hospitalizations Are Actually in the Vaccinated

The oft-repeated refrain is that we're in a "pandemic of the unvaccinated," meaning those who have not received the COVID jab make up the bulk of those hospitalized and dying from the Delta variant. However, we're already seeing a shift in hospitalization rates from the unvaccinated to those who have gotten one or two injections.

For example, in Israel, the fully "vaccinated" made up the bulk of serious cases and COVID-related deaths in July 2021, as illustrated in the graphs below. The red is unvaccinated, yellow refers to partially "vaccinated" and green fully "vaccinated" with two doses. By mid-August, 59% of serious cases were among those who had received two COVID injections.

Data from the U.K. show a similar trend among those over the age of 50. In this age group, partially and fully "vaccinated" people account for 68% of hospitalizations and 70% of COVID deaths.

Link: 1. https://cdn.altnews.org/wp-content/uploads/2021/08/new-hospitalizations-thumb.jpg

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

3. https://cdn.nexusnewsfeed.com/images/2021/8/deaths-trend-thumb-1631973112475.png

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

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

6. https://www.standard.co.uk/news/uk/england-delta-donald-trump-government-public-health-england-b951620.html

18.4. 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

18.5. In Bangalore more than 56% of hospitalization of covid positive patient are vaccinated.

Link: https://www.deccanherald.com/amp/state/top-karnataka-stories/more-than-half-of-hospitalised-covid-19-cases-among-vaccinated-in-bengaluru-1015918.html?__twitter_impression=true&s=04%5C

"Source Name: Deccan Herald

Date:03.08.2021

More than half of hospitalised Covid-19 cases among vaccinated in Bengaluru

These hospitalisations are indicative of the extent of vaccine penetration in the public, explained BBMP Chief Commissioner, Gaurav Gupta"

18.6. 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

18.7. In K.E.M Hospital 27 out of 29 Covid-19 positive patients were vaccinated. [Around 93%]

Link: https://www.freepressjournal.in/mumbai/mumbai-29-mbbs-students-at-kem-hospital-test-positive-for-covid-19-27-were-fully-vaccinated

"29 MBBS students at KEM hospital test positive for COVID-19, 27 were fully vaccinated

SOURCE:- FREE PRESS JOURNAL"

18.8. In Nagpur 13 people tested positive for the virus out of which 12 were already vaccinated.".

Link:- https://www.freepressjournal.in/mumbai/covid-19-third-wave-has-entered-nagpur-guardian-minister-nitin-raut-urges-people-to-avoid-crowding

"Source:- *Free Press Journal.*

Date:- *Monday, September 06, 2021, 11:02 PM IST*

Relevant Important Para to be taken;

The district guardian minister, Dr Nitin Raut, told the Free Press Journal after a review meeting, ''The third wave has started in Nagpur, which is reporting a rise in positive cases for the last few days. Notably, on Monday, 13 people tested positive for the virus out of which 12 were already vaccinated."

19. Covishield unable to halt breakthrough Delta infections: Study
Fresh evidence on Covishield's inability to halt "breakthrough infections" caused by the Delta variant of SARS-CoV-2 in fully vaccinated individuals emerged on Sunday with a group of Indian researchers reporting an unexpectedly large proportion of Covid-19 infections among the vaccine recipients.
https://www.medrxiv.org/content/10.1101/2021.02.28.21252621v4
https://www.deccanherald.com/science-and-environment/covishield-unable-to-halt-breakthrough-delta-infections-study-1024960.html

19.1. 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

19.2. 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

20. Vaccines don't stop transmission, admitted by WHO

At a virtual press conference held by the World Health Organization on Dec. 28, 2020, officials warned there is no guarantee COVID-19 vaccines will prevent people from being infected with the SARS-CoV-2 virus and transmitting it to other people.

https://www.who.int/emergencies/diseases/novel-coronavirus-2019/media-resources/press-briefings

21. State definition of Fully Vaccinated including persons with medical certification of exemption from vaccination is not properly explained and said order is not communicated to the public.

21.1. That the State authority after getting a copy of this petition and after getting the reports of deaths and serious side effects of vaccination have taken a decision to include the person with a medical certificate in the category of fully vaccinated.

21.2. The letter issued by the ACM (COG) of the Mumbai CST on **14.10.2021** reads thus;

> *1. Any person who has received both doses of vaccination and 14 days having lapsed since the administration of the second dose of the vaccine.*
>
> *2. Any person having medical condition that does not allow him or her to take the vaccine and has a certificate to that extent from a recognized Doctor.*

3. If person is of age less than 18 years. (in the future when vaccine becomes available for this age group than this will continue for first 60 days of such availability.)

21.3. That order dated **8.10.2021** is not available at the website of the State Government. It is not made available to the common man.

21.4. No steps were taken to make the public aware about the side effects of the vaccines and prohibited category of the people.

21.5. Needless to mention here that the persons having previous Covid infection, pregnant women, etc. were not included in the clinical trials therefore there is no authentic data of the effects of their safety. But the State Government anyhow is hell-bent upon vaccinating everyone by dishonest concealment, suppression, and twisting of the crucial information and suggestions from the domain experts like Sanjay Rai of AIIMS.

21.6. State government is more interested in profit of vaccine companies than life of people. This needs an investigation to bring the truth to surface.

21.7. In a similar case the United State Federal Government ordered investigation and recovered more than **10.2. Billion US Dollar fine** in Court settlement from pharma companies due to their not informing the side effects to the public;

"GLAXOSMITHKLINE TO PLEAD GUILTY AND PAY $3 BILLION TO RESOLVE FRAUD ALLEGATIONS AND FAILURE TO REPORT SAFETY DATA"

Source:- The United States' Department of Justice.

Date:- July 2, 2012

Largest Health Care Fraud Settlement in U.S. History

"*1.* ***The United States alleges that GSK stated that Avandia had a positive cholesterol profile despite having no well-controlled studies to support that message.*** *The United States also alleges that the company sponsored programs suggesting cardiovascular benefits from Avandia therapy despite warnings on the FDA-approved label regarding cardiovascular risks. GSK has agreed to pay $657 million relating to false claims arising from misrepresentations about Avandia. The federal share of this settlement is $508 million and the state share is $149 million.*

2. In addition to the criminal and civil resolutions, GSK has executed a five-year Corporate Integrity Agreement (CIA) with the Department of Health and Human Services, Office of Inspector General (HHS-OIG). The plea agreement and CIA include novel provisions that require that GSK implement and/or maintain major changes to the way it does business, including changing the way its sales force is compensated to remove compensation based on sales goals for territories, one of the driving forces behind much of the conduct at issue in this matter. Under the CIA, GSK is required to change its executive compensation program to permit the company to recoup annual bonuses and long-term incentives from covered executives if they, or their

subordinates, engage in significant misconduct. GSK may recoup monies from executives who are current employees and those who have left the company. Among other things, the ***CIA also requires GSK to implement and maintain transparency in its research practices and publication policies and to follow specified policies in its contracts with various health care payors.***

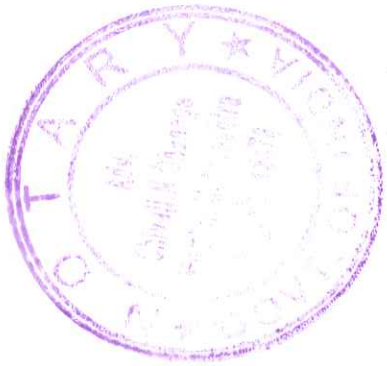
Federal employees deserve health care providers and suppliers, including drug manufacturers, that meet the highest standards of ethical and professional behavior," said Patrick E. McFarland, Inspector General of the U.S. Office of Personnel Management.

Assistant Director of the FBI's Criminal, Cyber, Response and Services Branch. "Together, we will continue to bring to justice those engaged in illegal schemes that threaten the safety of prescription drugs and other critical elements of our nation's healthcare system.

This matter was investigated by agents from the HHS-OIG; the FDA's Office of Criminal Investigations; the Defense Criminal Investigative Service of the Department of Defense; *the Office of the Inspector General for the Office of Personnel Management; the Department of Veterans Affairs; the Department of Labor; TRICARE Program Integrity; the Office of Inspector General for the U.S. Postal Service and the FBI.*

This resolution is part of the government's emphasis on combating health care fraud and another step for the Health

Care Fraud Prevention and Enforcement Action Team (HEAT) initiative, which was announced in May 2009 by Attorney General Eric Holder and Kathleen Sebelius, Secretary of HHS. The partnership between the two departments has focused efforts to reduce and prevent Medicare and Medicaid financial fraud through enhanced cooperation. Over the last three years, the department has recovered a total of more than $10.2 billion in settlements, judgments, fines, restitution, and forfeiture in health care fraud matters pursued under the False Claims Act and the Food, Drug and Cosmetic Act.



The company's unlawful promotion of certain prescription drugs, its failure to report certain safety data, and its civil liability for 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 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 data about 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 claims arising from this alleged conduct. The federal share of this settlement is $832 million and the state share is $210 million."

A copy of Article is at Exhibit "AA31" [Page 1124]

22. It is therefore, important for this Hon'ble Court to step in and exercise of its powers of judicial review of executive policy which is manifestly arbitrary and irrational and to set aside any vaccine mandates that have been brought in by the government or private bodies and thereby safeguard citizen's fundamental rights. This Hon'ble court has held in **Distribution of Essential Supplies and Services During**

Pandemic, In re, 2021 SCC OnLine SC 411 vide order dated **31 May 2021**, the Supreme Court held that:

> *"15. It is trite to state that separation of powers is a part of the basic structure of the Constitution. Policy-making continues to be in the sole domain of the executive. The judiciary does not possess the authority or competence to assume the role of the executive, which is democratically accountable for its actions and has access to the resources which are instrumental to policy formulation. However, this separation of powers does not result in courts lacking jurisdiction in conducting a judicial review of these policies.* ***Our Constitution does not envisage courts to be silent spectators when constitutional rights of citizens are infringed by executive policies Judicial review and soliciting constitutional justification for policies formulated by the Executive is an essential function, which the courts are entrusted to perform.***
>
> ...
>
> ***17. The Supreme Court of United States, speaking in the wake of the present COVID-19 pandemic in various instances, has overruled policies by observing, inter alia, that "Members of this Court are not public health experts. and we should respect the judgment of those with special expertise and responsibility in this area. But even in a pandemic, the Constitution cannot be put away and forgotten" 20 and "a public health emergency does not give Governors and other public officials carte blanche to***

disregard the Constitution for as long as the medical problem persists. As more medical and scientific evidence becomes available, and as States have time to craft policies in light of that evidence, courts should expect policies that more carefully account for constitutional rights"

18. Similarly, courts across the globe have responded to constitutional challenges to executive policies that have directly or indirectly violated rights and liberties of citizens. Courts have often reiterated the expertise of the executive in managing a public health crisis, but have also warned against arbitrary and irrational policies being excused in the garb of the "wide latitude" to the executive that is necessitated to battle a pandemic. *This Court in Gujarat Mazdoor Sabha vs State of Gujarat, albeit while speaking in the context of labour rights, had noted that policies to counteract a pandemic must continue to be evaluated from a threshold of proportionality to determine if they, inter alia, have a rational connection with the object that is sought to achieved and are necessary to achieve them.*

A copy of the judgment **Distribution of Essential Supplies and Services During Pandemic, In re, 2021 SCC OnLine SC 411** is annexed as **Exhibit -"AA 32" [Page 1130 to 1148]**

Date: 20.11.2021

Place: Mumbai

DEPONENT

VERIFICATION

I, **Mr. Yohan Tengra**, aged 24 years, residing at **21 No. Building, 1st Floor, Flat No. 3, Old Khareghat Colony, Hughes Rd, Mumbai – 400007.**, do hereby state on solemn affirmation/declare that whatever is stated in the foregoing Para's are true to my personal knowledge and belief, whereas, the legal submission are made as per legal advice given and I believe the same as true.

Solemnly affirmed at Mumbai)

This day 20th of November, 2021)

for

Advocate for the Petitioner

Yohan

For Petitioner

BEFORE ME

NOTARY ★ GOVT. OF INDIA ★ ADV. Shivaji N. Dhange Reg. No. 15376 Mumbai (MS)

BEFORE ME

Adv. S. N. Dhanage
Notary Govt. Of India
Regd. No. 15376 MUMBAI (MS)
404-405, 4th Floor, Davar House,
197/199, Near Central Camera Bldg.,
D.N. Road. Fort, Mumbai - 400001.

NOTED & REGISTERED

Page No. 24 Sr. No. 156

Dated 20/11/2021

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20 NOV 2021

1014

EXHIBIT "AA1"

IN THE HIGH COURT OF BOMBAY AT GOA

WRIT PETITION No. 1820 of 2021

IN THE MATTER OF:

Mr. Nelson Paulo Fernandes & Another

.....Petitioners

Versus

The State of Goa & Ors.

.....Respondents

COUNTER AFFIDAVIT ON BEHALF OF ANSWERING RESPONDENT NO. 6 (MINISTRY OF HEALTH & FAMILY WELFARE, GOVT. OF INDIA)

I, Satyendra Singh, S/o Sh. Phool Singh, aged about 41 years, working as Under Secretary COVID Vaccination Administration Cell in the Ministry of Health and Family Welfare, Nirman Bhawan, New Delhi do hereby solemnly affirm and sincerely state as follows:

1. That, I am well acquainted with the facts of the case from the records. I am filing this Counter Affidavit on behalf of the Ministry of Health & Family Welfare, Govt. of India, as I am authorized to do so.

08 OCT 2021

2. I have perused the Writ Petition of the petitioner and I deny the averments made therein, except those that are specifically admitted hereunder.

3. I humbly submit that, the Petitioner has filed this writ petition seeking directions predominantly as against the State Government. However, since we are also made a party, I am filing this counter affidavit.

4. That, it is humbly submitted by the Answering Respondent No. 6 that, instead of traversing various allegations para-wise, this respondent deems it appropriate to counter the whole set of the facts in this matter as follows:

It is submitted that in the Writ Petition the petitioner has prayed the interim prayer as follows: -

"1. *For an appropriate Writ, order or direction, thereby quashing the circular dated 13/07/2021 issued by respondent no. 2 (Director, Directorate of Education, Govt of Goa).*

For an appropriate Writ, order or direction, thereby directing the respondent no. 1 and 2 (State of Goa and Director, Directorate of Education, Govt of Goa) to consider the petitioner's representations dated 30/07/2021 and 11/08/2021 and to issue a corrigendum

08 OCT 2021

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thereby making the vaccination by the teaching and non-teaching staff voluntary.

3. *For an interim relief, staying the operation of circulars dated 16/07/2021, 28/07/2021 and 16/08/2021 thereby directing the respondent No 2 and 3 (Headmistress, Little Flower of Jesus High School) not to take any coercive measures/actions against the petitioners pending the hearing and final disposal of petition.*

4. *For ex parte relief in terms of prayer clause 3.*

5. It is further humbly submitted that the matter has been examined and from the prayer (at para 1, 2 & 3 above) and the statements of the petitioner in the writ petition, it is evidently clear that the grievances of the petitioner in the prayer is related to the Departments of State Government of Goa (Respondent No. 1 and 2).

6. That, it is further humbly submitted that the annexures as mentioned in the Writ Petition by the petitioner have been issued by the Departments under State Government of Goa.

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08 OCT 2021

7. That, it is further submitted that the subject matter of the present Petition does not fall within the domain of the Answering Respondent No. 6 (Union of India).

8. That, it is further humbly submitted that however, since this matter is related to vaccination, and Union of India is the respondent no. 6; thus, it is pertinent to present the stand of Union of India with regards to vaccination. It is humbly submitted that vaccination for Covid-19 is a matter of social obligation and is of a larger public interest. As a responsible citizen looking to contribute in the nation and humanity's fight against the Pandemic of Covid-19 infection, it is natural that every person would get her/himself vaccinated against Covid-19 so as to prevent the spread of Covid-19 infection in the community.

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

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08 OCT 2021

citizens of India on the basis of their vaccination status.

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 Center 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.

12. Therefore, it is humbly submitted that in order to prevent the transmission and spread of Covid-19 pandemic, it is expected that all responsible citizens especially the teachers who are also the role models and influencers for the society get themselves vaccinated as soon as possible against Covid-19 and meticulously follow Covid Appropriate Behaviour.

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13. **Prayer:**

It is therefore most humbly prayed that, this Hon'ble Court may be pleased to admit this Counter Affidavit on behalf of Answering Respondent No. 6 (Union of India) on this petition for the ends of justice.

DEPONENT

(सत्येन्द्र सिंह)
(SATYENDRA SINGH)
अवर सचिव / Under Secretary
स्वास्थ्य एवं परिवार कल्याण मंत्रालय
Ministry of Health & Family Welfare
भारत सरकार / Govt. of India
नई दिल्ली / New Delhi

Indentified by

VERIFICATION:

Verified at New Delhi on October 08, 2021 that the contents of this affidavit are true and correct to the best of my knowledge and belief and no part of it is false thereof, and no material fact has been canceled therefrom.

DEPONENT

(सत्येन्द्र सिंह)
(SATYENDRA SINGH)
अवर सचिव / Under Secretary
स्वास्थ्य एवं परिवार कल्याण मंत्रालय
Ministry of Health & Family Welfare
भारत सरकार / Govt. of India
नई दिल्ली / New Delhi

NOTARY PUBLIC
M. P. SHUKLA
Regd. No. 17817
DELHI
Expiry Date: 22.12.2024
GOVT. OF INDIA

08 OCT 2021

CERTIFIED THAT THE DEPONENT
Shri/Smt/Km. Satyendra Singh Aged......
S/o, W/o, D/o, Sh......
Identified by ......
has solemnly affirmed ......
on......
that the contents ......
been read & explained to him/her

M. P. SHUKLA
Notary Public, Delhi

(TRUE COPY)

1020

EXHIBIT AA-2

मिसिल संख्या जेड.60011/06/2020-सीवीएसी
भारत सरकार
स्वास्थ्य और परिवार कल्याण मंत्रालय
सीवीएसी अनुभाग

09 MAR 2021

निर्माण भवन, नई दिल्ली
दिनांक09 मार्च, 2021

To,

Sh. Anurag Sinha,
Qtr no. 10 po swang bokaro
Jharkhand, gomia, 829128
Jharkhand

विषय: आरटीआई अधिनियम, २००५ के अंतर्गत मांगी गई जानकारी के संबंध में।

महोदय,

कृपया आप अपनी आर.टी.आई. एमओएचएफ़डब्ल्यू/आर/ई/21/00630, आर.टी.आई. अधिनियम, 2005 के संदर्भ ले जोकि अधोहस्ताक्षरी को दिनांक 27.02.2021 को प्राप्त हुआ था जिसमें आर.टी.आई.(RTI) अधिनियम, २००५ के तहत जानकारी मांगी गई है

संख्या क्रम	आवेदक के प्रश्न	उत्तर
i.	कोरोना वैक्सीन लेना स्वैच्छिक है या अनिवार्य, जबरदस्ती	कोरोना वैक्सीन लेना स्वैच्छिक है।
ii	क्या वैक्सीन नहीं लेने पर सारी सरकारी सुविधाएं बंद कर दी जायगी, सरकारी योजना पेंशन	आवेदन मे लिखी बातें निराधार है । किसी भी सरकारी सुविधा, नागरिकता, नौकरी इत्यादि से वैक्सीन का कोई सम्बन्ध नही है ।
iii	क्या वैक्सीन नहीं लेने पर नौकरी नहीं मिलेगा, ट्रेन, बस, मेट्रो मे चढ़ने नहीं मिलेगी	
iv	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 है	
v	क्या वैक्सीन नहीं लेने पर स्कूलों, कॉलेज, विश्वविद्यालय, गैस कनेक्शन, पानी, बिजली कनेक्शन, राशन आदि के लिए क्या वैक्सीन नहीं मिलेगे	
vi	क्या वैक्सीन नही लेने पर नौकरी से निकला जा सकता है वेतन रोका जा सकत है, निजी और सरकारी विभाग दोनों मे ।	

EXHIBIT" AA-3 1021

Eq. Citation : 2011 SCC OnLineBom 2021, 2011 (4) AIR Bom R 238

IN THE BOMBAY HIGH COURT

In Maharashtra Govt., through G. B. Gore, Food Inspector, Nanded Vs Rajaram Digamber Padamwar & Anr. **2011 SCC OnLineBom 2021**

Criminal Appeal No. 264 of 2000, D/- 8-4-2011..

CORAM: : SHRI HARI P. DAVARE, J.

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In **Maharashtra Govt., through G. B. Gore, Food Inspector, Nanded Vs Rajaram Digamber Padamwar & Anr. 2011 SCC OnLineBom 2021** it is rled as under;

"JUDICIAL DISCIPLINE – Judgement of another High court – Observations of trial Magistrate that the judgement of Kerala High Court is not binding on him – Further observing the legality and correctness of the judgement of another High Court is against the judicial discipline and propriety – Registrar General directed to take suitable action against concerned Judge. (Paras 42, 43, 44, 45)"

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JUDGMENT

1. This appeal is directed against the judgment and order of acquittal, dated 14-3-2000, rendered by the Judicial Magistrate, First Class, Kandhar, in R.C.C. No. 284 of 1995, thereby acquitting the respondent No^ 1 i.e. original accused No. 1 RajaramDigamberPadamwar for the offences under Section 7(1) r/w Section 2(ia)(a) punishable under Section 16(l)(a)(ii) of the Prevention of Food Adulteration Act, 1954 (hereinafter referred to as, 'the said Act') and also acquitting respondent No. 2 i.e. original accused:? MohammadSalim Haji Harun for committing breach of provision of Section 7(v) of the said, Act and Rule of the Prevention of Food Adulteration Rules, 1955 (Jiereinafter referred *« as, 'the said Rules') punishable under Section 16 (l)(a)(i) of the said Act.

2. Briefly stated, the case of the prosecution is as follows:—

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It is alleged that on 27-4-1994 at about 12.45' p.m., accused No. 1 sold the packets of adulterated turmeric powder of 'Taja Brand' td.-PW1 Food Inspector M. S. Patil at Kandhar. and after verification,of chemical analysrs: thereof, the said turmeric power found to be adulterated, and assiaeh thereby accused No. 1 has contraveneditfiarprovisions of Section 7(1) r/w Section 2 (ia) (a) and thereby committed an offenee'panishable under SectigaJ 16(l)(a){ii) of the/said Act. It is also alleged: that respondent No. 2 i.e. accused No. 2 has manufactured the said adulterated turmeric powder and distributed and sold it in packets in the market, more particularly through respondent No. 1 and contravened the provisions under Section 7(v) of me said Act and Rule 44H of the said Rules punishable under Section 16(lXa)(i) of the said Act. Accordingly the allegations against accused No. 1 are in respect of storage and selling of adulterated turmeric powder of Taja Brand and the allegation against respondent No. 2 is that he is the manufacturer of the adulterated turmeric powder of 'Taja Brand', and therefore, they have committed the offences as aforestated.

3. Moreover, the complainant Food Inspector i.e. PW2 G. B. More is claimed to have sent all the papers to the Joint Commissioner, Food & Drugs Administration, Aurangabad under Section 20 of the Act and obtained the consent through the Assistant Commissioner, Food and Drugs Administration, Nanded for filing criminal case against the accused persons, and accordingly, complaint was filed against the accused before the Court on 16-10-1995. It was registered as R.C.C. No. 284 of 1995. The said complaint discloses the name of the witnesses, such as (1) M. S. Patil, Food Inspector, Food and Drugs Administration, BukUiana; (2) MilindSuryakantMahajan, r/o ShivajiChowk, Kandhar; (3) G. G. Joshi, Assistant Commissioner, Food and Drugs Administration, M. S., Nanded; and (4) S. B. Kamble, Public Analyst, District Health Laboratory, Nanded. Thereafter, summons came to be issued against the accused persons and they appeared hi the case. Thereafter, evidence before charge was recorded before the Court and the prosecution examined in all two witnesses and the Trial Court framed the charge against the accused at Exhl'&3 on 13-7-1998.

The accused pleaded not guilty to the charges levelled against them and claimed to be tried.

4. To substantiate the charges levelledagainst the accused and to prove the guilt against them, the prosecutktt examined inasmuch as five witnesses, as mentioned below: PW1 MadhukarSopanPatil, Food Inspector PW2 GulabBabaraojiGoft, Food Inspector, complainant

PW3 SubhashBalkishanKamble, Junior Scientific Officer, Public Analysis, Solapur.

PW4 MilindSuryakantMahajan, panch witness in respect of panchanamaExh. 29

PW5 GajananGovind Joshi, Assistant Commissioner, Food and Drugs Administration, Nanded

5. The defence of the accused is of total denial, which was reflected through the cross-examination and their statements under Section 313 of the Code of Criminal Procedure. After scrutinizing and assessing the oral and documentary evidence on record and considering the rival submissions advanced by the learned counsel for the parties, the Trial Court acquitted respondent Nos. 1 and 2 from the charges levelled against them, by judgment and order, dated 14-3-2000.

6. Being aggrieved and dissatisfied by the aforesaid judgment and order of acquittal, the appellant/State has preferred the present appeal praying for the quashment thereof.

7. Before adverting the submissions advanced by the learned counsel for the parties, it is necessary to scrutinize the material oral and documentary evidence, adduced and produced by the prosecution, and in the said con-text, at the outset, coming to the deposition of PW1 MadhukarSopanPatil, Food Inspector, he stated that on 27-4-1994 at 12.45 p.m. he visited the provision shop of M/s. Rajaram Shankar Padamwar, ShivajiChowk, Kandhar along with his assistant and PW4 panchMilindMahajan and

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disclosed his identity to the shop keeper and ensured about the owner of the shop and the said shop keeper stated that he himself was me owner of the shop and thereupon he showed the licence and PW1 MadhukarPatil noted the facts of the licence in his note sheets, which are produced at Exh. 25 and copy thereof bearing signature of panch was given to the said shopkeeper i.e. accused No. 1. PW1 Patil also stated that he noticed that there were 60 packets of chilly powder manufactured by JantaSevaMirchMasaley and each packet contained 50 gms. chilly powder. There were about 100 packets of turmeric powder produced by M. S. Food Product, Nanded under the name and style as, 'Taja', and each packet contained 50 grms. turmeric powder, having batch No. 16 and manufacturing date of March, 1994 and the maximum retail price printed on each packet was Rs. 2/-, as well as name and address of the manufacturer was printed thereon.

8. PW1 Patil stated to accused No. 1 that he intended to purchase 12 packets of chilly powder as well as 12 packets of turmeric powder for analysis, and accordingly, accused No. 1 sold him 12 packets of chilly powder and 12 packets of turmeric powder, respectively, and PW1 paid price thereof and accused No. 1 issued bill about the purchased goods and said bill is produced at Exh. 26. Thereafter PW1 Patil issued notice under Section 14A of the Act to accused No. 1 with intention to collect the information from whom he has purchased the said goods. Thereupon, accused No. 1 stated that he did not possess the bills of purchased goods, but he assured that he would produce the original bill in his office and the office copy of the said notice is produced at Exh. 27. PW1 issued notice under Form No. 6 informing accused No. 1 that he purchased the above goods for analysis as required under the said Act and produced the office copy thereof at Exh.28. He also stamped the specimen of seal which was utilized for purchase of packets of chilly powder and turmeric powder.

9. The purchased chilly powder was found to be of standard quality during analysis.

10. As regards the turmeric powder, PW1 Patil stated that he divided 12 purchased packets of turmeric powder in equal three parts and packed four packets in dry clean and empty plastic pack and prepared three samples accordingly, which were labelled with the signatures of panch witness and signature of PW1 Patil and sealed as per the usual procedure and panchanama of the aforesaid things was prepared on the spot and the said packets were seized thereunder. The signature of accused NQ_T 1 was obtained thereon andPWlPatil also signed thereon and carbon copy of the pan-chanama was supplied to accused No. 1 and thfe said panchanama is produced at Exh. 29. Thereafter, PW1 Patil sent one sealed packet along with copy of Form No. 7 in a seal packet to |he Public Analyst, Public Health Laboratory, Nanded on 28-4-1994 by hand delivery, and produced the office copy of Form No. 7 at Exh. 30. On 28-4-1994, hesept copy of Form No. 7 along with specimen impression of seal used to steal the sample and covering letter, to the Public Analyst, Nanded and produced the office copy of letter at Exh. 31. He also sent the remaining two parts of the sample along with two copies of Form No. 7 along with the covering letter to the Local Health Authority-Assistant Commissioner, Food and Drugs Administration, Nanded, and produced copy thereof at Exh. 32. He also sent specimen impression of a seal used for the seal of samples along with covering letter to Local Health Authority, Food and Drugs Administration, Nanded in a separate seal packet on 28.4.1994 and produced office copy thereof at Exh. 33.

11. Accordingly, PW1 Patil stated that he received the samples at Exhs. 34 and 35 and also received receipts from the Local Health Authority about the receipt of sample, which are produced at Exhs. 36 and 37. Thereafter, since he was transferred, he handed over the charge and the documents and papers to ShriUmrani, Food Inspector, Nanded.

12. During cross-examination, he stated thajt he does not remember whether he has taken samples from other shop keepers. He also stated that he called only one panch witness and accused No.l was present in the shop and he purchased samples simultaneously i.e. chilly powder manufactured

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by JantaSeva M ichaMasalla and turmeric powder manufactured by M/s. Food Products under 'Taja' brand. He stated that he purchased 12 packets of turrneric powder each containing 50 gram, turmeric powder, which was kept on a rack by the accused and which was personally delivered by accused No. 1 and said packets were packed as it is and there was no leakage and same were shown to PW4 panchMilindMahajan.

13. Moreover, he stated that he has not mentioned on every form that he narrated the contents of form in Marathi to accused No. 1. He further stated that he kept four turmeric powder packets in another polythene bag as it is. So also, he kept other packets in another polythene bag in three sets thereof, since he possessed polythene bags for packing the samples officially. It is stated in the pan-chanama that samples were packed in a clean and dry polythene bags. Hence, suggestion was given to, him that the polythene bags which ' were possessed by him were not clean and dry, but he denied the same. He further stated that be drew the panchanama after sealing of the purchased articles and returned to Nanded on the same day and deposited the samples at' Public Health Authority, Nanded. He also stated that he deposited duplicate copy of Form No. 7 along with specimen signature in the office of Public Analysis, Nanded separately and obtained the receipt of deposit of samples and deposit of specimen seal separately. The suggestion was given to him that the analysis report issued by the Public Analyst is false, but same was denied by him. PW1 Patil admitted that accused No. 1 never submitted the bill of purchased goods of turmeric powder before him.

14. Coming to the deposition of PW2 GulabBabaraoji Gore complainant, who stated that he was working as Food Inspector at Nanded since 1994 and received the case papers from Food Inspector Umrani in a charge on 4-8-1994 and demanded the original bill of turmeric powder purchased by accused No.1 from accused No. 2. Accordingly, the accused produced original bill dated22-4-1994, which is marked Exh. .40. Thereafter, he stated that notice was issued to accused No. 2 reflecting the fact that sample of turmeric powder was collected from accused No. .1 for analysis,

which was supplied by accused No. 2 and copy of the said notice is produced at Exh. 4 J. He also stated that he sent copy of Form No. & dated 27-4-1994 to accused No. 2 along wjjh notice dated 20-5-1994 and same was served upon hjjn<*nd he produced the acknowledgment thereof at Exh. 42. He further stated that he perused the analysis report dated 30-5-1994 and found that the sample analysed was of sub-standard and the said analysis report is produced at Exh. 43.

15. He also deposed diat he received letters about collection of information from Licensing Authorities in respect of issuance of license to accused No. 1, which are produced at Exhs. 44 and 45. Moreover, additional information was demanded from accused Nos. 1 and 2 through letters and office copies thereof are produced at Exhs. 46 and 47. Accordingly, accused No. 1 submitted his information on 16-7-1994 and same is produced atExh. 48. Moreover, accused No. 1 also produced photo copy of renewal of his license. Besides, the Licensing Authorities also supplied the information about accused Nos. 1 and 2. which are produced at Exhs. 49 and 50. He further stated that he submitted his report and sought permission for filing complaint against accused Nos. 1 and 2 from the Joint Commissioner, Food and Drugs Administration, Aurangabad. Accordingly, he received die consent letter to file complaint against accused Nos. 1 and 2 on 14-8-1995, which is produced atExh. 51. Pursuant to the said consent letter, he lodged the complaint against accused Nos. 1 and 2 on 16-10-1995. He also stated that he issued notices under Section 13(2) of the said Act to the Local Authority.

