IN THE SUPREME COURT OF INDIA

(CIVIL ORIGINAL JURISDICTION)

I. A. No. 158746 OF 2021

IN

WRIT PETITION (Civil) No. 572 of 2021

Ambar H. Koiri)
B – 1501, Runwal Hts.)
L.B.S. Marg, Mulund (W))
Mumbai – 400 080 …Applicant/
Intervener

IN THE MATTER OF:

Delhi Commission for Protection of Child Rights) ...Petitioner

Versus

Union of India & Anr.) …Respondents

SUGGESTIONS ON BEHALF OF APPLICANT REGARDING VACCINATION POLICIES FOR PREGNANT WOMEN

1. That, before taking any decision, it is just and necessary to go through the imperial data available.

2. The data suggests that, it is not advisable to ask the pregnant women to get vaccinated when there is a possibility of fatal side effects and many countries have banned the use of Covishield for such reasons.

3. That, the applicant has covered his suggestions in following headings.

4. WHO warned on risk of getting serious paralytic disease of Guillain-Barre Syndrome (GBS) following Covishield Vaccine Administration therefore it is strictly not advisable to give said vaccines to the pregnant woman.

On 13th and 20th July 2021, the COVID-19 subcommittee of the WHO Global Advisory Committee on Vaccine Safety (GACVS) met virtually to discuss rare reports of Guillain-Barré Syndrome (GBS) following vaccination with the Janssen and AstraZeneca COVID-19 vaccines. Both vaccines use an adenovirus platform as their backbone.

GBS is a rare immune system disorder that results in muscle weakness, pain or numbness, and, in more severe cases, paralysis. GBS could result from different causes, including infections, and occurs more frequently in males and persons over 50 years old. Cases may occur coincidentally following vaccination. For example, rare cases of GBS have been observed following seasonal influenza vaccines and vaccines to protect against shingles, but it is not known if the vaccines cause GBS. A systematic review and meta-analysis in 2011 estimated the background incidence for GBS as 0.8-1.9/100 000 in Europe and Northern America.

For Vaxzevria (the AstraZeneca COVID-19 vaccine manufactured in Europe), the European Medicines Agency (EMA)'s Pharmacovigilance Risk Assessment Committee (PRAC) issued a statement on 9 July recommending the addition of a warning to raise awareness of GBS following vaccination, although they could not confirm nor rule out an association with the vaccine. A total of 227 cases of GBS had been reported from the EU/EEA to EMA with Vaxzevria by 27 June 2021, while around 51.4 million doses of Vaxzevria had been given to people in the EU/EEA by 20 June 2021.

Source:-

https://www.who.int/news/item/26-07-2021-statement-of-the-who-gacvs-covid-19-subcommittee-on-gbs

5. Pregnant Women were not included in the Covid-19 vaccine clinical trials, therefore there cannot be an experiment on them.

Source:-

1. https://www.sciencedirect.com/science/article/pii/S0140673620326611

2. https://www.thelancet.com/journals/lancet/article/PIIS01406736(20)32466- 1/fulltext

3. https://www.medrxiv.org/content/10.1101/2020.12.21.20248643v1.full.pdf

4. https://www.thelancet.com/journals/laninf/article/PIIS1473-3099(20)30942-7/fulltext#sec1

6. Caution by manufacturers on who should not get the vaccine.

6.1. <u>COVAXIN</u>

It is submitted that fact sheet Bharat Biotech Covaxin website, put out by manufacturers itself states that:

> ***WHAT IF I AM PREGNANT?***
>
> *If you are pregnant, you should not get the vaccine as the safety of the vaccine has not been studied in pregnant women."*

6.2. Contradiction of vaccines on pregnant and lactating mothers.

As per Summary of Product Characteristic available with Central Drugs Standard Control Organisation (CDSCO), relevant section is reproduced below:

*"**4.3** Contraindications ● Pregnant and lactating mothers."*

6.3. <u>Sputnik V</u>

The fact sheet of Sputnik V Vaccine categorically clarifies the use in Pregnant Women. The relevant part of the Fact sheet is as under;

> ***"WHAT IF I AM PREGNANT OR BREASTFEEDING?***
>
> *The product is not for use during pregnancy, since its effectiveness and*

safety during this period have not been studied."

7. Manufacturers own statements from their factsheet regarding caution for vaccination of pregnant women.

Covishield: WHAT IF I AM PREGNANT OR BREASTFEEDING?
You may discuss your options with the healthcare provider/doctor.

Source:-
https://www.seruminstitute.com/pdf/covishield_fact_sheet.pdf

Covaxin: WHAT IF I AM PREGNANT?

Available data on COVAXIN® Vaccine administered to pregnant women are insufficient to inform vaccine associated risks in pregnancy.

Source:-
https://www.bharatbiotech.com/images/covaxin/covaxin-factsheet.pdf

7.1. Cases of Pregnant Women facing adverse events post vaccination in India.

Biraul, Pandaul Jilla, Madhubani, Bihar

1.5 month old baby of a breastfeeding mother died on 6-Dec-2021. Puja Devi took Covaxin earlier that day at a vaccination camp after advice from Asha health staff.

3 hours later, the mother breastfed milk to her child, but the baby suddenly died on the same night around 10 pm.

The child was normal that day laughing and playing.

https://twitter.com/MUKUNDJ56681511/status/1468500050435198979

7.2. Madhya Pradesh: Datia district,

Bhander tehsil, Berachh village.

24 y/o pregnant woman Rinki Rajak & her 8 month old unborn baby died on Wednesday, October 13, 2021, less than 2 weeks after receiving COVID-19 vaccine.

She was forcefully vaccinated by a nurse at the local hospital on Sept 30th, despite her refusal.

https://www.naidunia.com/lite/madhya-pradesh/datia-datiya-woman-dead-7098709

7.3. Madhya Pradesh: Gwalior district,

A 7-month old baby died due to premature delivery of mother Rinku Kushwaha (28), resident of Ajaypur village, due to severe fever a day after receiving first dose of COVID-19 vaccine.

http://www.naidunia.com/madhya-pradesh/gwalior-gwalior-vaccination-news-seven-months-pregnant-delivered-two-days-after-the-vaccine-the-child-died-7076813

7.4. Karnataka: Koppal district

An unborn baby died with 25 year old pregnant woman, Manjula Yamanurappa Meti, resident of Sebankatti village of Kushtagi tehsil, who died early morning of August 06, due to heavy bleeding whichy started few hours of receiving first dose of COVID-19 vaccine.

14 pregnant women were vaccinated on August 05 at Hulgera village vaccination center.

https://www.prajavani.net/amp/district/koppal/a-pregnant-lady-died-in-kustagi-due-to-bleeding-856241.html

7.5. Kerala: Kottayam district

7 week unborn baby died in womb, with Mahima Mathew (31), resident of Kanjirapally tehsil, who died on Friday, August 20, due to brain haemorrhage, just 15 days after receiving first dose of COVID-19 vaccine.

https://keralakaumudi.com/en/news/mobile/news-amp.php?id=622988&u

7.6. Tamilnadu: Theni district

Village: Badrakalipuram, Tehsil: Dombucheri

6 month old unborn baby of Sylvia (23), died in womb, on July 10, a day after she was vaccinated with first dose of Covishield COVID-19 vaccine on advice of Dombucheri PHC staff, where she went for a pregnancy test.

http://www.dailythanthi.com/districts/chennai/2021/07/10220414/infant-death-in-the-womb-of-a-pregnant-woman-vaccinated.vpf

7.7. Tamil Nadu: Tiruvallur district

A 9-month old unborn baby died with mother, Lavanya (25), resident of Thiruttani town, who died on September 29, due to sudden breathlessness, just within 8 hours after receiving second

does of COVID-19 vaccine.

https://www.puthiyathalaimurai.com/newsview/117307/A-pregnant-woman-who-took-2nd-dose-covid-vaccine-died-due-to-sudden-suffocation-in-Thiruvallur.html

7.8. Karnataka: Koppal district

25 year old pregnant woman, Manjula Yamanurappa Meti, resident of Sebankatti village of Kushtagi tehsil, died early morning of August 06, due to heavy bleeding which started few hours of receiving first dose of COVID-19 vaccine.

14 pregnant women were vaccinated on August 05 at Hulgera village vaccination center.

https://www.prajavani.net/amp/district/koppal/a-pregnant-lady-died-in-kustagi-due-to-bleeding-856241.html

8. Evidence of vaccine caused adverse events.

8.1. In multiple cases of Adverse Events following Covid Vaccination, it has been concluded that the cause was the Covid Vaccine. The National AEFI Committee has also accepted atleast 4 cases of Death due to classification "A1- Vaccine Product Related Reaction". The Details are asunder:

a. IND(CO-AEFI)MHBMC21025 – 2021 - 68 YRS – M – DEATH - 8/03/21 - COVISHIELD – Anaphylaxis - Vaccine product related reaction - 31 March 2021

b. 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

c. IND(CO-AEFI)CGRGH21006 – 2021 – 47 – MALE – DEATH - 03-06-2021 – COVAXIN – ANAPHYLAXIS - A1 - 27-08-2021

d. IND(CO-AEFI)MHBMC21025 – 2021 - 68 YRS – M – DEATH - 8/03/21 – COVISHIELD – Anaphylaxis - Vaccine product related reaction - 31 March 2021

8.2. Health Rights Activist group has also collected medical records/documents of some cases of Death after Vaccination where local authorities have accepted Causal relationship to the vaccine, however, the National AEFI committee report is still awaited for these cases.

Summary of such cases are as under;

a. Mahima Mathew took the Covishield vaccine on 6th August 2021 and passed away on 20th August 2021. Death Report from Mar Sleeva mentions the Cause of Death as "Cerebral Venous Thromobosis – Vaccine associated Thrombocytopenia (pending autopsy).

