IN THE HON'BLE SUPREME COURT OF INDIA

(CIVIL ORIGINAL WRIT JURISDICTION)

I.A. NO. _____ OF 2021

IN

WRIT PETITION (CIVIL) NO. 607 OF 2021

IN THE MATTER OF

DR. JACOB PULIYEL .....PETITIONER

VERSUS

THE UNION OF INDIA & ORS. .....RESPONDENTS

APPLICATION FOR DIRECTION ON BEHALF OF THE PETITIONER

1. That the petitioner has filed the instant writ petition under Article 32 of the Constitution of India for the enforcement of fundamental rights under Article 14 and 21 of the Constitution of India, seeking a writ directing the respondents to make public the segregated data of the clinical trials for the COVID-19 vaccines that are being administered to the population in India under Emergency Use Authorization and declare that the coercive mandates for use of these inadequately tested vaccines are repugnant to the right of humans to autonomy.

2. Through the instant application the petitioner seeks to bring on record and seek a stay on the coercive COVID-19 vaccine mandates that are introduced in various states and by private establishments for children in the age group 15-18 years. These mandates have started surfacing after the Ministry to Health and Family welfare on the 27th of December issued guidelines for COVID-19 Vaccination of Children between 15 to

18years from 3rd January 2022 onwards. The petitioner also seeks disclosure of clinical trial data for the vaccines that are being administered to children in India.

(A copy of the guidelines issued by the Ministry of Health and Family Welfare are annexed as Annexure 1 at Page _____to _____).

3. It is pertinent to note that that these guidelines were issued only a few days after the announcement through a presser on the 24th of December 2021, by the vaccination drive Chief Vinod K Paul, Indian Council of Medical Research Chief, Balram Bhargava and Union health secretary Rajesh Bhushan that their decisions are guided by science and that there isn't any scientific basis yet to necessitate paediatric vaccination. In a complete ~~you~~U-turn therefore the scientific basis seems to have altered and within three days guidelines were issued by the Ministry of Health and Family Welfare for vaccinating 15-18 year olds.

(A copy of The Wire report dated 26th December 2021, titled "10 Questions the Indian Government Must Answer About Vaccines for Minors and Boosters" is annexed as Annexure _____at Page _____to _____)

The data and scientific studies clearly show that children are hardly at any risk of serious illness due to COVID

4. No medical intervention should be introduced on a 'one size fits all' basis, but instead should be fully assessed for suitability according to the characteristics of the age cohort and of the individuals concerned, weighing up the risk versus benefit profile for each cohort and the individuals within a group. It has been established through published research that healthy children are at almost no risk from COVID-19. Previously healthy children dying of COVID or requiring admissions to hospital or intensive care are exceedingly rare, with most children having no or very mild symptoms. All medical interventions carry a risk of harm, so we have a duty to act with caution and proportionality. This is particularly the case when considering mass intervention in a healthy population, in which situation there must be firm evidence of benefits far greater

than harms. The current, available evidence clearly shows that the risk versus benefit calculation does not support administering rushed and experimental COVID-19 vaccines to children, who have virtually no risk from COVID-19, yet face known and unknown risks from the vaccines. The Declaration of the Rights of the Child states that, "the child, by reason of his physical and mental immaturity, needs special safeguards and care, including appropriate legal protection".

5. An article in Nature.com tilted "Deaths from COVID incredibly rare among children" states that studies find that the overall risk of death or severe disease from COVID-19 is very low in kids.

"A comprehensive analysis of hospital admissions and reported deaths across England suggests that COVID-19 carries a lower risk of dying or requiring intensive care among children and young people than was previously thought.

Covid caused 25 deaths in that age group between March 2020 and February 2021, researchers reported in a series of preprints published on medRxiv. About half of those deaths were in individuals with an underlying disability with high health-care needs, such as tube feeding or assistance with breathing."

(A copy of the article in Nature.com titled "Deaths from COVID incredibly rare among children" is annexed as Annexure _____at page _____to _____).