16. During cross-examination, he stated that he perused the public analysis report and percentage of rice starch is not shown in the said report. Hence, he volunteered that there is no need to mention exact percentage of rice starch as per Rule 44H of the said Rules. He also admitted that he has not sent notice as required under Section 13(2) of the said Act to die accused. He also stated mat he does not know as to whether the said notice was served upon the accused.

17. That takes mfc to the deposition of PW4 MilindSuryakantMahajan, who deposed that on 27-4-1994, PW1M. S. Patil, Food Inspector called him to act as Panch at the shop of accused No. 1 Rajaram, andPW1 M. S. Patil purchased 12 packets of turmeric powder weighing each of 50 grams and same were divided into three parts. He also stated that same were packed in brown paper and Food Inspector prepared three packings thereof and sealed the same with the help of wax and thread. He also stated that said Food Inspector might have paid Rs. 25/- for the said packets. He further stated that the Food Inspector obtained his signature and panchanama was shown to him andhe. further stated that the contents thereof were; read over to him and he: admitted it to be true., which was marked Exh. 29. He also identified accused Rajaram before the Court.

18. In cross-examination, he stated that he perused the packing of sample as well as personally verified the packets of turmeric powder purchased by the Food Inspector and same were packed in a plastic bag and brand thereof was, 'Taj Brand' and seal thereof were intact. He further stated that accused No. 1 informed' the Food Inspector mat the Company has supplied the packings of turmeric powder to him and he sold it in retail as it is. He admitted that he did not notice the fact of breaking of seal of packets of turmeric powder. He also stated that the Food Inspector prepared packings of each sample before him. Hence suggestion was given to him that the Food Inspector prepared the panchanama for samples before his arrival, but same was denied by him.

19. Turning to the deposition of PW3 SubhashBalkishanKamble, Junior Scientific Officer, Public Analyst's Office, Solapur, who stated that he was posted at Nanded office from November, 1993 till December, 1997 and on 28-4-1994 he received sample of turmeric powder-and duplicate copy of Form No. 7 along with specimen seal, from PW1 M. S. Pati 1. He stated that he tallied the specimen seal with the seal affixed oh the container and found that sample was fit for analysis. Thereafter he got analysed the tufmetibpowder from the Chemist, namely P. B. Halkunde in their Laboratory and they noric'ed'rifce starch and common salt in turmeric

pfofwtfer. However, they found that there was salt of 2.31 per cent, adulterated in turmeric powder: However, he could not calculate the exact percentage of adulterated rice starch and stated that there is no specific method to find out percentage of rice starch if adulterated in turmeric powder. Accordingly, he prepared the analysis report and prepared four copies thereof and sent the same to die office of Food and Drugs Inspector, Nanded and copy thereof is produced at Exh. 43. He further stated that adulteration of any foreign substance in turmeric powder is prescribed under Rule 44H-Gftl»e said Rules, as well as he stated that he 'found that the analysed sample was adulterated one.

20. During cross-examination he admitted that, he analysed the sampte after 14 days of its'receipt, but till then the said sample was kept in the custody of Chemist. He also stated that be possessed the form on which the re-sult of analysis of sample is noticed. However, he could not state as to whether it is mentioned on me form of analysis mat samples analysed were found in tact before its analysis. As regards analysis, he stated that he opened the sample on 28-4-1994 and found four packets of turmeric powder packed in a container, and thereafter he handed over two packets out of four for analysis purpose. Accordingly, he received its report from Chemist on 11-5-1994, but he could not state on which date which chemical test was com-pleted. As regards the said reports, he stated that the same were upto the permitted level except starch test and the turmeric powder contained starch. He also stated that microscopic test was carried out in this particular case and same was mentioned in the report. He further stated that he noticed kinds of rice starch and turmeric powder under the microscope, but stated that they did not conduct any other chemical test to bifurcate the rice starch and turmeric powder. He further stated that on the basis of results, test report was submitted by the Chemist. However, he could not state how much other samples were analysed by the Chemist during the analysis of turmeric sample simultaneously. Hence, suggestion was given to him that there was possibility of adulteration of foreign substance in their laboratory, but same was denied by, him. Suggestions were also given to him that there

was mistake on the part of the Chemist at the time of .analysis of sample and the said Chemist analysed the sample negligently, but same were denied by him.

21. That takes me to the testimony of PW5 GajananGovind Joshi, Investigating Officer, who was serving as Assistant Commissioner, Food and Drugs Administration,Nanded at the relevant time i.e. on 26-7-1993 and PW1 M. S. Patil was working as Food Inspector in his office. He stated that PWI M. S. Patil, was Food Inspector handed over two sealed packets to him on 28-4-1-994 and in one packet out of the same, there were sealed counterpart, of the samples, taken, and in addition to .that there were twacopies of Form No. 7; whereas in the second .Racket, two specimen seal impressions of the seal used for sampling and a covering letter were found. He further stated that after receipt of the above two packets from M. S. Patil, Food Inspector,' he gave two separate receipts on the same day i.e. 28-4-1994 and said receipts are produced at Exhs. 36 and 37, respectively. He admitted that the said receipts bear his signatures.

22. It is recited in his deposition that the Public Analyst, Nanded had given a report on 30-5-1994, but it does not reflect what was sent to Public Analyst, District Health Laboratory arid it was received oil 3-6-1994 and one of the copies of the said report was handed over to the Food Inspector Patil and copy thereof is produced at Exh. 43. Moreover, original report was also filed before the Court, which bore his signature and date, which is marked Exh. 88. Thereafter the Food Inspector communicated him fri respect of filing of present case against the accused on 17-10-1995, which is produced along with list Exh. 85 at Sr. No. 4, and which is marked Exh. 89, which bore the signature of Food Inspector Gore and his signature in token of receipt thereof. Accordingly, an'ifftimation was given to the accused in respect of filing of case against them in the Court by letter dated 18-10-1995 and the said letter/iiotice, along with copy of the report of Public Analyst, District Health Laboratory, was Self 'by R.P.A.D., as well as separate letter was sent to each of the accused and office copy, thereof dated 18-1- 1995 is filed by him off/record, which is marked Exh. 90. He also produced postal

receipts of R.P.A.D. showing that the said letters were sent to the accused by R.P. A.D. and marked Exh. 91. The said letter was received by accused No. 1 and his postal acknowledgment is produced on record mid marked Exh. 92. However, the letter sentto accused No. 2 was returned back without service to him and same is produced on record and marked Exh. 93 and same was received back by the Investigating Officer on 31-10-1995,

23. During cross-exa'hima'tion, he admitted that he has not made it *s&te* that signature appearing on the acknowledgment receipt Exh. 92 was of accused No; 1; as well as he cannot say whether the signature on Exh. 92 was not of accused No. 1. He afso further stated cordance with Rules 14 to 17 of the said Rules and the sample was taken in a polythene bag and not in a clean bottle or jar as contemplated and the said short comings vitiated the prosecution case and the Trial Court has rightly acquitted the accused persons and there are no extra ordinary reasons to interfere therein, and hence, urged that present appeal be dismissed and acquittal rendered by the Trial Court be upheld.

33. I have perused the oral and documentary evidence adduced and produced by the prosecution, as well as perused the impugned judgment and order dated 14-3-2000 and considered the submissions advanced by the learned counsel for the parties anxiously, as well as perused the observations made and ratios laid down in the judicial pronouncements cited by the learned counsel for the respondents carefully and it is evident that Rule 44H of the said Rules in respect of restriction on sale of common salt has been deleted with effect from 30-9-200Qas per G.S.R. No. 716(E), dated 13-9-2000. Moreover, as canvassed by the learned Senior counsel for the respondents, as regards compliance of Section 10(2) of the said Act, there is no evidence to show that the samples were taken from the turmeric powder for the sale, as well as the procedure in accordance with Section 11 pf the said Act was complied with by,,the Food Inspector M-S. Patil. Moreover, it is evident from the evidence that PW1 M.S. Patil Food Inspector has not taken bulk quantity of turmeric powder for sample purpose. It is also evident from the evidence on record that Food Inspector, M. S. Patil

while sampling separated 12 packets in three equal parts i.e. four packets each containing turmeric powder therein and he did not collect the turmeric powder from the said, 12 packets together and did not separate the said quantity of turmeric powder in three parts for analysis purpose and the said such separation of 12 packets Itself in three parts as samples for analysis purpose is not permissible, which leads to jibe position that sampling was not doneby PW1 Food Inspector M. S. Patil properly Which certainly causes' prejudice to the respondents/accused and since the sampling of the'turmeric powder itself is faulty, there is substance in the submissions advanced by the learned Senior Counsel ShriMandlik for the respondents. In the said context, reliance can very well be placed on the judgment of Division Bench of. this Court in, the case of State of Maharashtra v. Lakhmi-chandSuganchandAgrawal& others, reported at 1998 All MR (Cri) 953 (supra).

34. Moreover, it is also apparent from the evidence on record that PW2 M. S. Patil Food Inspector has not taken the sample in bottle or jar or container, but took the sample in a polythene bag and sent to the Public Analyst, which is not permissible and such taking of sample in polythene bag amounts to violation of mandatory provision of Rule 14 of the said Rules, and therefore, conviction cannot be based against the respondents on such defective sampling and the view adopted by th$ learned single Judge of Patna High Court (in the case of Binod Kumar v. State of Bihar; reported at 2004 FAJ 465, (supra) supports the said proposition.

35. So also, the submissions made by the learned Senior Counsel ShriMandlik for the respondents that the prosecution has not complied with the mandatory provisions of Rules 14 to 17 of the said Rules in respect of sealing, fastening and dispatching of samples, as well as PW1 M. S. Patil Food Inspector has not complied with Section 11 of the said Act in respect of procedure tobefbltewed by the Food Inspectors cannot be overlooked while assessing the evidence on record;

36. As regards the compliance of Section 13(2) of the said Act, after receiving the report of Public Analyst, the reasoning adopted by the learned Trial Judge that notice thereof was properly served upon accused No. 1 and the defence of violation of mandatory provision under Section 13(2) of the said Act i.e. serving of notice to accused'No. 1 is not available to accused No. 1, appears to be proper. In the said context, it is material to note that accused No. 1 has submitted the bill of pur-chise of packets of turmeric powder from accused No. 2, which is produced at Exh. 40 andit has come in the evidence of (PW2) that accused No. i has product tfie[1] original bifl dated 22-4-1994 along with letter dated 18-5-1984 Exh.39 and the said lBtt^lsaddiessed tortile Assistant CommissiOiidF, Food and Drugs Administration.(M.S.), Nanded and it is admitted fact that PW1 M. S. Patil Food Inspector visited the shop of accused No. 1 on 27-4-1994 and purchased 12 packets of turmeric powder from his shop. Hence, considering the said aspect, it is amply clear that accused No. 1 purchased the said packets of turmeric powder from accused No. 2 on 22-4-1994 as per bill Exh. 40, which were consequently purchased by PW1 M. S. Patil Food Inspector from accused No. 1 on 27-4-1994 for analysis purpose, and accordingly, since accused No; 1 purchased the packets of turmeric powder from accused No. 2 as per printed bill Exh.40, accused No. 1 has been absolved from the liability, since accused No. 2 is the manufacturer of the said turmeric powder,

37. As regards the report of Public Analyst in accordance with Section 13 of the said Act, PW3 SubhashKamble, Junior Scientific Officer categorically stated in his deposition that he .got analysed the, turmeric powder from the Chemist in the Laboratory, namely P. B. Halkunde, who is subordinate to him and lie received the test report from the said Chemist on 11-5-1994. However, he could not state on which day which chemical test was completed: Pertinently, although PW3 SubhashKamble admitted in his testimony that said P. B. Halkunde, Chemistis alive, the said material witness, who, in fact, carried out the analysis of the turmeric, powder, was not examined by the prosecution. It is important to note that PW3

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SubhashKajnpte admitted in his deposition that he prepared analysis report on the basis of result of test reports submitted by Chemist, but he cannot state howmuch other samples were analysed by the Chemist during the analysis of turmeric powder sample simultaneously. Therefore, it is significant to note that PW3 SubhashKamble has no personal knowledge; whereas P. B. Halkunde, Chemist, who carried,out the analysis of the sample of turmeric powder, although was alive, was.., withheld and not examined by the prosecution and the said inaction on the part of the pros, ecutionsustain,S|fatal blow to the case of the prosecution.

38. As regards compliance of Section. 113(2) of the said Act in respect of accused

No. 2, it appears that accused No. 2 was not served at all and Form No. 7 was not sent along with the sample by the Food Inspector, and the said fact is evident from the R.P.A.D. Packet Exh. 93, and therefore, the liability of accused No. 2, who is the manufacturer of the said turmeric powder, is also absolved in view of non-compliance of Section 13(2) of the said Act.

39. Coming to the report of the Public Analyst Exh.88, apparently there is substance in die submissions made by the learned Senior Counsel ShriMandlik for die appellant that all the ingredients of turmeric powder shown . therein are within the permissible limits prescribed under Rule A.05.20.01 pertaining to turmeric (Haldi) powder, which conforms the prescribed standards in respect of moisture, total ash, ash insoluble in dilute HCI, test for lead chromate and total starch, as mentioned in para No. 28 herein above. Besides, it can- ' not be ignored that although microscopic examination was not prescribed under the Act, ; PW5 Gajanan Joshi admitted that such microscopic examination was carried out.

40. Moreover, there is'also substance in the submission made by learned Senior Counsel regarding the sodium contents in the sample of turmeric powder, which[1] is within the limits as prescribed by the afore said Rules, since the sodium chloride contained 2.31 per cent, i.e. salt, which is not hazardous to human be- ing, and hence, it is amply clear that me sample of

turmeric powder doeStibt come within the mischief of alleged charges against the ac- cused.

41. Having the comprehensive view of the matter, I am inclined to accept the submissions advanced by the learned Senior Counsel ShriMandlik that the prosecution has failed to make out any case for adulteration, and as discussed herein above, PW1M. S. Patil has failed to follow the procedure, which was required to be followed whiletaking the samples in ac- cordance with Rules 14 to17 of the said Rules and more particularly, the sample which was taken by him in polythene bag and not in clean bottle or jar, as contemplated in the afore said Rules, vitiates the prosecution case, and the Trial Court has rightly acquitted the accused .persons. Besides that, aner scrutinizing and analysing the evidence, the view adopted by the Trial Court while acquitting the accused persons is a possible view, and same does not appear to be perverse, and therefore, no interference therein is called for in the present appeal, and hence, there is no substance in the present appeal and same is devoid of any merits, and therefore, same deserves to be rejected.

42. Before departing, it is inevitable to make mention that, the learned A.P.P. while making the arguments before the learned Trial Judge cited the Ruling of Kerala High Court in the case of Food Inspector v. James, (reported in Prevention of Food Adulteration Cases) at 1998 (1) P.320, and while discussing the observations made in the said Ruling, the learned Trial Judge has observed in para No. 31 of the impugned judgment that:

"With great respect, I do not agree with the 'view taken' and observations made by Their Lordships in the above case law. Moreover, the said case law is admittedly of Kerala High Court and the same is not binding on this Court."

43. Moreover, while making submissions before the learned Trial Judge, learned A.P.P. also cited Ruling in the case of Rambhai v. State of Madhya Pradesh (Reported in Prevention of Food Adulteration Cases) at 1991 (1) P. 6, as stated in para 34 of the impugned judgment, but the learned Trial

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Judge, after considering the said ratio laid down in the said Ruling, observed in para No. 35 6T the impugned judgment that: "After going through the observations made by Their Lordships in the above case law, I am of the opinion that though the Ruling is applicable to the present case, however, according to me, with great respect the view taken in the observations of the Ruling is not correct."

44. It manifestly appears from the text and tenor of the observations made by the learned Trial Judge in para Nos. 31 and 35 of the impugned judgment that same do not conform with the judicial discipline and propriety, and apparently amount to disrespect, and therefore, the Registrar General is directed to take suitable action against the concerned Judge, if he is in Judicial Service.

45. In the result, present appeal, which is sans merits, stands dismissed and office to take necessary steps to initiate suitable action against the learned Trial Judge, if he is in Judicial Service, as per the afore said directions. Office to send a copy of the impugned judgment, dated 14-3-2000 and also copy of the present judgment to the Registrar General for the necessary compliance. **Appeal dismissed.**

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EXHIBIT "AA-4"

जिल्हाधिकारी कार्यालय, औरंगाबाद

(पुरवठा विभाग)

संदर्भ

१. साथरोग अधिनियम १८९७ खंड २, ३ व ४.
२. आपत्ती व्यवस्थापन अधिनियम २००५.
३. या कार्यालयाचे आदेश दि. ०५/१०/२०२१
४. शासन आदेश क्र.कोरोना/प्र.क्र.४२१/आरोग्य -५/ दि.०६/१०/२०२१
५. या कार्यालयाचे आदेश दि. ०९/१०/२०२१
६. मा.मुख्यमंत्री महोदय व मा. मुख्य सचिव,महाराष्ट्र राज्य यांचे दूरचित्रवाणी [illegible] दि ३१.१०.२०२१ व दि ०२/११/२०२१
७. या कार्यालयाचे आदेश दि. ३१/१०/२०२१
८. मा.पंतप्रधान व मा.मुख्यमंत्री यांचे संयुक्त दूरचित्रवाणी दि.०३/११/२०२१ मधील [illegible] व निर्देश
९. जिल्हा आपत्ती व्यवस्थापन प्राधिकारण, औरंगाबाद यांचे आदेश क्र.जा.क्र.२०२१/[illegible] ४७४, दिनांक ०९.११.२०२१

जा.क्र.२०२१/पुरवठा/केरोसिन/प्र.क्र. 134

दिनांक ०९ नोव्हेंबर, २०२१

कोविड-१९ लसीकरण मोहिम प्रभावीपणे राबविण्याच्या अनुषंगाने मार्गदर्शक सूचना आदेश : लसीकरण मोहिम
No Vaccine No Entry

ज्याअर्थी, कोविड-१९ विषाणूच्या संसर्गाचा प्रादुर्भाव [illegible] दि.३१.१०.२०२१ [illegible] सचिव, महाराष्ट्र राज्य यांनी दूरचित्रवाणीद्वारे (VC) सूचना दिल्या आहेत.

ज्याअर्थी, राज्यातील Covid-१९ लसीकरणाचे प्रमाण [illegible] असून, औरंगाबाद जिल्ह्यात [illegible] केवळ ५५% एवढे आहे. हे प्रमाण राज्याच्या टक्केवारीच्या तुलनेत अत्यंत कमी असून, [illegible] औरंगाबाद जिल्हा हा २६ व्या क्रमांकावर गेला आहे. शासनाने संपूर्ण राज्याच्या [illegible] कमी केलेले असून, संभाव्य तिसऱ्या लाटेची शक्यता विचारात घेता, औरंगाबाद जिल्ह्यामध्ये [illegible] होणे अपेक्षित आहे, जेणेकरून Covid-१९ च्या संभाव्य तिसऱ्या लाटेस [illegible]

त्याअर्थी, मा.मुख्यमंत्री महोदय व मा. मुख्य सचिव, महाराष्ट्र शासन यांच संदर्भ क्र. ०६ च्या [illegible] सूचनानुसार सर्व शासकीय/ निमशासकीय, खाजगी व औद्योगिक आस्थापनामध्ये Covid-१९ [illegible] तातडीने पूर्ण करण्याच्या अनुषंगाने संदर्भ क्र. ०५ नुसार या कार्यालयाच्या आदेशाद्वारे मार्गदर्शक सूचना [illegible] करण्यात आल्या आहेत. संदर्भ क्र.८ च्या दूरचित्रवाणी मध्ये मा. पंतप्रधान [illegible] दिलेले आहे. त्याचप्रमाणे सदर मार्गदर्शक सूचना व लसीकरण मोहिम अधिक प्रभावीपणे [illegible] जिल्ह्यातील सर्व पेट्रोल पंप धारक, सर्व गॅस एजन्सी धारक, सर्व [illegible] समित्या बाबत सदर आदेश माझ्या स्वाक्षरीने निर्गमित करण्यात येत आहे.

शेतकऱ्यांचा माल स्विकृत करण्यात यावा व लिलावाची प्रक्रिया पुर्ण [illegible] करणेपूर्वी लस प्रमाणपत्राबाबत खात्री करावी. तसेच पेट्रोल पंपावर [illegible] लसीकरण प्रमाणपत्राबाबत विचारणा करावी. [illegible]

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सूचना करावे. सदर आदेश औरंगाबाद जिल्ह्यासठी खालील बाबी करीता पुढील आदेशापर्यंत निर्बंध लागू करण्यात येत आहेत.

खालीलप्रमाणे लसीकरण बाबत आदेश लागू करण्यात येत आहेत.

१. सर्व पेट्रोल पंप धारक, २. सर्व गॅस एजन्सी धारक, ३. सर्व रास्त भाव दुकानदार, ४. कृषि उत्पन्न बाजार समित्या

सदर आदेशाची अंमलबजावणी दि.१० नोव्हेंबर, २०२१ चे सकाळी सुर्योदया पासून ते पुढील आदेशापर्यंत लागू राहील.

उपरोक्त सर्व बाबींसाठी Covid Appropriate Behavior (CAB) अनिवार्य आहे.

१) मास्क वापरणे ६) गज दुरी २ (२फुट अंतर (४ सॅनीटायझर (३ (आवश्यकतेनुसार फेसशिल्ड वापरणे आनिवार्य

विशेष सूचना

१. लोकजागृतीतून लसीकरण मोहोम राबविण्यावर भर देण्यात यावा. लसीकरणास पात्र लाभार्थ्यांचे,१००% लसीकरण (प्रथम मात्रा : First Dose) झाले पाहिजे. लसीकरणाचा दुसरा डोस Covishield -८४ दिवस व Covaxin-२८ दिवसांनी घेणे अनिवार्य आहे. त्यासाठी प्रथम मात्रा विहित कालावधी पूर्ण झालेल्या नागरिकांकडे **" हर घर दस्तक व माझा वार्ड शतप्रतीशत लसीकरण वार्ड"** या कार्यक्रमांतर्गत दुसऱ्या डोस साठी पाठपुरावा करावा.

२. Covid Appropriate Behavior (CAB) उल्लंघन करणा-यांवर कठोर दंडात्मक कारवाई केली जाईल.
   - निम्न स्वाक्षरीकार प्रस्तुत आदेश आवश्यकतेनुसार रद्द किंवा सुधारित करु शकतील.
   - सदर आदेशाची अंमलबजावणी पुढील आदेशापर्यंत लागू राहील.

सदर आदेशाची कोणतीही व्यक्ती, संस्था किंवा संघटना यांनी अंमलबजावणी करण्यास टाळाटाळ केल्यास अथवा विरोध दर्शविल्यास संबंधीत आपत्ती व्यवस्थापन कायदा, २००५ चे कलम ५१ ते ६० व भारतीय दंड संहिता १८६० चे कलम १८८ तसेच साथरोग कायदा १८९७ अन्वये दंडनीय/कायदेशीर कार्यवाहीस पात्र राहतील.

सदरील आदेश दिनांक ०९ नोव्हेंबर, २०२१ रोजी निर्गमित करण्यात येत आहेत.

(सुनील चव्हाण) भाप्रसे
जिल्हाधिकारी, औरंगाबाद
9/11/2021

प्रत -

१) मा.अपर मुख्य सचिव, गृहविभाग (विशेष) मंत्रालय, मुंबई-३२ यांना माहितीस्तव सविनय सादर.
२) मा.विभागीय आयुक्त, औरंगाबाद यांना माहितीस्तव सविनय सादर.
३) मा.पोलीस आयुक्त (शहर) औरंगाबाद.
४) मा.विशेष पोलीस महानिरीक्षक,परीक्षेत्र औरंगाबाद यांना माहितीस्तव.

प्रत माहितीस्तव तथा आवश्यक कार्यवाहीस्तव :

५) मा.पोलीस आयुक्त (शहर) औरंगाबाद.
६) आयुक्त तथा प्रशासक, महानगरपालिका, औरंगाबाद
७) सहव्यवस्थापकीय संचालक, म.रा.वि.वि.कंपनी, औरंगाबाद
८) मुख्य कार्यकारी अधिकारी, जि.प. औरंगाबाद. ८

(1039)

९) पोलीस अधिक्षक (ग्रामीण), औरंगाबाद.
१०) कुलसचिव डॉ.बाबासाहेब आंबेडकर, मराठवाडा विद्यापीठ, औरंगाबाद
११) अधिष्ठाता, शासकीय वैद्यकीय महाविद्यालय व रुग्णालय, औरंगाबाद.
१२) मुख्य अभियंता, महाराष्ट्र राज्य विद्युत वितरण / पारेषण कंपनी मर्या. औरंगाबाद.
१३) जिल्हा शल्य चिकित्सक, औरंगाबाद यांना आवश्यक कार्यवाहीस्तव.
१४) जिल्हा आरोग्य अधिकारी, जि.प. औरंगाबाद यांना निर्देशित करण्यात येते की, वरील आदेशात नमूद लसीकरणा संबंधीत बाबी व लसीकरण बुथ संबंधी तात्काळ दक्षतापूर्वक कार्यवाही करण्यात यावी.
१५) आरोग्य अधिकारी म.न.पा. औरंगाबाद यांना निर्देशित करण्यात येते की, वरील आदेशात नमूद लसीकरणा संबंधीत बाबी व लसीकरण बुथ संबंधी तात्काळ दक्षतापूर्वक कार्यवाही करण्यात यावी.
१६) हिवताप अधिकारी, औरंगाबाद
१७) अधिक्षक, भारतीय पुरातत्व सर्वेक्षण, औरंगाबाद विभाग
१८) प्रादेशिक व्यवस्थापक, महाराष्ट्र पर्यटन विकास महामंडळ, औरंगाबाद
१९) सहसंचालक (उद्योग), औरंगाबाद.
२०) सहसंचालक (उद्योग सुरक्षा) व मुख्य अभियंता (मऔविम), औरंगाबाद
२१) प्रादेशिक परिवहन अधिकारी, औरंगाबाद.
२२) अधीक्षक, राज्य उत्पादन शुल्क, औरंगाबाद
२३) उपायुक्त, अन्न व औषध प्रशासन, औरंगाबाद.
२४) सहाय्यक धर्मदाय आयुक्त कार्यालय, औरंगाबाद.
२५) प्रादेशिक अधिकारी, म.औ.वि.म. औरंगाबाद
२६) जिल्हा पुरवठा अधिकारी, औरंगाबाद
२७) सर्व उपविभागीय अधिकारी तथा उपविभागीय दंडाधिकारी, औरंगाबाद जिल्हा
२८) सर्व उपविभागीय पोलिस अधिकारी औरंगाबाद जिल्हा
२९) उपमुख्य कार्यकारी अधिकारी, ग्रामपंचायत जिल्हा परिषद औरंगाबाद
३०) जिल्हा अधिक्षक कृषी अधिकारी, औरंगाबाद
३१) विभाग नियंत्रक, महाराष्ट्र राज्य परिवहन महामंडळ, औरंगाबाद.
३२) जिल्हा माहिती अधिकारी, औरंगाबाद.
३३) सर्व सेल्स ऑफीसर, जिल्हा औरंगाबाद (गॅस/पेट्रोल)
३४) सर्व तहसिलदार तथा तालुकादंडाधिकारी, जिल्हा औरंगाबाद
३५) जिल्हा प्रशासन अधिकारी, नगरविकास शाखा जिल्हाधिकारी कार्यालय औरंगाबाद
३६) सर्व गट विकास अधिकारी, पंचायत समिती जिल्हा औरंगाबाद
३७) सर्व मुख्याधिकारी,नगरपरिषद/ नगरपंचायत जिल्हा औरंगाबाद
३८) शिक्षणाधिकारी (प्राथमिक / माध्यमिक) जिल्हा परिषद औरंगाबाद
३९) सर्व पेट्रोल पंप परवानाधारक, जिल्हा औरंगाबाद (मार्फत- संबंधित सेल्स ऑफीसर)
४०) सर्व गॅस एजन्सी वितरक, जिल्हा औरंगाबाद (मार्फत- संबंधित सेल्स ऑफीसर)
४१) सर्व रास्त भाव दुकानदार, जिल्हा औरंगाबाद (मार्फत-संबंधित अन्नधान्य वितरण अधिकारी/तहसिलदार, जिल्हा औरंगाबाद)
४२) सर्व कृषि उत्पन्न बाजार समिती, जिल्हा औरंगाबाद (मार्फत- संबंधित तहसिलदार/अन्नधान्य वितरण अधिकारी)

NOTARY Adv. Shivaji N. Dhanaga Mumbai Maharashtra GOVT OF INDIA

(सुनील चव्हाण) भाप्रसे 9/11/2021
जिल्हाधिकारी, औरंगाबाद

EXHIBIT "AA-5" 1040

आरोग्य मंत्रालयाकडून कोणतेही आदेश नसताना जिल्हाधिकाऱ्यांची लसीकरणासाठी सक्ती

✦ आरोग्य मंत्र्यांनी लसीकरण सक्तीकरणाला घातले निर्बंध
✦ सक्ती करणाऱ्या जिल्हाधिकाऱ्यांवर गुन्हे दाखल करण्याचे आवाहन

देशोन्नती वृत्तसंकलन...

यवतमाळ ■ लसीकरण हा केंद्र सरकारचा पूर्णपणे ऐच्छिक कार्यक्रम असताना व लस न घेतल्यास कोणालाही सरकारी सुविधांपासून वंचित ठेवता येणार नाही, असे प्रतिज्ञापत्र अनेक उच्च न्यायालयांमध्ये केंद्र सरकारने सादर केले असतांनाही लस घेतली नाही तर राशन किंवा इतर कोणत्याही सरकारी सुविधा मिळणार नाही, पगार देण्यात येणार नाही. तसेच विद्यार्थ्यांना सुध्दा महाविद्यालयात प्रवेश , किंवा परीक्षा देण्यास मज्जाव असे असंविधानिक, दंडेलशाही, मनमानी व बेकायदेशीर आदेश महाराष्ट्र सरकार तसेच सरकारमधील मंत्री, जिल्हाधिकारी, उपविभागीय अधिकारी व तहसीलदार त्यांच्या त्यांच्या स्तरावर काढत आहेत. अशा आदेशांविरुद्ध मुंबई उच्च न्यायालयात एक जनहित याचिका फौजदारी गुन्ह्याच्या स्वरूपात दाखल केली आहे, ज्याची येत्या २२ नोव्हेंबरला सुनावणी आहे, तरी अशा दंडेलशाही व तोंडी आदेशांना घाबरून लोकांनी लस घेऊ नये.

कारण ह्या लसीची कुठल्याही प्रकारची चाचणी घेण्यात आलेली नाही, आणि त्याचमुळे ही लस घेतल्यामुळे जर कुठल्याही प्रकारचे दुष्परिणाम झाले तर त्याच्या जबाबदारी पासून सर्वच संबंधित संस्था आणि व्यक्ती यांनी हात झटकून टाकले आहेत. दैनिक देशोन्नतीचे मुख्य संपादक, लोकनेते प्रकाश पोहरेंनी आवाहन केले आहे की आपल्या दारावर येऊन जर आरोग्य विभागाचे कर्मचारी लसीकरणासाठी बळजबरी करत असतील, तर ही लस घेतल्या नंतर कुठल्याही प्रकारची रिॲक्शन आल्यास किंवा मृत्यू झाल्यास नुकसानभरपाई देण्यास बाध्य राहील अशा बंधपत्रावर त्यांच्या सह्या घेऊनच त्यांना लस टोचण्याची परवानगी द्यावी, असेही पोहरेंनी आवाहन केले आहे.