   Furthermore, the Postmortem mentions "Opinion as to Cause of Death – Postmortem findings are consistent with death due to intracranial haemorrhage. Final opinion is reserved pending laboratory investigations.

b. Nova Sabu took the Covishield vaccine on 28.7.21 and passed away on 12.8.21. Enquiry Report by District Medical Officer mentions "As per the available data and evidence Ms. Nova Sabu has died of intra cerebral blood. This was second to immunogenic thrombosis, thrombocytopenia syndrome which is a rare complication of Covishield vaccine."

c. Rithaika Omtri took the Covishield vaccine 29.5.21 and passed away on 20.6.21. The Postmortem report prepared by Department of Forensic Medicine and Toxicology Osmania Medical College mentions under Opinions as to the Cause of Death – "The cause of Death to the best of my knowledge and belief was: Intracranial Haemorrhage and Bleeding Diathesis consequent to vaccination with Covishield."

9. Video testimonies with the family of the deceased show healthy person dying directly on account of the vaccine.

Source:- :

https://u.pcloud.link/publink/show?code=kZ03dwXZcrC28I987y41sJlCLpBSUbgJHz07

10. Vaccine deaths reported in media has crossed figure of 10,000.

"Awaken India Movement Vaccine Deaths Weekly Update."

Awaken India Movement (AIM) has sent details of Covid Vaccine deaths covered by media/social media in India as on 30.11.21, to various high authorities of our country.

PRSEC/E/2021/34004

Vaccine Deaths in India covered by the Media! File updated till Victim #10561

Actual cases of death after taking the Covid Vaccines can be at least 100 times more than the cases listed in this document.

Source:-

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

11. Government is hiding the vaccine deaths.

11.1. In fact Union of India is suppressing/hiding the data. In an RTI reply by District medical officer (Health), Mallapuram dist. Kerala, Dated **27/11/2021**, its point 13 states that:-

> "11 people deceased in Malappuram district due to the side effect of vaccination against covid 19 till 25-09-2021".

A copy of the said RTI reply is enclosed herewith and marked as **[Annexure "A" Page No. 88]**

11.2. Justice D.Y. Chandrachud had said that "the Government hides data, gives false information on covid19 pandemic and intellectual citizen of the country should bring the truth."

Source:-

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

"Supreme Court Judge

Hon'ble Justice Dr. D. Y. Chandrachud on 29th August, 2021 said that the State officer can spread lies, but citizens must be vigilant. Public intellectuals have a duty to expose lies of the state. Emphasizing the need for truth in a democracy, he said the state can indulge in falsehood and it was the duty of citizens to strengthen public institutions and question the state to determine the truth. In the context of the

Covid-19 pandemic, we see that there is an increasing trend of countries across the world trying to manipulate data. Hence, one cannot only rely on the state to determine the truth"

12. Under reporting in <u>VAERS</u>.

VAERS is a passive system that is severely under reported. The CDC and FDA have never conducted a study to determine what this under-reported factor is, but independent scientists have, and we have previously published the analysis conducted by Dr. Jessica Rose, who has determined that a conservative under-reported factor would be X41.

Source:-

https://downloads.regulations.gov/CDC-2021-0089-0024/attachment_1.pdf

In a separate 2011 study titled "Electronic Support for Public Health-Vaccine Adverse Event Reporting System" commissioned by Department of Health and Human Services (U.S.A) and performed by Harvard Consultants, concluded that "fewer than 1 % of vaccine adverse events are reported". The link of this report can be found at:

https://digital.ahrq.gov/sites/default/files/docs/publication/r18hs017045-lazarus-final-report-2011.pdf

13. Studies & Data which link AstraZeneca (Covishield) to serious adverse events.

13.1. "The first cases of large vessel arterial occlusion strokes linked to the AstraZeneca COVID-19 vaccine have been described in the United Kingdom.

The three cases (one of which was fatal) occurred in two women and one man in their 30s or 40s and involved blockages of the carotid and middle cerebral artery. Two of the three patients also had venous thrombosis involving the portal and cerebral venous system. All three also had extremely low platelet counts, confirmed antibodies to platelet factor 4, and raised D-dimer levels, all characteristic of the vaccine-induced immune thrombotic thrombocytopenia (VITT) reaction associated with the AstraZeneca vaccine."

They are described in detail in a letter published online on May 25 in the Journal of Neurology, Neurosurgery & Psychiatry. **[Annexure "B" Page No. 89]**

"These are first detailed reports of arterial stroke believed to be caused by VITT after the AstraZeneca COVID vaccine, although stroke has been mentioned previously in the VITT data," senior author, David Werring, PhD, FRCP, commented to Medscape Medical News.

"VITT has more commonly presented as CVST [Cerebral venous sinus thrombosis] which is stroke caused by a venous thrombosis; these cases are showing that it can also cause stroke caused by an arterial thrombosis," Werring, who is professor of clinical neurology at the Stroke Research Centre, University College London Queen Square Institute of Neurology, United Kingdom, explained."

"In patients who present with ischemic stroke, especially younger patients, and who have had the AstraZeneca vaccine within the past month, clinicians need to consider VITT as a possible cause, as there is a

specific treatment needed for this syndrome," he said.

Young patients presenting with ischemic stroke after receiving the AstraZeneca vaccine should urgently be evaluated for VITT with laboratory tests, including platelet count, D-dimers, fibrinogen, and anti-PF4 antibodies, the authors write, and then managed by a multidisciplinary team including hematology, neurology, stroke, neurosurgery, neuroradiology, for rapid access to treatments including intravenous immune globulin, methylprednisolone, plasmapheresis and nonheparin anticoagulants such as fondaparinux, argatroban, or direct oral anticoagulants."

Source:-

- https://www.medscape.com/viewarticle/951852
- https://jnnp.bmj.com/content/92/11/1247

13.2 New research published in The BMJ confirmed evidence of blood clotting and found a small risk after receiving just one dose of AstraZeneca's vaccine.

"We did, however, observe an increased rate of venous thromboembolic events, corresponding to 11 excess venous thromboembolic events per 100,000 vaccinations and including a clearly increased rate of cerebral venous thrombosis with 7 observed events versus 0.3 expected events among the 282,572 vaccine recipients."

Researchers investigated the likelihood of blood clotting events for 282,572 people in Denmark and Norway. Using data from healthcare registries, they reviewed information on people 18 to 65 years old who received their first dose of AstraZeneca between Feb. 9 and March 11.

About 83 arterial events were found with a morbidity ratio of 0.97. Of the

83 events, researchers observed increases in intracerebral hemorrhages. This was estimated to occur 1.7 times for every 100,000 vaccinations.

The team expected to find 30 venous thromboembolic events, but found 59 with a morbidity ratio of 1.97. About 11 excess events were estimated to occur for every 100,000 vaccinations. There was also a small increased risk of pulmonary embolism, lower limb venous thrombosis and other venous thrombosis.

Researchers found 2.5 events of blood clotting in the brain for every 100,000 vaccinations, and the morbidity ratio was estimated to be 20.25 after observing seven instances of cerebral venous thrombosis, according to the study.

The morbidity ratio for any type of blood clotting disorder was 1.52, which corresponded with three excess events for every 100,000 vaccinations. About 5.1 excess bleeding events were observed for every 100,000 vaccinations.

Of the entire vaccinated cohort, there were 15 deaths in the general population. Researchers concluded that blood clotting is a very rare side effect, but the benefits of vaccination continue to outweigh the risks.

"Our study provides evidence of an excess rate of venous thromboembolism, including cerebral venous thrombosis, among recipients of the Oxford AstraZeneca COVID-19 vaccine ChAdOx1-S within 28 days of the first dose. The absolute risks of these events were, however, small," researchers said.

Source:-

https://www.bmj.com/content/373/bmj.n1114

13.3. This article was published on December 10 2021 in Business Today. Following are the relevant excerpts from the article :

"The AEFI committee has completed an in-depth case review of 498 serious and severe events, of which 26 cases have been reported to be potential thromboembolic (formation of a clot in a blood vessel that might also break loose and carried by the bloodstream to plug another vessel) events - following the administration of Covishield vaccine - with a reporting rate of 0.61 cases/ million doses," the statement said.

Source:-

https://www.businesstoday.in/coronavirus/story/india-has-26-cases-of-blood-clotting-after-covishield-vaccination-healthmin-296278-2021-05-17

13.4 "A private hospital has confirmed the incidence of a rare but potentially life-threatening, vaccine-induced blood clotting disorder among some Covishield recipients in India through what doctors have described as a "gold-standard" confirmatory test.

The findings corroborate observations from other countries that vaccine-induced thrombosis and thrombocytopenia (VITT) is an extremely rare adverse event, but underline the need for national guidelines to raise awareness on diagnosis and treatment, the doctors said.

Doctors at the Sir Ganga Ram Hospital, New Delhi, diagnosed VITT through an initial test that detects antibodies against a substance called platelet factor 4 (PF4), and then a confirmatory test that observes how

normal platelets respond to the patient's serum.

The first patient that the SGRH doctors diagnosed as suffering from VITT was an 18-year-old boy brought to the Army Hospital, New Delhi, from Mathura in June, 17 days after he had received his first dose of Covishield. The boy, who had a persistent headache and recurrent vomiting, died in hospital."

The World Health Organisation had in April this year flagged reports of thrombosis (formation of blood clots in blood vessels) and thrombocytopenia (low platelet counts) as a rare adverse event following vaccination with Vazeria and Covishield, the AstraZeneca-Oxford vaccines produced by AstraZeneca and the Serum Institute of India, respectively."

Source:-

https://www.telegraphindia.com/india/rare-blood-clot-tied-to-covishield/cid/1835038

13.5 This study was published on April 9 2021 in The New England Journal of Medicine by Sabine Eichinger et al. Following are the relevant excerpts from the study:

"Vaccination with ChAdOx1 nCov-19 can result in the rare development of immune thrombotic thrombocytopenia mediated by platelet-activating antibodies against PF4, which clinically mimics autoimmune heparin-induced thrombocytopenia."

Source:-

https://www.nejm.org/doi/10.1056/NEJMoa2104840

13.6 EMA's safety committee (PRAC) has concluded today that unusual

blood clots with low blood platelets should be listed as very rare side effects of Vaxzevria (formerly COVID-19 Vaccine AstraZeneca).

In reaching its conclusion, the committee took into consideration all currently available evidence, including the advice from an ad hoc expert group.

EMA is reminding healthcare professionals and people receiving the vaccine to remain aware of the possibility of very rare cases of blood clots combined with low levels of blood platelets occurring within 2 weeks of vaccination. So far, most of the cases reported have occurred in women under 60 years of age within 2 weeks of vaccination. Based on the currently available evidence, specific risk factors have not been confirmed.