6. In an article in The Lancet titled "Children and young people remain at low risk of COVID-19 mortality", states that severe COVID-19 disease was ~~rate~~rare in children.

> "In the USA, UK, Italy, Germany, Spain, France, and South Korea, deaths from COVID-19 in children remained rare up to February, 2021, at 0·17 per 100 000 population, comprising 0·48% of the estimated total mortality from all causes in a normal year (table, appendix p 2). Deaths from COVID-19 were relatively more frequent in older children compared with younger age groups."

(A copy of the article in The Lancet, "Children and young people remain at low risk of COVID-19 mortality", is annexed as Annexure _____at page _____to _____).

7. A report in the BBC titled "COVID: Children's extremely low risk confirmed by study" states:

   "The overall risk of children becoming severely ill or dying from Covid is extremely low, a new analysis of covid infection data confirms…those living with multiple chronic illnesses and neuro-disabilities were most at risk, though overall risk remained low."

(A copy of the article in the BBC titled "COVID: Children's extremely low risk confirmed by study" is annexed as Annexure _____At Page _____to _____).

8. In an article published in Science Direct the authors compared children's mortality from COVID-19 with all-deaths and other relevant causes of death to provide parents, teachers, clinicians and policy makers with epidemiological information for decision making regarding children. The article states:

   "The situation in each country was almost identical, and in accordance with early data from China i.e. COVID rarely kills children, even compared with influenza, against which many children are already vaccinated. Our data show that for mortality COVID-19 is similar to flu, or less severe, in children whilst being the opposite in adults."

(A copy of the article, "Children's mortality from COVID-19 compared with all-deaths and other relevant cause of death: epidemiological information for decision-making by parents, teachers, clinicians and policymakers" is annexed as Annexure _____At Page _____to _____).

Natural immunity is enduring and outweighs vaccine immunity

9. According to the World Health Organisation, the mean infection fatality rate ("**IFR**") for COVID-19 is 0.15%. IFR is a calculation of the percentage of people who are infected with a virus and die. The recovery rate of people who tested positive for the Virus is over 99% in most countries that have been materially affected by the Virus. It has been shown scientifically that the immunity that results from natural infection is enduring and possibly lasts a lifetime. Therefore the public health messaging in India that is being

used to coerce people to take the vaccine on pain or penalty that "no one is safe till everyone is safe" is also false and misleading on account of natural immunity acquired by those who have recovered from Covid being stronger and more enduring that any immunity that can be provided by a vaccine that has only been in use under emergency authorisation for about 6 months and whose efficacy is being tested, results of trials and long term side effects still being unknown. This when serological studies show that more than 67.6% of the population of India has already had covid and more than 80% of children have antibodies to COVID.

10. A large volume of studies have now demonstrated that an unvaccinated individual with prior infection is exponentially safer to be around than someone who had the vaccine but not prior infection. Studies have shown that those with prior infection are immune more so than those with vaccines. A report in theblaze.com points to 15 studies that have demonstrated naturally acquired immunity to be more durable and robust than vaccine immunity.

(A copy of the summary of the studies titled, "15 studies that indicate natural immunity from prior infections is more robust than the Covid vaccines" is annexed as **Annexure (Page to).**

11. Various research has shown that naturally acquired immunity is strong and long lasting. An article in The Defender, states that as covid surges among the fully vaccinated, the more the variant deviates from the original sequence used for the vaccine, the less effective the vaccine will be on that variant. The article also states how the break through infection in both the US and Israel are among those who are fully vaccinated.

> **"The CDC's latest breakthrough numbers, as of July 25, show 6,587 fully vaccinated people with COVID breakthrough cases. Of those, 6,239 people were hospitalized and 1,263 people died…**
>
> Brian Hooker, Ph.D., P.E., Children's Health Defense chief scientific officer and Professor of Biology at Simpson University, said while the Delta variant is likely

more transmissible, it's also likely less pathogenic. "What we're seeing is virus evolution 101," Hooker said.