लोकांनी जरा आजूबाजूला पाहायला शिकावे, ही लस घेतल्या नंतर अचानक मृत्यू, अंशिक लकवा , बुड क्लॉटिंग, असे दुष्परिणाम लक्षात येत आहेत. त्यामुळे असे कुठे लक्षात आले तर त्यावर जागृत नागरिक म्हणून संबंधित विभागात तक्रारी दाखल कराव्यात, आणि दुर्दैवाने जर मृत्यू झाल्यास मृतक व्यक्तीच्या कुटूंबीयाची जबाबदारी कोण घेणार असे अनेक प्रश्न उपस्थित झाले आहे. (प्रति)

■■ आरोग्य मंत्री राजेश टोपे यांच्या सोबत प्रकाश पोहरे यांची चर्चा

कोरोना प्रतिबंधक लस पुर्णत ऐच्छिक असुन याच्या सक्तीबाबत शासनस्तरावरून कोणतेच आदेश काढण्यात आलेले नाहीत. स्थानिक जिल्हा प्रशासनाने काढलेले आदेश केवळ चर्चेतुन आतातार्इपणाने काढले आहेत. यात शासनाचा जिल्हा प्रशासनावर दबाव नसुन शासन लसीकरण सक्तीच्या विरोधात आहे. केवळ नागरिकांना लस घेण्याबाबत प्रोत्साहीत करता येईल. त्यांच्या कोणत्याच प्रकारच्या हक्कावर गदा आणली जाणार नाही. काही ठिकाणी जिल्हा प्रशासनाने सक्तीच्या लसीकरणाबाबत काढलेले आदेश तत्काळ खारिज केले जातील असे राज्याचे आरोग्यमंत्री राजेश टोपे यांनी शनिवारी दैशोन्नतीचे मुख्य संपादक प्रकाश पोहरेशी बोलताना स्पष्ट केले.

EXHIBIT "AA-6" (1041)

AJAY BHALLA, IAS

सत्यमेव जयते

गृह सचिव
Home Secretary
भारत सरकार
Government of India
North Block,
New Delhi

D.O. No. 40-3/2020-DM-I(A)

22nd August, 2020

Dear Chief Secretary,

Please refer to Ministry of Home Affairs' Order of even number dated 29.07.2020 whereby Guidelines for Unlock-3 have been issued.

2. I would like to draw your kind attention to para-5 of these guidelines which clearly state that **there shall be no restriction on inter-State and Intra-State movement of persons and goods. No separate permission/ approval/ e-permit will be required for such movements**. This includes movement of persons & goods for cross land border trade under Treaties with neighboring countries.

3. It has, however, been reported that local level restrictions on movement are being imposed by various districts/States. Such restrictions are creating problems in inter-State movement of goods and services and are impacting the supply chain, resulting in disruption of economic activities and employment, besides affecting supply of goods and services.

4. Such restrictions at local level imposed by the District Administration or by the State Government, amount to violation of the guidelines issued by MHA under the provisions of Disaster Management Act, 2005.

5. I would, therefore, request that no restrictions may be imposed on inter-State and intra State movement of persons and goods and services and instructions issued to ensure that MHA guidelines mentioned above are strictly followed.

With regards,

NOTARY
Adv. Shivaji N. Dhanage
Mumbai Maharashtra
Reg. No. 15375
GOVT OF INDIA

Yours sincerely,

27/08/2020

(Ajay Bhalla)

Chief Secretaries of All States
(As per Standard List attached)

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EXHIBIT "AA-7"

Z.16025/02/2018-IMM-Part(1)
Government of India
Ministry of Health & Family Welfare
Immunization Division

Nirman Bhawan, New Delhi
Date: 02nd October 2021

Causality assessment result of one reported Serious Adverse Events Following Immunization (AEFI) case following COVID-19 vaccination approved by National AEFI Committee on 25th September 2021.

The Immunization Division, MOHFW has taken several steps to strengthen the national AEFI surveillance system for COVID-19 vaccinations. Considering the importance and critical nature of the task, steps were taken to include medical specialists, cardiologists, neurologists, pulmonary medicine specialists, obstetrician-gynecologist as members of the causality assessment sub-committee at the national level. A Special Group has been framed to conduct causality assessment of AEFIs following COVID-19 vaccination. The result of causality assessment done by this Special Group is discussed in the National AEFI committee meeting for final approval.

The result of the causality assessment of one case completed on 25th September 2021 after thorough review, deliberation and approval by the National AEFI Committee is given in the annexure (anonymized line list of the causality assessment done by the National AEFI Committee).

This death case for which Causality assessment has been done was found to have **consistent causal association to vaccination.**

Vaccine product related reactions are expected reactions that can be attributed to vaccination based on current scientific evidence. Examples of such reactions are allergic reactions and anaphylaxis, etc.

Indeterminate reactions are reactions which have occurred soon after vaccination but there is no definitive evidence in current literature or clinical trial data that this event could have been caused due to the vaccine. Further observations, analysis and studies are required.

Unclassifiable events are events which have been investigated but there is not enough evidence for assigning a diagnosis due to missing crucial information. When this relevant information becomes available, the case may be reconsidered for causality assessment.

Coincidental events are events that are reported following immunization but for which a clear cause other than vaccination is found on investigation.

Overall, the benefits of vaccination are overwhelmingly greater than the small risk of harm. However, as a measure of utmost precaution, all emerging signals of harm are being constantly tracked and reviewed periodically.

NOTARY
Adv. Shiraj N. Dichwar
Mumbai Maharashtra
Reg. No. 15376
GOVT OF INDIA

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CAUSALITY CLASSIFICATION OF one AEFI CASE APPROVED BY THE NATIONAL AEFI COMMITTEE ON 25 SEP 2021- (NEW DELHI)

A1 - VACCINE PRODUCT RELATED REACTION
A2 - VACCINE QUALITY DEFECT RELATED REACTION
A3 - IMMUNIZATION ERROR RELATED REACTION
A4 - IMMUNIZATION ANXIETY RELATED REACTION
B1 - TEMPORAL RELATIONSHIP IS CONSISTENT BUT THERE IS INSUFFICIENT DEFINITIVE EVIDENCE FOR VACCINE CAUSING EVENT
B2 - REVIEWING FACTORS RESULT IN CONFLICTING TRENDS OF CONSISTENCY AND INCONSISTENCY WITH CAUSAL ASSOCIATION TO IMMUNIZATION
C - COINCIDENTAL - UNDERLYING OR EMERGING CONDITION(s), OR CONDITIONS CAUSED BY EXPOSURE TO SOMETHING OTHER THAN VACCINE
D - UNCLASSIFIABLE

S. NO.	NATIONAL ID	YEAR	AGE (IN YEARS)	SEX	REASON FOR REPORTING/ OUTCOME	DATE OF VACCINATION (DD/MM/YYYY)	VACCINE	DIAGNOSIS	CLASSIFICATION BY NATIONAL AEFI COMMITTEE	DATE OF APPROVAL BY NATIONAL AEFI COMMITTEE
1	IND(CO-AEFI)MHNSK21001	2021	34	FEMALE	DEATH	28-01-2021	COVISHIELD	Right transverse sinus thrombosis with right temporal haemorrhagic infarct, right posterior frontal haemorrhagic infarct with thrombocytopaenia	A1	25-09-2021

*Covid vaccine is a new vaccine. The causality may change as more information become available.
Verified by Dr Anju Seth on 28th September 2021

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EXHIBIT "AA-8"

Source: The New Indian Express

Link: https://www.newindianexpress.com/states/kerala/2021/aug/20/half-of-indias-87k-breakthrough-covid-cases-in-kerala-2347145.html

Published: 20th August 2021 06:23 AM | Last Updated: 20th August 2021 11:36

Author: By Unnikrishnan S

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.

Express News Service

THIRUVANANTHAPURAM: 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. According to the latest report from the Union health ministry, 46% of the 87,000 breakthrough cases reported are from Kerala, which tops the national average in vaccination. That means around 40,000 infections were reported from the state. Breakthrough infections are defined as fresh infections in fully vaccinated people.

The alarmingly high rate of breakthrough infections have raised concerns among the public on the efficacy of vaccines, especially when the festive season is expected to increase the spread of the disease. Doubts about the presence of any fresh mutant of the virus in the state have been rejected by health experts, saying the proportion of breakthrough infections are within expected lines. They also vouched for the effectiveness of vaccines as the lone tool in controlling hospitalisation and preventing deaths.

NOTARY Adv. Shivaji N. Dhanage Mumbai Maharashtra Reg. No 15075 GOVT OF INDIA

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On Thursday, the state reported 21,116 new cases with a high test positivity rate of 16.15%. It also reported 197 deaths, the highest single day toll in the past two months. The total Covid deaths stood at 19,246. The Union health ministry report reveals that breakthrough infections have been noticed in Wayanad, which became the first district to administer at least one dose of vaccine to all eligible persons, and Pathanamthitta where the coverage is better than the state average with over 75% given the first dose. Earlier this month, the concern over breakthrough infection was brought to the fore through a central delegation report that stated Pathanamthitta reported more than 7,000 cases by July end.

A section of health department officials expressed disbelief at the high figure. An officer with the department said the numbers were exaggerated and the number of breakthrough infections reported so far could be less than 7,000. However, health experts said it was quite possible to have over 40,000 breakthrough infections in a state with high vaccination coverage and low immunity against the infection.

"It is quite natural that a high number of breakthrough infections are reported. The vaccines continues to show efficacy between 70 to 75%. That means not all will get protected against the infection. But the vaccines invariably are still good at saving lives," said Dr Padmanabha Shenoy, immunologist and public health analyst.

He had analysed the breakthrough infections in Pathanamthitta and found that there were over 5,000 breakthrough infections in the district by mid-July and that it has helped reduce hospitalisation and deaths. The large number of breakthrough infections in the state gave rise to questions on virus mutations which managed to escape the immunity offered by vaccines. However, the genetic studies conducted on the samples of breakthrough infections did not

find such a possibility. Health experts have also tried to explain why the new positives and breakthrough infections remained high in Kerala when compared to other states.

"Breakthrough infections are a small percentage of the total infection. The breakthrough infection we see in Kerala is similar to those reported in countries with good healthcare systems in place. The new variants have helped the virus to spread even in fully vaccinated people. But it couldn't reduce the efficiency of vaccine in preventing severity and deaths due to infection," said Dr Anish T S, a member of the Covid management committee and an assistant professor at the department of community medicine, Government Medical College Hospital, Thiruvananthapuram.

The nodal officer for Covid and H1N1, Dr Amar Fettle, said breakthrough infections have been reported in almost all viral diseases reported so far. "One can still get tuberculosis after taking the BCG vaccine, measles after taking the measles vaccine. There is no vaccine which offers 100% protection against disease. So one should not have unrealistic expectations from vaccines and lower the guard even after vaccination," he said.

European Journal of Epidemiology
https://doi.org/10.1007/s10654-021-00808-7

CORRESPONDENCE

Increases in COVID-19 are unrelated to levels of vaccination across 68 countries and 2947 counties in the United States

S. V. Subramanian[1,2] · Akhil Kumar[3]

Received: 17 August 2021 / Accepted: 9 September 2021

Vaccines currently are the primary mitigation strategy to combat COVID-19 around the world. For instance, the narrative related to the ongoing surge of new cases in the United States (US) is argued to be driven by areas with low vaccination rates [1]. A similar narrative also has been observed in countries, such as Germany and the United Kingdom [2]. At the same time, Israel that was hailed for its swift and high rates of vaccination has also seen a substantial resurgence in COVID-19 cases [3]. 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.

Methods

We used COVID-19 data provided by the Our World in Data for cross-country analysis, available as of September 3, 2021 (Supplementary Table 1) [4]. We included 68 countries that met the following criteria: had second dose vaccine data available; had COVID-19 case data available; had population data available; and the last update of data was within 3 days prior to or on September 3, 2021. For the 7 days preceding September 3, 2021 we computed the COVID-19 cases per 1 million people for each country as well as the percentage of population that is fully vaccinated.

For the county-level analysis in the US, we utilized the White House COVID-19 Team data [5], available as of September 2, 2021 (Supplementary Table 2). We excluded counties that did not report fully vaccinated population percentage data yielding 2947 counties for the analysis. We computed the number and percentages of counties that experienced an increase in COVID-19 cases by levels of the percentage of people fully vaccinated in each county. The percentage increase in COVID-19 cases was calculated based on the difference in cases from the last 7 days and the 7 days preceding them. For example, Los Angeles county in California had 18,171 cases in the last 7 days (August 26 to September 1) and 31,616 cases in the previous 7 days (August 19–25), so this county did not experience an increase of cases in our dataset. We provide a dashboard of the metrics used in this analysis that is updated automatically as new data is made available by the White House COVID-19 Team (https://tiny.cc/USDashboard).

Findings

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 (Fig. 1). 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.

Across the US counties too, the median new COVID-19 cases per 100,000 people in the last 7 days is largely similar across the categories of percent population fully vaccinated (Fig. 2). Notably there is also substantial county variation in

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Published online: 30 September 2021

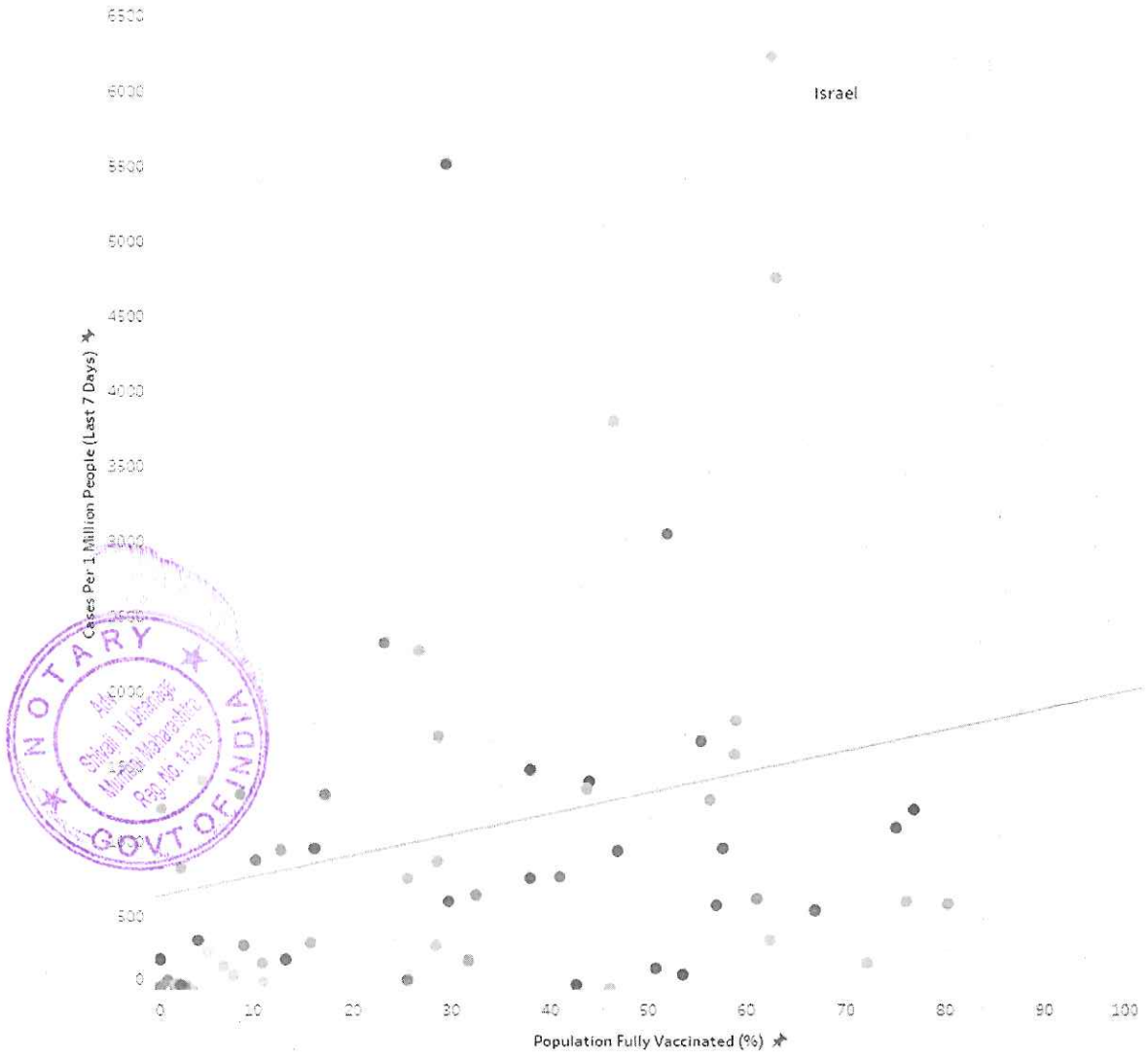

Fig. 1 Relationship between cases per 1 million people (last 7 days) and percentage of population fully vaccinated across 68 countries as of September 3, 2021 (See Table S1 for the underlying data)

new COVID-19 cases *within* categories of percentage population fully vaccinated. There also appears to be no significant signaling of COVID-19 cases decreasing with higher percentages of population fully vaccinated (Fig. 3).

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%.

Since full immunity from the vaccine is believed to take about 2 weeks after the second dose, we conducted sensitivity analyses by using a 1-month lag on the percentage population fully vaccinated for countries and US counties. The above findings of no discernable association between COVID-19 cases and levels of fully vaccinated was also observed when we considered a 1-month lag on the levels of fully vaccinated (Supplementary Figure 1, Supplementary Figure 2).

We should note that the COVID-19 case data is of confirmed cases, which is a function of both supply (e.g., variation in testing capacities or reporting practices) and demand-side (e.g., variation in people's decision on when to get tested) factors.

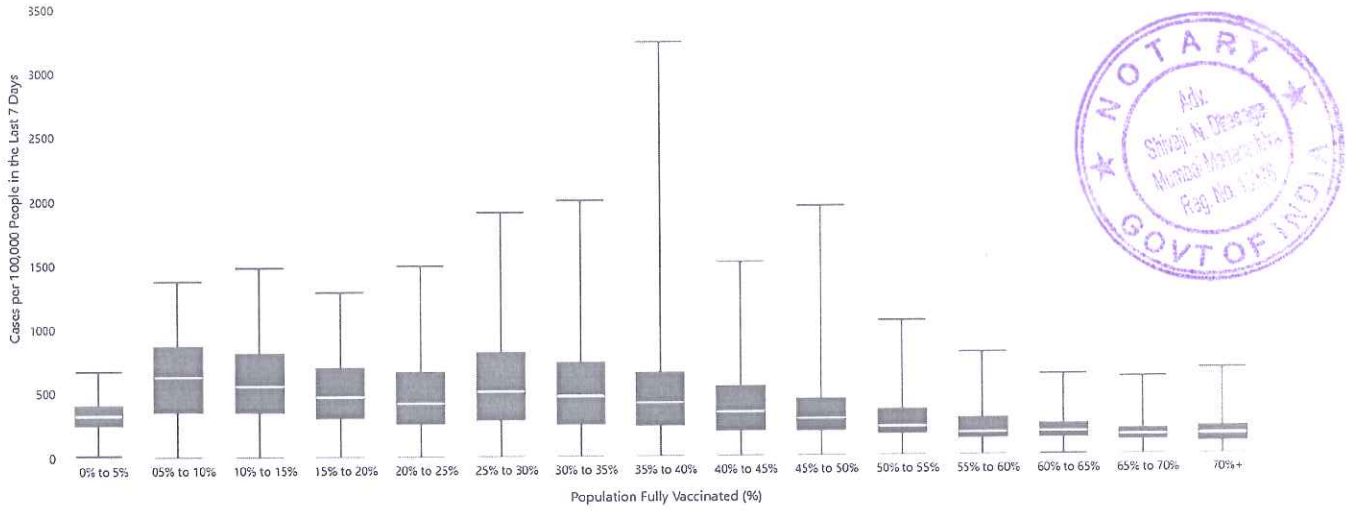

Fig. 2 Median, interquartile range and variation in cases per 100,000 people in the last 7 days across percentage of population fully vaccinated as of September 2, 2021

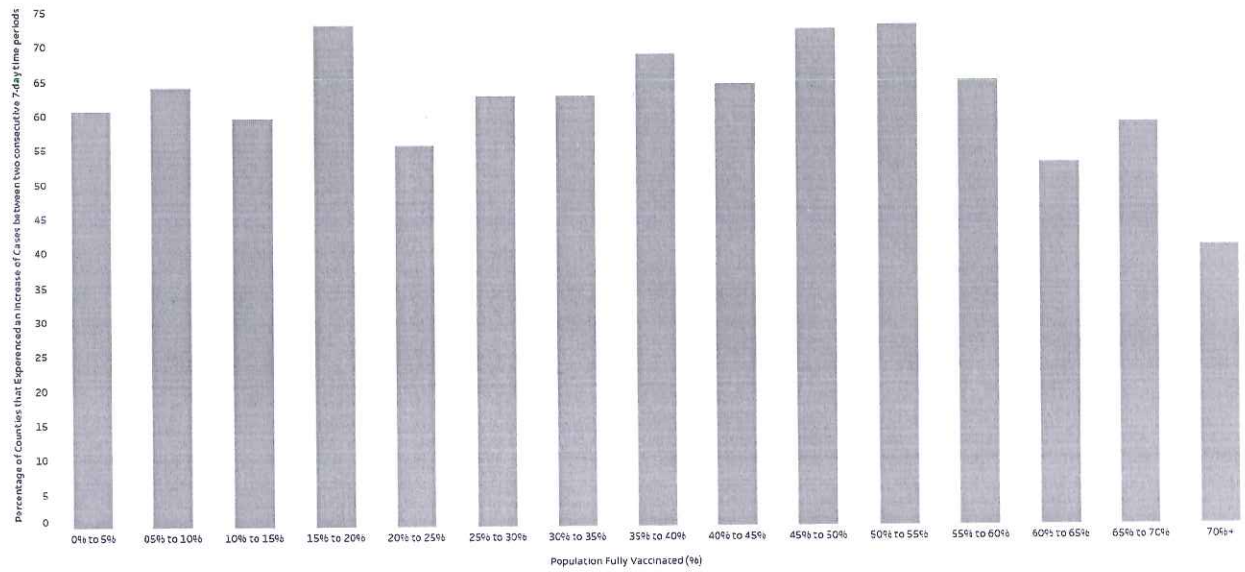

Fig. 3 Percentage of counties that experienced an increase of cases between two consecutive 7-day time periods by percentage of population fully vaccinated across 2947 counties as of September 2, 2021

Interpretation

The sole reliance on vaccination as a primary strategy to mitigate COVID-19 and its adverse consequences needs to be re-examined, especially considering the Delta (B.1.617.2) variant and the likelihood of future variants. Other pharmacological and non-pharmacological interventions may need to be put in place alongside increasing vaccination rates. Such course correction, especially with regards to the policy narrative, becomes paramount with emerging scientific evidence on real world effectiveness of the vaccines.

For instance, in a report released from the Ministry of Health in Israel, the effectiveness of 2 doses of the BNT162b2 (Pfizer-BioNTech) vaccine against preventing COVID-19 infection was reported to be 39% [6],

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substantially lower than the trial efficacy of 96% [7]. It is also emerging that immunity derived from the Pfizer-BioNTech vaccine may not be as strong as immunity acquired through recovery from the COVID-19 virus [8]. A substantial decline in immunity from mRNA vaccines 6-months post immunization has also been reported [9]. Even though vaccinations offers protection to individuals against severe hospitalization and death, the CDC reported an increase from 0.01 to 9% and 0 to 15.1% (between January to May 2021) in the rates of hospitalizations and deaths, respectively, amongst the fully vaccinated [10].

In summary, even as efforts should be made to encourage populations to get vaccinated it should be done so with humility and respect. Stigmatizing populations can do more harm than good. Importantly, other non-pharmacological prevention efforts (e.g., the importance of basic public health hygiene with regards to maintaining safe distance or handwashing, promoting better frequent and cheaper forms of testing) needs to be renewed in order to strike the balance of learning to live with COVID-19 in the same manner we continue to live a 100 years later with various seasonal alterations of the 1918 Influenza virus.

Supplementary Information The online version contains supplementary material available at https://doi.org/10.1007/s10654-021-00808-7.

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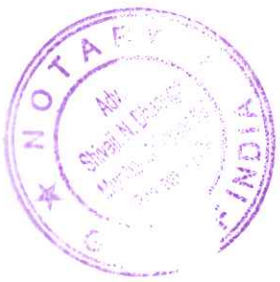

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EXHIBIT "AA-10" 1051

No Significant Difference in Viral Load Between Vaccinated and Unvaccinated, Asymptomatic and Symptomatic Groups When Infected with SARS-CoV-2 Delta Variant

Authored by: Charlotte B. Acharya, John Schrom, Anthea M. Mitchell, David A. Coil, Carina Marquez, Susana Rojas, Chung Yu Wang, Jamin Liu, GenayPilarowski, Leslie Solis, Elizabeth Georgian, Maya Petersen, Joseph DeRisi, Richard Michelmore, Diane Havlirdoi:

Abstract: We found no significant difference in cycle threshold values between vaccinated andunvaccinated, asymptomatic and symptomatic groups infected with SARS-CoV-2 Delta. Giventhe substantial proportion of asymptomatic vaccine breakthrough cases with high viral levels,interventions, including masking and testing, should be considered for all in settings withelevatedCOVID-19transmission.

Background

Vaccines reduce infection, severe disease, and death from SARS-CoV-2 (COVID-19)[1], yet breakthrough cases occur [2]. Several reports show no difference in cycle thresholdvalues (Ct-values) between vaccinated and unvaccinated individuals [2, 3, 4]; however, othershave suggested that breakthrough infections, particularly among asymptomatic individuals, havea lowerviralloadandthereforemaybelesslikelytoresultintransmission[5, 6].

Effective epidemic control requires contemporary data to guide public health mitigationmeasures. Here, we report on Ct-values among fully vaccinated and unvaccinated individuals,asymptomatic and symptomatic at time of testing, during a period of high transmission of theDelta variant in two distinct populations: aUnidosenSalud (UeS) community-based site in theMission District of San Francisco and Healthy Yolo Together (HYT) asymptomatic testingthroughtheUniversityofCalifornia (UC), Davis.

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MaterialsandMethods

StudyPopulations

Data was collected on individuals who voluntarily sought testing for SARS-CoV-2 fromtwo demographically distinct populations in California during a two-month period from June 17toAugust31,2021, duringwhichDeltawasthepredominantvariant.

HYT: Aspartoftheresponse to theCOVID-19pandemic,UCDavisdeployedan

extensive free asymptomatic testing program that included the City of Davis and Yolo County(HealthyYoloTogether).Asymptomaticindividualsovertheageof2wereeligiblefortesting.

Asymptomatic cases were classified as individuals not reporting symptoms at the time of testing.Samples were collected through a supervised method in which individuals transferred their salivainto abarcoded tube(COVID-19 Testing |CampusReady).Smallernumbersofsymptomaticindividuals were processed using a different workflow and an antigen test; therefore, they werenotincludedinthis study.

UeS:Thestudypopulationincludedindividualswhosought SARS-CoV-2testingatthe

UeS walk-up site, an ongoing academic (UC San Francisco, CZ Biohub, and UC Berkeley),community organization (Latino Task Force), and government (SFDPH) partnership. Theoutdoor, free BinaxNOW™ testing site was located at a public transport and commercial hub inthe Mission District, a setting of ongoing transmission in San Francisco [7]. Individuals one yearofageandolder, withorwithoutsymptoms,wereeligiblefortesting.

Measurements

Infections were classified as breakthrough infections if the individual was

fullyvaccinated (two weeks following receipt of all vaccine doses). Individuals that had had only onedose or were tested within two weeks of the second dose, in the case of Pfizer and Modernavaccines,werenotincludedinthe analysis.

HYT: Demographicinformationwascollected from individualsat thetimeof registration. Vaccination status information was obtained at the time of contact tracing andconfirmed in the California Vaccine Registry. Only confirmed, fully vaccinated individuals wereused in the analysis; discordant samples, self-reported as vaccinated but unconfirmed, weretreated as status unknown. Saliva samples from asymptomatic individuals were tested for thepresence of the N1 and N2 regions of the viral nucleocapsid (N) gene using primers and probesdescribed in the CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR DiagnosticPanel, using IntelliQube high-throughput quantitative PCR instruments (LGC BiosearchTechnologies).Ct-valueswerecalculated with FastFindersoftware(UgenTec|FastFinder).

Genotypes of all N1/N2 positive samples were determined using RT-PCR SNP analysisat11 loci diagnosticforvariantsofconcern(SARS-CoV-2 Variant ValuPanelassays| LGC BiosearchTechnologies).Asubsetofsamples(39%)werealsosequencedusingtheIllumina MiSeq sequencing platform. Consensus genomes were generated with Viralrecon2 and variantscalled in Pangolin version 3.1.11 and PLEARN-v1.2.66. Sequencing confirmed the variantscalledbygenotyping.

UeS: Individualsprovided demographicdataand information onsymptomsimmediately prior to testing using BinaxNOW™ kits. COVID-19 vaccine status, including date of final shot,was obtained through the California Vaccine Registry. Anterior-nasal swab samples (iClean,Chenyang Global) collected by certified lab assistants from BinaxNOW positive individualswere placed in DNA/RNA Shield (Zymo, Inc.) and processed for qRT-PCR, genome recovery,and variant/lineage determination as previously described [8, 9]. Ct-

values for the detection of Nand E genes [8] were determined via the single threshold Cq-determination mode using Bio-RadCFX Maestro v4.1 (Bio-Rad Inc). SARS-CoV-2 genomes were sequenced using the IlluminaNovaSeq platform. Consensus genomes were generated via the COVID module of the IDseqpipeline (https://idseq.net)as described[9].

Analysis

Ct-valueswereplotted,stratifiedbysite;fullyvs.notvaccinated;andsymptom status.

Partially vaccinated samples and stratification by age and vaccine type are reported insupplementarymaterials. Ct-valuesbetweenstratawerecomparedusingatwosidedt-test.EthicsStatement

HYT: TheGenomeCenterlaboratorythatconductedCOVID-19 testingwasCLIA

approved asan extension to theStudentHealthCenter'slaboratory.TheUCDavisIRB Administration determined that the study met criteria for public health reporting and was exemptfromIRB reviewandapproval.

UeS: The UCSan Francisco CommitteeonHumanResearch determined thestudy met

criteriafor publichealthsurveillance.Allparticipantsprovidedinformedconsentfor testing.

Results

Atotal of869 samples,500from HYTand 369from UeS,wereincluded intheanalysis.

All analyzed samples from HYT were asymptomatic at the time of collection and 75% of thepositive samples were from unvaccinated individuals (N=375). Positive samples from UeS werefrom both symptomatic (N=237) and asymptomatic individuals (N=132). The frequency ofvaccine breakthroughs among the UeS samples (171 fully vaccinated, 198

unvaccinated) wasgreater than among the HYT samples, reflecting the different types of populations sampled. TheDeltavariant wasthepredominant variantdetected in bothpopulations(SupplementaryTable1).

There were no statistically significant differences in mean Ct-values of vaccinated (UeS:23.1; HYT: 25.5) vs. unvaccinated (UeS: 23.4; HYT: 25.4) samples. In both vaccinated andunvaccinated, there was great variation among individuals, with Ct-values of <15 to >30 in bothUeS and HYT data (Fig. 1A, 1B). Similarly, no statistically significant differences were found inthe mean Ct-values of asymptomatic (UeS: 24.3; HYT: 25.4) vs. symptomatic (UeS: 22.7)samples, overall or stratified by vaccine status (Fig. 1B). Similar Ct-values were also foundamong differentage groups,betweengenders,andvaccinetypes(SupplementalFigure1).

In all groups, there were individuals with low Ct-values indicative of high viral loads. Atotal of 69 fully vaccinated individuals had Ct-values <20. Of these, 24 were asymptomatic at thetime oftesting.