People who have received the vaccine should seek medical assistance immediately if they develop symptoms of this combination of blood clots and low blood platelets (see below).

The PRAC noted that the blood clots occurred in veins in the brain (cerebral venous sinus thrombosis, CVST) and the abdomen (splanchnic vein thrombosis) and in arteries, together with low levels of blood platelets and sometimes bleeding.

The Committee carried out an in-depth review of 62 cases of cerebral venous sinus thrombosis and 24 cases of splanchnic vein thrombosis reported in the EU drug safety database (EudraVigilance) as of 22 March 2021, 18 of which were fatal.1 The cases came mainly from spontaneous reporting systems of the EEA and the UK, where around 25 million

people had received the vaccine."

Source:-

https://www.ema.europa.eu/en/news/astrazenecas-covid-19-vaccine-ema-finds-possible-link-very-rare-cases-unusual-blood-clots-low-blood

14. The SOP/guidelines by the Health Ministry regarding informed consent is an eyewash as it does not contain details as mandated in Montogomerry's case 2015 UKSC 11 and Universal Declaration on Bioethics & Human Rights, 2005.

14.1 The SOP/guidelines by the Health Ministry regarding informed consent is an eyewash as it does not contain any the following things:-

(a) What exact information the concerned doctor is going to give pregnant women before taking her informed consent.

(b) The SOP is false document as it has suppressed the side effects of the vaccination/vaccinating the pregnant woman, which is mandatorily to be told to her before obtaining her informed consent as has been laid down in Montogomerry's case 2015 UKSC 11.

(c) The SOP has also suppressed the most important aspect of the natural immunity and no need to vaccinate the women with natural immunity as the study shows that it will cause much harm than benefit and it is misappropriation of public money to vaccinate such woman because the natural immunity is proven to be more robust, life long and 13 times better than vaccine immunity.

14.2. The **Universal Declaration on Bioethics & Human Rights, 2005** reads thus:

Article 3 – Human dignity and human rights

1. Human dignity, human rights and fundamental freedoms are to be fully respected.

2. The interests and welfare of the individual should have priority over the sole interest of science or society.

Article 4 – Benefit and harm

In applying and advancing scientific knowledge, medical practice and associated technologies, direct and indirect benefits to patients, research participants and other affected individuals should be maximized and any possible harm to such individuals should be minimized.

Article 5 – Autonomy and individual responsibility

The autonomy of persons to make decisions, while taking responsibility for those decisions and respecting the autonomy of others, is to be respected. For persons who are not capable of exercising autonomy, special measures are to be taken to protect their rights and interests.

Article 6 – Consent

1. Any preventive, diagnostic and therapeutic medical intervention is only to be carried out with the prior, free and informed consent of the person concerned,

based on adequate information. The consent should, where appropriate, be express and may be withdrawn by the person concerned at any time and for any reason without disadvantage or prejudice.

2. Scientific research should only be carried out with the prior, free, express and informed consent of the person concerned. The information should be adequate, provided in a comprehensible form and should include modalities for withdrawal of consent. Consent may be withdrawn by the person concerned at any time and for any reason without any disadvantage or prejudice. Exceptions to this principle should be made only in accordance with ethical and legal standards adopted by States, consistent with the principles and provisions set out in this Declaration, in particular in Article 27, and international human rights law.

3. In appropriate cases of research carried out on a group of persons or a community, additional agreement of the legal representatives of the group or community concerned may be sought. In no case should a collective community agreement or the consent of a community leader or other authority substitute for an individual's informed consent.

Article 7 – Persons without the capacity to consent

In accordance with domestic law, special protection is to be given to persons who do not have the capacity to consent:

(a) authorization for research and medical practice should be obtained in accordance with the best interest of the person concerned and in accordance with domestic law. However, the person concerned should be involved to the greatest extent possible in the decision-making process of consent, as well as that of withdrawing consent;

(b) research should only be carried out for his or her direct health benefit, subject to the authorization and the protective conditions prescribed by law, and if there is no research alternative of comparable effectiveness with research participants able to consent. Research which does not have potential direct health benefit should only be undertaken by way of exception, with the utmost restraint, exposing the person only to a minimal risk and minimal burden and, if the research is expected to contribute to the health benefit of other persons in the same category, subject to the conditions prescribed by law and compatible with the protection of the individual's human rights. Refusal of such persons to take part in research should be respected.

Article 8 – Respect for human vulnerability and personal integrity

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

Article 9 – Privacy and confidentiality

The privacy of the persons concerned and the confidentiality of their personal information should be respected. To the greatest extent possible, such information should not be used or disclosed for purposes other than those for which it was collected or consented to, consistent with international law, in particular international human rights law.

Article 10 – Equality, justice and equity

The fundamental equality of all human beings in dignity and rights is to be respected so that they are treated justly and equitably.

Article 11 – Non-discrimination and non-stigmatization

No individual or group should be discriminated against or stigmatized on any grounds, in violation of human dignity, human rights and fundamental freedoms.

Article 18 – Decision-making and addressing bioethical issues

1. Professionalism, honesty, integrity and transparency in decision-making should be promoted, in particular declarations of all conflicts of interest and appropriate sharing of knowledge. Every endeavour should be made to use the best available scientific knowledge and methodology in addressing and periodically reviewing bioethical issues.

2. Persons and professionals concerned and society as a whole should be engaged in dialogue on a regular basis.

3. Opportunities for informed pluralistic public debate, seeking the expression of all relevant opinions, should be promoted.

Article 19 – Ethics committees

Independent, multidisciplinary and pluralist ethics committees should be established, promoted and supported at the appropriate level in order to:

(a) assess the relevant ethical, legal, scientific and social issues related to research projects involving human beings;

(b) provide advice on ethical problems in clinical settings;

(c) assess scientific and technological developments, formulate recommendations and contribute to the preparation of guidelines on issues within the scope of this Declaration;

(d) foster debate, education and public awareness of, and engagement in, bioethics.

Article 20 – Risk assessment and management

Appropriate assessment and adequate management of risk related to medicine, life sciences and associated technologies should be promoted.

Article 22 – Role of States

1. States should take all appropriate measures, whether of a legislative, administrative or other character, to give effect to the principles set out in this Declaration in accordance with international human rights law. Such measures should be supported by action in the spheres of education, training and public information

2. States should encourage the establishment of independent, multidisciplinary and pluralist ethics committees, as set out in Article 19.

Article 27 – Limitations on the application of the principles

If the application of the principles of this Declaration is to be limited, it should be by law, including laws in the interests of public safety, for the investigation, detection and prosecution of criminal offences, for the protection of public health or for the protection of the rights and freedoms of others. Any such law needs to be consistent with international human rights law.

Article 28 – Denial of acts contrary to human rights, fundamental freedoms and human dignity

Nothing in this Declaration may be interpreted as implying for any State, group or person any claim to engage in any activity or to perform any act contrary to human rights, fundamental freedoms and human dignity."

15. Comparison of deaths and serious adverse events in India and other countries.

A comparative table of Vaccine adverse events between Europe (27 countries), USA and India is reproduced asunder:

Sr. No.	Description	USA*	Europe**	India***
1	Total No. of Doses administered	462 million	606 million	1.29 billion
2	Total Population Size	333.8 million	748 million	1.4 billion
3	% of Population given	72.00%	71.10%	58.90%

	single dose			
4	% of Population given both doses	60.40%	66.80%	35.60%
5	Number of people given first dose	240.3 million	531.8 million	824.6 million
6	Number of people given second dose	201.6 million	499.6 million	498.4 million
7	Number of Injuries Reported post vaccination	6,64,745	28,90,600	49,819
8	Number of Deaths Reported post vaccination	8,898	31,014	946
9	Number of Injuries Reported post AZ/Covishield		10,75,335	
10	Number of Deaths reported post AZ/Covishield		6145	

Note:

* Data for the USA is captured from VAERS

** Data for 27 countries of Europe is captured from EUDRA

*** Data for India is taken from ToI news report published on 8.12.21

Sources:-

- https://timesofindia.indiatimes.com/india/2k-serious-cases-of-aefi-0-004-of-123-crore-of-shots-given-government/articleshow/88153594.cms

- https://ourworldindata.org/covid-vaccinations
- https://www.nytimes.com/interactive/2021/world/covid-vaccinations-tracker.html
- https://www.statista.com/statistics/1218676/full-covid-19-vaccination-uptake-in-europe/
- https://tradingeconomics.com/european-union/coronavirus-vaccination-rate
- https://graphics.reuters.com/world-coronavirus-tracker-and-maps/vaccination-rollout-and-access/
- https://www.nytimes.com/interactive/2021/world/covid-vaccinations-tracker.html
- https://www.bloomberg.com/graphics/covid-vaccine-tracker-global-distribution/
- https://ig.ft.com/coronavirus-vaccine-tracker/?areas=gbr&areas=isr&areas=usa&areas=eue&areas=can&areas=chn&areas=ind&cumulative=1&doses=total&populationAdjusted=1
- https://childrenshealthdefense.org/defender/vaers-cdc-omicron-vaccine-makers-stock-adverse-events-deaths/
- https://vaccineimpact.com/2021/31014-deaths-2890600-injuries-following-covid-shots-in-european-database-of-adverse-reactions-as-young-previously-healthy-people-continue-to-die/

https://vaccinetracker.ecdc.europa.eu/public/extensions/COVID-19/vaccine-tracker.html#uptake-tab

16. Proof that studies of CDC are flawed.

In October, 2021 the New England Journal of Medicine admitted that the original study used to justify the CDC and the FDA in recommending the shots to pregnant women was flawed.

Source:-

:https://www.nejm.org/doi/full/10.1056/NEJMx210016?query=recirc_curatedRelated_article

Since then, researchers in New Zealand have conducted a new study on the original data, and concluded:

A re-analysis of these figures indicates a cumulative incidence of spontaneous abortion ranging from 82% (104/127) to 91% (104/114), 7–8 times higher than the original authors' results.