…Hooker said the more the variant deviates from the original sequence used for the vaccine, the less effective the vaccine will be on that variant, which could explain why fully vaccinated people are getting infected with the Delta variant. But this isn't the case for natural immunity, he explained.

Hooker said:

"The vaccine focuses on the spike protein, whereas natural immunity focuses on the entire virus. Natural immunity — with a more diverse array of antibodies and T-cell receptors — will provide better protection overall as it has more targets in which to attack the virus, whereas vaccine-derived immunity only focuses on one portion of the virus, in this case, the spike protein. Once that portion of the virus has mutated sufficiently, the vaccine no longer is effective."

…

According to research published last week in Scientific Reports, the highest risk for establishing a vaccine-resistant virus strain occurs when a large fraction of the population has already been vaccinated but the transmission is not controlled.

The data was consistent with a study released July 30, by the CDC which showed vaccinated people may transmit the Delta variant — now responsible for 80% of COVID cases in the U.S. — just as easily as the unvaccinated.

The team of scientists who published the data in Scientific Reports said their findings follow what's known as selective pressure — the force that drives any organism to evolve.

"Generally, the more people infected, the more the chances for vaccine resistance to emerge," said Fyodor Kondrashov of the Institute of Science and Technology Austria.

"So the more Delta is infectious, the more reason for concern," Kondrashov said. **"By having a situation where you vaccinate everybody, a vaccine-resistant mutant actually gains a selective advantage."**

…

At least 233 staffers at two major San Francisco hospitals tested positive for COVID — the majority of whom were fully vaccinated and became infected with the Delta variant.

Between 75% and 80% of the more than 50 staff members infected with COVID at Zuckerberg San Francisco General Hospital were fully vaccinated, Dr. Lukejohn Day, the hospital's chief medical officer, told The New York Times Saturday."

(A copy of the article in The Defender dated 3.08.2021 "Scientist: 'What We're Seeing Is Virus Evolution 101' — Delta Variant More Transmissible, Not More Deadly" is annexed as Annexure P (Page to).

12. In an interview with journalist Girijesh Vashistha on Knocking News, Dr. Sanjay Rai, Professor at Department of Community Medicine at AIIMS, Delhi states 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 that 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, Professor at Department of Community Medicine at AIIMS, Delhi in Conversation with Girijesh Vashistha of Knocking News is

annexed as **Annexure AA 9** at Page _____to _____) https://www.youtube.com/watch?v=-btDk0eSi5U

Serological Surveys indicate a large number of people including children already have antibodies to COVID-19

13. An Indian Express article dated 26th July 2021 titled "2 of 3 Indians have Covid-19 antibodies: ICMR serosurvey findings explained" reports that two-thirds of the general population above the age of 6 years had COVID-19 antibodies and that more than half of the children were sero-positive:

> "..Two-third of Indians above the age of 6 had SARS-CoV-2 antibodies, show findings of the fourth nationwide serological survey conducted by the Indian Council of Medical Research (ICMR) in June-July…
>
> ..The survey findings shows that more than half of the children (6 -17 years) were seropositive. It means they have been exposed to Covid-19 in the past months. The sero-prevalence among children was 57.2 per cent in the age group 6-9 years and 61.6 per cent in the age group 10-17 years…"

(A copy of the Indian Express article dated 26th July 2021 and titled "2 of 3 Indians have Covid-19 antibodies: ICMR serosurvey findings explained" has been annexed as **Annexure 1 (Page ____to____)**

14. A news report titled "Delhi: 97% people have Covid -19 antibodies, shows sero survey" in the Indian Express Times reported that:

> "Delhi has a seropositivity of 97 per cent for Covid-19 antibodies, the sixth serological survey conducted in the city has revealed, Delhi Health Minister Satyendar Jain said Thursday. Every district has a seropositivity of above 95 per cent, he said.
>
> …
>
> In children below the age of 18, the sero prevalence is 88 per cent, while it is 97 per cent to 98 per cent in adults."