Discussion

In our study, mean viral loads as measured by Ct-value were similar for large numbers ofasymptomatic and symptomatic individuals infected with SARS-Cov-2 during the Delta surge,regardless of vaccine status, age, or gender. This contrasts with a large ongoing UK communitycohort in which the median Ct-value was higher for vaccinated individuals (27.6) than forunvaccinated individuals (23.1) [5]. Also, a study from San Francisco reported that 10 fullyvaccinated asymptomatic individuals had significantly lower viral loads than 28 symptomatic,vaccinated individuals [6]. Our study is consistent with other recent reports showing similar viralloads among vaccinated and unvaccinated individuals in settings with transmission of the Deltavariant. In a Wisconsin study, Ct-values were similar and culture positivity was not different in asubset of analyses between 11 vaccinated and 24 unvaccinated cases [4]. In both Massachusettsand Singapore, individuals with vaccination breakthroughs caused by the Delta variant hadsimilar Ct-values as unvaccinated individuals [3, 10]. Our findings are supported by consistencyacrosslarge sample sets usingdifferentassaysfromtwodistinctlocations.

A substantial proportion of asymptomatic, fully vaccinated individuals in our study hadlow Ct-values, indicative of high viral loads. Given that low Ct-values are indicative of

highlevelsof virus,culturepositivity,andincreasedtransmission[11], our detectionof lowCt-valuesin asymptomatic, fully vaccinated individuals is consistent with the potential for transmissionfrom breakthrough infections prior to any emergence of symptoms. Interestingly, the viral loadsdecreased more rapidly in vaccinated than unvaccinated individuals in Singapore [3], suggestingthat vaccinated individuals may remain infectious for shorter periods of time. Also, aretrospective observational cohort study of contacts of SARS-CoV-2-infected index cases inEngland documented reduced transmission from vaccinated individuals [12]. In our study, over20%ofpositive,vaccinatedindividualshadlow Ct-values(<20),a thirdofwhichwereasymptomatic when tested. This highlights the need for additional studies of the immunologicalstatus of such vaccine escapes and how infectious they are. If such individuals carry high loadsof active virus, asymptomatic vaccinated individuals may increasingly contribute to the ongoingpandemic as theproportionofvaccinatedindividuals grows.

Ct-values in some children under 12 who are not yet eligible for vaccination were alsolow. Twenty out of 109 (18.3%) children under 12 years of age had Ct-values <20, of which 14were asymptomatic at the time of testing. Low Ct indicates that the children had high viral loadsand were likely infectious. This emphasizes the value of regular, rapid testing for school childrento detect infection early and block chains of transmission in settings where the Delta variant iscirculating.

While vaccination remains the best protection against becoming infected and severedisease [12], the data gathered in this study during the surge of the Delta variant strongly supportthe notion that neither vaccine status nor the presence or absence of symptoms should influencethe recommendation and implementation of good public health practices, including maskwearing, testing, social distancing, and other measures, designed to mitigate the spread of SARS-CoV-2.

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AuthorContributionStatement:

JD, RWM, DH, and MP conceived the project. DC, CM, SR, DH, and GP helped collect thedata. CA, AM, CYW, and JL helped perform the tests, genotyping, and sequencing. CA, JH, LS,JD, AM, CYW, JS, and JL prepared the data for publication. RM, EG, DH, MP, DC, JS, and JDcontributed tothewritingofthemanuscript.Allauthorsread and approvedthefinal manuscript.

Funding: This work was supported by the Chan Zuckerberg Biohub, Healthy Yolo Together, theUniversity of California, San Francisco, the Chan Zuckerberg Initiative and The University ofCalifornia,Davis.

Acknowledgements: Many people were responsible for collecting the samples, running thetests, performing the genotyping and sequencing, and processing the data as listed inSupplementaryTable2.

Conflict of Interest: Dr. DeRisi reports being a scientific advisor to the Public Health Co. and ascientific advisor to Allen & Co. Dr. Havlir reports non-financial support from Abbott outside ofthe submittedwork.Theotherauthorsdeclarenocompetinginterests.

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LINK: https://www.medrxiv.org/content/10.1101/2021.09.28.21264262v2

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EXHIBIT "AA-11"

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'Most vaccinated' place on earth cancels Christmas

NOTARY Adv. Shirish N. Dhonage Mumbai Maharashtra Reg. No. 15376 GOVT OF INDIA

Source Name : RT QUESTION MORE

Date: 16 Nov, 2021

Link: https://www.rt.com/news/540442-gibraltar-cancels-christmas-covid/

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.

"The drastic increase in the numbers of people testing positive for Covid-19 in recent days is a stark reminder that the virus is still very prevalent in our community and that it is the responsibility of us all to take every reasonable precaution to protect ourselves and our loved ones," Health Minister Samantha Sacramento said.

Gibraltar, a tiny British Overseas Territory sharing a land border with Spain, has seen an average of 56 Covid-19 cases per day over the last seven days, up from fewer than 10 per day in September. The rise in cases, described by the government as *"exponential,"* comes despite Gibraltar having the highest vaccination rate in the world.

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

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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 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.

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EXHIBIT "AA-12"

Source: CBS Boston

Link: **https://boston.cbslocal.com/2021/09/15/brown-university-covid-dining-stduents-gathering/**

NOTARY Adv. Shivaji N. Dhanage Mumbai Maharashtra Reg. No. 19376 GOVT OF INDIA

Published: September 15, 2021 at 8:43 am

Filed Under:Brown University, Coronavirus, Rhode Island News

Brown University Pauses Indoor Dining, Limits Student Gatherings As COVID Cases Rise

PROVIDENCE, R.I. (AP) — Brown University has paused in-person dining and placed a limit of five people for undergraduate social gatherings in response to a recent rise in confirmed coronavirus cases on campus.

The Ivy League school had 82 confirmed positive COVID-19 tests, primarily among undergraduate students, in the past seven days, according to a statement Monday.

"The increase in positive asymptomatic test results is a reflection of the transmissibility of the delta variant, our significant increase in the number of tests conducted at Brown, and an increase in our student population, some of whom have been engaging with other students in multiple smaller groups outside the classroom, especially indoors without masks," the school's statement said.

Those testing positive generally remain asymptomatic and there are no indications of serious illness and no hospitalizations, the school said.

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There is no evidence of spread in classrooms, and classes will continue, the school said.

The "short-term" restrictions also include increased undergraduate student testing from once to twice per week and an indoor mask requirement.

Brown requires vaccinations for students and employees.

EXHIBIT "AA-13" 1064

Health Ministry chief says coronavirus spread reaching record heights

As over 10,000 new cases are diagnosed, Nachman Ash tells lawmakers he had hoped recent downward trend would continue

By **STUART WINER** 14 September 2021, 2:25 pm

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.

Ash's remarks via video call to the Knesset Constitution, Law, and Justice Committee came as Health Ministry figures showed that over 10,000 new COVID-19 cases were diagnosed the day before and that the positive test rate was climbing.

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.

Ash expressed some pessimism, though he observed that, belying fears, there wasn't a large spike in infections following last week's Rosh Hashanah holiday — the Jewish New Year — or the opening of the school year at the beginning of the month.

After bringing daily infections down to little more than a dozen a day in June, Israel has been battling to control a resurgence of COVID-19 in what has been its fourth wave of infections since the start of the global pandemic.

"A week ago we were in a clear downward trend; in recent days we've been seeing that decline stop, and the virus reproduction number is [again] above 1," Ash said of the so-called R number, which indicates how many people each virus carrier will infect. Values above 1 show that the outbreak is growing, below 1 that it is shrinking.

"I hoped that we would see a clearer drop, but we are still not seeing it," he said.

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Ash noted the number of seriously ill ranges between 670 and 700. Every day 70-80 new patients fall seriously ill, slightly fewer than in recent weeks.

The number of patients on ventilators has climbed in the past ten days from 150 to 190, while the number of those on the more critical ECMO machines rose from 23 to 31, he said.

Despite the numbers, Ash said that the so-called Green Pass restriction would be removed from open-air swimming pools, in part to help out parents searching for activities for their children during the holiday period when schools are closed. The holiday period, including the weeklong Sukkot festival, ends September 28.

The Green Pass enables only those who have been vaccinated against COVID-19, recovered from the disease, or recently tested negative for the virus to access most indoor public places, as well as crowded outdoor attractions. Since children below the age of 12 are not eligible for vaccination, they — if they're over the age of 3 — must get rapid virus tests to attend many recreation venues.

The Knesset meeting was convened to discuss the Green Pass system.

National coronavirus czar Salman Zarka, who also participated in the meeting, said that 50 percent of confirmed cases on Monday were children. He said that the Health Ministry was working on the assumption that it will in the future need to deal with a fifth wave of virus infections.

Zarka said that the ministry will prepare by continuing to use the Green Pass system, asserting that it helps prevent the virus spread, while noting that it would be eased as morbidity drops off.

"I hope that we will pass the month of September and stabilize in October," Zarka said. "Then we will take a fresh look at the policy."

Zarka said the ministry had urged the government to restrict large gatherings and ban events such as a major student festival in Eilat, crowds at soccer matches, and an annual pilgrimage by tens of thousands of Israelis to Uman, Ukraine, to visit the grave of a venerated rabbi. Officials feared that hundreds of pilgrims would return with the virus. Dozens of infected travelers have been caught with forged paperwork declaring they tested negative for COVID-19 before boarding planes home.

"The cabinet sees things differently from us and decided that the events can be held," Zarka said.

EXHIBIT "AA-14" 1066

Spain, Belgium and Italy restrict AstraZeneca Covid vaccine to older people
The Guardian

Thu 8 Apr 2021 11.22 BST

Italy, Spain and Belgium have joined other European countries in limiting the use of the Oxford/AstraZeneca vaccine to older age groups as the EU struggles to agree common guidelines to counter expected public hesitancy.

The European Medicines Agency (EMA) on Wednesday found a possible link between the vaccine and very rare cases of blood clots, although it said its benefits far outweighed the risks and did not announce any restrictions.

In Britain, the government's joint committee on vaccines and immunisation said healthy people aged 18 to 24 who were not at high risk of Covid should have the option of a different jab if one was available in their area.

Belgium's national and regional health ministers subsequently agreed to restrict the vaccine to the over-55s for a month, while Italy's health minister, Roberto Speranza, said late on Wednesday the shot should be offered only to those aged 60 and over.

Franco Locatelli, the head of the country's health council, said people who had already had the first dose of the AstraZeneca jab could proceed with the second, and officials stressed that while the shot was not recommended for under-60s, it was not prohibited.

After meeting regional health chiefs, Spain's health minister, Carolina Darias, also announced late on Wednesday that administration of the AstraZeneca vaccine would be temporarily suspended nationwide to people under the age of 60.

Spain's autonomous regions have given more than 2.1m first shots of the Anglo-Swedish shot under a patchwork of rules and at various paces. Authorities now have to decide whether to use a different vaccine for the second dose.

EU countries that have already imposed restrictions include Germany, which is limiting its use to under-60s and priority groups and has recommended that people under 60 who have had a first shot should receive a different second dose.

But countries are setting a range of age limits for the shot, with France restricting its use to people aged 55 and over, the Netherlands to those aged 60 and over, and Finland and Sweden to people aged 65 and over.

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EU health ministers failed at an extraordinary meeting on Wednesday night to agree a coordinated approach despite a plea by Portugal, which holds the bloc's rotating presidency, to urgently seek common ground on the use of the vaccine.

"It is essential that we follow a coordinated European approach – an approach which does not confuse citizens, and that does not fuel vaccine hesitancy," the EU health commissioner, Stella Kyriakides, reportedly told ministers at the meeting.

The EMA said it received reports of 169 cases of the rare brain blood clot by early April, after 34m doses had been administered in the European Economic Area (EEA), adding that most occurred in women under 60 withintwo weeks of vaccination.

In Germany, Christian Bogdan, a member of the country's vaccine committee, said instances of the condition in women under 60 who had been given the AstraZeneca shot were 20 times higher than would normally be expected, representing what he called a "very clear risk signal".

Countries that have imposed age restrictions on the AstraZeneca vaccine now face the conundrum of what to do about younger people who have had a first dose. Some experts say different vaccines could work together to fight the virus because all target the same outer "spike" protein of the virus.

Germany has recommended that people under 60 who have had a first AstraZeneca shot should receive a different product for their second dose. Other countries are waiting for the results of a British trial launched in February to explore mixing doses of Pfizer and AstraZeneca vaccines.

France's top health advisory council is reportedly considering using mRNA vaccines such as those produced by Pfizer/BioNTech and Moderna as a second dose, but no formal decision has not been yet taken.

LINK : https://www.theguardian.com/society/2021/apr/08/spain-belgium-and-italy-restrict-astrazeneca-covid-vaccine-to-older-people

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EXHIBIT" AA-15" (1068)

NOTARY Adv. Shivaji N. Chavan Mumbai Maharashtra GOVT OF INDIA

NIH orders $1.67M study on how COVID-19 vaccine impacts menstrual cycle

NY Post

September 7, 2021 5:28pm

The National Institutes of Health has announced a $1.67 million study to investigate reports that suggest the COVID 19 vaccine may come with an unexpected impact on reproductive health.

It's been a little over six months since the three COVID-19 vaccines in the US - Pfizer, Moderna and Johnson & Johnson - became widely available to all adults. But even in the early days of vaccine rollout, some women were noticing irregular periods following their shots, as reported first by the Lily in April.

Shana Clauson, 45, spoke to the Washington Post's women's news site at the time, and again this week, about her experience after getting the jab- revealing that her period arrived earlier and heavier than what she considers normal. She was one of many who gathered on social media to share what they were seeing.

"Is this not being discussed, or is it even being looked at or researched because it's a woman's issue?" Clauson speculated to the Lily last spring.

It would appear that the NIH heard Clauson and others' reports, as they announced on Aug. 30 that they intended to embark on just such research-aiming to incorporate up to half a million participants, including teens and transgender and nonbinary people.

Researchers at Boston University, Harvard Medical School, Johns Hopkins University, Michigan State University and Oregon Health and Science University have been enlisted to embark on the study, commissioned by the NIH's National Institute of Child Health and Human Development (NICHD) and the Office of Research on Women's Health.

The approximately yearlong study will follow initially unvaccinated participants to observe changes that occur following each dose. More specifically, some groups will exclude participants on birth control or gender-affirming hormones, which may have their own impact on periods.

Our goal is to provide menstruating people with information, mainly as to what to expect, because I think that was the biggest issue: Nobody expected it to affect the menstrual system, because the information wasn't being collected in the early

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vaccine studies," said NICHD director Diana Bianchi in a statement to the Lily-reportedly crediting their early coverage for helping to make the NIH aware.

The NIH suggests that changes to the menstrual cycle could arise out of several of life's circumstances during a pandemic-the stress of lifestyle changes or possibly contending with illness. Moreover, the immune and reproductive systems are intrinsically linked, and the notion that the immune-boosting vaccine may disrupt the typical menstrual cycle is plausible, as demonstrated by previous studies concerning vaccine uptake.

It's also worth noting the vaccine does not cause infertility and the Centers for Disease Control and Prevention recommends the shot even for pregnant women.

As changes to the menstrual cycle are "really not a life and death issue," explained Bianchi, the Food and Drug Administration - fast-tracking their work-prioritized only the most critical risks associated with the COVID-19 vaccine.

The NIH, too, pulled together the initiative at breakneck speed. Funding for such a study would typically take years to see approval.

"We were worried this was contributing to vaccine hesitancy in reproductive-age women," said Bianchi.

LINK: https://nypost.com/2021/09/07/nih-to-study-how-covid-19-vaccine-impacts-menstrual-cycle/

(TRUE COPY)

EXHIBIT "AA-16" 1070

Ontario now recommending against Moderna vaccine for men 18-24-years old

Anthony Furey, Toronto Sun

Sep 29, 2021

The Ontario government is now recommending males aged 18 to 24 take Pfizer over Moderna as their COVID-19 vaccination due to the number of young men who have experienced myocarditis after getting the vaccine.

This comes after public health officials determined there is a 1 in 5,000 risk of myocarditis — a form of heart inflammation — following a second dose of the Moderna vaccine.

For any young men in that age bracket who received Moderna as their first dose and have not yet received a second dose, the government recommends they go with Pfizer. However, if any 18 to 24 year old males still wish to receive Moderna, the government says "they can continue to do so with informed consent."

The risk of myocarditis for this demographic in Pfizer is 1 in 28,000, according to government officials.

"The majority of reported cases have been mild with individuals recovering quickly, normally with anti-inflammatory medication," explains a guidance document released by the government. "Symptoms have typically been reported to start within one week after vaccination, more commonly after the second dose."

The number of young males who have been admitted to the ICU because of this side effect is "under 10," according to a government source.

While there are reports of myocarditis in Ontario among both males and females in all age brackets, the incidence rate among young males receiving their second Moderna shot was substantially higher than other categories.

This development comes after a Public Health Ontario report released last month showed over half of the province's approximately 200 cases of hospitalizations for myocarditis following mRNA vaccination were in people under the age of 25.

Prashant Bhushan
(TRUE COPY)

EXHIBIT "AA-17" (1071)

Sweden, Denmark pause Moderna COVID-19 vaccine for younger age groups

Reuters
October 6, 2021, 11:45 PM IST

Sweden and Denmark said on Wednesday they are pausing the use of Moderna's (MRNA.O) COVID-19 vaccine for younger age groups after reports of possible rare cardiovascular side effects.

The Swedish health agency said it would pause using the shot for people born in 1991 and later as data pointed to an increase of myocarditis and pericarditis among youths and young adults that had been vaccinated. Those conditions involve an inflammation of the heart or its lining.

"The connection is especially clear when it comes to Moderna's vaccine Spikevax, especially after the second dose," the health agency said, adding the risk of being affected was very small.

Shares of Moderna fell 4.9%, or $16.08, to $316.11 in afternoon trading.

A Moderna spokesperson said in an email the company was aware of the decisions by regulators in Denmark and Sweden to pause the use of its vaccine in younger individuals because of the rare risk of myocarditis and or pericarditis.

"These are typically mild cases and individuals tend to recover within a short time following standard treatment and rest. The risk of myocarditis is substantially increased for those who contract COVID-19, and vaccination is the best way to protect against this."

According to one U.S. study that has yet to undergo peer review young males under 20 are up to six times more likely to develop myocarditis after contracting COVID-19 than those who have been vaccinated.

Denmark said that, while it used the Pfizer/BioNTech vaccine as its main option for people aged 12-17 years, it had decided to pause giving the Moderna vaccine to people below 18 according to a "precautionary principle".

"In the preliminary data ... there is a suspicion of an increased risk of heart inflammation, when vaccinated with Moderna," the Danish Health Authority said in a statement.

It referred to data from a yet unpublished Nordic study, which would now be sent to the European Medicines Agency (EMA) for further assessment. Final data was expected within a month, it added.

Sweden and Denmark said they now recommended the Comirnaty vaccine, from Pfizer/BioNTech (PFE.N), instead.

The Danish Health Authority said it had made the decision even as "heart inflammation is an extremely rare side effect that often has a mild course and goes away on its own".

The EMA's safety committee concluded in July that inflammatory heart conditions can occur in very rare cases following vaccination with Comirnaty or Spikevax, more often in younger men after the second dose.

The benefits of shots based on so-called mRNA technology used by both Moderna and Pfizer-BioNTech in preventing COVID-19 continue to outweigh the risks, regulators in the United States, EU and the World Health Organization have said.

Data suggests reported cases of rare heart inflammation are relatively higher after Moderna's vaccine compared with the Pfizer/BioNTech shots, Canadian health officials said last week.

Although both vaccines are based on mRNA technology, the Pfizer shot contains 30 micrograms of vaccine per dose compared with 100 micrograms in the Moderna vaccine.

Data from one of two U.S. vaccine safety monitoring databases has also suggested that Moderna's vaccine may carry a higher risk of myocarditis among young people.

The vaccine is not approved for people under age 18 in the United States.

Norway already recommends the Cominarty vaccine to minors and said on Wednesday that it was reiterating this.

"Men under the age of 30 should also consider choosing Cominarty when they get vaccinated," GeirBukholm, head of infection control at the Norwegian Institute of Public Health, said in a statement.

A Finnish health official said Finland expected to publish a decision on Thursday.

The EMA approved the use of Comirnaty in May, while Spikevax was given the nod for children over 12 in July.

1073

LINK: https://www.reuters.com/business/healthcare-pharmaceuticals/sweden-pauses-use-moderna-covid-vaccine-cites-rare-side-effects-2021-10-06/

S&D

(TRUE COPY)

NOTARY
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1074

EXHIBIT "AA-18"

Finland joins Sweden and Denmark in limiting Moderna COVID-19 vaccine
Yahoo News

EssiLehto
October 7, 2021

HELSINKI (Reuters) -Finland on Thursday paused the use of Moderna's COVID-19 vaccine for younger males due to reports of a rare cardiovascular side effect, joining Sweden and Denmark in limiting its use.

Mika Salminen, director of the Finnish health institute, said Finland would instead give Pfizer's vaccine to men born in 1991 and later. Finland offers shots to people aged 12 and over.

"A Nordic study involving Finland, Sweden, Norway and Denmark found that men under the age of 30 who received Moderna Spikevax had a slightly higher risk than others of developing myocarditis," he said.

Swedish and Danish health officials had announced on Wednesday they would pause the use of the Moderna vaccine for all young adults and children, citing the same unpublished study.

Norwegian health officials reiterated on Wednesday that they recommended men under the age of 30 opt for Pfizer's vaccine.

The Finnish institute said the Nordic study would be published within a couple of weeks and preliminary data had been sent to the European Medicines Agency (EMA) for further assessment.

The EMA's safety committee concluded in July that such inflammatory heart conditions could occur in very rare cases following vaccination with Spikevax or the Pfizer/BioNTech Comirnaty jab, more often in younger men after the second dose.

Regulators in the United States, EU and the World Health Organization have however stressed that the benefits of shots based on the mRNA technology used by Moderna and Pfizer-BioNTech in preventing COVID-19 continue to outweigh the risks.

A Moderna spokesperson said late on Wednesday it was aware of the decisions by the Swedish and Danish regulators.

"These are typically mild cases and individuals tend to recover within a short time following standard treatment and rest. The risk of myocarditis is substantially increased for those who contract COVID-19, and vaccination is the best way to protect against this."

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Italy's Health Minister Roberto Speranza told reporters Italy was not planning to suspend the Moderna vaccine and said European countries should work together more closely to coordinate better.

"We have to trust international authorities, starting with EMA which is our reference agency and has expressed very clear judgments on the matter," he said.

LINK: https://news.yahoo.com/finland-pauses-moderna-covid-19-073018651.html?guccounter=1

(TRUE COPY)

EXHIBIT "AA-19" (1076)

Stop the use of the Moderna vaccine in Iceland in the light of new data

VISIR

October 8, 2021 2:55 PM

LINK: https://www.visir.is/g/20212167101d

The Chief Epidemiologist has decided that the Moderna vaccine against Covid-19 will not be used in Iceland while further information is obtained on the safety of the vaccine during booster vaccinations.

An announcement states that in recent days there has been data from the Nordic countries on the increased incidence of myocarditis and pericarditis after vaccination with the Moderna vaccine in addition to the Pfizer / BioNTech vaccine.

According to the epidemiologist, the Moderna vaccine has for the past two months been used almost exclusively here for stimulation vaccinations after the Janssen vaccine and after two-dose vaccinations for the elderly and immunocompromised. Very few individuals are said to have received the second dose of the basic vaccine that started with Moderna.

Sufficient supply of Pfizer

In Sweden, the use of Moderna has been restricted to individuals born before 1991. In Norway and Denmark, it has been emphasized that the Pfizer vaccine is recommended rather than Moderna for 12 to 17 year olds.

In Iceland, only the Pfizer vaccine has been recommended for primary vaccination at 12 to 17 years of age since the vaccination of the age group began.

According to the Chief Epidemiologist, the decision was made to wait with the use of Moderna as there is a sufficient supply of Pfizer vaccine for booster vaccinations of defined priority groups and basic vaccinations of those who have not yet been vaccinated.

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1077

EXHIBIT "AA-20"

The Unvaccinated Are Looking Smarter Every Week

By Thomas T. Siler, M.D.

16 October, 2016

There is a massive propaganda push against those choosing not to vaccinate against COVID-19 with the experimental mRNA vaccines. Mainstream media, the big tech corporations, and our government have combined efforts to reward compliance and to shame and marginalize non-compliance. Their mantra says that this is a pandemic of the unvaccinated. Persons who choose not to vaccinate are characterized as unintelligent, selfish, paranoid people who don't read much and live in a trailer park in Florida (or Alabama, or Texas, or name your state). Never has there been such an effort to cajole, manipulate through fear, and penalize people to take an experimental medical treatment.

However, as time has passed with this pandemic and more data accumulates about the virus and the vaccine, the unvaccinated are looking smarter and smarter with each passing week. It has been shown now that the vaccinated equally catch and spread the virus. Vaccine side effect data continues to accumulate that make the risk of taking the vaccine prohibitive as the pandemic wanes. Oral and IV medications (flccc.net) that work early in the treatment of COVID-19 are much more attractive to take now as the vaccine risks are becoming known, especially because the vaccinated will need endless boosters every six months.

First, let's address the intelligence of the unvaccinated. Vaccine hesitancy is multi-factorial and has little to do with level of education or intelligence. Carnegie Mellon University did a study assessing vaccine hesitancy across educational levels. According to the study, what's the educational level with the most vaccine hesitancy? Ph.D. level! Those can't all have been awarded to liberal arts majors. Clearly, scientists who can read the data and assess risk are among the least likely to take the mRNA vaccines.

The claim that there's a pandemic of the unvaccinated is, therefore, patently untrue. As a retired nurse from California recently asked, "Why do the protected need to be protected from the unprotected by forcing the unprotected to use the protection that did not protect the protected in the first place?" If the vaccine works to prevent infection, then the vaccinated have nothing to worry about. If the vaccine does not prevent infection, then the vaccinated remain at some risk, and the unvaccinated would be less likely to choose a vaccine that does not work well.

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The mRNA vaccine efficacy is very narrow and focused on the original alpha strain of COVID-19. By targeting one antigen group on the spike protein, it does help for the original alpha strain, but it is clear now it does not protect against Delta strain and is likely not protective against any future strains that might circulate. It also appears that the efficacy wanes in 4-6 months, leading to discussions about boosters.

Several authors have pointed out that vaccinating with a "leaky" vaccine during a pandemic is driving the virus to escape by creating variants. If the booster is just another iteration of the same vaccine, it likely won't help against the new strain but will, instead, produce evolutionary pressure on the virus to produce even more variants and expose us to more side effects. Why, then, is this booster strategy for everyone being pursued?

This vast Phase 3 clinical trial of mRNA vaccines in which Americans are participating mostly out of fear is not going well. It is abundantly clear for anyone advocating for public health that the vaccination program should be stopped. Iceland has just stopped giving the Moderna vaccine to anyone which is a good step in the right direction. Sweden, Denmark, and Finland have banned the Moderna vaccine for anyone under the age of 30.

VAERS, our vaccine adverse effect reporting system, showed at the beginning of this week 16,000 deaths, 23,000 disabilities, 10,000 MI/myocarditis, 87,000 urgent care visits, 75,000 hospital stays, and 775,000 total adverse events. The VAERS system is widely known to under-report events, with an estimated 90 to 99% of events going unreported there.

Eudravigilance, the European reporting system now associates 26,000 deaths in close proximity to administration of the vaccine. Whistleblower data from the CMS system (Medicare charts) showed close to 50,000 deaths in the Medicare group shortly after the vaccine.

An AI-powered tracking program called Project Salus also follows the Medicare population and shows vaccinated Medicare recipients are having worse outcomes week by week of the type consistent with Antibody Dependent Enhancement. This occurs when the vaccine antibodies actually accelerate the infection leading to worsening COVID-19 infection outcomes. Antibody Dependent Enhancement has occurred previously with trials of other coronavirus vaccines in animals. The CDC and the FDA are suppressing this data and no one who receives the vaccine has true informed consent.

The Rome declaration has 6,700 medical signatories attesting that the handling of the pandemic amounts to crimes against humanity for denying the best medical

treatment and continuing to advocate for harmful vaccines. The evidence is right in front of Americans to end the propaganda and mass mask psychosis.

The media narrative of perpetual fear is falling apart. Norway, Sweden, and Denmark have ended all COVID restrictions and are doing much better than the US, UK, and Israel, three countries that continue to vaccinate into the pandemic. Mexico, Guatemala, Indonesia, almost all of Africa, and parts of India have low vaccination rates and are doing much better than the US, something attributed to their managing the pandemic by using Ivermectin.

Over 500,000 people attended the Sturgis motorcycle rally in August and there was no super spread of COVID-19. Football season started in August and stadiums around the country are packed with 80,000 fans yelling and screaming with no masks. There have been no superspreader events, yet the students are forced to go back to masking in class. This makes no sense.

If the vaccine is so important why do our government leaders and illegal aliens not have to take it? Currently, 13 states that are Democratic with high vaccination rates have the highest "case" rates (using a faulty PCR test), while Republican states are all doing better. How does this happen?

It should be clear that the government has manipulated COVID to create perpetual fear, so we'll hand it our liberty. In this giant battle between our government and the unvaccinated, I hope enough people will refuse to comply so that we can unite to stop this madness.

I know this decision is very difficult for many people when it comes to losing their job. To the vaccinated, please don't take any boosters for you'll just be perpetuating the risk of side effects and new variants.

If we allow the government to decide this medical decision for us, it is a short step for the government to say it can decide other medical decisions for you, e.g., all persons over 75 never be resuscitated; people may have only three children (or two or one) with mandatory sterilization for women; or refusing the government's demands will see you denied health care.

Is this the totalitarian state you want to live in? If you are proudly vaccinated now and on the government side, what about the next government mandate, when you're on the other side, coerced into a decision you don't want, how will you feel then?

It is obvious that the government (with the Fauci subset), the media, and big tech, are trying to divide us and take away the freedoms we have enjoyed as Americans. I am praying that all who call themselves Americans can unite to end this medical

tyranny and regain a free America before it is too late. Peacefully resist and do not comply.

LINK:
https://www.americanthinker.com/articles/2021/10/the_unvaccinated_are_looking_smarter_every_week.html

(TRUE COPY)

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EXHIBIT "AA-21"

1081

United States Court of Appeals for the Fifth Circuit

No. 21-60845

BST Holdings, L.L.C.; RV Trosclair, L.L.C.; Trosclair Airline, L.L.C.; Trosclair Almonaster, L.L.C.; Trosclair and Sons, L.L.C.; Trosclair ; Trosclair, Incorporated; Trosclair Carrollton, L.L.C.; Trosclair Claiborne, L.L.C.; Trosclair Donaldsonville, L.L.C.; Trosclair Houma, L.L.C.; Trosclair Judge Perez, L.L.C.; Trosclair Lake Forest, L.L.C.; Trosclair Morrison, L.L.C.; Trosclair Paris, L.L.C.; Trosclair Terry, L.L.C.; Trosclair Williams, L.L.C.; Ryan Dailey; Jasand Gamble; Christopher L. Jones; David John Loschen; Samuel Albert Reyna; Kip Stovall; Answers in Genesis, Incorporated; American Family Association, Incorporated; Burnett Specialists; Choice Staffing, L.L.C.; Staff Force, Incorporated; Leadingedge Personnel, Limited; State of Texas; HT Staffing, Limited; doing business as HT Group; The State of Louisiana; Cox Operating, L.L.C.; Dis-Tran Steel, L.L.C.; Dis-Tran Packaged Substations, L.L.C.; Beta Engineering, L.L.C. Optimal Field Services, L.L.C.; The State of Mississippi; Gulf Coast Restaurant Group, Incorporated; The State of South Carolina; The State of Utah; Word of God Fellowship, Incorporated, doing busines as Daystar Television Network,

Petitioners,

versus

Occupational Safety and Health Administration, United States Department of Labor; United States

1082

No. 21-50353

DEPARTMENT OF LABOR; MARTIN J. WALSH, SECRETARY, U.S. DEPARTMENT OF LABOR; DOUGLAS PARKER, IN HIS OFFICIAL CAPACITY AS ASSISTANT SECRETARY OF LABOR FOR OCCUPATIONAL SAFETY AND HEALTH,

Respondents.

Petition for Review of
Occupational Safety and Health Administration
Emergency Temporary Standard

Before JONES, DUNCAN, and ENGELHARDT, *Circuit Judges.*

PER CURIAM:*

Before the court is the petitioners'[1] emergency motion to stay enforcement of the Occupational Safety and Health Administration's November 5, 2021 Emergency Temporary Standard[2] (the "Mandate") pending expedited judicial review.