Source:-

https://cf5e727d-d02d-4d71-89ff-9fe2d3ad957f.filesusr.com/ugd/adf864_2bd97450072f4364a65e5cf1d7384dd4.pdf

17. Natural Immunity developed due to previous infection is found to be 13 times more robust than the immunity developed due to vaccine.

17.1. That the Respondent no. 1 in its Preliminary Affidavit dated 02.10.2021 has not made any reference about the natural immunity.

17.2. 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.

Source:-

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

17.3 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 Professor at Department of Community Medicine at AIIMS , Delhi in his interview at

Source:-

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"

17.4. "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.

Source:-

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

17.5. The decision taken by the authority apart from its legality also amounts to an offense 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.

18. Research showing that giving vaccines to person with earlier Covid-19 infection causes serious harm than disease itself.

18.1. 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.

Source:-

https://www.mdpi.com/2075-1729/11/3/249/html

19. Vaccinated people are at higher risk of hospitalization & death.

19.1. "A majority of gravely ill patients in Israel are double vaccinated. A majority of deaths over 50 in England are also double vaccinated. **[Annexure "C" Page No. 91]**

Source:-

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

19.2. 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.

Source:-

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

19.3 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.

Source:-

https://www.eurosurveillance.org/content/10.2807/1560-7917.ES.2021.26.39.2100822

19.4. 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

19.5. 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

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

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

19.7. 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

19.8. 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

19.9. 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. Cases where vaccine causing more harm than the disease itself.

20.1. 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.

Source:-

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

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

21.1. "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

21.2. "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

21.3. "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

21.4. "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

21.5. 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/

21.6. 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

21.7. 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

21.8. 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

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

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

Source:-

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

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

Source:-

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

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

Source:-

https://boston.cbslocal.com/2021/09/l5/brown-university-covid-dining-stduents-gathering/

(A copy of the news articles related to these university outbreaks is annexed as **[Annexure "D" Page No. 98]**

23. How vaccines don't reduce Covid cases even at a country level.

23.1. Israel had a huge surge in mid-September despite leading most countries in vaccination levels.

> *"Health Ministry Director-General Nachman Ash said Tuesday that the current wave of coronavirus infections is surpassing anything seen in previous outbreaks and that he is disappointed that a recent downward trend appeared to be reversing....pointing out that there is an average of 8,000 new infections each day, with occasional peaks over 10,000, he said, "That is a record that did not exist in the previous waves,,, including the massive third wave at the end of last year."*

Source:-

https://www.timesofisrael.com/health-ministry-chief-says-coronavirus-spread-reaching-record-heights/

23.2. We investigate the relationship between the percentage of

population fully vaccinated and new COVID-19 cases across 68 countries and across 2947 counties in the US.

At the country-level, there appears to be no discernable relationship between percentage of population fully vaccinated and new COVID-19 cases in the last 7 days. In fact, the trend line suggests a marginally positive association such that countries with higher percentage of population fully vaccinated have higher COVID-19 cases per 1 million people. Notably, Israel with over 60% of their population fully vaccinated had the highest COVID-19 cases per 1 million people in the last 7 days. The lack of a meaningful association between percentage population fully vaccinated and new COVID-19 cases is further exemplified, for instance, by comparison of Iceland and Portugal. Both countries have over 75% of their population fully vaccinated and have more COVID-19 cases per 1 million people than countries such as Vietnam and South Africa that have around 10% of their population fully vaccinated.

Of the top 5 counties that have the highest percentage of population fully vaccinated (99.9–84.3%), the US Centers for Disease Control and Prevention (CDC) identifies 4 of them as “High” Transmission counties. Chattahoochee (Georgia), McKinley (New Mexico), and Arecibo (Puerto Rico) counties have above 90% of their population fully vaccinated with all three being classified as “High” transmission. Conversely, of the 57 counties that have been classified as “low” transmission counties by the CDC, 26.3% (15) have percentage of population fully vaccinated below 20%.

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

23.3. Amid a surge in Covid-19 cases, Gibraltar has canceled official Christmas events and "strongly" discouraged people from hosting private gatherings for four weeks. Gibraltar's entire eligible population is vaccinated.

The government of Gibraltar recently announced that *"official Christmas parties, official receptions and similar gatherings"* have been canceled, and advised the public to avoid social events and parties for the next four weeks. Outdoor spaces are recommended over indoor ones, touching and hugging is discouraged, and mask wearing is advised.

More than 118% of Gibraltar's population are fully vaccinated against Covid-19, with this figure stretching beyond 100% due to doses given to Spaniards who cross the border to work or visit the territory every day. Masks are still required in shops and on public transport.

The initial vaccine campaign on the British outpost came to a conclusion in early spring 2021, with a large proportion of the population fully inoculated against Covid-19. It became one of the first places in Europe to reduce restrictions following a winter of lockdowns, in what was dubbed 'Operation Freedom'.

Gibraltar is currently doling out booster doses to the over-40s, healthcare workers, and other *"vulnerable groups,"* and administering vaccines to children aged between five and 12.

Similarly well-vaccinated countries have also reported surges in Covid-19 infections recently. In Singapore, where 94% of the eligible population have been inoculated, cases and deaths soared to record highs at the end of October, and have since subsided slightly. In Ireland, where

around 92% of the adult population is fully vaccinated, cases of Covid-19 and deaths from the virus have roughly doubled since August.

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

24. That, the law of informed consent has to be strictly as per the ratio laid down in the case of Montgomery's case [2015] UKSC 11, where doctors are bound to tell all the side effects and also about other alternate remedies including natural immunity.

In case of **Montgomerry's case [2015] UKSC 11,** it is ruled as under;

> *"77. These developments in society are reflected in professional practice. The court has been referred in particular to the guidance given to doctors by the General Medical Council, who participated as interveners in the present appeal.* ***One of the documents currently in force (Good Medical Practice (2013)) states, under the heading "The duties of a doctor registered with the General Medical Council":***
>
> ***"Work in partnership with patients. Listen to, and respond to, their concerns and preferences. Give patients the information they want or need in a way they can understand. Respect patients' right to reach decisions with you about their treatment and care."***
>
> *78. Another current document (Consent: patients and doctors making decisions together (2008)) describes a*

basic model of partnership between doctor and patient:

"The doctor explains the options to the patient, setting out the potential benefits, risks, burdens and side effects of each option, including the option to have no treatment. The doctor may recommend a particular option which they believe to be best for the patient, but they must not put pressure on the patient to accept their advice. The patient weighs up the potential benefits, risks and burdens of the various options as well as any non-clinical issues that are relevant to them. The patient decides whether to accept any of the options and, if so, which one."

(para 5)

In relation to risks, in particular, the document advises that the doctor must tell patients if treatment might result in a serious adverse outcome, even if the risk is very small, and should also tell patients about less serious complications if they occur frequently (para 32). The submissions on behalf of the General Medical Council acknowledged, in relation to these documents, that an approach based upon the informed involvement of patients in their treatment, rather than their being passive and potentially reluctant recipients, can have therapeutic benefits, and is regarded as an integral aspect of professionalism in treatment.

80. *In addition to these developments in society and in medical practice, there have also been developments in the law. Under the stimulus of the Human Rights Act 1998, the courts have become increasingly conscious of the extent to which the common law reflects fundamental values. As Lord Scarman pointed out in Sidaway's case, these include the value of self-determination (see, for example, S (An Infant) v S [1972] AC 24, 43 per Lord Reid; McColl v Strathclyde Regional Council 1983 SC 225, 241; Airedale NHS Trust v Bland [1993] AC 789, 864 per Lord Goff of Chieveley). As well as underlying aspects of the common law, that value also underlies the right to respect for private life protected by article 8 of the European Convention on Human Rights. The resulting duty to involve the patient in decisions relating to her treatment has been recognised in judgments of the European Court of Human Rights, such as Glass v United Kingdom (2004) EHRR 341 and Tysiac v Poland (2007) 45 EHRR 947, as well as in a number of decisions of courts in the United Kingdom. The same value is also reflected more specifically in other international instruments: see, in particular, article 5 of the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine, concluded by the member states of the Council of Europe, other states*

and the European Community at Oviedo on 4 April 1997.

82. In the law of negligence, this approach entails a duty on the part of doctors to take reasonable care to ensure that a patient is aware of material risks of injury that are inherent in treatment. *This can be understood, within the traditional framework of negligence, as a duty of care to avoid exposing a person to a risk of injury which she would otherwise have avoided, but it is also the counterpart of the patient's entitlement to decide whether or not to incur that risk. The existence of that entitlement, and the fact that its exercise does not depend exclusively on medical considerations, are important. They point to a fundamental distinction between, on the one hand, the doctor's role when considering possible investigatory or treatment options and, on the other, her role in discussing with the patient any recommended treatment and possible alternatives, and the risks of injury which may be involved.*

83. *The former role is an exercise of professional skill and judgment: what risks of injury are involved in an operation, for example, is a matter falling within the expertise of members of the medical profession. But it is a non sequitur to conclude that the question whether a risk of injury, or the availability of an alternative form of treatment, ought to be discussed with the patient is also a matter of purely professional*

judgment. The doctor's advisory role cannot be regarded as solely an exercise of medical skill without leaving out of account the patient's entitlement to decide on the risks to her health which she is willing to run (a decision which may be influenced by non-medical considerations). Responsibility for determining the nature and extent of a person's rights rests with the courts, not with the medical professions.

87. *The correct position, in relation to the risks of injury involved in treatment, can now be seen to be substantially that adopted in Sidaway by Lord Scarman, and by Lord Woolf MR in Pearce, subject to the refinement made by the High Court of Australia in Rogers v Whitaker, which we have discussed at paras 77-73.* ***An adult person of sound mind is entitled to decide which, if any, of the available forms of treatment to undergo, and her consent must be obtained before treatment interfering with her bodily integrity is undertaken. The doctor is therefore under a duty to take reasonable care to ensure that the patient is aware of any material risks involved in any recommended treatment, and of any reasonable alternative or variant treatments.*** *The test of materiality is whether, in the circumstances of the particular case, a reasonable person in the patient's position would be likely to attach significance to the risk, or the doctor is or should reasonably be aware*

that the particular patient would be likely to attach significance to it.