(A copy of the Indian Express report dated 28th October 2021 titled "Delhi: 97% people have Covid -19 antibodies, shows sero survey", and available at https://indianexpress.com/article/cities/delhi/people-in-delhi-have-covid-19-antibodies-shows-sero-survey-7595390/is Annexed as **Annexure 3 (Page _____to_____)**

Non disclosure of phase 3 trial results in adults and children for vaccines being administered in India

15. That Zydus Cadila vaccine has also received approval in August 2021 for emergency use to be administered in children and adults above 12 years. The phase 3 trial data for this vaccine is also not available in the public domain. The clinical trial process and data for both these vaccines, the COVAXIN vaccine being administered through the government immunization programme and the Zydus Cadila vaccine which has received emergency use approval in August 2021, are unknown and remain opaque to public scrutiny. This raises serious concerns regarding the suitability of these vaccines for use especially in children since phase 3 trial data of these vaccines in adults have not been published in peer reviewed scientific journals nor has the raw data related to these trials been put out for independent scientific scrutiny. Bharat Biotech reportedly submitted data from phase 2/3 trials for COVAXIN for those aged 15-18 years, conducted in India over a period of 3 months, to the Drug Controller General. This data has not been put out in the public domain or available for independent verification. Administering experimental vaccines to children which have not gone through complete phase 3 trials and for which safety and efficacy data from phase 3 trials in adults is not available raises serious ethical concerns and amounts to gross medical malpractice.

16. The current vaccination drive using Covaxin is based on limited understanding of short term risks from the vaccine since clinical trials have been truncated and the vaccine is being administered under emergency use to the population at large. As with many other vaccines being administered under emergency authorization, risks of bias are high due to

limited studies, all done by manufacturers. Trials to establish efficacy and safety of the Covid 19 vaccines are not conducted by independent research teams but by the pharmaceutical companies, who stand to gain financially from their products. Raw trial data for Covaxin is not yet accessible to be scrutinized by independent researchers. Lack of critical interpretation of side effects observed during trials, weak pharmacovigilance in most countries in the absence of control groups adds to the problem. Safety cannot be established if due scientific process is not adhered to. The clinical trial results for Covaxin phase 3 trials were due in 2023. Until we have the results of Phase 3 trials and unless we have sufficient long-term understanding, fully informed consent especially for administering these vaccines to children is medically, scientifically and ethically impossible.

COVID Vaccines do not prevent infection and transmission

17. For any vaccine to be recommended universally in public interest, the public health rationale underlying such a policy must be based essentially on efficacy and safety of vaccination and transmission of the disease. It has now been well established through peer reviewed scientific studies that vaccines do not prevent infection or transmission for Covid-19 and are not effective in preventing against infection from the new variants. The efficacy of vaccines in preventing infection or transmission has not been established. This is not being communicated effectively to the public. Various studies have now been published that show that the vaccines do not prevent infection or transmission of the Covid 19 virus. There are many examples of outbreaks of the virus amongst fully vaccinated populations. Examples include Iceland and Israel where a high percentage of the population have been fully vaccinated, yet an increase of cases is being experienced. Therefore administering the vaccine through coercion or without informed consent to children cannot be a matter of public health since the vaccines are not an effective guarantee against infection and transmission.

18. On the 30th of December 2021, the ICMR Chief, Dr. Balram Bhargava stated in an interview that COVID vaccines do not prevent infection and are primarily disease

modifying. Therefore there is no rationale for vaccinating a vulnerable group such as children with a vaccine that will not prevent them from getting the disease and transmitting it to others.

(The interview is available at https://timesofindia.indiatimes.com/videos/news/covid-vaccines-are-disease-modifying-dont-prevent-infection-icmr/videoshow/88597995.cms and a screen shot of the Times of India report on the same is annexed as Annexure _____At page _____to _____)

19. In a recently published study (30th September 2021) in the European Journal of Epidemiology, the authors looked at statistical correlation between vaccination level in a population and the weekly average of Covid cases in that population. They found no significant correlation; in fact the correlation was a weak positive, i.e. higher vaccination level resulted in a slightly higher level of Covid cases. The study looked at data from 68 countries as well as nearly 3000 counties in the USA.