Because the petitions give cause to believe there are grave statutory and constitutional issues with the Mandate, the Mandate is hereby STAYED pending further action by this court.

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* Pursuant to 5TH CIRCUIT RULE 47.5, the court has determined that this opinion should not be published and is not precedent except under the limited circumstances set forth in 5TH CIRCUIT RULE 47.5.4.

[1] This order addresses only the emergency motion filed by the above-captioned petitioners. Going forward, the Clerk of Court shall ensure that all related motions and petitions in this court be consolidated under this case number, and that all parties—including the Government—make all related filings in this case.

[2] *See* COVID-19 Vaccination and Testing; Emergency Temporary Standard, 86 Fed. Reg. 61,402 (Nov. 5, 2021) (to be codified at 29 C.F.R. pts. 1910, 1915, 1917, 1918, 1926, and 1928).

The Government shall respond to the petitioners' motion for a permanent injunction by 5:00 PM on Monday, November 8.

The petitioners shall file any reply by 5:00 PM on Tuesday, November 9.

So ordered.

EXHIBIT "AA-22"

1084

United States Court of Appeals for the Fifth Circuit

United States Court of Appeals
Fifth Circuit
FILED
November 12, 2021
Lyle W. Cayce
Clerk

No. 21-60845

BST Holdings, L.L.C.; RV Trosclair, L.L.C.; Trosclair Airline, L.L.C.; Trosclair Almonaster, L.L.C.; Trosclair and Sons, L.L.C.; Trosclair ; Trosclair, Incorporated; Trosclair Carrollton, L.L.C.; Trosclair Claiborne, L.L.C.; Trosclair Donaldsonville, L.L.C.; Trosclair Houma, L.L.C.; Trosclair Judge Perez, L.L.C.; Trosclair Lake Forest, L.L.C.; Trosclair Morrison, L.L.C.; Trosclair Paris, L.L.C.; Trosclair Terry, L.L.C.; Trosclair Williams, L.L.C.; Ryan Dailey; Jasand Gamble; Christopher L. Jones; David John Loschen; Samuel Albert Reyna; Kip Stovall; Answers in Genesis, Incorporated; American Family Association, Incorporated; Burnett Specialists; Choice Staffing, L.L.C.; Staff Force, Incorporated; Leadingedge Personnel, Limited; State of Texas; HT Staffing, Limited; doing business as HT Group; The State of Louisiana; Cox Operating, L.L.C.; Dis-Tran Steel, L.L.C.; Dis-Tran Packaged Substations, L.L.C.; Beta Engineering, L.L.C. Optimal Field Services, L.L.C.; The State of Mississippi; Gulf Coast Restaurant Group, Incorporated; The State of South Carolina; The State of Utah; Word of God Fellowship, Incorporated, doing busines as Daystar Television Network,

Petitioners,

versus

Occupational Safety and Health Administration, United States Department of Labor; United States

DEPARTMENT OF LABOR; MARTIN J. WALSH, SECRETARY, U.S. DEPARTMENT OF LABOR; DOUGLAS PARKER, IN HIS OFFICIAL CAPACITY AS ASSISTANT SECRETARY OF LABOR FOR OCCUPATIONAL SAFETY AND HEALTH,

Respondents.

Petition for Review of
Occupational Safety and Health Administration
Emergency Temporary Standard

Before JONES, DUNCAN, and ENGELHARDT, *Circuit Judges.*

KURT D. ENGELHARDT, *Circuit Judge*:

The Occupational Safety and Health Administration (OSHA) "reasonably determined" in June 2020 that an emergency temporary standard (ETS) was "not necessary" to "protect working people from occupational exposure to infectious disease, including COVID-19." *In re AFL-CIO*, 2020 WL 3125324, at *1 (D.C. Cir. June 11, 2020). This was not the first time OSHA had done this; it has refused several times to issue ETSs despite legal action urging it do so. *See, e.g.*, *In re Int'l Chem. Workers Union*, 830 F.2d 369 (D.C. Cir. 1987) (per curiam). In fact, in its fifty-year history, OSHA has issued just ten ETSs.[1] Six were challenged in court; only one survived.[2] The reason for the rarity of this form of emergency action is

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[1] CONG. RSCH. SERV., OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION (OSHA): EMERGENCY TEMPORARY STANDARDS (ETS) AND COVID-19, at 34 tbl. A-1 (Nov. 10, 2021), *available at* https://crsreports.congress.gov/product/pdf/R/R46288.

[2] It bears noting at the outset that most of the few ETSs issued by OSHA were immediately stayed pending merits review. *See Asbestos Info. Ass'n/N. Am. v. OSHA*, 727 F.2d 415, 418 (5th Cir. 1984); *Indus. Union Dep't, AFL-CIO v. Bingham*, 570 F.2d 965, 968 (D.C. Cir. 1977); *Taylor Diving Salvage Co. v. U.S. Dep't of Lab.*, 537 F.2d 819, 820–21 (5th

simple: courts and the Agency have agreed for generations that "[e]xtraordinary power is delivered to [OSHA] under the emergency provisions of the Occupational Safety and Health Act," so "[t]hat power should be delicately exercised, and only in those emergency situations which require it." *Fla. Peach Growers Ass'n v. U.S. Dep't of Lab.*, 489 F.2d 120, 129–30 (5th Cir. 1974).

This case concerns OSHA's most recent ETS—the Agency's November 5, 2021 Emergency Temporary Standard (the "Mandate") requiring employees of covered employers to undergo COVID-19 vaccination or take weekly COVID-19 tests and wear a mask.[3] An array of petitioners seeks a stay barring OSHA from enforcing the Mandate during the pendency of judicial review. On November 6, 2021, we agreed to stay the Mandate pending briefing and expedited judicial review. Having conducted that expedited review, we reaffirm our initial stay.

I.

OSHA promulgated its much anticipated[4] vaccine mandate on November 5, 2021. Framed as an ETS, the Mandate requires all employers of 100 or more employees to "develop, implement, and enforce a mandatory COVID-19 vaccination policy" and require any workers who remain

Cir. 1976) (per curiam); *Fla. Peach Growers Ass'n v. U.S. Dep't of Lab.*, 489 F.2d 120, 126 (5th Cir. 1974).

[3] *See* COVID-19 Vaccination and Testing; Emergency Temporary Standard, 86 Fed. Reg. 61,402 (Nov. 5, 2021) (to be codified at 29 C.F.R. pts. 1910, 1915, 1917, 1918, 1926, and 1928).

[4] Debates over the Biden Administration's forthcoming vaccine mandate roiled the country throughout much of the Fall. For obvious reasons, the Mandate affects every person in America in one way or another.

unvaccinated to "undergo [weekly] COVID-19 testing and wear a face covering at work in lieu of vaccination." 86 Fed. Reg. 61,402, 61,402.

On the afternoon of the Mandate's publication, a diverse group of petitioners (including covered employers, States, religious groups, and individual citizens) moved to stay and permanently enjoin the mandate in federal courts of appeals across the nation. Finding "cause to believe there are grave statutory and constitutional issues with the Mandate," we intervened and imposed a temporary stay on OSHA's enforcement of the Mandate. For ease of judicial review, and in light of the pressing need to act immediately, we consolidated our court's petitions under the case number captioned above.

Many of the petitioners are covered private employers within the geographical boundaries of this circuit.[5] Their standing[6] to sue is obvious—the Mandate imposes a financial burden upon them by deputizing their participation in OSHA's regulatory scheme, exposes them to severe financial risk if they refuse or fail to comply, and threatens to decimate their workforces (and business prospects) by forcing unwilling employees to take their shots, take their tests, or hit the road.

[5] Because these petitioners are the targets of the Mandate and bear the brunt of OSHA's regulatory power, we principally analyze the petitions from their perspective. This is not to say that the claims of other petitioners such as States or individual citizens would be any less successful on a thorough analysis.

[6] "Only one of the petitioners needs to have standing to permit us to consider the petition for review." *Massachusetts v. EPA*, 549 U.S. 497, 518 (2007).

The petitioners seek a stay—and ultimately a permanent injunction—of the Mandate's enforcement pending full judicial review of the Mandate. We address their request for a stay today.[7]

II.

The "traditional stay factors . . . govern a request for a stay pending judicial review." *Nken v. Holder*, 556 U.S. 418, 426 (2009). Under the traditional stay standard, a court considers four factors: "(1) whether the stay applicant has made a strong showing that he is likely to succeed on the merits; (2) whether the applicant will be irreparably injured absent a stay; (3) whether issuance of the stay will substantially injure the other parties interested in the proceeding; and (4) where the public interest lies." *Hilton v. Braunskill*, 481 U.S. 770, 776 (1987).

Each of these factors favors a stay here.

A.

We first consider whether the petitioners' challenges to the Mandate are likely to succeed on the merits. For a multitude of reasons, they are.

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[7] Our November 6, 2021 stay order preserved the status quo during the pendency of briefing. The unusual procedural posture of this case makes for an unusual process. Ordinarily, a federal plaintiff aggrieved by an adversary's threatened course of action must go to a *district court* to seek injunctive relief at the outset. In this ordinary scenario, a preliminary injunction precedes a permanent injunction, and trial-court review precedes appellate review. But this is not a typical case. Here, the statute giving OSHA the power to issue emergency temporary standards like the Mandate also provides for direct and immediate judicial review in "the United States court of appeals for the circuit wherein" "[a]ny person who may be adversely affected by" an ETS "resides or has his principal place of business." *See* 29 U.S.C. § 655(f). Satisfied of our jurisdiction to proceed under that provision, but mindful of our unusual procedural posture, we apply the traditional factors for a stay pending judicial review and draw factual support from the attachments to the pleadings, uncontested facts, and judicial notice.

We begin by stating the obvious. The Occupational Safety and Health Act, which created OSHA, was enacted by Congress to assure Americans "safe and healthful working conditions and to preserve our human resources." *See* 29 U.S.C. § 651 (statement of findings and declaration of purpose and policy). It was not—and likely *could* not be, under the Commerce Clause and nondelegation doctrine[8]—intended to authorize a workplace safety administration in the deep recesses of the federal bureaucracy to make sweeping pronouncements on matters of public health affecting every member of society in the profoundest of ways. *Cf. Ala. Ass'n of Realtors v. HHS*, 141 S. Ct. 2485, 2488–90 (2021) (per curiam).

On the dubious assumption that the Mandate *does* pass constitutional muster—which we need not decide today[9]—it is nonetheless fatally flawed on its own terms. Indeed, the Mandate's strained prescriptions combine to make it the rare government pronouncement that is both overinclusive (applying to employers and employees in virtually all industries and workplaces in America, with little attempt to account for the obvious differences between the risks facing, say, a security guard on a lonely night shift, and a meatpacker working shoulder to shoulder in a cramped warehouse) *and* underinclusive (purporting to save employees with 99 or more coworkers from a "grave danger" in the workplace, while making no attempt to shield employees with 98 or fewer coworkers from the very same

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[8] The nondelegation doctrine constrains Congress's ability to delegate its legislative authority to executive agencies. *See, e.g.*, *Mistretta v. United States*, 488 U.S. 361, 371–72 (1989) ("The Constitution provides that '[a]ll legislative Powers herein granted shall be vested in a Congress of the United States' . . . and we have long insisted that 'the integrity and maintenance of the system of government ordered by the Constitution' mandate that Congress generally cannot delegate its legislative power to another Branch." (first quoting U.S. CONST. art. I, § 1; then quoting *Field v. Clark*, 143 U.S. 649, 692 (1892))).

[9] *But see infra* subsection II.A.2.f.

threat). The Mandate's stated impetus—a purported "emergency" that the entire globe has now endured for nearly two years,[10] and which OSHA itself spent nearly two *months* responding to[11]—is unavailing as well. And its promulgation grossly exceeds OSHA's statutory authority.

1.

After the President voiced his displeasure with the country's vaccination rate in September,[12] the Administration pored over the U.S. Code in search of authority, or a "work-around,"[13] for imposing a national

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[10] As Justice Gorsuch recently observed, society's interest in slowing the spread of COVID-19 "cannot qualify as [compelling] forever," for "[i]f human nature and history teach anything, it is that civil liberties face grave risks when governments proclaim indefinite states of emergency." *Does 1–3 v. Mills*, --- S. Ct. ---, 2021 WL 5027177, at *3 (Oct. 29, 2021) (Gorsuch, J., dissenting); *see also Fla. Peach Growers*, 489 F.2d at 131 (situation ongoing for "last several years . . . fail[ed] to qualify for [OSHA] emergency measures").

[11] The President announced his intention to impose a national vaccine mandate on September 9, 2021. *See, e.g.*, Kevin Liptak & Kaitlan Collins, *Biden Announces New Vaccine Mandates that Could Cover 100 Million Americans*, CNN (Sept. 9, 2021), https://www.cnn.com/2021/09/09/politics/joe-biden-covid-speech/index.html ("'We've been patient, but our patience is wearing thin, and your refusal has cost all of us,' Biden said, his tone hardening toward Americans who still refuse to receive a vaccine despite ample evidence of their safety and full approval of one . . . ."). OSHA issued the Mandate nearly two months later, on November 5, 2021, and the Mandate itself prominently features yet another two-month delay. One could query how an "emergency" could prompt such a "deliberate" response. In similar cases, we've held that OSHA's failure to act promptly "does not conclusively establish that a situation is not an emergency," but "may be evidence that a situation is not a *true* emergency." *Asbestos Info.*, 727 F.2d at 423 (emphasis added).

[12] *See supra* note 11.

[13] On September 9, 2021, White House Chief of Staff Ron Klain retweeted MSNBC anchor Stephanie Ruhle's tweet that stated, "OSHA doing this vaxx mandate as an emergency workplace safety rule *is the ultimate work-around for the Federal govt to require vaccinations.*" *See, e.g.*, Pet'rs Burnett Specialists, Choice Staffing, LLC, and Staff Force Inc.'s Reply Brief at 4 (emphasis added).

vaccine mandate. The vehicle it landed on was an OSHA ETS. The statute empowering OSHA allows OSHA to bypass typical notice-and-comment proceedings for six months by providing "for an emergency temporary standard to take immediate effect upon publication in the Federal Register" if it "determines (A) that employees are exposed to grave danger from exposure to substances or agents determined to be toxic or physically harmful or from new hazards, and (B) that such emergency standard is necessary to protect employees from such danger." 29 U.S.C. § 655(c)(1).

As the name suggests, *emergency* temporary standards "are an 'unusual response' to 'exceptional circumstances.'" *Int'l Chem. Workers*, 830 F.2d at 371 (quoting *Pub. Citizen Health Rsch. Grp. v. Auchter*, 702 F.2d 1150, 1155 (D.C. Cir. 1983)). Thus, courts have uniformly observed that OSHA's authority to establish emergency temporary standards under § 655(c) "is an 'extraordinary power' that is to be 'delicately exercised' in only certain 'limited situations.'" *Id.* at 370 (quoting *Pub. Citizen*, 702 F.2d at 1155).[14]

But the Mandate at issue here is anything *but* a "delicate[] exercise[]" of this "extraordinary power." *Cf. Pub. Citizen*, 702 F.2d at 1155. Quite the opposite, rather than a delicately handled scalpel, the Mandate is a one-size-fits-all sledgehammer that makes hardly any attempt to account for differences in workplaces (and workers) that have more than a little bearing on workers' varying degrees of susceptibility to the supposedly "grave danger" the Mandate purports to address.

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[14] The Agency has thus conceded in the past that "[t]he OSH Act does not authorize OSHA to issue sweeping health standards to address entire classes of known and unknown infectious diseases on an emergency basis without notice and comment." *See* Department of Labor's Resp. to the Emergency Pet. for a Writ of Mandamus at 33–34, *In re AFL-CIO*, No. 20-1158 (D.C. Cir. May 29, 2020) [hereinafter OSHA D.C. Circuit Brief].

2.

Thus, as § 655(c)(1) plainly provides, to be lawfully enacted, an ETS must: (1) address "substances or agents determined to be toxic or physically harmful"—or "new hazards"—in the workplace; (2) show that workers are exposed to such "substances," "agents," or "new hazards" in the workplace; (3) show that said exposure places workers in "grave danger"; and (4) be "necessary" to alleviate employees' exposure to gravely dangerous hazards in the workplace. As we have noted in the past, the precision of this standard makes it a difficult one to meet. *See Fla. Peach Growers*, 489 F.2d at 130 (observing that OSHA's ETS authority "requires determination of danger from exposure to harmful substances, not just a danger of exposure; and, not exposure to just a danger, but to a grave danger; and, not the necessity of just a temporary standard, but that an emergency [temporary] standard is necessary").[15]

(a)

In its brief, Texas makes a compelling argument that § 655(c)(1)'s neighboring phrases "substances or agents" and "toxic or physically harmful" place an airborne virus beyond the purview of an OSHA ETS in the first place. To avoid "giving unintended breadth to the Acts of Congress," courts "rely on the principle of *noscitur a sociis*—a word is known by the company it keeps." *Yates v. United States*, 574 U.S. 528, 543 (2015) (cleaned up). Here, OSHA's attempt to shoehorn an airborne virus that is both widely present in society (and thus not particular to any workplace) and non-life-

[15] In prior litigation, OSHA acknowledged that many "workplaces" covered by a COVID-19 ETS "are not merely workplaces," but are also "stores, restaurants, and other places occupied by workers and the general public alike, in which the measures called for require a broader lens—and at times a broader mandate—than available to OSHA." *See* OSHA D.C. Circuit Brief at 20.

threatening to a vast majority of employees into a neighboring phrase connoting *toxicity* and *poisonousness* is yet another transparent stretch. Other cases involving OSHA (though not ETSs per se) shed further light on the intended meaning of these terms. *See, e.g.*, *UAW v. OSHA*, 938 F.2d 1310, 1314 (D.C. Cir. 1991). *See generally Indus. Union Dep't, AFL-CIO v. Am. Petroleum Inst.*, 448 U.S. 607 (1980). Any argument OSHA may make that COVID-19 is a "new hazard[]" would directly contradict OSHA's prior representation to the D.C. Circuit that "[t]here can be no dispute that COVID-19 is a *recognized* hazard." *See* OSHA D.C. Circuit Brief at 25 (emphasis added).

(b)

A natural first step in enacting a lawful ETS is to show that employees covered by the ETS are in fact *exposed* to the dangerous substances, agents, or hazards at issue—here, COVID-19. *See, e.g.*, *Int'l Chem. Workers*, 830 F.2d at 371 (noting OSHA's stated view "that a finding of 'grave danger' to support an ETS be based upon exposure in actual levels found in the workplace"). As it pertains to the vast majority of private employees covered by the Mandate, however, OSHA fails to meet this threshold burden. In defending the Mandate before this court, the Government credits OSHA with "describ[ing] myriad studies showing workplace [COVID-19] 'clusters' and 'outbreaks' and other significant 'evidence of workplace transmission' and 'exposure.'" *See* Resp'ts' Opp'n to Emergency Stay Mot. at 8. But this misses the mark, as OSHA is required to make findings of exposure—or at least the presence of COVID-19—in *all* covered workplaces.

Of course, OSHA cannot possibly show that every workplace covered by the Mandate currently has COVID-positive employees, or that every industry covered by the Mandate has had or will have "outbreaks." As

discussed below, this kind of overbreadth plagues the Mandate generally. *See infra* subsection II.A.2.d.

(c)

Equally problematic, however, is that it remains unclear that COVID-19—however tragic and devastating the pandemic has been—poses the kind of grave danger § 655(c)(1) contemplates. *See, e.g.*, *Int'l Chem. Workers*, 830 F.2d at 371 (noting that OSHA itself once concluded "that to be a 'grave danger,' it is not sufficient that a chemical, such as cadmium, can cause *cancer* or *kidney damage* at a high level of exposure" (emphasis added)). For starters, the Mandate itself concedes that the effects of COVID-19 may range from "mild" to "critical." As important, however, the status of the spread of the virus has varied since the President announced the general parameters of the Mandate in September. (And of course, this all assumes that COVID-19 poses any significant danger to workers to begin with; for the more than *seventy-eight* percent[16] of Americans aged 12 and older either fully or partially inoculated against it, the virus poses—the Administration assures us—little risk at all.) *See, e.g.*, 86 Fed. Reg. 61,402, 61,402–03 ("COVID-19 vaccines authorized or approved by the [FDA] effectively protect vaccinated individuals against severe illness and death from COVID-19.").

The Administration's prior statements in this regard further belie the notion that COVID-19 poses the kind of emergency that allows OSHA to take the extreme measure of an ETS. In reviewing agency pronouncements, courts need not turn a blind eye to the statements of those issuing such pronouncements. *See, e.g.*, *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009). In fact, courts have an affirmative duty *not* to do so. It is thus

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[16] *See* CDC, COVID DATA TRACKER, https://covid.cdc.gov/covid-data-tracker/#datatracker-home.

critical to note that the Mandate makes no serious attempt to explain why OSHA and the President himself[17] were against vaccine mandates before they were for one here. *See, e.g.*, Occupational Exposure to Bloodborne Pathogens, 54 Fed. Reg. 23,042, 23,045 (May 30, 1989) ("Health in general is an intensely personal matter. . . . OSHA prefers to encourage rather than try to force by governmental coercion, employee cooperation in [a] vaccination program."); Letter from Loren Sweatt, Principal Deputy Assistant Sec'y, OSHA, to Richard L. Trumka, President, AFL-CIO at 3 (May 29, 2020) [hereinafter Sweatt Letter] (acknowledging as a general matter that it "would not be necessary for OSHA to issue an ETS to protect workers from infectious diseases" because "OSHA lacks evidence to conclude that all infectious diseases to which employees may be exposed at a workplace constitute a 'grave danger' for which an ETS is an appropriate remedy"). Because it is generally "arbitrary or capricious" to "depart from a prior policy *sub silentio*," agencies must typically provide a "detailed explanation" for contradicting a prior policy, particularly when the "prior policy has engendered serious reliance interests." *FCC v. Fox*, 556 U.S. at 515. OSHA's reversal here strains credulity, as does its pretextual basis.[18] Such shortcomings are all hallmarks of unlawful agency actions.

To be sure, "OSHA's assessment of . . . scientifically complex [facts] and its balancing of the competing policies that underlie the decision whether to issue an ETS . . . are entitled to great deference," but this is not a case

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[17] In December of 2020, the President was quoted as saying, "No I don't think [vaccines] should be mandatory." *See, e.g.*, Jacob Jarvis, *Fact Check: Did Joe Biden Reject Idea of Mandatory Vaccines in December 2020*, NEWSWEEK (Sept. 10, 2021), https://www.newsweek.com/fact-check-joe-biden-no-vaccines-mandatory-december-2020-1627774.

[18] *See supra* note 13 (Klain endorsement of the term "work-around").

where any amount of deference would make a bit of difference. *Int'l Chem. Workers*, 830 F.2d at 371.

(d)

We next consider the necessity of the Mandate. The Mandate is staggeringly overbroad. Applying to 2 out of 3 private-sector employees in America, in workplaces as diverse as the country itself, the Mandate fails to consider what is perhaps the most salient fact of all: the ongoing threat of COVID-19 is more dangerous to *some* employees than to *other* employees. All else equal, a 28 year-old trucker spending the bulk of his workday in the solitude of his cab is simply less vulnerable to COVID-19 than a 62 year-old prison janitor. Likewise, a naturally immune unvaccinated worker is presumably at less risk than an unvaccinated worker who has never had the virus. The list goes on, but one constant remains—the Mandate fails almost completely to address, or even respond to, much of this reality and common sense.

Moreover, earlier in the pandemic, the Agency recognized the practical impossibility of tailoring an effective ETS in response to COVID-19. *See* OSHA D.C. Circuit Brief at 16, 17, 21, 26 ("Based on substantial evidence, OSHA determined that an ETS is not necessary both because there are existing OSHA and non-OSHA standards that address COVID-19 and because an ETS would actually be counterproductive. . . . To address all employers and to do so with the requisite dispatch, an ETS would at best be an enshrinement of these general and universally known measures that are already enforceable through existing OSHA tools that require employers to assess and address extant hazards. OSHA's time and resources are better spent issuing industry-specific guidance that adds real substance and permits flexibility as we learn more about this virus. Given that we learn more about COVID-19 every day, setting rules in stone through an ETS (and later a

permanent rule) may undermine worker protection by permanently mandating precautions that later prove to be inefficacious. . . . [A]n ETS could only enshrine broad legal standards that are already in place or direct employers to develop COVID-19 response plans specific to their businesses, something employers are already doing. Such a step would be superfluous at best and could be counterproductive to ongoing state, local, and private efforts. . . . Additionally, employers may choose any effective method to abate a recognized hazard under the general duty clause. Contrary to AFL-CIO's argument, this flexibility is likely to improve worker safety, because employers must choose a means of abatement that eliminates the hazard or materially reduces it to the extent feasible."). OSHA itself admitted that "an ETS once issued could very well become ineffective or counterproductive, as it may be informed by incomplete or ultimately inaccurate information." *Id.* at 30, 32–33 (acknowledging further that "[a]dequate safeguards for workers could differ substantially based on geographic location, as the pandemic has had dramatically different impacts on different parts of the country. State and local requirements and guidance on COVID-19 are thus critical to employers in determining how to best protect workers, and OSHA must retain flexibility to adapt its advice regarding incorporation of such local guidance, where appropriate. . . . [A]n ETS meant to broadly cover all workers with potential exposure to COVID-19—effectively *all* workers across the country—would have to be written at such a general level that it would risk providing very little assistance at all").

In light of this immense complexity, one might naturally ask the Agency—is this situation truly amenable to a one-size-fits-all Mandate? The likely answer may be why OSHA has in the past "determined that the best approach for responding to the pandemic is to enforce the existing OSH Act requirements that address infectious disease hazards, while also issuing detailed, industry-specific guidance," which is generally "more effective

than promulgating a rigid set of requirements for all employers in all industries based on limited information." *See* Sweatt Letter at 2. In sum, as OSHA itself has previously acknowledged, an ETS appears to be a "poorly-suited approach for protecting workers against [COVID-19] because no standard that covers all of the Nation's workers would protect all those workers equally." *See id.* at 9.

At the same time, the Mandate is also *underinclusive*. The most vulnerable worker in America draws no protection from the Mandate if his company employs 99 workers or fewer. The reason why? Because, as even OSHA admits, companies of 100 or more employers will be better able to administer (and sustain) the Mandate. *See* 86 Fed. Reg. 61,402, 61,403 ("OSHA seeks information about the ability of employers with fewer than 100 employees to implement COVID-19 vaccination and/or testing programs."). That may be true. But this kind of thinking belies the premise that any of this is truly an *emergency*. Indeed, underinclusiveness of this sort is often regarded as a telltale sign that the government's interest in enacting a liberty-restraining pronouncement is not in fact "compelling." *Cf. Church of the Lukumi Babalu Aye, Inc. v. City of Hialeah*, 508 U.S. 520, 542–46 (1993) (city's ban on religious animal sacrifice but corresponding allowance of other activities similarly endangering public health belied its purportedly "compelling" interest in safe animal disposal practices). The underinclusive nature of the Mandate implies that the Mandate's true purpose is not to enhance workplace safety, but instead to ramp up vaccine uptake by any means necessary.[19]

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[19] The Mandate is also underinclusive in the solutions it proposes. Indeed, even in its fullest force, the Mandate cannot prevent vaccinated employees from spreading the virus in the workplace, or prevent unvaccinated employees from spreading the virus in between weekly tests.

(e)

If the deficiencies we've already covered aren't enough, other miscellaneous considerations seal the Mandate's fate. For one, "[t]he Agency cannot use its ETS powers as a stop-gap measure," *Asbestos Info.*, 727 F.2d at 422, but concedes that that is precisely what the Mandate is intended to do here. *See* 86 Fed. Reg. 61,402, 61,434–35 (admitting that "[c]rafting a multi-layered standard that is comprehensive and feasible for all covered work settings, including mixed settings of vaccinated and unvaccinated workers, is an extraordinarily challenging and complicated undertaking, yet the grave danger that COVID-19 poses to unvaccinated workers obliges the agency to act as quickly as possible"). For another, courts have consistently recognized that the "protection afforded to workers [by an ETS] should outweigh the economic consequences to the regulated industry," *Asbestos Info.*, 727 F.2d at 423, but for all the reasons we've previously noted, the Mandate flunks a cost-benefit analysis here.

(f)

It lastly bears noting that the Mandate raises serious constitutional concerns that either make it more likely that the petitioners will succeed on the merits, or at least counsel against adopting OSHA's broad reading of § 655(c) as a matter of statutory interpretation.

First, the Mandate likely exceeds the federal government's authority under the Commerce Clause because it regulates noneconomic inactivity that falls squarely within the States' police power. A person's choice to remain unvaccinated and forgo regular testing is noneconomic inactivity. *Cf. NFIB v. Sebelius*, 567 U.S. 519, 522 (2012) (Roberts, C.J., concurring); *see also id.* at 652–53 (Scalia, J., dissenting). And to mandate that a person receive a vaccine or undergo testing falls squarely within the States' police power. *Zucht v. King*, 260 U.S. 174, 176 (1922) (noting that precedent had long "settled that

it is within the police power of a state to provide for compulsory vaccination"); *Jacobson v. Massachusetts*, 197 U.S. 11, 25–26 (1905) (similar). The Mandate, however, commandeers U.S. employers to compel millions of employees to receive a COVID-19 vaccine or bear the burden of weekly testing. 86 Fed. Reg. 61,402, 61,407, 61,437, 61,552. The Commerce Clause power may be expansive, but it does not grant Congress the power to regulate noneconomic inactivity traditionally within the States' police power. *See Sebelius*, 567 U.S. at 554 (Roberts, C.J., concurring) ("People, for reasons of their own, often fail to do things that would be good for them or good for society. Those failures—joined with the similar failures of others—can readily have a substantial effect on interstate commerce. Under the Government's logic, that authorizes Congress to use its commerce power to compel citizens to act as the Government would have them act."); *see also Bond v. United States*, 572 U.S. 844, 854 (2014) ("The States have broad authority to enact legislation for the public good—what we have often called a 'police power.' . . . The Federal Government, by contrast, has no such authority. . . ." (citations omitted)). Indeed, the courts "*always* have rejected readings of the Commerce Clause . . . that would permit Congress to exercise a police power." *United States v. Lopez*, 514 U.S. 549, 584 (1995) (Thomas, J., concurring). In sum, the Mandate would far exceed current constitutional authority.

Second, concerns over separation of powers principles cast doubt over the Mandate's assertion of virtually unlimited power to control individual conduct under the guise of a workplace regulation. As Judge Duncan points out, the major questions doctrine confirms that the Mandate exceeds the bounds of OSHA's statutory authority. Congress must "speak clearly if it wishes to assign to an agency decisions of vast economic and political significance." *Util. Air Regul. Grp. v. EPA*, 573 U.S. 302, 324 (2014) (cleaned up). The Mandate derives its authority from an old statute employed in a

novel manner,[20] imposes nearly $3 billion in compliance costs, involves broad medical considerations that lie outside of OSHA's core competencies, and purports to definitively resolve one of today's most hotly debated political issues. *Cf. MCI Telecomms. Corp. v. AT&T*, 512 U.S. 218, 231 (1994) (declining to hold that the FCC could eliminate telecommunications rate-filing requirements); *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 159–60 (2000) (declining to hold that the FDA could regulate cigarettes); *Gonzales v. Oregon*, 546 U.S. 243, 262 (2006) (declining to allow DOJ to ban physician-assisted suicide). There is no clear expression of congressional intent in § 655(c) to convey OSHA such broad authority, and this court will not infer one. Nor can the Article II executive breathe new power into OSHA's authority—no matter how thin patience wears.

At the very least, even if the statutory language were susceptible to OSHA's broad reading—which it is not—these serious constitutional concerns would counsel this court's rejection of that reading. *Jennings v. Rodriguez*, 138 S. Ct. 830, 836 (2018).

* * *

Accordingly, the petitioners' challenges to the Mandate show a great likelihood of success on the merits, and this fact weighs critically in favor of a stay.

B.