89. *Three further points should be made. First, it follows from this approach that the assessment of* ***whether a risk is material cannot be reduced to percentages****. The significance of a given risk is likely to reflect a variety of factors besides its magnitude: for example, the nature of the risk, the effect which its occurrence would have upon the life of the patient, the importance to the patient of the benefits sought to be achieved by the treatment, the alternatives available, and the risks involved in those alternatives. The assessment is therefore fact-sensitive, and sensitive also to the characteristics of the patient.*

90. *Secondly, the doctor's advisory role involves dialogue, the aim of which is to ensure that the patient understands the seriousness of her condition, and the anticipated benefits and risks of the proposed treatment and any reasonable alternatives, so that she is then in a position to make an informed decision. This role will only be performed effectively if the information provided is comprehensible.* ***The doctor's duty is not therefore fulfilled by bombarding the patient with technical information which she cannot reasonably be expected to grasp, let alone by routinely demanding her signature on a consent form****.*

> ***116.*** *As NICE (2011) puts it, "Pregnant women should be offered evidence-based information and support to enable them to make informed decisions about their care and treatment" (para 1.1.1.1). Gone are the days when it was thought that, on becoming pregnant, a woman lost, not only her capacity, but also her right to act as a genuinely autonomous human being.*

25. Guidelines issued by Japan's Health Ministry on informed consent and mandatory publication of side effects of vaccines.

25.1. Japan Health Ministry made rule that public and private sectors cannot discriminate against those who refuse to take vaccines. If any such complaint received then Human Rights Department will take action.

25.2. Govt made companies of Covid "vaccines" to warn of dangerous and potentially deadly side effects such as myocarditis. In addition, the country is reaffirming its commitment to adverse event reporting requirements to ensure all possible side effects are documented.

25.3. Japan's Ministry of Health of health website says that the Govt. encourages citizens to receive the "vaccine"; however, they stress it is not mandatory,

> *" Although we encourage all citizens to receive the COVID-19 vaccination, it is not compulsory or mandatory. Vaccination will be given only with the consent of the person to be vaccinated after the information provided."*

25.4. In addition, the government recommends those who are considering taking the shot carefully consider both its effectiveness and side effects.

> ***Please get vaccinated of your own decision, understanding both the effectiveness in preventing infectious diseases and the risk of side effects. No vaccination will be given without consent.***

25.5. Furthermore, they stress that businesses do not force employees to receive the experimental gene therapy. Nor should employees discriminate against those who refuse the injections,

> *Please do not force anyone in your workplace or those who around you to be vaccinated, and do not discriminate against those who have not been vaccinated.*

25.6. The government even links to a **"Human Rights Advice,"** including instructions for handling any complaints if individuals face **"vaccine"** discrimination at work.

25.7. Similar law is laid down by the Supreme Court of India in the case of **Common Cause Vs. Union of India (2018) 5 SCC 1, Airedale NHS Trust Vs. Bland (1993) 2 WLR 316.**

25.8. That, as per above said legal precedents when the patient/person approaches doctor for taking vaccine or guidance then it is duty of every Doctor to:

(i) To inform the patient about dangerous - death causing or any side effects of the vaccines and taking vaccine is not completely safe.

(ii) To inform the patient about all the alternate remedies and better or any options available such that, the

natural immunity developed in the body is much much better and superior than taking vaccines.

(iii) To inform that the vaccine is not a guarantee of any protection from Covid-19 caused due to the Sars-CoV-2 virus.

(iv) To inform that the patient about any other alternate remedies which are either available in the official protocol of Government of India such as Ivermectin, Vitamin-D, Ayurvedic, Naturopathy, Anandia's Ayurvedic composition as approved by the Hon'ble High Court in **Ponnekanti Rao Vs. State 2021 SCC OnLine AP 2171** etc.

(v) To inform the patient that the vaccines are experimental and given **Emergency Use Authorization (EUA)**.

(vi) To inform the patient that even if he signs the **'Informed Consent Form',** he is having rights to withdraw the said consent at any time.

(vii) To inform that if he is having any allergy to any of the contents of the vaccine or if he is in any prohibited category then as per law and as per vaccine manufacturer's own declarations, the person should not take the vaccines.

(viii) To explain everything to the patient in the language known to him/her and it should be in a simplified manner not in a high term scientific manner.

25.9. The government made companies of Covid "vaccines" to warn of dangerous and potentially deadly side effects such as myocarditis. In addition, the country is reaffirming its commitment to adverse event reporting requirements to ensure all possible side effects are documented.

These efforts from Japan's health authority are in stark contrast to the deceptive measures taken by other countries to coerce citizens into taking the injection, downplaying side effects, and discouraging proper adverse event reporting.

For more details read the article:

https://rairfoundation.com/alert-japan-places-myocarditis-warning-on-vaccines-requires-informed-consent/

Alert: Japan Places Myocarditis Warning on 'Vaccines' - Requires Informed Consent Amy Mek.

26. In Master Haridaan Kumar Vs. UOI 2019 SCC OnLine Del 11929, it is mandated that, the Government is bound to publish the side effects of vaccines.

26.1. Hon'ble Delhi High Court while dealing with the issue of MR vaccines in the case of **Master Haridaan Kumar (Minor through Petitioners Anubhav Kumar and Mr. Abhinav Mukherji) Versus Union of India, 2019 SCC OnLine Del 11929,** the Hon'ble High Court of Delhi directed that;

> ***"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"

27. Government is bound to pay compensation to all pregnant women, who were vaccinated by deception and obtaining their consent on the basis of false, incorrect & misleading information that the vaccines are completely safe and does not have death causing side effects.

27.1. Hon'ble Meghalaya High Court in the case of **Registrar General Vs. State of Meghalaya High Court of Meghalaya 2021 SCC OnLine Megh 130,** ruled that **vaccination by deceiption or by force is a civil criminal wrong.**

27.2. Recently, Singapore Government granted Rs. 1 Crore 78 Lacs compensation to victim for side effects of vaccine.

Source:-

https://greatgameindia.com/pfizer-heart-attack-compensation/

27.3. That, in a case of side effects of vaccines, the United States Government has set up the **'National Vaccine Injury Compensation Program'**. In a case of side effects of MMR vaccines the court granted a settlement of 101 Million U.S Dollars (7, 50, 34, 31,400 Crores).

A Copy of the news published and Court's judgment is at Annexed at **[Annexure "E" Page No. 98]**

27.4. That, in another case related with misrepresentation by pharma companies by suppressing the side effects of medicines. The companies

failure to report certain safety data was also taken into consideration. The investigating agency of US at their own investigated and recovered an amount 10.2 Billion U.S. Dollars around **7,57,71,92,40,000** Crore Rupees from the pharma companies. The excerpts from the news published on **July 2, 2012** in The United States' Department of Justice.

> "***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."

The details of abovesaid article is annexed at **[Annexure "F" Page No. 101]**

27.6. Constitution Bench of Hon'ble Supreme Court in the case of **Anita Kushwaha Vs. Pushap Sadan (2016) 8 SCC 509,** has ruled that the life of Indian Citizen is not less pricy than the life of people in England or anywhere. But in India the rights are more precious.

It is ruled that;

***"18…** Bose, J. emphasised the importance of the right of any person to apply to the court and demand that he be dealt with according to law. He said: (Prabhakar Kesheo case [Prabhakar Kesheo Tare v. Emperor, AIR 1943 Nag 26 : 1942 SCC OnLine MP 78] , SCC OnLine MP para 1)*

> *"1. ... **The right is prized in India no less highly than in England, or indeed any other part of the Empire**, perhaps even more highly here than elsewhere; and it is zealously guarded by the courts."*

27.7. That, the case of victim, who are vaccinated against their will or compelled to take vaccines under pressure is on highest footing of getting compensation because here the case is of putting the life into danger by giving vaccines under threat, pressure, coercion and deception. The material injected through vaccine may cause side effects after some time or after years and person may die due to it or may face life long disabilities.

27.8. That, Hon'ble Supreme Court & Hon'ble High Courts in India have time and now made it clear that, when the fundamental rights of the citizen are violated then the Supreme Court or High Court should grant monetary interim compensation to paid by the state and then to be recovered from the guilty officers.

27.9. In **Nambi Narayan (2018) 10 SCC 804,** Hon'ble Supreme Court granted interim compensation of Rs. 50 Lacs for mental torture & harassment due to wrongful confinement.

27.10. That, Hon'ble Civil Court in Pune has granted a compensation of Rs. 100 Crores for defamation for half an hours news in a case of mistaken identity. Said fact was also taken in to consideration by Hon'ble Bombay High Court while granting interim compensation for wrongful confinement by police. In the case of **Veena Sippy Vs. Mr. Narayan Dumbre & Ors. 2012 SCC OnLine Bom 339**, it is observed as under;

*"**20….**We must state here that the Petitioner in person has relied upon an interim order passed by this Court in First Appeal arising out of a decree passed in a suit. The decree was passed in a suit filed by a retired Judge of the Apex Court wherein he claimed compensation on account of act of defamation. Considering the evidence on record, the Trial Court passed a decree for payment of damages of **Rs. 100/- crores**. While admitting the Appeal and while considering the prayer for grant of stay, this Court directed the Appellant-Defendant to deposit a sum of Rs. 20/- crores in the Court and to furnish Bank Guarantee for rest of the decretal amount as a condition of grant of stay. However, this Court directed investment of the amount of Rs. 20/- crores till the disposal of the Appeal. The interim order of this Court has been confirmed by the Apex Court.*

23….

***i.** We hold that the detention of the Petitioner by the officers of Gamdevi Police Station from 5th April, 2008 to 6th April, 2008 is illegal and there has been a gross violation of the fundamental right of the Petitioner guaranteed by Article 21 of the Constitution of India.*

***ii.** We direct the 5th Respondent-State of Maharashtra to pay compensation of Rs. 2,50,000/- to the Petitioner together with interest thereon at the rate of 8% per annum from 5th April, 2008 till the realization or payment. We direct the State Government to pay costs quantified at Rs. 25,000/- to the Petitioner. We grant time of six weeks to the State Government to pay the said amounts to the Petitioner by an account payee cheque. It will be also open for the fifth Respondent - State Government to deposit the amounts in this*

Court within the stipulated time. In such event it will be open for the Petitioner to withdraw the said amount.

iii. *We clarify that it is open for the State Government to take proceedings for recovery of the amount of compensation and costs from the officers responsible for the default, if so advised.*

iv. *Petition stands dismissed as against the Respondent No. 4.*

vi. *We make it clear that it will be open for the Petitioner to adopt a regular remedy for recovery of compensation/damages in addition to the amount directed to be paid under this Judgment.*

28. Criminal offences committed by the National Task Force members having conflict of interest in getting sponsorship/funding from pharma mafia.