"**Findings**

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

(A copy of the Paper titled "Increases in COVID-19 are unrelated to levels of vaccination across 68 countries and 2947 counties in the United States", published 30 Sep 2021 is annexed as **Annexure P** at Page _____to _____)

20. Even at the level of a country, vaccination does not reduce Covid cases. Israel had a huge surge in mid September despite leading most countries in vaccination levels.

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

(A copy of the article in The Times of Israel titled "Health Ministry chief says coronavirus spread reaching record heights" dated 14 Sep 2021 is annexed as **Annexure AA8** At Page _____to _____)

Serious adverse events in children in the age group 15-18 who have been vaccinated in other countries

21. The potential benefit to an individual child of receiving a Covid-19 vaccine is statistically zero. Children play an insignificant role in transmission of Covid-19. There is therefore no demonstrable benefit to the wider society in vaccinating children. In a population cohort at minimal risk of severe disease such as young people and children, acquiring natural immunity will serve a better purpose, as it will be more comprehensive, longer lasting and cover broad range of virus variants. Serious adverse events and vaccine related deaths have been reported in the UK, the US and Europe especially in children who have been administered COVID vaccines. Adverse events recording systems show unprecedented levels of adverse events, including death, resulting from the administering of the Vaccines. There continue to be new side effects being reported and/or listed by regulatory bodies in various countries. These side effects are only the short-term side

effects. These side effects include myocarditis, blood clots and facial nerve disorders, with new reports indicating a possible side effect related to a nerve/nervous system disease (Guillain-Barre syndrome). The long-term side effects are a completely unknown.

22. Changes to women's menstrual cycle have been reported in the UK. Blood clotting after the AstraZeneca (Covishield) vaccine is rare but can even cause death as has been reported. In Apr 2021, various European countries restricted the use of AstraZeneca (Covishield) to older people. It is not recommended for the young, based on safety concerns.

(A copy of the article in The Guardian titled "Spain, Belgium and Italy restrict Astra Zeneca Covid vaccine to older people" dated 8th April 2021 is annexed as Annexure _____at Page _____to _____).

23. Associated with the mRNA vaccines is the risk of myocarditis (heart inflammation). Data from various countries such as the USA shows that the incidence of myocarditis increased after the receipt of the vaccine particularly after the second dose among young make recipients and Israel show that this risk for children is about 1 in 6000. Considering this, many European countries recently stopped the use of the Moderna vaccine for those under 30.

(A copy of the paper titled "Risk of Myocarditis from COVID 19 infection in people under age of 20: A population-Based Analysis" is annexed as Annexure _____At Page _____to _____).

24. A paper published in the New England Journal of medicine discusses the increased cases of myocarditis in young males after the second dose of the vaccine.

"In most cases, symptoms of myocarditis developed within a few days after the second dose of vaccine. The incidence of myocarditis declined as the number of newly vaccinated persons decreased over time. This finding was suggestive of a possible causal relationship between two doses of the vaccine and the risk of myocarditis. Overall, we estimated that definite or probable cases of myocarditis occurred in the overall Israeli population at a rate of approximately 1 per 26,000 males and 1 per 218,000 females after the second vaccine dose, with the highest risk again among young male recipients. This result may explain why a phase 3 trial of the vaccine, which included only 15,000 male

and female recipients,[8] showed no cases of myocarditis. The mechanism of vaccine-induced myocarditis is not known but may be related to the active component of the vaccine, the mRNA sequence that codes for the spike protein of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), or to the immune response that follows vaccination."

(A copy of the paper in the New England Journal of Medicine titled "Myocarditis after BNT162b2 mRNA Vaccine against Covid-19 in Israel" is annexed as Annexure _____At Page _____to _____).