It is clear that a denial of the petitioners' proposed stay would do them irreparable harm. For one, the Mandate threatens to substantially burden the

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[20] Here, it is simply unlikely that Congress assigned authority over such a monumental policy decision to OSHA—hard hats and safety goggles, this is not.

liberty interests[21] of reluctant individual recipients put to a choice between their job(s) and their jab(s). For the individual petitioners, the loss of constitutional freedoms "for even minimal periods of time . . . unquestionably constitutes irreparable injury." *Elrod v. Burns*, 427 U.S. 347, 373 (1976) ("The loss of First Amendment freedoms, for even minimal periods of time, unquestionably constitutes irreparable injury.").

Likewise, the companies seeking a stay in this case will also be irreparably harmed in the absence of a stay, whether by the business and financial effects of a lost or suspended employee, compliance and monitoring costs associated with the Mandate, the diversion of resources necessitated by the Mandate, or by OSHA's plan to impose stiff financial penalties on companies that refuse to punish or test unwilling employees. The Mandate places an immediate and irreversible imprint on all covered employers in America, and "complying with a regulation later held invalid almost *always* produces the irreparable harm of nonrecoverable compliance costs." *See Texas v. EPA*, 829 F.3d 405, 433 (5th Cir. 2016) (quoting *Thunder Basin Coal Co. v. Reich*, 510 U.S. 200, 220–21 (1994) (Scalia, J., concurring in part and in the judgment)).

The States, too, have an interest in seeing their constitutionally reserved police power over public health policy defended from federal overreach.

C.

In contrast, a stay will do *OSHA* no harm whatsoever. Any interest OSHA may claim in enforcing an unlawful (and likely unconstitutional) ETS is illegitimate. Moreover, any abstract "harm" a stay might cause the Agency

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[21] Not to mention the free religious exercise of certain employees. *See* U.S. CONST. amend. I; *cf. Holt v. Hobbs*, 574 U.S. 352, 361 (2015).

pales in comparison and importance to the harms the absence of a stay threatens to cause countless individuals and companies.

D.

For similar reasons, a stay is firmly in the public interest. From economic uncertainty to workplace strife, the mere specter of the Mandate has contributed to untold economic upheaval in recent months. Of course, the principles at stake when it comes to the Mandate are not reducible to dollars and cents. The public interest is also served by maintaining our constitutional structure and maintaining the liberty of individuals to make intensely personal decisions according to their own convictions—even, or perhaps *particularly*, when those decisions frustrate government officials.

* * *

The Constitution vests a limited legislative power in Congress. For more than a century, Congress has routinely used this power to delegate policymaking specifics and technical details to executive agencies charged with effectuating policy principles Congress lays down. In the mine run of cases—a transportation department regulating trucking on an interstate highway, or an aviation agency regulating an airplane lavatory—this is generally well and good. But health agencies do not make housing policy, and occupational safety administrations do not make health policy. *Cf. Ala. Ass'n of Realtors*, 141 S. Ct. at 2488–90. In seeking to do so here, OSHA runs afoul of the statute from which it draws its power and, likely, violates the constitutional structure that safeguards our collective liberty.

For these reasons, the petitioners' motion for a stay pending review is GRANTED. Enforcement of the Occupational Safety and Health Administration's "COVID-19 Vaccination and Testing; Emergency

Temporary Standard"[22] remains STAYED pending adequate judicial review of the petitioners' underlying motions for a permanent injunction.[23]

In addition, IT IS FURTHER ORDERED that OSHA take no steps to implement or enforce the Mandate until further court order.

[22] 86 Fed. Reg. 61,402 (Nov. 5, 2021) (to be codified at 29 C.F.R. pts. 1910, 1915, 1917, 1918, 1926, and 1928).

[23] The Clerk of Court shall ensure that this order applies with equal force to all related motions consolidated into this case in accordance with the court's November 6, 2021 order.

STUART KYLE DUNCAN, *Circuit Judge*, concurring:

In addition to the many reasons ably identified by Judge Engelhardt's opinion, I underscore one reason why these challenges to OSHA's unprecedented mandate are virtually certain to succeed.

Courts "expect Congress to speak clearly when authorizing an agency to exercise powers of 'vast economic and political significance.'" *Ala. Ass'n of Realtors v. Dep't of Health & Human Servs.*, 141 S. Ct. 2485, 2489 (2021) (quoting *Utility Air Regul. Grp. v. EPA*, 573 U.S. 302, 324 (2014)). OSHA's rule reaches "two-thirds of all private-sector workers in the nation." 86 Fed. Reg. 61,402, 61,403 (Nov. 5, 2021). It compels covered employers to (1) make employees get vaccinated or get weekly tests at their expense and wear masks; (2) "remove" non-complying employees; (3) pay per-violation fines; and (4) keep records of employee vaccination or testing status. 86 Fed. Reg. at 61,402–03, 61,551–54; 29 U.S.C. § 666. OHSA invokes no statute expressly authorizing the rule. Instead, OSHA issued it under an emergency provision addressing workplace "substances," "agents," or "hazards" that it has used only ten times in the last 50 years and never to mandate vaccines. 86 Fed. Reg. at 61,403; *see* 29 U.S.C. § 655(c)(1).

Whether Congress could enact such a sweeping mandate under its interstate commerce power would pose a hard question. *See NFIB v. Sebelius*, 567 U.S. 519, 549–61 (2012). Whether OSHA can do so does not.

I concur in granting a stay.

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EXHIBIT "AA-23"

Vaccine mandate for public employees in Slovenia blocked

RTE News

Thursday, 30 Sep 2021 18:15

Slovenia's Constitutional Court has blocked a government plan to make coronavirus vaccines mandatory for public employees, hours before it was due to come into force.

The government had planned to require around 31,000 people including civil servants, policemen and soldiers to either be vaccinated or to have recovered from Covid-19 in order to continue working.

The mandate was due to come into effect tomorrow, but in response to a complaint against the measure brought by the police officers' union the court decided to block its implementation.

In its decision the court said that "despite the very serious epidemic situation", it considered that "implementing the potentially unconstitutional (measure) ... would have worse consequences than delaying implementation".

The block on the mandate will remain in place until the court rules definitively on the complaint brought by the police union, but no date has been fixed for this.

Public Administration Minister BostjanKoritnik told reporters that he "regrets the court's decision but will absolutely carry it out".

He insisted the vaccine mandate was aimed at "ensuring safer working conditions in the premises under the government's responsibility".

Under the measure employees had faced losing their jobs if they rejected vaccination and their position did not allow them to work from home.

Slovenia has vaccinated just 45% of its two million people, one of the lowest levels in the European Union.

Rising case numbers have pushed officials to introduce new measures, including a form of health pass that must be shown in workplaces and shops.

Health authorities say those measures have contributed to a steep increase in vaccinations.

An increasing number of countries have taken steps to boost their vaccination rates, including France and Italy where health workers have to be inoculated.

A Covid-19 outbreak within Disney's stage show Aladdin prompted an 11th-hour cancellation of last night's performance in New York.

The production had opened just 24 hours earlier, joining the return of Broadway's biggest musicals from a pandemic-induced hiatus.

In a notice posted on Twitter shortly before the curtain was due to go up, producers said testing protocols had detected an unspecified number of "breakthrough" infections among vaccinated members of the Aladdin company at The New York Amsterdam Theatre.

"Because the wellness and safety of our guests, cast, and crew are our top priority, tonight's performance, Wednesday, 29 September, is cancelled," the tweet said, adding that tickets would be refunded at their points of purchase.

It added that the status of future performances of Aladdin, based on Disney's 1992 animated hit film, would be announced today.

A number of Broadway's leading shows, among them Hamilton and The Lion King, reopened earlier this month, 18 months after the Covid-19 crisis forced an unprecedented shutdown of New York City's theatre community. Aladdin had just joined the fray on Tuesday.

Under health and safety rules agreed between theatre unions and producers, cast and crew members for shows are required to provide proof of vaccination or a valid exemption in order to work, and must be tested for the coronavirus every three days.

According to the New York Times, yesterday's cancellation was the first and only one confirmed for a reopened Broadway production since Springsteen on Broadway kicked off the industry's return in June.

1108

Covid-19 cases in Australia's Victoria state have surged to record levels despite Melbourne, the state capital, being stuck in a hard lockdown for nearly two months as officials race to vaccinate the population before easing restrictions.

A total of 1,438 new infections were reported, the majority in Melbourne, eclipsing the previous daily high of 950. Five new deaths were also recorded in the state.

Australia's largest cities, Sydney and Melbourne, and the capital Canberra are in a weeks-long lockdown to combat a third wave of infections fuelled by the fast-moving Delta variant.

Authorities have ditched a Covid-zero strategy and are looking at higher vaccination rates as their exit strategy from lockdowns.

The record cases in Victoria come as the federal government decided to phase out its emergency financial support for businesses impacted by the lockdowns, in line with its plan to end support to virus-impacted employees.

Treasurer Josh Frydenberg said the temporary payments will stop once 80% of the adult population in states and territories becomes fully vaccinated.

But Victoria's businesses will receive a fresh €1 billion support from the federal government through the next six weeks at which point the state should hit that dosage target, from around 50% now.

"We can't eliminate the virus, we need to learn to live with it in a Covid-safe way", Mr Frydenberg said in a statement.

Australian Prime Minister Scott Morrison has been pressing all states and territories to begin living with the virus once full inoculations reach 70%-80% but Queensland and Western Australia, largely Covid-free, flagged they may delay their reopening.

Despite the latest Delta outbreaks, total cases in Australia stand at around 104,000 and deaths at 1,283, well below other comparable nations.

Egypt has received 1.6 million doses of the Covid-19 vaccine produced by Pfizer as a gift from the United States as part of the COVAX initiative, the first batch of a total of five million doses, the country's health ministry said in a statement.

Egypt has been quickly accumulating a stock of vaccines for its population of over 100 million, having already received vaccines produced by AstraZeneca, Sinopharm, Sputnik and Johnson & Johnson, as well as Sinovac, which it is also producing locally.

Germany supplied a total of 2.3 million doses to Egypt over two days last week, the Egyptian health ministry said.

The COVAX facility, backed by the World Health Organization and the Global Alliance for Vaccines and Immunization (GAVI), has delivered over 301 million doses to 142 countries.

The Beijing Winter Olympics in February next year will be held without overseas spectators and athletes must be fully vaccinated against coronavirus or face 21 days' quarantine, the International Olympic Committee said.

The measures, which do allow spectators who are living in mainland China, were revealed with the Games just four months away and after the Tokyo 2020 Olympics similarly juggled with how to go ahead safely during the pandemic.

The Tokyo Games, which were postponed by a year because of the health crisis, mostly took place without any spectators to prevent infections.

Another difference from Tokyo will be that all participants must be vaccinated or will need to do a 21-day quarantine on arrival in the Chinese capital.

Athletes who can provide a "justified medical exemption" will have their cases considered.

All attendees will enter a strict "bubble" as soon as they land that covers Games-related areas and stadiums as well as accommodation, transport, catering and the opening and closing ceremonies.

1110

LINK: https://www.rte.ie/news/world/2021/0930/1249811-global-virus-latest/

(TRUE COPY)

EXHIBIT "AA-24"

Federal appeals court blocks NYC teacher vaccine mandate

The Hill

BY JORDAN WILLIAMS - 09/25/21 03:53 PM EDT

A federal appeals court blocked New York City's coronavirus vaccine mandate late Friday evening, dealing a blow to the city days before the mandate goes into effect.

The 2nd Circuit Court of Appeals granted an expedited injunction on Friday blocking the city from mandating that all public school employees submit proof of their first coronavirus vaccine dose by Monday.

The court referred the case to a three-judge panel on an expedited basis.

New York City Mayor Bill de Blasio (D) said in late August that all of the city's public school teachers and staff would need to have their first dose by Sept. 27. There was no alternative option for regular testing.

A group of New York City public school employees sued earlier this month to block the mandate, arguing that their rights to due process and equal protection were violated. The complaint specifically alleged that the order violated their right to pursue their profession.

On Thursday, U.S. District Judge Brian Cogan upheld the mandate, prompting the plaintiffs to quickly appeal the decision.

About 82 percent of the city's roughly 149,000 public school employees are vaccinated, the agency told The Hill, including 88 percent of roughly 78,000 teachers and 95 percent of roughly 1,600 principals.

Danielle Filson, press secretary for the New York City Department of Education [DOE], said in a statement to The Hill that the agency is "confident our vaccine mandate will continue to be upheld once all the facts have been presented, because that is the level of protection our students and staff deserve."

"Over 82 percent of DOE employees have been vaccinated and we continue to urge all employees to get their shot by September 27," Filson said.

Prashant Bhushan

(TRUE COPY)

1112

EXHIBIT "AA - 25"

BREAKING: Judge grants temporary injunction preventing vaccine mandates for city employees

By WCJB Staff

Published: Sep. 23, 2021 at 12:17 AM GMT+5:30

GAINESVILLE, Fla. (WCJB) - A Circuit Court judge has issued a temporary injunction preventing the City of Gainesville from requiring a COVID-19 vaccine for employees or terminating employees that do not get the vaccine.

Judge Monica Brasington of the Eighth Judicial Circuit Court issued the ruling.

In her ruling, Judge Brasington stated the city did not present any evidence that the vaccine mandate serves "a compelling interest through the least restrictive means," and that the burden is on the city to prove the mandate is in the best interest of the public.

This injunction is a temporary measure until the courts are able to reach a decision on the vaccine mandate enacted by the city.

Attorney Jeff Childers is representing 200 city employees in a lawsuit who are in opposition to the mandate.

Governor Ron DeSantis previously announced a $5000 fine for any government entity requiring vaccines for its employees.

A date has not been set for the next court hearing about the mandate.

LINK: https://www.wcjb.com/2021/09/22/breaking-judge-grants-temporary-injunction-preventing-vaccine-mandates-city-employees/

(TRUE COPY)

1113

EXHIBIT "AA-26"

GOVERNOR GREG ABBOTT

October 11, 2021

FILED IN THE OFFICE OF THE
SECRETARY OF STATE
4:30PM O'CLOCK
OCT 11 2021
Secretary of State

Mr. Joe A. Esparza
Deputy Secretary of State
State Capitol Room 1E.8
Austin, Texas 78701

Dear Deputy Secretary Esparza:

Pursuant to his powers as Governor of the State of Texas, Greg Abbott has issued the following:

> Executive Order No. GA-40 relating to prohibiting vaccine mandates, subject to legislative action.

The original executive order is attached to this letter of transmittal.

Respectfully submitted,

Gregory S. Davidson
Executive Clerk to the Governor

GSD/gsd

Attachment

1114

Executive Order

BY THE
GOVERNOR OF THE STATE OF TEXAS

Executive Department
Austin, Texas
October 11, 2021

EXECUTIVE ORDER
GA 40

Relating to prohibiting vaccine mandates, subject to legislative action.

WHEREAS, I, Greg Abbott, Governor of Texas, issued a disaster proclamation on March 13, 2020, certifying under Section 418.014 of the Texas Government Code that the novel coronavirus (COVID-19) poses an imminent threat of disaster for all Texas counties; and

WHEREAS, in each subsequent month effective through today, I have renewed the COVID-19 disaster declaration for all Texas counties; and

WHEREAS, I have issued a series of executive orders aimed at protecting the health and safety of Texans, ensuring uniformity throughout Texas, and achieving the least restrictive means of combatting the evolving threat to public health; and

WHEREAS, COVID-19 vaccines are strongly encouraged for those eligible to receive one, but must always be voluntary for Texans; and

WHEREAS, I issued Executive Orders GA-35, GA-38, and GA-39 to prohibit governmental entities and certain others from imposing COVID-19 vaccine mandates or requiring vaccine passports; and

WHEREAS, in yet another instance of federal overreach, the Biden Administration is now bullying many private entities into imposing COVID-19 vaccine mandates, causing workforce disruptions that threaten Texas's continued recovery from the COVID-19 disaster; and

WHEREAS, countless Texans fear losing their livelihoods because they object to receiving a COVID-19 vaccination for reasons of personal conscience, based on a religious belief, or for medical reasons, including prior recovery from COVID-19; and

WHEREAS, through Chapter 161 of the Texas Health and Safety Code, as well as other laws including Chapters 38 and 51 of the Texas Education Code, the legislature has established its primary role over immunizations, and all immunization laws and regulations in Texas stem from the laws established by the legislature; and

WHEREAS, the legislature has taken care to provide exemptions that allow people to opt out of being forced to take a vaccine for reasons of conscience or medical reasons; and

WHEREAS, I am adding this issue to the agenda for the Third Called Session of the legislature that is currently convened so that the legislature has the opportunity to consider this issue through legislation; and

WHEREAS, I will rescind this executive order upon the effective date of such legislation;

FILED IN THE OFFICE OF THE
SECRETARY OF STATE
4:30PM O'CLOCK

OCT 11 2021

1115

NOW, THEREFORE, I, Greg Abbott, Governor of Texas, by virtue of the power and authority vested in me by the Constitution and laws of the State of Texas, do hereby order the following on a statewide basis effective immediately:

1. No entity in Texas can compel receipt of a COVID-19 vaccine by any individual, including an employee or a consumer, who objects to such vaccination for any reason of personal conscience, based on a religious belief, or for medical reasons, including prior recovery from COVID-19. I hereby suspend all relevant statutes to the extent necessary to enforce this prohibition.

2. The maximum fine allowed under Section 418.173 of the Texas Government Code and the State's emergency management plan shall apply to any "failure to comply with" this executive order. Confinement in jail is not an available penalty for violating this executive order.

3. This executive order shall supersede any conflicting order issued by local officials in response to the COVID-19 disaster. Pursuant to Section 418.016(a) of the Texas Government Code, I hereby suspend Sections 418.1015(b) and 418.108 of the Texas Government Code, Chapter 81, Subchapter E of the Texas Health and Safety Code, and any other relevant statutes, to the extent necessary to ensure that local officials do not impose restrictions in response to the COVID-19 disaster that are inconsistent with this executive order.

This executive order does not supersede Executive Orders GA-13, GA-37, GA-38, or GA-39. This executive order shall remain in effect and in full force unless it is modified, amended, rescinded, or superseded by the governor. This executive order may also be amended by proclamation of the governor.

Given under my hand this the 11th day of October, 2021.

Greg Abbott

GREG ABBOTT
Governor

ATTESTED BY:

JOE A. ESPARZA
Deputy Secretary of State

FILED IN THE OFFICE OF THE SECRETARY OF STATE
4:30pm O'CLOCK
OCT 11 2021

Prashant Burnham
(TRUE COPY)

1116

EXHIBIT "AA-27"

Covid passport policy lacks scientific evidence base

UK Parliament

9 September 2021

The Public Administration and Constitutional Affairs Committee publishes the Government's response to the Committee's report on Covid-status certification released on 12 June.

Covid passports are being introduced for entry to some venues, including nightclubs and live sporting events, to control the spread of the virus according to the Government. However, new analysis and a lack of evidence provided by the Government in its response to the Committee's report casts doubt on whether this will work in practice.

Citing the diminishing benefits of a certification system as more and more people get vaccinated, the Committee's report demanded that the Government provide scientific evidence backing-up its claims that requiring Covid passports was necessary to reopening the economy and society if it pressed ahead with plans to implement them. Doing so through the publication of the public health case, cost-benefit analyses, and modelling of the potential impacts would be essential to public understanding and acceptance of the system, the report said.

The Government failed to give any such evidence in its response.

Added to this, the latest analysis by Public Health England (PHE) found that although being fully vaccinated protects against infection and severe symptoms, it unlikely to do much to stop the spread of the virus if people become infected. Jabbed and unjabbed individuals carry similar amounts of the virus. Researchers call this having a similar viral load.

Concerns over viral load of the Delta variant appeared in Sage meeting minutes from 22 July. Sage, the Government's scientific advisory panel, warned that there is 'limited vaccine effect against onward transmission' of the variant. Given that this meeting was held before the Government responded to the Committee's report, the Committee has severe concerns about the way in which this policy has been developed and kept under consideration.

Chair's comments

Reacting to the Government's response, Committee Chair William Wragg said,

"We have often heard throughout the pandemic that the Government will follow the science, but when afforded the opportunity to provide it on Covid passports, it has failed to do so. All we have is a flimsy claim that there is a public health case, but without any foundation for the claim to stand on."

"With recent analysis suggesting that vaccinated people carry as much of the virus as the unvaccinated into any setting, the disappointing lack of any scientific basis for the Government's decision to go ahead could reasonably lead people to conclude that there is in fact no such basis. If the real goal is to drive vaccine uptake, then it is a deeply cynical approach that will be counterproductive."

1117

"Following through on such a costly, discriminatory and, potentially, ineffective policy will have consequences for trust in and acceptance of the Government's measures to tackle the pandemic. It's surely either time to prove how this'll work or to put an end to it."

LINK: https://committees.parliament.uk/committee/327/public-administration-and-constitutional-affairs-committee/news/157355/covid-passport-policy-lacks-scientific-evidence-base/

(TRUE COPY)

1118

EXHIBIT "AA-26"

Galicia courts overturn regional government requirement for Covid passports in bars and restaurants

Spanish News Today

Published on: 12:08:2021

Galicia courts overturn regional government requirement for Covid passports in bars and restaurants Covid certificates are no longer required for entry into hostelries and nightlife venues in Galicia as the regional government falls foul of the courts for the first time. The High Court in the north-western Spanish region of Galicia has overturned regional government measures to make Covid passports obligatory for entry into bars, restaurants and nightlife venues, renewing the debate over the uses for which the health and vaccination certificates should be used.

The Spanish government has already resisted pressure to introduce such measures on the grounds that this is not the purpose for which the EU passport scheme was devised, and instead prioritizes vaccination as the key strategy in combating the coronavirus pandemic. The reason given by the court for overturning the requirement in Galicia, though, is that no approval was ever given by the court in the first place, and that the regulation therefore lacks validity.

It seems that the Galicia government only requested approval for other measures presented on July 21, but not for the Order issued on July 22 in which the obligation to present Covid passports was contained. This "anomaly" effectively nullifies the second Order, according to the ruling. Since then various groups have expressed their opposition to policy, including Lugo Monumental in the city of Lugo and the hostelries association of Santiago de Compostela.

It had been the regional government's intention to drop the requirement in any case on August 14 in both Santiago and Orense due to decreasing Covid incidence rates, but the measure was to be maintained in the cities of A Coruña, Ferrol, Lugo, Pontevedra and Vigo as well as other municipalities. This will now no longer be possible as the regional government has fallen foul of the High Court for the first time in its management of the pandemic in Galicia.

LINK: https://spanishnewstoday.com/galicia-courts-overturn-regional-government-requirement-for-covid-passports-in-bars-and-restaurants_1631248-a.html

940

(TRUE COPY)

1119

EXHIBIT "AA-29"

Andalusian justice rejects the requirement of the covid certificate to enter the nightclubs

El Pais

07 AUG 2021 - 22:17 CEST

The Contentious-Administrative Chamber of the TSJA, based in Granada, in the wake of the high courts of the Canary Islands and Cantabria, has rejected the obligation to present the covid certificate or a negative antigen test to enter nightlife venues that the Junta de Andalucía had proposed last Monday. The magistrates understand that the measure affects the right to privacy and non-discrimination and that it does not meet the criteria of suitability or necessity.

The Chamber considers that this requirement could affect the right to privacy "insofar as it implies the need to show data related to health, considered, in accordance with European regulations, as sensitive" and with the principle of non-discrimination because "establishes a differentiated treatment for access to such premises, based on the possession or not of the aforementioned certificate "

The magistrates understand, however, that these fundamental rights affected "are not of great importance" because the accreditation of being vaccinated or having passed the disease "does not seem to seriously condition the right to personal privacy" and as there is a greater percentage of the population that is vaccinated, the requirement "affects a much lower percentage of people than could benefit from being already vaccinated." However, the court does understand that the measure would affect the "suitability and necessity" of its application.

In this sense, the TSJA maintains that "it is not an ideal measure to the required degree", because it establishes the compatibility of the requirement of the COVID certificate with that of a PCR test or antigen test. For the judges, if the people who have been vaccinated or have passed the covid, despite having developed immunity may be potential transmitters, "it is not possible to understand how the possible contagion of those who have accessed the premises covered by the presentation of a receipt for the performance of a PCR or an antigen test, which only proves that at the time of its performance they were not carriers of the active virus, but not that they had any immunization against it".

Regarding the need, the magistrates consider that it is not sufficiently proven that "the greatest number of infections of the so-called fifth wave has its origin

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precisely in nightlife venues", an argument similar to that used by businessmen in the sector when on Monday they learned of the Board's intention to apply this measure only to access the interior of their premises. The ruling also warns that the Board has not stipulated an effective term for this requirement, "without knowing what criteria will be followed to render it ineffective or modify it . "

The meaning of this ruling contradicts, in terms of the argument of proportionality, necessity and suitability to the resolutions issued by the same court, although by rooms of Seville, this morning, in which the request for confinement was ratified for eight municipalities of the Andalusian territory, having exceeded 1,000 cases per 100,000 inhabitants.

It is not the first time that the Granada room contradicts the criteria established by the Seville rooms. After the end of the confinement, the same court based in Seville endorsed the perimeter closure for several municipalities of Córdoba and Cádiz, while the magistrates of Granada denied it on two occasions in the case of Montefrío (Granada).

The Junta de Andalucía announced this Monday, after the meeting of the expert committee, that it would impose the measure requiring the covid passport to enter the clubs and that it would come into effect this Thursday. A day later, he backed off and decided to suspend it until the TSJA ruled. For the Andalusian Government, the endorsement of justice was essential to continue with the extension of this measure in other areas such as restoration. The nightlife entrepreneurs themselves were willing to apply this measure, but always in exchange for keeping their hours and lifting restrictions on capacity.

LINK: https://elpais.com/sociedad/2021-08-06/la-justicia-andaluza-rechaza-la-exigencia-del-certificado-covid-para-entrar-en-las-discotecas.html

(TRUE COPY)

1124

EXHIBIT "AA-30"

Denmark ditches vaccine passports, its last remaining Covid restriction

News.au.com

September 10, 2021 - 8:15PM

Offices are buzzing, concerts are full and there are no masks in sights. This country with no restrictions says it is "on the other side of the pandemic"

With no masks in sight, buzzing offices and concerts drawing tens of thousands, Denmark on Friday ditched vaccine passports in nightclubs, ending its last Covid curb.

The vaccine passports were introduced in March 2021 when Copenhagen slowly started easing restrictions.

They were abolished at all venues on September 1, except in nightclubs, where they will be no longer necessary from Friday.

"We are definitely at the forefront in Denmark as we have no restrictions, and we are now on the other side of the pandemic thanks to the vaccination rollout," UlrikOrum-Petersen, a promoter at event organiser Live Nation, told AFP.

On Saturday, a sold-out concert in Copenhagen will welcome 50,000 people, a first in Europe.

Already on September 4, Live Nation organised a first open-air festival, aptly named "Back to Live", which gathered 15,000 people in Copenhagen.

"Being in the crowd, singing like before, it almost made me forget Covid and everything we've been through these past months," said Emilie Bendix, 26, a concert-goer.

Denmark's vaccination campaign has gone swiftly, with 73 per cent of the 5.8 million population fully vaccinated, and 96 per cent of those 65 and older.

"We're aiming for free movement … What will happen now is that the virus will circulate and it will find the ones who are not vaccinated," epidemiologist Lone Simonsen told AFP.

"Now the virus is no longer a societal threat, thanks to the vaccine," said Simonsen, who works at the University of Roskilde.

According to the World Health Organisation, the Scandinavian country has benefited from public compliance with government guidelines and the Covid strategy adopted.

"Like many countries, Denmark has, throughout the pandemic, implemented public health and social measures to reduce transmission. But at the same time it has greatly relied on individuals and communities to comply voluntarily," said Catherine Smallwood, WHO Europe's emergency officer.

With around 500 daily Covid cases and a reproduction rate of 0.7, Danish authorities say they have the virus under control.

Health Minister Magnus Heunicke has however vowed that the government would not hesitate to swiftly reimpose restrictions if necessary.

Authorities insist that the return to normal life must be coupled with strict hygiene measures and the isolation of sick people.

The WHO still considers the global situation critical and has urged caution. "Every country needs to remain vigilant as and when the epidemiological situation changes," Smallwood said.

Denmark has said it will keep a close eye on the number of hospitalisations — just under 130 at the moment — and conduct meticulous sequencing to follow the virus.

A third dose has also been available to risk groups since Thursday. Simonsen said the vaccines have so far provided immunity from variants "but if escape variants (resistant to the vaccine) were to appear, we will have to rethink our strategy." Christian Nedergaard, who owns several restaurants and wine bars in Copenhagen, said that while everyone is happy about the return to normal life, "the situation is still complicated." "The memory of coronavirus will fade very quickly from some people's minds but not for everyone, and for restaurants this period has for sure been a game-changer," he said.

"The industry needs to think about how to become more resilient." Travellers entering Denmark must still present either a vaccine passport or a negative PCR test, and masks are mandatory in airports.

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LINK: https://www.news.com.au/world/europe/denmark-ditches-vaccine-passports-its-last-remaining-covid-restriction/news-story/7a66cd2404693934cc1ddde0671bd970

(TRUE COPY)

1124

EXHIBIT "AA-31"

THE UNITED STATES DEPARTMENT of JUSTICE
JUSTICE NEWS

Department of Justice

Office of Public Affairs

FOR IMMEDIATE RELEASE

Monday, July 2, 2012

GlaxoSmithKline to Plead Guilty and Pay $3 Billion to Resolve Fraud Allegations and Failure to Report Safety Data

Largest Health Care Fraud Settlement in U.S. History

Global health care giant GlaxoSmithKline LLC (GSK) agreed to plead guilty and to pay $3 billion to resolve its criminal and civil liability arising from the company's unlawful promotion of certain prescription drugs, its failure to report certain safety data, and its civil liability for alleged false price reporting practices, the Justice Department announced today. The resolution is the largest health care fraud settlement in U.S. history and the largest payment ever by a drug company.

GSK agreed to plead guilty to a three-count criminal information, including two counts of introducing misbranded drugs, Paxil and Wellbutrin, into interstate commerce and one count of failing to report safety data about the drug Avandia to the Food and Drug Administration (FDA). Under the terms of the plea agreement, GSK will pay a total of $1 billion, including a criminal fine of $956,814,400 and forfeiture in the amount of $43,185,600. The criminal plea agreement also includes certain non-monetary compliance commitments and certifications by GSK's U.S. president and board of directors. GSK's guilty plea and sentence is not final until accepted by the U.S. District Court.

GSK will also pay $2 billion to resolve its civil liabilities with the federal government under the False Claims Act, as well as the states. The civil settlement resolves claims relating to Paxil, Wellbutrin and Avandia, as well as additional drugs, and also resolves pricing fraud allegations.

"Today's multi-billion dollar settlement is unprecedented in both size and scope. It underscores the Administration's firm commitment to protecting the American people and holding accountable those who commit health care fraud," said James M. Cole, Deputy Attorney General. "At every level, we are determined to stop practices that jeopardize patients' health, harm taxpayers, and violate the public trust – and this historic action is a clear warning to any company that chooses to break the law."

"Today's historic settlement is a major milestone in our efforts to stamp out health care fraud," said Bill Corr, Deputy Secretary of the Department of Health and Human Services (HHS). "For a long time, our health care system had been a target for cheaters who thought they could make an easy profit at the expense of public safety, taxpayers, and the millions of Americans who depend on programs like Medicare and Medicaid. But thanks to strong enforcement actions like those we have announced today, that equation is rapidly changing."

This resolution marks the culmination of an extensive investigation by special agents from HHS-OIG, FDA and FBI, along with law enforcement partners across the federal government. Moving forward, GSK will be subject to stringent requirements under its corporate integrity agreement with HHS-OIG; this agreement is designed to increase accountability and transparency and prevent future fraud and abuse. Effective law enforcement partnerships and fraud prevention are hallmarks of the Health Care Fraud Prevention and Enforcement Action Team (HEAT) initiative, which fosters government collaboration to fight fraud.