28.1. That the reason behind unscientific, unlawful, illegal and arbitrary decision by task force members which ultimately putting the life of pregnant women and common man into danger and helps the vaccine companies only is brought to the notice of health ministers in a legal notice dated **23.09.2021** sent on behalf of Applicant.

A copy of said notice is at **[Annexure "G" Page No. 107]**

28.2. That, the subject of the said notice is self-explanatory. It reads thus;

To forthwith stop the contempt of law laid down by Hon'ble Supreme Court and follow the law and binding precedents of Constitution Bench of Hon'ble Supreme Court, and Hon'ble High Courts more particularly in the case of ;

(i) *Mineral Development Ltd. Vs. State* ***(1960) 2 SCR 609.***

(ii) *A.K. Kraipak Vs. Union of India* ***(1969) 2 SCC 262,***

(iii) *State of Punjab Vs. Davinder Pal Singh Bhullar* ***(2011) 14 SCC 770,***

(iv) *Suresh Palande Vs. Govt. of Maharashtra* ***2015 SCC OnLine Bom 6775.***

AND TO FORTHWITH;

(i) *Remove the persons/bureaucrats, members of the Task Force etc. from any decision-making process related with remedies and solutions regarding Covid-19 pandemic, who are directly or indirectly connected with any entity, NGO or Board that receives funds from Bill & Melinda Gates Foundation, Rockefeller Foundation, PATH, PHFI, where sole agenda is to reap profits for the vaccine manufacturers;*

(ii) *Issue immediate direction as per law laid down by the Constitution Bench of Hon'ble Supreme Court in the case of* ***Mineral Development Ltd. Vs State (1960) 2 SCR 609,*** *there by directing to all authorities not to follow, the illegal, unconstitutional, unscientific and nonsensical circulars and orders based on the recommendations and suggestions regarding vaccination, masks, RT-PCR test etc., issued by these disqualified members;*

(iii) *Issue directions for forthwith removal and withdrawl of all the false, misleading and illegal advertisements, caller tunes, Questions and Answers (FAQs) published by the Ministry of Health and Family Welfare on the basis of recommendations given by*

members who are in the disqualified category as per law laid down by Hon'ble Supreme Court.

(iv) *Immediate direction to protect the rights of covid cured citizens who are safest person as their immunity is proved to be 13 times better than fully vaccinated people and the citizen who are covid cured or having natural immunity developed due to contract with corona are entitled for relief from covid appropriate behavior before vaccinated people.*

(v) *Issue specific directions after enquiry to all the authorities to not to allow to take part in any of the meetings or decision making process the following person who are in the category of disqualified:*

(i) *Prof. K. Shrinath Reddy,*

(ii) *Dr. Cherry Gagandeep Kang,*

(iii) *Dr. Balram Bhargava,*

(iv) *Shri. V.K. Paul,*

(v) *Dr. Soumya Swaminathan* **,**

(vi) *Dr. Randeep Guleria,*

(vii) *Dr. K. Vijay Raghvan,*

(viii) *Dr. N.K. Arora ;*

and others as mentioning in para 14 of this notice.

(vi) *Direction to prohibit the members of ICMR, PATH, PHFI, Bill Gates etc., who found prima facie guilty by*

the Parliamentary committee in 72nd Report and bsed on the evidences given in this notice from participating any board or body dealing with the corona management.

(vii) *Direct prosecution u/s 51(b) of Disaster Management Act, 2005 against all the entities and all the persons who are directly or indirectly forcing the people to take vaccines or restricting their entries on the ground of non-vaccination.*

(viii) *Directions to authorities to not to publish misleading advertisements, slogans and publish correct fact that vaccines are not completely safe but having many side effects and vaccines are not solution or there is no guarantee that citizens will not get corona and the person taking vaccine may die due to corona.*

(ix) *Directions to authorities to issue circulars to all State Governments and Central Government entities to not to conduct RTPCR/RAT Test of asymptotic and healthy persons.*

(x) *Direction to authorities to not to draw any conclusions or not to take any policy decisions of lockdown or quarantine on the basis of RTPCR/RAT Test and only use the Gold Standard test of* ***'Virus Culture'*** *for taking any policy decisions or recommendations etc.*

(xi) *Give directions to all authorities to issue circulars, advertisements et. al to make public aware that:*

(a) *Natural immunity caused due to Contract with Covid-19 is more than13 times better than the person fully vaccinated and such people are most safest persons. They will not get corona again and they cannot spread infection.*

(b) *Wearing mask is voluntary and there is no scientific proof that masks can prevent infection. And the healthy or asymptomatic people need not to wear mask. Also publish the scientific studies regarding damage caused to the lungs and also other side effects of wearing masks.*

(xii) *Give wide publicity & proper support to the following result oriented remedies and treatments which are having far more efficacy than vaccines and not having no side effects with zero deaths as compared with many side effects and deaths due to vaccines:-*

i) *Naturopathy's - Three step Fluid Diet as formulated by Dr. Biswaroop Roy Choudhary and verified by National Institute of Naturopathy, Pune.*

ii) *Anandia's Ayurvedic 'K' medicine as verified & approved by the State Government of Andhra Pradesh and confirmed by the Hon'ble Andhra Pradesh High Court.*

iii) *Ayurvedic & yoga treatment as suggested by Baba Ramdev.*

28.3. Inaction on the part of Union of India on these serious allegations is also a matter of concern as to what is important for the Government Either Life and Welfare of the Citizens or Welfare of the Pharma Companies?

28.4. That as per provisions of Indian Penal Code, the act of commission and omission is also an offence.

29. Very High Fetal Deaths Reported in VAERS Data from USA.

Search Results

From the 11/26/2021 release of VAERS data:

Found 2,761 cases where Vaccine is COVID19 and Symptom is Aborted pregnancy or Abortion or Abortion complete or Abortion early or Abortion incomplete or Abortion induced or Abortion late or Abortion missed or Abortion of ectopic pregnancy or Abortion spontaneous or Abortion spontaneous complete or Abortion spontaneous incomplete or Foetal cardiac arrest or Foetal death or Premature baby death or Premature delivery or Stillbirth.

Compared to this, yearly average of recorded fetal deaths following the vaccination of pregnant women for the past 30 years has been an average of 74 fetal deaths per year.

Source:-

https://medalerts.org/vaersdb/findfield.php?TABLE=ON&GROUP1=MAN&EVENTS=ON&PERPAGE=100&ESORT=ONSET-DATE&SYMPTOMS[]=Aborted+pregnancy+%2810000209%29&SYMPTOMS[]=Abortion+%2810000210%29&SYMPTOMS[]=Abortion+complete+%2810061614%29&SYMPTOMS[]=Abortion+early+%2810052

846%29&SYMPTOMS[]=Abortion+incomplete+%2810000217%29&SYMPTOMS[]=Abortion+induced+%2810000220%29&SYMPTOMS[]=Abortion+late+%2810052847%29&SYMPTOMS[]=Abortion+missed+%2810000230%29&SYMPTOMS[]=Abortion+of+ectopic+pregnancy+%2810066266%29&SYMPTOMS[]=Abortion+spontaneous+%2810000234%29&SYMPTOMS[]=Abortion+spontaneous+complete+%2810061616%29&SYMPTOMS[]=Abortion+spontaneous+incomplete+%2810061617%29&SYMPTOMS[]=Foetal+cardiac+arrest+%2810084280%29&SYMPTOMS[]=Foetal+death+%2810055690%29&SYMPTOMS[]=Premature+baby+death+%2810076700%29&SYMPTOMS[]=Premature+delivery+%2810036595%29&SYMPTOMS[]=Stillbirth+%2810042062%29&VAX=COVID19

https://vaccineimpact.com/2021/2620-dead-babies-in-vaers-after-covid-shots-more-fetal-deaths-in-11-months-than-past-30-years-following-all-vaccines-as-scotland-begins-investigation/

30. Impact of Covid-19 vaccines on menstrual cycle still unknown, NIH sanctioned 1.67 million dollars to study the link between both.

”NICHD recently awarded five institutions one-year supplemental grants totaling $1.67 million to explore potential links between COVID-19 vaccination and menstrual changes. Researchers at Boston University, Harvard Medical School, Johns Hopkins University, Michigan State University, and Oregon Health and Science University will investigate whether such changes may be linked to the COVID-19 vaccine itself or if they are coincidental, the mechanism underlying any vaccine-related changes, and how long any changes last.”

Source:-

https://covid19.nih.gov/news-and-stories/covid-19-vaccines-and-menstrual-cycle

31. Reasons for Banning or Age Restricting Astrazeneca Covid Vaccine (Covishield) in 15 Countries Worldwide.

31.1. Brazil: This article was published on May 11, 2021 on Reuters by Pedro Fonseco and Ricardo Brito. Following are the relevant excerpts from the article:

Brazil's federal government on Tuesday nationally suspended the vaccination of pregnant women with the AstraZeneca (AZN.L) COVID-19 shot, after an expectant mother in Rio de Janeiro died from a stroke possibly related to the inoculation.

Franciele Francinato, coordinator of the Health Ministry's vaccination program, told reporters the suspension was enacted as a precautionary measure after health regulator Anvisa issued a warning about the vaccine's use in pregnant women earlier in the day.

Authorities are investigating the incident. The suspension applies only to AstraZeneca's shot and not to vaccines developed by Sinovac (SVA.O) and Pfizer Inc (PFE.N) that are also being used in the country.

The pregnant woman in Rio de Janeiro died after receiving the AstraZeneca shot, according to state Health Secretary Alexandre Chieppe.

Anvisa said the 35-year-old woman, who was 23 weeks pregnant, died of a hemorrhagic stroke on Monday after checking into a hospital five days earlier.

"The serious adverse event of a hemorrhagic stroke was assessed as possibly related to the use of the vaccine given to the pregnant woman," Anvisa said in a statement.

Source:-

https://www.reuters.com/business/healthcare-pharmaceuticals/brazil-health-agency-calls-halt-astrazeneca-vaccine-pregnant-women-2021-05-11/

31.2. Norway: This article was published on May 10, 2021 on Reuters by Terje Solsvik and Gwladys Fouche. Following are the relevant excerpts from the article:

Norway should exclude the COVID-19 vaccines made by AstraZeneca (AZN.L) and Johnson & Johnson (JNJ.N) from its inoculation programme due to a risk of rare but harmful side-effects, a government-appointed commission said on Monday.

However, those who volunteer to take either vaccine should be allowed to do so, it said,stressing the importance of dispelling any vaccine hesitancy.

Norway suspended the AstraZeneca vaccine rollout on March 11 after a small number of younger inoculated people suffered a combination of blood clots, bleeding and a low platelet count. read more

The Norwegian Institute of Public Health (FHI) urgedon April 15 that the AstraZeneca shot be dropped entirely but the government sought the advice of its commission on both it and on the J&J shot, which has not been used in Norway despite European Medicines Agency (EMA) approval. read more

Explaining its recommendations, the commission said eight Norwegian cases of severe clotting had been linked to the AstraZeneca vaccine, and four of those recipients had died.

Source:-

https://www.reuters.com/world/europe/norway-should-exclude-jj-astrazeneca-covid-vaccination-scheme-says-commission-2021-05-10/

31.3. Sweden: This article was published on March 15, 2021 on National Public Radio (NPR) by Jaclyn Diaz. Following are the relevant excerpts from the article:

Sweden is the latest European country to suspend the administration of a COVID-19 vaccine made by AstraZeneca following reports of abnormal blood clotting in recipients.

Venezuela on Monday announced it wouldn't authorize use of the vaccine in the country at all following those reports.

The Swedish Public Health Agency said early Tuesday that as a precautionary measure it would suspend use of the Oxford-AstraZeneca COVID-19 vaccine until the European Medicines Agency, or EMA, reveals findings from its ongoing investigation into reports of negative side effects in patients.

The country joins several other European nations including France, Germany, the Netherlands and Ireland that suspended administration of the vaccine this week.

In a briefing with reporters on Tuesday, EMA's Executive Director Emer Cooke said the agency was investigating reports of at least 30 cases of unusual blood disorders and would release its findings on Thursday.

Source:-

https://www.npr.org/sections/coronavirus-live-updates/2021/03/16/977731757/sweden-venezuela-latest-countries-to-question-astrazeneca-vaccine#:~:text=Sweden%20is%20the%20latest%20European,at%20all%20following%20those%20reports.

31.4. Bulgaria: This article was published on December 3, 2021 on Reuters by Reuters Staff. Following are the relevant excerpts from the article:

Bulgaria on Friday temporarily halted COVID-19 inoculations using the AstraZeneca vaccine after a woman died hours after receiving a shot, and said it wanted the European Medicine Agency (EMA) to dispel all doubts about the vaccine's safety.

Several other countries have also temporarily suspended their rollout of the AstraZeneca vaccine, but the EMA said on Thursday the shots should continue to be administered, saying the benefits outweighed any risks.

"Until all doubts are dispelled... we are halting inoculations with this vaccine," Bulgarian Prime Minister Boyko Borissov said in a statement.

Health Minister Kostadin Angelov said a 57-year-old woman from a village in southern Bulgaria had died of heart failure some 15 hours after receiving an AstraZeneca shot on Thursday.

Source:-

https://www.reuters.com/article/us-health-coronavirus-astrazeneca-bulgar/bulgaria-suspends-rollout-of-astrazeneca-covid-19-vaccine-idUSKBN2B4196

31.5. Slovakia: This article was published on May 11, 2021 on EuroNews. Following are the relevant excerpts from the article:

Slovakia has suspended the use of the AstraZeneca COVID-19 jab for first-time vaccinations.

"People who are waiting for the second dose of this vaccine are currently being vaccinated with Astra Zeneca," said the country's health ministry. "Vaccination with this company for first-time vaccines has been suspended.

"The Ministry of Health is currently considering several alternatives for how we will proceed in this matter in Slovakia.

"We are completing all expert opinions and will follow up on this later this week.

The decision comes after the country's State Institute for Drug Control (ŠÚKL) ruled that the death of a 47-year-old woman was likely connected to the jab.

In a statement, issued on Friday, ŠÚKL said that it had determined the cause of death to be related to cerebral venous sinus thrombosis, a blood clotting disorder that sees clots form in the veins that drain blood from the brain.

"Genetic examination also revealed blood clotting disorders in the patient," the regulator said.

"Due to the existence of a genetic predisposition to a thrombophilic state, an association between [the AstraZeneca jab] and subsequent venous sinus thrombosis was established as likely," it said.

Source:-

https://www.euronews.com/2021/05/11/slovakia-suspends-use-of-the-astrazeneca-jab-for-first-time-vaccinations

31.6. Canada: This article was published on April 26, 2021 on Indian Express. Following are the relevant excerpts from the article:

Canada's National Advisory Committee on Immunization (NACI) has recommended that the AstraZeneca Covid-19 vaccine not be used for individuals below the age of 55.

The committee stated that until a type of an adverse event associated with the vaccine is investigated, its usage should for those below the age of 55 be stopped. Even so, individuals above the age of 55 can continue getting the AstraZeneca vaccine in Canada, considering that the adverse event is more common in people below the age of 55, the committee said.

Source:-

https://indianexpress.com/article/explained/explained-why-canada-has-stopped-use-of-astrazeneca-vaccine-for-those-below-55-years-7251250/

31.7. Denmark:- This article was published on March 11, 2021 on Euronews by Lauren Chadwick. Following are the relevant excerpts from the article:

The Danish health authority said that there was a reported death in the country but that "at present, it cannot be concluded whether there is a link between the vaccine and the blood clots."

Use of the vaccine will be suspended until further notice, the health authority said on Thursday, but the decision will be reviewed in two weeks' time.

Source:-

https://www.euronews.com/2021/03/11/denmark-suspends-astrazeneca-covid-19-vaccinations-as-a-precaution-after-blood-clot-report

31.8. Iceland: This article was published on March 25, 2021 on NDTV by Agence France - Presse. Following are the relevant excerpts from the article:

As a precaution while tests continue, the vaccine will remain suspended for those aged under 65, the agency added.

Source:-

https://www.ndtv.com/world-news/finland-iceland-approve-astrazeneca-covid-19-vaccine-for-seniors-2398488

31.9. Italy: This article was published on June 12, 2021 on Business Standard by IANS. Following are the relevant excerpts from the article:

Italy on Friday suspended the use of the AstraZeneca vaccine for people under 60 years old, health officials announced at a weekly press conference on the Covid-19 pandemic.

The move came after an 18-year-old woman died of a blood clot Thursday after receiving an initial dose of AstraZeneca on May 25, Xinhua reported.

According to local media reports, the young woman suffered from autoimmune thrombocytopenia (meaning that she had a low blood platelet count) and was on double hormone therapy.

Source:-

https://www.business-standard.com/article/current-affairs/italy-suspends-use-of-astrazeneca-vaccine-for-people-under-60-year-old-121061200086_1.html

31.10. Venezuela – This article was published on March 16, 2021 on France 24 by Agence France - Presse. Following are the relevant excerpts from the article:

Venezuela decided it will not authorize or license AstraZeneca's COVID vaccine at all due to complications in vaccinated recipients. The country had reserved 1.4 to 2.4 million doses through COVAX.

Source:-

https://www.france24.com/en/live-news/20210316-venezuela-will-not-authorize-astrazeneca-covid-vaccine

31.11. France: This article was published on March 15, 2021 on Reuters by Thomas Escritt and Stephanie Nebehay. Following are the relevant excerpts from the article:

Germany, France and Italy said on Monday they would suspend AstraZeneca COVID-19 shots after several countries reported possible serious side-effects.

France said it was suspending the vaccine's use pending an assessment by EMA.

"The decision taken, in conformity also with our European policy, is to suspend, out of precaution, vaccination with the AZ shot, hoping that we can resume quickly if the EMA's guidance allows," French President Emmanuel Macron said.

Source:-

https://www.reuters.com/article/us-health-coronavirus-idUSKBN2B722U

31.12. Portugal: This article was published on April 9, 2021 on Reuters by Caterina Demony. Following are the relevant excerpts from the article:

Portugal will from now on recommend the AstraZeneca COVID-19 vaccine only for people aged over 60, the health authority DGS said on Thursday, amid concerns over possible links between the shot and very rare cases of blood clots.

Source:-

https://www.reuters.com/article/us-health-coronavirus-portugal-astrazene-idUSKBN2BV2RF

31.13. Netherlands: This article was published on April 2, 2021 on Reuters by Reuters Staff. Following are the relevant excerpts from the article:

The Netherlands on Friday temporarily suspended use of the AstraZeneca COVID-19 vaccine for people under 60 following the death of a woman who had received a shot, the Health Ministry said.

About 10,000 scheduled appointments for vaccinations were to be scrapped as a result of the decision, news agency ANP reported.

The decision was made following new reports from medicine monitoring agency Lareb and discussions with health authorities, a Health Ministry statement said.

Source:-

https://www.reuters.com/article/us-health-coronavirus-netherlands-astraz-idUSKBN2BP13Q

31.14. United Kingdom: This article was published on May 7, 2021 on The Guardian by Ian Sample. Following are the relevant excerpts from the article:

People under 40 will be offered an alternative to the Oxford/AstraZeneca vaccine where possible and while infection rates remain low, following a recommendation from government advisers.

It comes after the Joint Committee on Vaccination and Immunisation (JCVI) reviewed the speed and uptake of Covid vaccines in the UK and the latest figures on very rare blood clots after first shots of the AstraZeneca vaccine.

Source:-

https://www.theguardian.com/world/2021/may/07/people-under-40-in-uk-to-be-offered-alternative-to-astrazeneca-jab

31.15. Austria: This article was published on May 18, 2021 on Medical Express. Following are the relevant excerpts from the article:

Austria will phase out AstraZeneca from its COVID-19 immunisation programme because of delivery problems and wariness among the population following reports of the vaccine's rare side effects, the health minister said.