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Criminal Plea Agreement

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Under the provisions of the Food, Drug and Cosmetic Act, a company in its application to the FDA must specify each intended use of a drug. After the FDA approves the product as safe and effective for a specified use, a company's promotional activities must be limited to the intended uses that FDA approved. In fact, promotion by the manufacturer for other uses – known as "off-label uses" – renders the product "misbranded."

Paxil: In the criminal information, the government alleges that, from April 1998 to August 2003, GSK unlawfully promoted Paxil for treating depression in patients under age 18, even though the FDA has never approved it for pediatric use. The United States alleges that, among other things, GSK participated in preparing, publishing and distributing a misleading medical journal article that misreported that a clinical trial of Paxil demonstrated efficacy in the treatment of depression in patients under age 18, when the study failed to demonstrate efficacy. At the same time, the United States alleges, 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 to an audience of doctors and paid for the meal or spa treatment for the doctors who attended. Since 2004, Paxil, like other antidepressants, included on its label a "black box warning" stating that antidepressants may increase the risk of suicidal thinking and behavior in short-term studies in patients under age 18. GSK agreed to plead guilty to misbranding Paxil in that its labeling was false and misleading regarding the use of Paxil for patients under 18.

Wellbutrin: The United States also alleges that, from January 1999 to December 2003, GSK promoted Wellbutrin, approved at that time only for Major Depressive Disorder, for weight loss, the treatment of sexual dysfunction, substance addictions and Attention Deficit Hyperactivity Disorder, among other off-label uses. The United States contends that GSK paid millions of dollars to doctors to speak at and attend meetings, sometimes at lavish resorts, at which the off-label uses of Wellbutrin were routinely promoted and also used sales representatives, sham advisory boards, and supposedly independent Continuing Medical Education (CME) programs to promote WIlbutrin for these unapproved uses. GSK has agreed to plead guilty to misbranding Wellbutrin in that its labeling did not bear adequate directions for these off-label uses. For the Paxil and Wellbutrin misbranding offenses, GSK has agreed to pay a criminal fine and forfeiture of $757,387,200.

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Avandia: The United States alleges that, between 2001 and 2007, GSK failed to include certain safety data about Avandia, a diabetes drug, in reports to the FDA that are meant to allow the FDA to determine if a drug continues to be safe for its approved indications and to spot drug safety trends. 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.

"This case demonstrates our continuing commitment to ensuring that the messages provided by drug manufacturers to physicians and patients are true and accurate and that decisions as to what drugs are prescribed

to sick patients are based on best medical judgments, not false and misleading claims or improper financial inducements," said Carmen Ortiz, U.S. Attorney for the District of Massachusetts.

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"Patients rely on their physicians to prescribe the drugs they need," said John Walsh, U.S. Attorney for Colorado. "The pharmaceutical industries' drive for profits can distort the information provided to physicians concerning drugs. This case will help to ensure that your physician will make prescribing decisions based on good science and not on misinformation, money or favors provided by the pharmaceutical industry."

Civil Settlement Agreement

As part of this global resolution, GSK has agreed to resolve its civil liability for the following alleged conduct: (1) promoting the drugs Paxil, Wellbutrin, Advair, Lamictal and Zofran for off-label, non-covered uses and paying kickbacks to physicians to prescribe those drugs as well as the drugs Imitrex, Lotronex, Flovent and Valtrex; (2) making false and misleading statements concerning the safety of Avandia; and (3) reporting false best prices and underpaying rebates owed under the Medicaid Drug Rebate Program.

Off-Label Promotion and Kickbacks: The civil settlement resolves claims set forth in a complaint filed by the United States alleging that, in addition to promoting the drugs Paxil and Wellbutrin for unapproved, non-covered uses, GSK also promoted its asthma drug, Advair, for first-line therapy for mild asthma patients even though it was not approvedor medically appropriate under these circumstances. GSK also promoted Advair for chronic obstructive pulmonary disease with misleading claims as to the relevant treatment guidelines. The civil settlement also resolves allegations that GSK promoted Lamictal, an anti-epileptic medication, for off-label, non-covered psychiatric uses, neuropathic pain and pain management. It further resolves allegations that GSK promoted certain forms of Zofran, approved only for post-operative nausea, for the treatment of morning sickness in pregnant women. 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 claims arising from this alleged conduct. The federal share of this settlement is $832 million and the state share is $210 million.

This off-label civil settlement resolves four lawsuits pending in federal court in the District of Massachusetts under the *qui tam*, or whistleblower, provisions of the False Claims Act, which allow private citizens to bring civil actions on behalf of the United States and share in any recovery.

Avandia: In its civil settlement agreement, the United States alleges that GSK promoted Avandia to physicians and other health care providers with false and misleading representations about Avandia's safety profile, causing false claims to be submitted to federal health care programs. Specifically, the United States alleges that GSK stated that Avandia had a positive cholesterol profile despite having no well-controlled studies to support that message. The United States also alleges that the company sponsored programs suggesting cardiovascular benefits from Avandia therapy despite warnings on the FDA-approved label regarding cardiovascular risks. GSK has agreed to pay $657 million relating to false claims arising from misrepresentations about Avandia. The federal share of this settlement is $508 million and the state share is $149 million.

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Price Reporting: GSK is also resolving allegations that, between 1994 and 2003, GSK and its corporate predecessors reported false drug prices, which resulted in GSK's underpaying rebates owed under theMedicaid

Drug Rebate Program. By law, GSK was required to report the lowest, or "best" price that it charged its customers and to pay quarterly rebates to the states based on those reported prices. When drugs are sold to purchasers in contingent arrangements known as "bundles," the discounts offered for the bundled drugs must be reallocated across all products in the bundle proportionate to the dollar value of the units sold. The United States alleges that GSK had bundled sales arrangements that included steep discounts known as "nominal" pricing and yet failed to take such contingent arrangements into account when calculating and reporting its best prices to the Department of Health and Human Services. Had it done so, the effective prices on certain drugs would have been different, and, in some instances, triggered a new, lower best price than what GSK reported. As a result, GSK underpaid rebates due to Medicaid and overcharged certain Public Health Service entities for its drugs, the United States contends. GSK has agreed to pay $300 million to resolve these allegations, including $160,972,069 to the federal government, $118,792,931 to thestates, and $20,235,000 to certain Public Health Service entities who paid inflated prices for the drugs at issue.

Except to the extent that GSK has agreed to plead guilty to the three-count criminal information, the claims settled by these agreements are allegations only, and there has been no determination of liability.

"This landmark settlement demonstrates the Department's commitment to protecting the American public against illegal conduct and fraud by pharmaceutical companies," said Stuart F. Delery, Acting Assistant Attorney General for the Justice Department's Civil Division. "Doctors need truthful, fair, balanced information when deciding whether the benefits of a drug outweigh its safety risks. By the same token, the FDA needs all necessary safety-related information to identify safety trends and to determine whether a drug is safe and effective. Unlawful promotion of drugs for unapproved uses and failing to report adverse drug experiences to the FDA can tip the balance of those important decisions, and the Justice Department will not tolerate attempts by those who seek to corrupt our health care system in this way."

Non-monetary Provisions and Corporate Integrity Agreement

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In addition to the criminal and civil resolutions, GSK has executed a five-year Corporate Integrity Agreement (CIA) with the Department of Health and Human Services, Office of Inspector General (HHS-OIG). The plea agreement and CIA include novel provisions that require that GSK implement and/or maintain major changes to the way it does business, including changing the way its sales force is compensated to remove compensation based on sales goals for territories, one of the driving forces behind much of the conduct at issue in this matter. Under the CIA, GSK is required to change its executive compensation program to permit the company to recoup annual bonuses and long-term incentives from covered executives if they, or their subordinates, engage in significant misconduct. GSK may recoup monies from executives who are current employees and those who have left the company. Among other things, the CIA also requires GSK to implement and maintain transparency in its research practices and publication policies and to follow specified policies in its contracts with various health care payors.

"Our five-year integrity agreement with GlaxoSmithKline requires individual accountability of its board and executives," said Daniel R. Levinson, Inspector General of the U.S. Department of Health and Human Services. "For example, company executives may have to forfeit annual bonuses if they or their subordinates engage in significant misconduct, and sales agents are now being paid based on quality of service rather than sales targets."

"The FDA Office of Criminal Investigations will aggressively pursue pharmaceutical companies that choose to put profits before the public's health," said Deborah M. Autor, Esq., Deputy Commissioner for Global Regulatory Operations and Policy, U.S. Food and Drug Administration. "We will continue to work with the Justice Department and our law enforcement counterparts to target companies that disregard the protections of the drug approval

process by promoting drugs for uses when they have not been proven to be safe and effective for those uses, and that fail to report required drug safety information to the FDA."

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"The record settlement obtained by the multi-agency investigative team shows not only the importance of working with our partners, but also the importance of the public providing their knowledge of suspect schemes to the government," said Kevin Perkins, Acting Executive Assistant Director of the FBI's Criminal, Cyber, Response and Services Branch. "Together, we will continue to bring to justice those engaged in illegal schemes that threaten the safety of prescription drugs and other critical elements of our nation's healthcare system."

" Federal employees deserve health care providers and suppliers, including drug manufacturers, that meet the highest standards of ethical and professional behavior," said Patrick E. McFarland, Inspector General of the U.S. Office of Personnel Management. "Today's settlement reminds the pharmaceutical industry that they must observe those standards and reflects the commitment of Federal law enforcement organizations to pursue improper and illegal conduct that places health care consumers at risk."

"Today's announcement illustrates the efforts of VA OIG and its law enforcement partners in ensuring the integrity of the medical care provided our nation's veterans by the Department of Veterans Affairs," said George J. Opfer, Inspector General of the Department of Veterans Affairs. "The monetary recoveries realized by VA in this settlement will directly benefit VA healthcare programs that provide for veterans' continued care."

"This settlement sends a clear message that taking advantage of federal health care programs has substantial consequences for those who try," said Rafael A. Medina, Special Agent in Charge of the Northeast Area Office of Inspector General for the U.S. Postal Service. "The U.S. Postal Service pays more than one billion dollars a year in workers' compensation benefits and our office is committed to pursuing those individuals or entities whose fraudulent acts continue to unfairly add to that cost."

A Multilateral Effort

The criminal case is being prosecuted by the U.S. Attorney's Office for the District of Massachusetts and the Civil Division's Consumer Protection Branch. The civil settlement was reached by the U.S. Attorney's Office for the District of Massachusetts, the U.S. Attorney's Office for the District of Colorado and the Civil Division's Commercial Litigation Branch. Assistance was provided by the HHS Office of Counsel to the Inspector General, Office of the General Counsel-CMS Division and FDA's Office of Chief Counsel as well as the National Association of Medicaid Fraud Control Units.

This matter was investigated by agents from the HHS-OIG; the FDA's Office of Criminal Investigations; the Defense Criminal Investigative Service of the Department of Defense; the Office of the Inspector General for the Office of Personnel Management; the Department of Veterans Affairs; the Department of Labor; TRICARE Program Integrity; the Office of Inspector General for the U.S. Postal Service and the FBI.

This resolution is part of the government's emphasis on combating health care fraud and another step for the Health Care Fraud Prevention and Enforcement Action Team (HEAT) initiative, which was announced in May 2009 by Attorney General Eric Holder and Kathleen Sebelius, Secretary of HHS. The partnership between the two departments has focused efforts to reduce and prevent Medicare and Medicaid financial fraud through enhanced cooperation. Over the last three years, the department has recovered a total of more than $10.2 billion in

settlements, judgments, fines, restitution, and forfeiture in health care fraud matters pursued under the False Claims Act and the Food, Drug and Cosmetic Act.

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Court documents related to today's settlement can be viewed online at www.justice.gov/opa/gsk-docs.html .

Related Materials:

Remarks by the Deputy Attorney General James M. Cole at the GSK Press Conference
Remarks by Acting Assistant Attorney General for the Civil Division Stuart F. Delery at the GSK Press Conference

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Topic(s):
Consumer Protection

Component(s):
Civil Division

Press Release Number:
12-842

Updated May 22, 2015

2021 SCC OnLine SC 411

In the Supreme Court of India

(BEFORE D.Y. CHANDRACHUD, L. NAGESWARA RAO AND S. RAVINDRA BHAT, JJ.)

In Re: Distribution of Essential Supplies and Services During Pandemic

Suo Motu Writ Petition (Civil) No. 3 of 2021

Decided on May 31, 2021

ORDER

1. This order has been divided into the following sections to facilitate analysis:

A Introduction

2. Proceedings in the present *suo motu* writ petition were initiated on 22 April 2021, when this Court took cognizance of the management of the COVID-19 pandemic during the second wave. Subsequently, hearings were conducted on 23 April 2021, 27 April 2021 and 30 April 2021 when submissions were heard on behalf of the *Union of India*[1], *States/Union Territories*[2], learned *Amici* appointed by this Court and some of the intervenors.

3. On 30 April 2021, this Court passed a detailed order in relation, *inter alia*, to the following issues : vaccination policy, supply of essential drugs, supply of medical oxygen, medical infrastructure, augmentation of healthcare workforce and the issues faced by them, and issues of freedom of speech and expression during the COVID-19 pandemic. In its order, this Court had noted that its observations and directions were in consonance with a bounded-deliberative approach[3] and hence, the UoI was directed to re-consider its policies on the above issues, taking into account this Court's observations.

4. Following the order dated 30 April 2021, another two judge Bench of this Court heard a Special Leave Petition[4] against an order of the High Court of Delhi in relation to the supply of medical oxygen to the National Capital Territory[5] of Delhi. During the course of the proceedings in that matter, the Bench primarily issued directions in relation to the supply of medical oxygen to the NCT of Delhi. However, through its order dated 6 May 2021, it also constituted a National Task Force to provide a public heath response to the COVID-19 pandemic on the basis of a scientific approach. The terms of reference of this National Task Force included, *inter alia*, assessing and making recommendations for the need, availability and distribution of medical oxygen; devising a methodology for allocation of medical oxygen and periodical review of the

allocation based on the stage of the pandemic; providing recommendations for augmenting the supplies of oxygen; facilitating audits in each State/UT to determine whether oxygen supplies had reached its destination; efficacy, transparency and efficiency of the distribution networks within the State/UT; providing recommendations for ensuring availability of essential drugs, augmentation of medical and paramedical staff, management of the pandemic and treatment of cases.

5. During the course of the proceedings on 31 May 2021, we had the benefit of perusing the details provided in the affidavit filed by the UoI on 9 May 2021. The submissions contained in the affidavit were supplemented and updated in the hearing by Mr. Tushar Mehta, learned Solicitor General of India, appearing on behalf of the Central Government. We have further heard the learned *Amici*, Mr. Jaideep Gupta and Ms. Meenakshi Arora, learned Senior counsel.

6. Since the last hearing in this matter, the second wave of the COVID-19 pandemic has started receding across the nation and the situation appears to have become more manageable. Hence, some of the issues discussed in the previous orders can await further deliberation. However, the issue of vaccination is absolutely crucial, since health experts globally agree that vaccination of the nation's entire eligible population is the singular most important task in effectively combating the COVID-19 pandemic in the long run. Hence, during the course of the proceedings on 31 May 2021, this Court has limited itself to hearing submissions on the UoI's vaccination policy and its roadmap for the future. By way of abundant clarification, we note that all of the issues contained in this Court's previous orders still retain their overall importance, and this Court shall continue to monitor them alongside the National Task Force and intervene whenever necessary.

7. It is also important to note that numerous interlocutory applications and affidavits by individual State/UT Governments and members of civil society have been filed before us in this matter. We have perused them to understand the key issues being raised there, along with the helpful notes provided by the *Amici*.

B Submission by Counsel

8. Mr. Tushar Mehta, learned Solicitor General, relying on the UoI's affidavit dated 9 May 2021, has made the following submissions to supplement it, in view of the recent updates:

(i) The vaccination drive will be complete by the end of December 2021, and the Central Government is in active talks with foreign vaccine manufacturers at the highest political and diplomatic levels, to ensure the adequate supply of vaccines;

(ii) It would be incorrect to state that a consequence of the UoI's updated policy on vaccination of those in the 18-44 age group is that there will be competition amongst the States/UTs; and

(iii) Everyone above the age of 45 years can continue to get vaccinated at a facility through on-site registration, without previously having to book an appointment through CoWIN.

9. Mr. Jaideep Gupta and Ms. Meenakshi Arora, learned Senior counsel and *Amici*, have raised the following issues relating to vaccination distribution, augmentation of vaccine production and differential pricing of vaccines and the future preparedness for dealing with the COVID-19 pandemic:

(i) With respect to the procurement of vaccines, reports suggest that foreign vaccine manufacturers are generally not receptive or open to a dialogue with State/UT Governments on the basis that, as a matter of corporate policy, they only deal with federal governments of different nations;

(ii) Since 1978 till 1 May 2021, the UoI has implemented the Universal Immunization Programme[6] under which essential vaccines were procured by the

UoI and were distributed to States/UTs free of cost for administering them to the end beneficiary. The said policy has held the test of times. Even during the vaccination drive for COVID-19 in phases 1 and 2 for vaccination of healthcare workers[7], frontline workers[8] and persons above the age of 45 years, the UoI procured all the vaccines and distributed them to State/UT Governments for administration. The single procurement model has also been followed by other nations for ensuring fast and effective administration of vaccines against COVID-19;

(iii) The UIP has been replaced by the Liberalized Pricing and Accelerated National COVID-19 Vaccination Strategy[9] from 1 May 2021 in phase 3 of the vaccination drive, whereby State/UT Governments or private hospitals are required to procure vaccines for persons between the age group of 18-44 years from the private manufacturers on the basis of a *pro rata* quota set by the UoI;

(iv) The Liberalized Vaccination Policy leaves the State/UT Governments to fend for themselves, rather than the Central Government acting on behalf of the entire nation. As a consequence, the vaccine manufacturers are free to implement a differential procurement price for the UoI for vaccinating persons above 45 years of age, and for the State/UT Governments and private hospitals for vaccinating the persons between 18-44 years of age;

(v) While the Liberalized Vaccination Policy has been introduced to spur competitive prices, there are multiple States/UTs competing to purchase a scarce commodity from a few vaccine manufacturers. Consequently, the manufacturers have the advantage of creating a monopoly and selling it at any price that they desire to private healthcare institutions. The State/UT Governments do not enjoy the unique position of the UoI, which has the advantage of being a monopolistic buyer and can negotiate an appropriate price for the vaccines on behalf of the entire population of India;

(vi) The Liberalized Vaccination Policy puts an undue burden on persons between the age group of 18-44 years, specifically persons belonging to a poor socioeconomic background, who have to purchase two doses of vaccines either from the State/UT Governments or private hospitals;

(vii) In the alternative, the UoI has stated that all State/UT Governments have agreed to vaccinate their population free of cost and have undertaken to bear the burden of the vaccines which are available at a higher purchase price than the one available to the UoI. Thus, the end beneficiary is not impacted by the differential pricing in the Liberalized Vaccination Policy. With regard to this submission, the *Amici* have raised the following concerns:

(a) While some States/UTs have announced that they will vaccinate their population for free, this policy statement must be confirmed by the State/UT Governments on affidavit before this Court. The Liberalized Vaccination Policy as it stands today, does not incorporate a condition whereby the cost of vaccination is imposed on the State/UT Governments. Instead, the end beneficiary is liable to pay the cost. There is a necessity for the State/UT Governments to place their decisions on record and for it to be part of the formal policy, such that persons can enforce their right to free vaccination, including before the courts;

(b) Although the State/UT Governments may have announced free vaccination for their population, some of them are contesting the Liberalized Vaccination Policy before this Court and have advanced submissions for universal vaccination by the Central Government. Thus, it cannot conclusively be stated that State/UT Governments have agreed to the policy decision taken by the Central Government of deviating from the single procurement model;

(c) The Liberalized Vaccination Policy, as a consequence of its differential pricing, treats individuals living across India residing in different States/UTs unequally, as States/UTs that are financially distressed may not be able to afford to purchase the vaccines at the prices set by the vaccine manufacturers or to lift the quantity allocated to them; and

(d) The end result of the Liberalized Vaccination Policy is that the UoI can purchase vaccines at Rs. 150 per dose for Covishield and Covaxin, while the State/UT Governments have to pay Rs. 300 and Rs. 400 per dose respectively. If the UoI were to be the single procurement agency for all vaccines at a fixed cost, then the cost of vaccination to the public exchequer would be substantially lower. Thus, it is incorrect to suggest that the end beneficiary, who contributes to the public exchequer, will not be unduly impacted;

(viii) Although public health is a subject under Entry 6 of List II (State List) of the Seventh Schedule to the Constitution, Entry 81 of List I (Union List) deals with inter-State migration and inter-State quarantine and Entry 29 of List III (Concurrent List) deals with prevention of extension from one State to another of infectious or contagious diseases. Thus, the management of the pandemic, control of the spread of COVID-19, vaccination policy and pricing, are the responsibility of the Central Government, which must work in tandem with the State/UT Governments. The Liberalized Vaccination Policy, by putting the burden of vaccination of persons between 18-44 years of age on the State/UT Governments, conflicts with this constitutional balance of responsibilities between the Centre and States/UTs;

(ix) With regard to the vaccine distribution, the Liberalized Vaccination Policy has created a quota of 50 : 25 : 25 for the 18-44 age group. The quota of 25% that is available to State/UT Governments, which is equivalent to the private hospitals, is extremely disproportionate and not in touch with societal realities, as a large number of persons may not be able to afford two doses of a vaccine from a private hospital. Thus, if State/UT Governments are to bear the burden of vaccinating a majority of the persons in their States/UTs, the quota available to the private hospitals must be reduced;

(x) The Liberalized Vaccination Policy does not provide any clarity on the basis of the *pro rata* allotment of the doses to each State/UT (available for purchase by the State/UT Government and private hospitals). The Policy does not indicate whether such apportionment will be on the basis of population; state of the pandemic in each State/UT; or the number of persons with comorbidities between 18-44 years of age, among others. Further, the Policy does not indicate whether the *pro rata* allotment will be made by the UoI or the private vaccine manufacturer;

(xi) It is reported that UoI on certain occasions has stated that it will refrain from interfering in the issue of vaccine distribution. Contrarily, UoI has also been stated that it may decide to redistribute the vaccines procured by it among State/UT Governments. The basis on which the re-distribution of vaccines will take place among States/UTs has not been provided in the policy document;

(xii) The Liberalized Vaccination Policy does not provide for prioritizing of persons with co-morbidities; persons with disabilities or suffering from other illnesses; care-givers for the elderly and sick; teachers and others in the age group of 18-44 years. Further, the CoWIN application is not built with functions which prioritize a certain category of persons, as it only books appointments on a first-cum-first-served basis;

(xiii) News reports indicate that crematorium workers have either not been vaccinated, or are unaware that they are eligible for vaccination in phases 1 and

2;

(xiv) With regard to preparedness, the UoI has claimed that it will be able to vaccinate a substantial number of persons (around 100 crore persons requiring 200 crore doses) by December 2021. However, no projections have been shared with this Court regarding how this target would be achieved. Based on reports, it appears that the UoI has factored a number of vaccines that are currently in their development stages to reach its projected number of 200 crore doses. This approach would be misguided as the success and efficacy of vaccines that are currently in the stage of clinical trials is uncertain and cannot be guaranteed;

(xv) There is material to suggest that the augmentation of vaccine production will be inadequate to vaccinate the population between 18-44 years of age. The total population of this age group is 59 crores, which would require around 122 crore doses. Based on reports, the existing manufacturers (Serum Institute of India[10] and Bharat Biotech India Limited[11]) will be able to produce less than 10 crore doses per month. Optimistically, around 15-20 crores doses of Sputnik V will be available per month. At this rate, it would take around 12 months for the population in this age group to be inoculated, by which time the virus may have mutated, causing further waves of the pandemic;

(xvi) Meanwhile, there is a necessity to ensure that guidelines regarding standardization of masks are formulated and publicized. Thus, medical guidance is necessary to ensure that masks of appropriate quality are produced and distributed free of cost to curb the spread of the infection; and

(xvii) It has been reported that due to dearth of electric crematoria, persons who have succumbed to COVID-19 are not dignified with a proper cremation and are cremated without any rituals. The UoI and State/UT Governments may consider forming appropriate guidelines which augment the creation of infrastructure for electric crematoria and a protocol for cremation of the dead.

C National Vaccination Policy

10. Phase 1 of the National COVID-19 Vaccination Strategy was launched on 16 January 2021 and 1 February 2021 and was targeted towards protecting HCWs and FLWs. Phase 2 was initiated on 1 March 2021 and 1 April 2021, and was directed towards protecting the most vulnerable population in the age group of persons above 45 years of age. In phase 1 and 2, the UoI was procuring the vaccines and distributing them to the States/UTs free of cost for disbursal through government and private COVID-19 vaccination centres. The private facilities were not allowed to charge a sum above Rs. 250 per person per dose (Rs 150 for vaccines and Rs. 100 as operational charges) from a beneficiary.

11. During phase 2, eligible beneficiaries could register and book appointments for vaccination on the CoWIN 2.0 portal or other IT applications such as Aarogya Setu. From 1 March 2021 onwards, the population aged 60 years or which would attain the age of 60 years or more as on 1 January 2022 was eligible to register on the CoWIN platform. Further, persons who were aged 45 years or would attain the age of 45 years to 59 years as on 1 January 2022 and had any of the 20 specified co-morbidities were also eligible to register on the CoWIN platform. From 1 April 2021 onwards, all persons who were aged 45 years or would attain the age of 45 years to 59 years as on 1 January 2022 were eligible to register on the CoWIN platform. On-site registration facility was also made available at vaccination centres in this phase.

12. In phase 3, a Liberalized Vaccination Policy was introduced by the UoI, which came into effect on 1 May 2021. We have perused the documents available in the public domain (guidance note[12], press releases[13] and policy document[14]) issued by the Central Government to understand the written policy of the Central Government with regard to phase 3. Based on such documents, the main elements of the Liberalized

Vaccination Policy can be identified as:

(i) Vaccine manufacturers are required to supply 50% of their monthly Central Drugs Laboratory[15] doses to the UoI and would be free to supply the remaining 50% doses to State/UT Governments and in 'other than Government of India channel'[16];

(ii) Manufacturers were required to make a declaration of the price of the 50% supply that would be available to State/UT Governments and in the 'other than GoI channel' before 1 May 2021. Based on this price, States/UTs, private hospitals and industrial establishments through their hospitals may procure vaccines from the manufacturers. Private hospitals would be able to procure their supplies only from the 50% supply earmarked for 'other than GoI channel';

(iii) The prices charged for vaccination by private hospitals would be monitored. As a result, the earlier dispensation where private COVID-19 vaccination centres which received doses from the UoI could charge up to Rs. 250 per dose ceased to exist;

(iv) The population which is now eligible to obtain vaccines at UoI's vaccination centres is limited to HCWs, FLWs and those above 45 years of age. The population between 18-44 years is eligible to obtain vaccines from 'other than GoI channel';

(v) The vaccination would continue to be available for free for eligible population groups in those vaccination centres which receive their vaccine doses from UoI;

(vi) The vaccination would continue to be a part of the National Vaccination Programme and would follow all existing guidelines. The CoWIN platform would capture the vaccination, stocks and price per vaccination applicable in all vaccination centres. The vaccination drive would comply with 'Adverse Event Following Immunization' management and reporting, digital vaccination certificate and all other prescribed norms;

(vii) The division of 50% supply to UoI and 50% to 'other than GoI channel' would be applicable uniformly across all the vaccine manufactures in the country;

(viii) The fully ready to use imported vaccines are allowed to be utilized entirely in the 'other than GoI channel'; and

(ix) The UoI from its share will allocate vaccines to States/UTs based on criteria of performance (speed of administration, average consumption) and extent of infection (number of COVID-19 cases). Wastage of vaccines would also be considered in the criteria and would affect the allocation negatively. Based on the above criteria, a State-wise quota would be decided and communicated to the States/UTs in advance.

13. The facility of only online appointment on the CoWIN portal was initially introduced for the entirety of the population between the ages of 18-44 years. Later, on 24 May 2021[17], the UoI announced that on-site registration will be made available for the 18-44 years age group. However, this is contingent on : (i) the State/UT Government enabling this policy; and (ii) only in cases of wastage at a particular government COVID-19 vaccination centre due to a no-show by an online appointee. Further, this facility has not been expanded to private COVID-19 vaccination centres.

D Separation of Powers

14. At the outset, we seek to clarify the nature of this Court's jurisdiction in the exercise of the power of judicial review over the management of the COVID-19 pandemic in India. In its affidavit dated 9 May 2021, the UoI has highlighted a few concerns which are detailed below:

(i) The executive is battling an unprecedented crisis and the government needs discretion to formulate policy in larger interest and its wisdom should be trusted;

(ii) The current vaccine policy conforms to Articles 14 and 21 of the Constitution, and requires no interference from the courts as the executive has "room for free play in the joints" while dealing with a pandemic of this magnitude;

(iii) The current steps are thoughtfully undertaken to tide over an imminent crisis, which may turn out to be imprudent in the long run. However, they need to be appreciated from a short-term and holistic perspective;

(iv) Judicial review over executive policies is permissible only on account of manifest arbitrariness. No interference from judicial proceedings is called for when the executive is operating on expert medical and scientific opinion to tackle a medical crisis; and

(v) Any over-zealous judicial intervention, though well-meaning, in the absence of expert advice or administrative experience may lead to unintended circumstances where the executive is left with little room to explore innovative solutions.

15. It is trite to state that separation of powers is a part of the basic structure of the Constitution. Policy-making continues to be in the sole domain of the executive. The judiciary does not possess the authority or competence to assume the role of the executive, which is democratically accountable for its actions and has access to the resources which are instrumental to policy formulation. However, this separation of powers does not result in courts lacking jurisdiction in conducting a judicial review of these policies[18]. Our Constitution does not envisage courts to be silent spectators when constitutional rights of citizens are infringed by executive policies. Judicial review and soliciting constitutional justification for policies formulated by the executive is an essential function, which the courts are entrusted to perform.

16. We had clarified in our order dated 30 April 2021, that in the context of the public health emergency with which the country is currently grappling, this Court appreciates the dynamic nature of the measures. Across the globe, the executive has been given a wider margin in enacting measures which ordinarily may have violated the liberty of individuals, but are now incumbent to curb the pandemic. Historically, the judiciary has also recognized that constitutional scrutiny is transformed during such public health emergencies, where the executive functions in rapid consultation with scientists and other experts. In 1905, the Supreme Court of the United States in *Jacobson* v. *Massachusetts*[19] considered a constitutional liberty challenge to a compulsory vaccination law that was enacted to combat the smallpox epidemic. Justice Harlan had noted the complex role of the government in battling public health emergencies in the following terms:

> "..the State may invest local bodies called into existence for purposes of local administration with authority in some appropriate way to safeguard the public health and the public safety... While this court should guard with firmness every right appertaining to life, liberty or property as secured to the individual by the Supreme Law of the Land, it is of the last importance that it should not invade the domain of local authority except when it is plainly necessary to do so in order to enforce that law. The safety and the health of the people of Massachusetts are, in the first instance, for that Commonwealth to guard and protect.....So far as they can be reached by any government, they depend, primarily, upon such action as the State in its wisdom may take, and we do not perceive that this legislation has invaded any right secured by the Federal Constitution."

17. The Supreme Court of United States, speaking in the wake of the present COVID-19 pandemic in various instances, has overruled policies by observing, *inter alia*, that "*Members of this Court are not public health experts, and we should respect the judgment of those with special expertise and responsibility in this area. But even in a pandemic, the Constitution cannot be put away and forgotten*"[20] and "*a public*

health emergency does not give Governors and other public officials carte blanche to disregard the Constitution for as long as the medical problem persists. As more medical and scientific evidence becomes available, and as States have time to craft policies in light of that evidence, courts should expect policies that more carefully account for constitutional rights"[21].

18. Similarly, courts across the globe have responded to constitutional challenges to executive policies that have directly or indirectly violated rights and liberties of citizens. Courts have often reiterated the expertise of the executive in managing a public health crisis, but have also warned against arbitrary and irrational policies being excused in the garb of the "wide latitude" to the executive that is necessitated to battle a pandemic. This Court in *Gujarat Mazdoor Sabha* v. *State of Gujarat*[22], albeit while speaking in the context of labour rights, had noted that policies to counteract a pandemic must continue to be evaluated from a threshold of proportionality to determine if they, *inter alia*, have a rational connection with the object that is sought to be achieved and are necessary to achieve them.