Austria becomes the third European country to drop AstraZeneca, after Norway and Denmark ditched the vaccine over rare cases of severe blood clots in people receiving the jab.

Source:-

https://medicalxpress.com/news/2021-05-austria-phase-astrazeneca-virus-vaccine.html

32. Total Adverse Reaction Profile of Covishield In Europe.

Total reactions for the **vaccine AZD1222/VAXZEVRIA (CHADOX1 NCOV-19) from Oxford/AstraZeneca**: **6,145 deaths** and **1,075,335 injuries** to 20/11/2021

13,124	Blood and lymphatic system disorders **incl. 248 deaths**
19,128	Cardiac disorders **incl. 696 deaths**
195	Congenital familial and genetic disorders **incl. 8 deaths**
12,669	Ear and labyrinth disorders **incl. 3 deaths**
597	Endocrine disorders **incl. 4 deaths**

18,919 Eye disorders **incl. 29 deaths**

102,402 Gastrointestinal disorders **incl. 312 deaths**

283,288 General disorders and administration site conditions **incl. 1,469 deaths**

950 Hepatobiliary disorders **incl. 60 deaths**

4,834 Immune system disorders **incl. 29 deaths**

32,441 Infections and infestations **incl. 413 deaths**

12,358 Injury poisoning and procedural complications **incl. 177 deaths**

23,611 Investigations **incl. 150 deaths**

12,369 Metabolism and nutrition disorders **incl. 91 deaths**

159,668 Musculoskeletal and connective tissue disorders **incl. 94 deaths**

624 Neoplasms benign malignant and unspecified (incl cysts and polyps) **incl. 22 deaths**

221,536 Nervous system disorders **incl. 958 deaths**

521 Pregnancy puerperium and perinatal conditions **incl. 12 deaths**

188 Product issues **incl. 1 death**

19,933 Psychiatric disorders **incl. 58 deaths**

4,031 Renal and urinary disorders **incl. 58 deaths**

15,124 Reproductive system and breast disorders **incl. 2 deaths**

37,980 Respiratory thoracic and mediastinal disorders **incl. 735 deaths**

49,247 Skin and subcutaneous tissue disorders **incl. 48 deaths**

1,498 Social circumstances **incl. 6 deaths**

1,404 Surgical and medical procedures **incl. 25 deaths**

26,696 Vascular disorders **incl. 437 deaths**

Source:-

https://vaccineimpact.com/2021/31014-deaths-2890600-injuries-following-covid-shots-in-european-database-of-adverse-reactions-as-young-previously-healthy-people-continue-to-die/

33. Letters from Indian Doctors Opining on the State of Aefi System in India.

33.1. An email was sent by Dr. Amitav Banerjee, Professor & Head, Community Medicine Clinical Epidemiologist, to a Health Rights Activist on the subject: "My concerns about indiscriminate and mass vaccination of populations with Covid-19 vaccine", which is being reproduced asunder:

Dear Yohan,

Greetings from Pune!

I have been following the concerns raised by some eminent scientists and other citizens across the world since the vaccine rollout which was done in unholy haste and is still under "emergency use authorization" in trial mode. I have also been closely following your well researched arguments put forward from time to time on the Covid-19 situation in the country. I am sharing my concerns, based on my analysis of the opinions of independent scientists, on mass vaccination on your platform.

Geert VanDen Bossche, an independent vaccine researcher and virologist, formerly with Bill & Melinda Gates Foundation, had warned that indiscriminate mass vaccination would give rise to more virulent mutants. We are already seeing such mutations in parts of the world after vaccines were rolled out.

Besides, eminent scientists have cautioned about the short and long term adverse events which are largely unknown. Robert Malone, one of the pioneers of mRNA technology is one of them.

Mass vaccination & vaccine mandates of experimental vaccines will blur the scientific evidence of the efficacy of the vaccines since such a strategy will deprive the comparison between vaccinated and unvaccinated groups on effectiveness of the vaccines as well as short term and long term harms, if any.

Of much greater concern in a large country with poor public health infrastructure is the inadequate monitoring and surveillance of adverse events following immunization (AEFI) for which a robust public health infrastructure is needed. Indiscriminate and rapid roll out of mass vaccination in a country with poor health resources is like running a superfast train on old rickety rail tracks.

Even Western countries with their far smaller population and much better health infrastructure capture only 1% of the adverse events following immunization according to a peer reviewed research paper in a prestigious journal Toxicology Reports (Kostoff et al, Why are we vaccinating children? available at: https://www.sciencedirect.com/science/article/pii/S221475002100161X)

So one can imagine the difficulty of ascertaining the side effects of vaccination in our country with far less resources and much larger population.

There is also no scientific evidence for mass vaccine roll out presently in India, given that serosurveys have found that more than 80% of our densely crowded population in many parts of the country, have acquired antibodies after recovering from natural infection.

Around 132 research studies show that recovery after natural infection renders more robust immunity compared to vaccine induced immunity: https://brownstone.org/articles/79-research-studies-affirm-naturally-acquired-immunity-to-covid-19-

documented-linked-and-quoted/

This is also evident from our rapidly declining trends of cases and deaths compared to the Western countries which have a much higher vaccine coverage of their population, almost two to three times higher than ours. From the data it is evident we have reached herd immunity, naturally.

Given the current epidemiology of Covid-19 in India, there is no indication for mass vaccination at a huge cost and more importantly due to concern of short term and long term adverse effects. Vaccines can be offered to high risk groups on merits of each case on the opinion of a personal physician instead of mass indiscriminate and unmonitored roll out.

With warm personal regards,

Amitav

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33.2. A Letter has been sent to the Hon'ble Prime Minister by a group of Indian Doctors on the subject: **"Petition to improve and make functional, AEFI Reporting and it's active Monitoring in India"**. The Letter can be found in **[Annexure "H" Page No. 330].** Relevant extracts from the letter are reproduced asunder:

"We, Indian Doctors for Truth, are alarmed that there is practically no proper protocol to report Adverse Event Following Immunization (AEFI) in India, as mass vaccination drive for Covid vaccines is implemented."

"Briefing the press, Dr. N.K. Arora had said, "As of now, monitoring the vaccine recipient up to 72 hours post-vaccination is the norm. It should be done in at least 28 days. There must be a proper mechanism to report AEFI on the CoWin app and all the data should be available in the public domain," adding that severe AEFIs were reported in less than 0.5 percent of recipients out of seven crore vaccinated people assessed so far. This translates to 5 severe cases out of 1,000 vaccinations."

"Though some advisory might exist on paper, "there is so much chaos that nobody knows who to approach in the system and how," says Shobhit, son of a victim."

"However, in the absence of proper reporting mechanism and proactive approach of authorities to trace vaccinated people after they leave the vaccination site, such a claim may not be reflecting the true picture and full magnitude of AEFI and it is possible several cases of AEFI may be going unreported or undetected, says Vineeta Pandey, while writing about her first hand struggle to get her 21 yr old son's AEFI."

"The National AEFI Committee has assessed only 363 of severe or serious AEFIs till 18th October 2021, of which only 4 cases of death were found to be directly linked to Covid Vaccine Product Related. Though 3 out of 4 were cases of anaphylaxis, there was one case where the diagnosis given was "Right transverse sinus thrombosis with right temporal haemorrhagic infarct, right posterior frontal haemorrhagic infarct with thrombocytopaenia". We beg to ask the question, is it really possible that we have only one confirmed case Vaccine-Induced Immune Thrombotic Thrombocytopenia (VITT), when 16 countries have banned or age-restricted Astrazeneca (Covishield) Covid vaccine for the same reason?!"

"In the EU, anyone can report post-vaccine illness directly to the national authority or vaccine makers. The patient volunteers are followed up for at least six weeks post-vaccination and tracking of even long-term effects, says European Medicines Agency (EMA) rules for COVID vaccines. In the US there is an online system of reporting VAERS. Given the scale of vaccination in India, why isn't there a proper AEFI reporting mechanism in India? In the US, we can see 18,853 deaths as per the official US VAERS database (a total of 894,143 Adverse Event reports till 12/11/21). In Europe, in just 27 countries, 31,014 death reports are available in the official European Union database Eudra Vigilance (a total of 2,890,600 Adverse Event reports till 20/11/21). What are the equivalent numbers in a huge country such as India? It is unbelievable that a country of our size with the largest Covid Vaccination drive on this planet has only 2116 AEFIs which also includes death."

33.3. Mail Communication from Dr. Sanjay Rai (credentials asunder) to a

Health Rights Activist:

Dr. Sanjay K. Rai, MD, FIPHA

Professor, Centre for Community Medicine, AIIMS, New Delhi

· Editor, WHO-South-East Asia Journal of Public Health

· Nodal person for HIV Sentinel Surveillance at National Institute AIIMS (NI-AIIMS).

· National President, Indian Public Health Association (2019-2022)

· Vice President, National Medical Organization (NMO), Delhi State

"AEFI reporting is very important and mandatory step to track the short term and long term side effects of vaccines. Ideally an independent body should investigate all the reported AEFI. However, in India reported AEFI are reviewed by same implementing agency that are involved in vaccine administration. Therefore there is a strong possibility of conflict of interest. Such a situation is not desirable and doesn't inspire confidence in their impartiality. It is likely that the reported AEFI is an underestimate of the total incidence.

Therefore a separate independent body to investigate all the AEFI including fetal AEFI is the need of the hour.

Thanks & Regards

Sanjay Rai"

34. Petition with details showing no need to vaccinate pregnant women is filed by Riddhi Arora and needs to be taken into consideration.

35. CONCLUDING PARAGRAPH:-

Hence it is not advisable to vaccinate pregnant woman and it is necessary to order investigation and action against 'Task Force members' acting in casual and cavalier fashion and making such SOP/guidelines which is only for the benefit of vaccine companies and putting the life of the pregnant women in danger and misappropriating/misutilizing the thousands of crores of public money and machinery.

AND FOR THIS ACT OF KINDNESS AND JUSTICE THE PETITIONER AS IN DUTY BOUND SHALL EVER PRAY

Date: 15.12.2021

Place: Mumbai

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