19. In grappling with the second wave of the pandemic, this Court does not intend to second-guess the wisdom of the executive when it chooses between two competing and efficacious policy measures. However, it continues to exercise jurisdiction to determine if the chosen policy measure conforms to the standards of reasonableness, militates against manifest arbitrariness and protects the right to life of all persons. This Court is presently assuming a dialogic jurisdiction where various stakeholders are provided a forum to raise constitutional grievances with respect to the management of the pandemic. Hence, this Court would, under the auspices of an open court judicial process, conduct deliberations with the executive where justifications for existing policies would be elicited and evaluated to assess whether they survive constitutional scrutiny.

E Issues with the Liberalized Vaccination Policy

E.1 Vaccine Procurement and Distribution among Different Categories of the Population

20. In our order dated 30 April 2021, the UoI was directed to clarify its vaccination procurement and distribution policy, especially after the introduction of the Liberalized Vaccination Policy. We had also directed the UoI to apprise this Court regarding the projected numbers of vaccinations that would be made available in the coming months to the public and the efforts being taken to augment vaccine production. In its affidavit dated 9 May 2021, UoI has made the following submissions:

(i) The vaccination policy for COVID-19 that was adopted prior to 1 May 2021 in phases 1 and 2, was designed as a system of prioritization. After vaccinating the HCWs and FLWs, vaccination was opened up for age groups on account of their heightened vulnerability and mortality to COVID-19, in consonance with the WHO guidelines and international practice;

(ii) In phase 1, HCWs (starting from 16 January 2021) and FLWs (starting from 2 February 2021) were vaccinated. In phase 2, persons above 60 years of age and persons over 45 years of age with certain co-morbidities (starting from 1 March 2021) and all persons over 45 years of age (starting from 1 April 2021) were eligible for vaccination. This priority was accorded in view of the fact that COVID-19 deaths across the world demonstrate that over 85% of all deaths occurred in the age group over 45 years;

(iii) FLWs such as municipal workers (including crematorium workers) and panchayat workers were also vaccinated in phase 1 of the vaccination drive;

(iv) With effect from 1 May 2021, the Liberalized Vaccination Policy was implemented as a response to repeated requests by State/UT Governments, and after detailed deliberations with domain experts. The parallel decentralized policy

aims to achieve higher efficiency and reach;

(v) Currently, vaccine manufacturers are obligated to supply 50% of their monthly CDL released doses to the UoI and the remaining 50% doses to the "other than GoI channel" which can be procured by State/UT Governments, private hospitals and hospitals of industrial establishments to vaccinate persons in the age group of 18-44 years;

(vi) The priority of the UoI remains vaccinating persons aged 45 years and above for free since they are more vulnerable. The simultaneous vaccinations for persons aged between 18-44 years has been introduced to respect the wishes of the State/UT Governments. In view of the differential vulnerability and mortality rates, the Liberalized Vaccination Policy conforms to the mandate of Articles 14 and 21 of the Constitution;

(vii) In order to eliminate disparity in bargaining powers, "*the Central Government has, in consultation with the vaccine manufacturers determined the pro-rata population of each State in the age group of 18-44 and each State will procure only that quantity*";

(viii) The Central Government will notify States/UTs, every fortnight, on the quantity of vaccines that will be distributed for vaccinating persons aged 45 years and above;

(ix) With regard to the augmentation of production of vaccines, it is stated that the National Expert Group on Vaccine Administration for COVID-19[23] had procured 6.6 crore doses for the initial phases. Support for other vaccine candidates under clinical development is being provided by the 'Mission COVID Suraksha the Indian COVID-19 Vaccine Development Mission';

(x) The Central Government is in talks with several vaccine developers/manufacturers outside India and is seeking to facilitate imports. The Drugs Controller General of India[24] has already approved import of 1.5 lakh doses of the Sputnik V vaccine by Dr Reddy's Laboratories';

(xi) The availability of vaccines for the next 6 months would be difficult to project as it is dynamic and contingent on foreign procurement and successful ramping of production by the two existing manufacturers;

(xii) However, it is also stated that manufacturing capacity is being increased in the following terms:

(a) SII : from 5 crore doses/month to 6.5 crore doses/month by July 2021;

(b) BBIL : from 90 lakh doses/month to 2 crore doses/month, and further increase to 5.5 crore doses/month by July 2021; and

(c) Sputnik V : from 30 lakh doses to 1.2 crore doses/month by July 2021; and

(xiii) The regulatory and testing process for foreign vaccines has been simplified by the NEGVAC which now allows bridging trials (a nearly 4-month long process) of foreign vaccines to occur simultaneously with market development.

21. Based on the response of the UoI and the submissions made by the *Amici*, we understand that there are three broad issues that are of concern : (i) vaccine distribution between different age groups; (ii) vaccine procurement process; and (iii) the augmentation of the vaccine availability in India.

22. The affidavit of the UoI sufficiently clarifies the prioritization of the groups in phases 1 and 2 for obtaining the COVID-19 vaccines. These include HCWs, FLWs and persons above the age of 45 years. The prioritization of these groups was based on the experience of India and other countries during the first wave of the pandemic in 2020. It was largely observed that these groups faced a higher risk of infection and thus, it was necessary to inoculate them free of cost and on a priority basis by the Central Government. During the vaccination for these groups, the Central Government had

allowed on-site registration and there was no prior requirement for booking an appointment on CoWIN. Having said that, the vaccination policy has been substantially changed for persons between 18-44 years of age. The Liberalized Vaccination Policy requires some of these persons to pay for the vaccines; limited vaccines are made available for this category with the State/UT Governments/private hospitals and an additional requirement of mandatory digital registration and booking an appointment through CoWIN has been imposed, among others. Unlike the prior policy, the Liberalized Vaccination Policy does not prioritize persons with comorbidities and other diseases, persons with disabilities, or any other vulnerable groups. This is especially at issue because the experience of the second wave of the pandemic has provided an experiential learning that the COVID-19 virus is capable of mutation and now poses a threat to persons in this age group as well. Reports indicate that persons between 18-44 years of age have not only been infected by COVID-19, but have also suffered from severe effects of the infection, including prolonged hospitalization and, in unfortunate cases, death. Due to the changing nature of the pandemic, we are now faced with a situation where the 18-44 age group also needs to be vaccinated, although priority may be retained between different age groups on a scientific basis. Hence, due to the importance of vaccinating individuals in the 18-44 age group, the policy of the Central Government for conducting free vaccination themselves for groups under the first 2 phases, and replacing it with paid vaccination by the State/UT Governments and private hospitals for the persons between 18-44 years is, *prima facie*, arbitrary and irrational.

23. With regard to the procurement process for vaccinations which is to be followed in view of the Liberalized Vaccination Policy, there are a number of issues that need to be addressed. The *Amici* have indicated that many State/UT Governments and local municipal bodies have issued tenders and attempted to negotiate with foreign manufacturers but they have largely been unsuccessful, as foreign manufacturers are not inclined to negotiate with individual State/UT Governments and prefer negotiating with federal governments of countries. Additionally, it has been urged that Central Government is also better placed to use its monopoly as a buyer (India being the second most populous country) to bargain for higher quantities of vaccines at reasonable prices. We find that the submissions urged by the *Amici* are extremely pertinent and have indicated that in practice, the Liberalized Vaccination Policy may not be able to yield the desired results of spurring competitive prices and higher quantities of vaccines.

24. Additionally, the Liberalized Vaccination Policy seeks to remove the issue of bargaining disparities by stating that each State/UT would have a prefixed *pro rata* quota based on their population in the 18-44 age group, 50% of which will be available to the State/UT Governments and 50% to the private hospitals. The *Amici* have raised concerns that there is a lack of clarity regarding whether the UoI will intervene in the distribution process. Given that inter-State barriers in India are porous and persons are free to migrate and work in different parts of the country, it is essential to understand if the *pro rata* allotment will take into account such migration to more densely populated industrial and urban States/UTs. Other concerns, such as the stage of the pandemic, the healthcare infrastructure and existing capacities of a State/UT, the literacy rate, age and overall health condition of its population, may also be relevant factors in making such a *pro rata* determination. The UoI should thus specify whether it seeks to address these concerns within the vaccination policy such that the State/UT Governments have a realistic assessment of the assistance they can anticipate from the UoI.

25. We shall now address the issue related to augmentation of vaccine production/availability. We have noted the submissions of the UoI in its affidavit dated 9 May 2021, that it is difficult to predict the projections for vaccines given that it

depends on variable factors such as introduction of new foreign vaccines, capability of increased production by existing manufacturers, among others. Mr. Tushar Mehta has during the course of his oral submissions stated that he is in a position to address these concerns of this Court and that the UoI aims to vaccinate approximately 100 crore persons by the end of December 2021. Mr. Mehta has agreed to provide a detailed roadmap regarding projected availability of vaccines from the various vaccine manufacturers. It has also been highlighted that the Central Government is in active negotiations with various private foreign manufacturers to augment the availability of vaccines in the near future.

26. In view of the above, we direct the UoI to undertake a fresh review of its vaccination policy addressing the concerns raised. Further, we direct the UoI to provide the following clarifications:

- As noted above, the UoI is directed to place on record a roadmap of projected availability of vaccines till 31 December 2021;
- The preparedness with respect to specific needs of children in the event of a third wave of the pandemic in terms of medical infrastructure, vaccination trials and regulatory approval, and compatible drugs;
- Whether under the policy of the UoI, it is permissible for State/UT Governments or individual local bodies to access vaccine supplies of foreign manufacturers;
- The number of crematorium workers vaccinated in phase 1. A targeted drive can be conducted for vaccination of the remaining crematorium workers;
- The State/UT Governments are diverting the vaccines (procured by them at a higher price than Central Government) for the persons in the age group of 18-44 years to vaccinate persons above 45 years of age, due to a shortage of vaccines being supplied by the Central Government. The manner in which the Central Government will factor this quantity and price differential into their subsequent allocation and disbursal of vaccines to States/UTs for the persons above 45 years of age; and
- The mechanism for redistribution, if the 25 : 25 quota in a particular State/UT is not picked up by the State/UT Government or the private hospitals.

E.2 Effects of Vaccination by Private Hospitals under the Liberalized Vaccination Policy

27. Under the Liberalized Vaccination Policy covering persons in the age group of 18 -44 years, the total vaccines produced will be divided in a ratio of 50 : 25 : 25 between the Central Government, State/UT Governments and private hospitals. In its affidavit dated 9 May 2021, the UoI notes the following salient features of this Liberalized Vaccination Policy, in relation to vaccination by private hospitals:

(i) Out of the 50% quota allocated for the 'other than GoI channel', 50% will go to the State/UT Governments, calculated on a *pro rata* basis as per the population. The balance 50% would be open for private hospitals' procurement, based on contracts with the manufacturers. As such, the State/UT Governments and private hospitals would each end up with 25% of the total CDL doses;

(ii) Vaccination through the private sector of 25% of the total CDL quantity would reduce the operational stress on government facilities and help with issues of crowding at vaccination centres; and

(iii) Paid vaccination through private hospitals has been introduced for persons who can afford to pay, thereby reducing the operational stress on the Government. However, it has also been submitted that this policy may undergo a change based on performance and future availability of vaccines.

28. As a consequence of this Liberalized Vaccination Policy, 50% of the population of any State/UT in the 18-44 age group is expected to pay for its vaccination. From the

UoI's affidavit, we understand that this has been done while taking into account the ability of a certain section of the population to pay for their vaccination. However, the present system of allowing only digital registration and booking of appointment on CoWIN, coupled with the current scarcity of vaccines, will ultimately ensure that initially all vaccines, whether free or paid, are first availed by the economically privileged sections of the society. As such, even those who may have been able to afford a vaccine, may opt for a free vaccine simply because of issues of availability, even if it would entail travelling to far-flung rural areas. Hence, any calculations of the economic ability of a given individual may not directly correspond to the vaccination route (paid/unpaid) they opt for. Consequently, it is plausible that private hospitals may have vaccine doses left over with them because everyone who could afford them has either already bought it or availed of a free vaccine, while those who need it may not have the ability to pay for it.

29. Further consequences of the vaccination by private hospitals under the Liberalized Vaccination Policy relate to a simple issue at the core of their existence : that while they provide a public health service, they still remain private, for-profit entities. Consequently, they may sell the vaccine doses procured at a higher price, unless regulated stringently. Private hospitals also may not sell all their vaccine doses publicly through appointments on CoWIN, but rather sell them for lucrative deals directly to private corporations who wish to vaccinate their employees. Finally, private hospitals are not equally spread out across a State/UT and are often limited to bigger cities with large populations. As such, a larger quantity will be available in such cities, as opposed to the rural areas.

30. It is pertinent to clarify here that we are not opposed to the involvement of private hospitals in the vaccination drive. Private health care institutions have an important role as well. The UoI has correctly noted in its affidavit that these hospitals will reduce the burden on government facilities. This was also happening earlier for the vaccination of those above 45 years of age, where the Central Government was providing these hospitals with vaccines and they were allowed to charge patients a nominal fee (Rs 250). However, the issue is about the effect of privatizing 50% of all vaccines available for the 18-44 age group. In view of the above concerns, we direct the UoI to provide the following clarifications:

- The manner in which Central Government will monitor the disbursal of vaccines to private hospitals, specifically those who have hospital chains pan India. Further, whether (i) private hospitals are liable to disburse vaccines *pro rata* the population of States/UTs; and (ii) the mechanism to determine if private players are genuinely administering the lifted quota in that State/UT alone. The UoI shall place on record any written policy in relation to this.
- Whether the Central Government conducted a "means-test" of the demographic of a State/UT to assert that 50% of the population in the 18-44 age group would be able to afford the vaccine. If not, the rationale for private hospitals being provided an equal quota for procurement as the State/UT Governments.
- The manner in which the Centre and States/UTs shall ensure an equitable distribution of vaccines across sections of the society, and how this factors into the rationale of equal apportionment between State/UT Governments and private hospitals.
- The nature of the intervention with respect to the final, end-user price that is being charged by private hospitals, especially when a cap on procurement by the private hospitals has been set.

E.3 Basis and Impact of Differential Pricing

Impact of differential pricing

31. In our order dated 30 April 2021, we had elicited the UoI's justification for

enabling decentralized procurement where a pre-fixed and differential price was set for the Central Government, States/UTs and private hospitals. The UoI through its affidavit dated 9 May 2021, has submitted the following:

(i) The Liberalized Vaccination Policy was introduced to incentivize existing manufacturers and invite more manufacturers, which will ensure fastest vaccination of the majority of the population. Differential pricing has been introduced in order to instill a competitive market which would drive the market towards affordability and attract offshore vaccine manufacturers;

(ii) Vaccine manufacturers are mandated to transparently declare the price in advance for procurement by State/UT Governments and private hospitals. The price for the Central Government is pre-fixed and declared;

(iii) Extensive consultations with the manufacturers were held to ensure that pricing is uniform and reasonable. The UoI stated that these were "due to consultations and persuasion" by the Central Government;

(iv) On the differential pricing of the vaccines, it is stated that "*the Central Government by nature of its large vaccination programme, places large purchase orders for vaccines as opposed to the State Governments and/or Private Hospitals and therefore, this reality has some reflection in the prices negotiated*"; and

(v) In any event, all persons of all age groups will get free vaccination throughout the country since all State/UT Governments have announced free vaccination for persons aged 18-44 years, in addition to the Central Government vaccinating persons over 45 years for free.

32. The current Liberalized Vaccination Policy enables State/UT Governments and private hospitals to procure 50% of the monthly CDL approved doses in the country at a pre-fixed price. The justification for this Policy has been adduced in a bid to spur competition which would attract more private manufacturers that could eventually drive down prices. *Prima facie*, the only room for negotiation with the two vaccine manufacturers was on price and quantity, both of which have been pre-fixed by the Central Government. This casts serious doubts on UoI's justification for enabling higher prices as a competitive measure. Furthermore, the Central Government justifying its lower prices on account of its ability to place large purchase orders for vaccines, raises the issue as to why this rationale is not being employed for acquiring 100% of the monthly CDL doses. The Union Budget for Financial Year 2021-2022 had earmarked Rs. 35000 crores for procuring vaccines[25]. In light of the Liberalized Vaccination Policy, the Central Government is directed to clarify how these funds have been spent so far and why they cannot be utilized for vaccinating persons aged 18-44 years.

33. In response to our questions on the poor and marginalized suffering on account of the vaccine prices, the Central Government in its affidavit stated that the eventual beneficiary of the vaccine would not be affected by the Liberalized Vaccination Policy since every State/UT has promised to vaccinate its residents free of cost. Nevertheless, it is reiterated that the UoI should consider utilizing its position as the monopolistic buyer in the market and pass down the benefit to all persons. Even if the States/UTs were to fund the higher-priced vaccines, a burden they were not discharging before the Liberalized Vaccination Policy was introduced and potentially may not have planned in advance for, these funds are expended at the behest of the public exchequer. The Centre and States/UTs, both operate in the service of the Indian population, and raise and disburse funds in their name. The additional funds expended on procuring vaccines against a deadly pandemic are necessary expenditure for any State/UT Government which has battled the public health emergency for over 15 months now. However, an avoidable expense would eventually hurt the welfare of

individuals residing within those States/UTs, who may potentially be benefitted by the differential funds being utilized for ramping up the health infrastructure in the State/UT, which is equally important to combat the pandemic. If the Central Government's unique monopolistic buyer position is the only reason for it receiving vaccines at a much lower rate from manufacturers, it is important for us to examine the rationality of the existing Liberalized Vaccination Policy against Article 14 of the Constitution, since it could place severe burdens, particularly on States/UTs suffering from financial distress.

Basis of pricing

34. In our order dated 30 April 2021, we had requested for data on government funding and support, direct or indirect, into the two vaccines that are currently authorized for public use - SII's Covishield and BBIL's Covaxin. Additionally, in order to evaluate the bottlenecks in vaccine scarcity, we had sought the UoI's stance on invoking its powers of compulsory licensing under the Patents Act, 1970 in order to ramp up manufacturing and other statutory provisions to drive down costs. The UoI has adduced the following justifications in its affidavit dated 9 May 2021:

(i) SII and BBIL have taken a financial risk in developing and manufacturing these vaccines and prudence dictates pricing through a transparent and consultative negotiation, and statutory provisions must be invoked in the last resort;

(ii) Covaxin is developed under a public-private partnership through a formal MoU between Indian Council of Medical Research[26] and BBIL. ICMR would receive a 5% royalty on net sales, the intellectual property is shared between ICMR and BBIL and clauses such as prioritization of in-country supplies have been included. Phase 3 trials of Covaxin have been funded by the ICMR to the tune of Rs. 35 crores;

(iii) Covishield is manufactured by SII. The Central Government has directly transferred Rs. 11 crores to 14 clinical trials sites for conducting phase 3 trials of over 1600 participants; and

(iv) Covaxin production is being augmented with government support to the tune of Rs. 200 crores to one private manufacturer and 3 public sector manufacturing facilities - Bharat Biotech, Hyderabad; Indian Immunologicals, Hyderabad; Haffkine Biopharmaceuticals, Mumbai; and Bharat Immunologicals and Biologicals, Bulandshar. This is projected to enhance Covaxin's current manufacturing of 1 crore doses/month to nearly 10 crore doses/month in the next 8-10 months. Grant-in-aids have been recommended, but the disbursements are yet to be made.

35. We commend the co-operative efforts of the UoI and the private manufacturers in developing and distributing vaccines which are critical to mitigate the pandemic. The import of our further line of questioning is to facilitate a better understanding of the process of development and augmentation of vaccine production and its pricing for States/UTs and private hospitals. Hence, we direct that the UoI to provide the following clarifications:

- Since the Central Government has financed (officially, Rs. 35 crores to BBIL and Rs. 11 crore to SII for phase 3 clinical trials) and facilitated the production (or augmentation of production) of these vaccines through concessions or otherwise, it may not be accurate to state that the private entities have alone borne the risk and cost of manufacture. Additionally, the Central Government would have minimized the risks of the manufacturers by granting Emergency Use Authorization to the vaccines, which should factor into its pricing.
- The manner in which public financing is reflected in the procurement price for the Central Government, which is significantly lower than price for the State/UT Governments and private hospitals. Given that the R&D cost and IP have either

been shared between the Central Government and the private manufacturer (in case of *Covaxin*) or the manufacturer has not invested in R&D of the vaccine (in case of *Covishield*), the manner in which the pricing of vaccines has been arrived at, with the Central Government refusing to intervene statutorily. The justification for intervening in pre-fixing procurement prices and quantities for States/UTs and private hospitals, but not imposing statutory price ceilings.

- Comparison between the prices of vaccines being made available in India, to their prices internationally.
- Whether ICMR/BBIL formally invited contracts for voluntary licensing and if so, whether they have they received viable offers. The manner in which the UoI is independently trying to assist manufacturers for developing BSL3 labs which are essential for Covaxin production.

E.4 Vaccine Logistics

36. We have already noted that as a consequence of the Liberalized Vaccination Policy, the responsibility for the vaccination in phase 3 is being divided between the Central Government (for those above 45 years of age, HCWs and FLWs) and the State/UT Government along with the private hospitals (for the age group of 18-44 years). This would mean that the limited vaccine logistics available in a State/UT would have to be shared between the State/UT Government and the Central Government. This is different from the situation under the UIP, where the Central Government buys and allocates vaccines to States/UTs, in order to ensure that their cold storage facilities are not overwhelmed. Hence, we direct the UoI to provide the following clarifications:

- The manner in which cold storage equipment capacity is being balanced between the Central and State/UT Governments. The manner in which the States/UTs are managing the logistical burden for vaccinating persons aged between 18-44 years, along with persons aged over 45 years.
- Whether cold storage facilities in India have increased for the COVID-19 vaccination drive; the present numbers, and comparison with the numbers prior to March 2020;
- Whether the cold storage equipment is indigenously manufactured or is imported. If it is imported, the steps which have been taken to start indigenous manufacturing.
- The steps being taken to improve the cold storage management for vaccines which may require lower temperature to be stored, compared to the ones which currently have approval in India.

E.5 Digital Divide

37. In our order dated 30 April 2021, we had highlighted the concerns relating to the ability of the marginalized members of society to avail of vaccination, exclusively through a digital portal in the face of a digital divide. The UoI's affidavit made the following submissions in relation to the accessibility of the CoWIN portal:

(i) The CoWIN portal enables one person to register 4 persons using the same mobile number;

(ii) All gram panchayats in the country have Common Service Centres[27] which can effectively enable people residing in rural areas to register online for the vaccination;

(iii) Citizens who do not have access to digital resources could take help from family, friends, NGOs and CSCs;

(iv) Walk-ins cannot be permitted due to the scarcity of vaccines and fears of over-crowding at centres. The online registration requirement counters this fear and also effectively monitors the administration of the second dose. The policy may

be re-considered subsequently when more vaccines are available;

(v) Identity proofs are required for the purpose of determining age and keeping a track of persons who are due for the second dose. However, in recognizing the issues arising with the insistence of one of the seven prescribed photo-ID proofs, the Central Government issued an SoP dated 23 April 2021 which enables bulk registration of certain identifiable groups, such as homeless persons, who would be identified and registered by the District Immunization Task Force; and

(vi) It is clarified that walk-in vaccination facilities will continue for persons over the age of 45 years in separate, designated vaccination centres. This is because vaccinations have been underway for this age group for a while and overcrowding has not been experienced so far.

38. A survey on 'Household Social Consumption : Education' was conducted by National Statistics Office (July 2017-June 2018)[28] which revealed the following:

(i) Around 4% of the rural households and 23% of the urban households possessed a computer. In the age group of 15-29 years, around 24% in rural households and 56% in urban areas were able to operate a computer; and

(ii) Nearly 24% of the households in the country had internet access during the survey year 2017-18. The proportion was 15% in rural households and 42% in urban households. Around 35% of persons in the age group of 15-29 years reported use of internet during the 30 days prior to the date of survey. The proportions were 25% in rural areas and 58% in urban areas.

39. The Telecom Regulatory Authority of India in its report titled 'Wireless Data Services in India'[29] noted that:

(i) Out of the total population of 1.3 billion, only 578 million people in India (less than 50%) have subscription to wireless data services. The wireless tele density in rural areas is 57.13% as compared to 155.49% in urban areas as on 31 March 2019. The report stated that:

> "[this] reflects the rural-urban divide in terms of telecom services' penetration. Since, the number of wireless data subscribers are less than 50% of the total wireless access subscribers, the number of wireless data subscribers in rural areas would be much lower".

(ii) The report also noted that in a few Indian States like Bihar, Uttar Pradesh and Assam the tele density is less than 75%; and

(iii) The monthly income of persons living below the poverty line in urban areas and rural areas is Rs. 1316 and Rs. 896, respectively. However, to access internet data services, a minimum tariff plan would cost around Rs. 49, which includes 1 GB data every 28 days. This would constitute 4-5% of the month's income of such persons accessing data. As such, the report notes that this would bear a considerable cost for persons living below the poverty line.

40. According to the Annual Report of CSC for 2019-20, published by the Ministry of Electronics and Information Technology, while there are 2,53,134 Gram Panchayats in India, as on 31 March 2020 only 2,40,792 Gram Panchayats are covered with at least one registered CSC[30]. Hence, approximately 13,000 Gram Panchayats in India do not have a CSC.

41. It is clear from the above statistics that there exists a digital divide in India, particularly between the rural and urban areas. The extent of the advances made in improving digital literacy and digital access falls short of penetrating the majority of the population in the country. Serious issues of the availability of bandwidth and connectivity pose further challenges to digital penetration. A vaccination policy exclusively relying on a digital portal for vaccinating a significant population of this country between the ages of 18-44 years would be unable to meet its target of

universal immunization owing to such a digital divide. It is the marginalized sections of the society who would bear the brunt of this accessibility barrier. This could have serious implications on the fundamental right to equality and the right to health of persons within the above age group. In this regard, we direct that the UoI to provide the following clarifications:

- It may not be feasible to require the majority of our population to rely on friends/NGOs for digital registrations over CoWIN, when even the digitally literate are finding it hard to procure vaccination slots.
- The issue of over-crowding may also arise at CSCs in rural areas where people would have to visit constantly in hope of a vaccine slot opening up.
- Certain vaccination centres may be earmarked for on-site registrations for the population aged between 18-44 years without the existing conditions prescribed in the circular dated 24 May 2021, potentially with a view to prioritize those with co-morbidities/disabilities/other socio-economic vulnerabilities. Alternatively, whether specific daily quotas may be introduced for on-site registration at each centre or specific centres.
- This policy may not allay the issue of hesitancy which may arise from approaching a State authority (such as the District Immunization Task Force) to obtain registration for the vaccination. Whether on-site registration with self-attestation of age to ensure widespread vaccination can be provided.
- The CoWIN platform and other IT applications like Aarogya Setu should be made available in regional languages. The timeline for ensuring the availability of the platform in multiple regional languages.
- Conducting a disability audit for the CoWIN website and other IT application like Aarogya Setu to ensure that they are accessible to persons with disabilities.

42. It has been brought to our notice that the CoWIN platform is not accessible to persons with visual disabilities. The website suffers from certain accessibility barriers which should be addressed. These include:

(i) Audio or text *captcha* is not available;

(ii) The seven filters, which *inter alia*, include age group, name of vaccine and whether the vaccine is paid or free, are not designed accessibly. This issue can be addressed by creation of a drop-down list;

(iii) While visually challenged persons can determine the number of available vaccine slots, one cannot find out the day those slots correspond to. This can be resolved by ensuring that table headers correspond to associated cells;

(iv) Keyboard support for navigating the website is absent;

(v) Adequate time should be given to disabled users to schedule their appointment without the possibility of being automatically logged off; and

(vi) Accessibility protocols, such as use of appropriate colour contrasts, should be adhered to.

F Conclusion

43. We direct the UoI to file an affidavit, which shall address the issues and questions raised in Section E, wherein it shall ensure that each issue is responded to individually and no issue is missed out. We also direct that the affidavit should provide the following information:

- The data on the percentage of population that has been vaccinated (with one dose and both doses), as against eligible persons in the first three phases of the vaccination drive. This shall include data pertaining to the percentage of rural population as well as the percentage of urban population so vaccinated;
- The complete data on the Central Government's purchase history of all the COVID -19 vaccines till date (Covaxin, Covishield and Sputnik V). The data should

clarify : (a) the dates of all procurement orders placed by the Central Government for all 3 vaccines; (b) the quantity of vaccines ordered as on each date; and (c) the projected date of supply; and

- An outline for how and when the Central Government seeks to vaccinate the remaining population in phases 1, 2 and 3.
- The steps being taken by the Central Government to ensure drug availability for mucormycosis.

44. While filing its affidavit, UoI shall also ensure that copies of all the relevant documents and file notings reflecting its thinking and culminating in the vaccination policy are also annexed on the vaccination policy. Hence, we direct the UoI to file its affidavit within 2 weeks.

45. We also note that UoI's stated position in its affidavit dated 9 May 2021 is that every State/UT Government shall provide vaccination free of cost to its population. It is important that individual State/UT Governments confirm/deny this position before this Court. Further, if they have decided to vaccinate their population for free then, as a matter of principle, it is important that this policy is annexed to their affidavit, so that the population within their territories can be assured of their right to be vaccinated for free at a State vaccination centre. Hence, we direct each of the State/UT Governments to also file an affidavit within 2 weeks, where they shall clarify their position and put on record their individual policies.

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[1] "**UoI**"/interchangeably referred to as the "**Central Government**"

[2] "**UTs**"

[3] Sandra Fredman, "Adjudication as Accountability : A Deliberative Approach" in Nicholas Bamforth and Peter Leyland (eds), Accountability in the Contemporary Constitution (Oxford University Press, 2013)

[4] *Union of India* v. *Rakesh Malhotra*, SLP (Civil) (Diary) No 11622 of 2021

[5] "**NCT**"

[6] "**UIP**"

[7] "**HCWs**"

[8] "**FLWs**"

[9] "**Liberalized Vaccination Policy**"

[10] "**SII**"

[11] "**BBIL**"

[12] Guidance Note For COWIN 2.0 dated 28 February 2021, available at <https : //www.mohfw.gov.in/pdf/GuidancedocCOWIN2.pdf>

[13] Press releases dated 28 February 2021 and 19 April 2021, available at <https : //pib.gov.in/PressReleseDetail.aspx?PRID=1701549> and <https : //pib.gov.in/PressReleseDetail.aspx?PRID=1712710>

[14] Liberalized Pricing and Accelerated National Covid-19 Vaccination Strategy dated 24 April 2021, available at <https : //www.mohfw.gov.in/pdf/LiberalisedPricingandAcceleratedNationalCovid19VaccinationStrategy2042021.pdf>

[15] "**CDL**"

[16] "**other than GoI channel**"

[17] Available at <https : //www.pib.gov.in/PressReleasePage.aspx?PRID=1721225>

[18] *DDA* v. *Joint Action Committee*, (2008) 2 SCC 672

[19] 197 U.S. 11 (1905)

[20] *Roman Catholic Diocese of Brooklyn, New York* v. *Cuomo*, 592 U.S., 141 S. Ct. 63

[21] *Calvary Chapel Dayton Valley* v. *Steve Sisolak, Governor of Nevada*, et al, 140 S.Ct. 2603 (Mem) (Justice Alito Dissenting Opinion)

[22] (2020) 10 SCC 459 : AIR 2020 SC 4601, para 9

[23] **"NEGVAC"**

[24] **"DCGI"**

[25] Available at <https : //www.indiabudget.gov.in/doc/Budget_Speech.pdf>, page 7

[26] **"ICMR"**

[27] **"CSC"**

[28] Available at <http : //mospi.nic.in/sites/default/files/publication_reports/Report_585_75th_round_Education_final_15 07_0.pdf>

[29] Available at <https : //www.trai.gov.in/sites/default/files/Wireless_Data_Service_Report_21082019_0.pdf>

[30] Available at <https : //csc.gov.in/assets/events-report/Annual-Report-2019-20.pdf>, at page 8

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