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

(A copy of an article in the New York Post titled "NIH orders $1.67M study on how COVID-19 vaccine impacts menstrual cycle" dated 7th September 2021 is annexed as Annexure___ at Page _____to _____)

26. Moderna related risks:

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

(A copy of the article in the Toronto Sun tiled "Ontario now recommending against Moderna vaccine for men 18-24 years old" dated 29th September 2021, is annexed as **Annexure** at Page _____to _____)

b) In the first week of October 2021, various European countries followed suit with Sweden and Denmark pausing Moderna COVID-19 vaccine for younger age groups after reports of rare cardiovascular side effects.

(A copy of an article in Reuters titled "Sweden, Denmark pause Moderna Covid-19 vaccine for younger age groups" dated 6th October 2021 is annexed as **Annexure** at Page _____to _____)

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

(A copy of the article titled “Finland joins Sweden and Denmark in limiting Moderna COVID-19 vaccine” dated 07 Oct 2021 is annexed as **Annexure AA** At Page _____to _____)

d) The Chief Epidemiologist in Iceland decided to stop the use of Moderna vaccine against Covid 19 while further information is obtained on safety of the vaccine during booster vaccinations.

(A copy of the report titled “Stop the use of the Moderna vaccine in Iceland in the light of new data” dated 08 Oct 2021 is Annexed as **Annexure A** at Page _____to _____)

27. Johnson & Johnson vaccine

e) Slovenia has temporarily suspended use of the Johnson & Johnson (Janssen) Covid-19 vaccine after a 20-year-old woman died of a brain hemorrhage and blood clots just days after getting the jab.

> "The health ministry has called on the Public Health Institute to temporarily suspend vaccinations with the Janssen vaccine until all details related to this case are cleared up," Health Minister Janez Poklukar told a news conference in Ljubljana.”

(A copy of the article titled “Slovenia suspends Johnson & Johnson vaccine after death” dated 29 Sep 2021 is annexed as **Annexure** at Page _____to _____)

28. It is important to note here that the above risks were not signaled in the initial vaccine trials: the trial size itself was too small to uncover rare risks (32,449for AstraZeneca/Covishield). That these risks have been found after mass vaccination is deeply concerning. The trial sizes for childrens vaccines in India are too small (525: Covaxin, 1000: ZyCov-D). Such low trial sizes cannot capture anything but the most obvious risks. Long term and more serious effects of these vaccines would only be uncovered in larger numbers and when observed over a longer period of time.

29. The past history of emergency vaccines is very concerning. Swine flu vaccine, Pandemrix, was rolled out in response to the 2010 pandemic. It was later withdrawn when it was found that around one in every 55,000 jabs led to narcolepsy in children. Dengvaxia, a vaccine against Dengue, was withdrawn in 2017 after 19 children (1 in 44,000) died of possible Antibody-Dependent Enhancement (ADE).

(A copy of the British Medical Journal paper titled "Risk of narcolepsy in children and young people receiving AS03 adjuvanted pandemic A/H1N1 2009 influenza vaccine: retrospective analysis, dated 26th February 2013 is annexed as Annexure _____At Page _____to _____).

30. As of August 2021 in the USA, nearly 600,000 deaths have been officially attributed to COVID-19. Almost 5,000 deaths following inoculation have been reported to VAERS by late May 2021; specifically, "Over 285 million doses of COVID-19 vaccines were administered in the United States from December 14, 2020, through May 24, 2021. During this time, VAERS received 4,863 reports of death (0.0017 %) among people who received a COVID-19 vaccine." (the Vaccine Adverse Events Reporting System (VAERS) is a passive surveillance system managed jointly by the CDC and FDA. Historically, VAERS has been shown to report about 1% of actual vaccine/inoculation adverse events. By mid-June last year alone, deaths following COVID-19 inoculations had reached the~6000 levels in the USA.

The data and scientific studies in countries where children have been given COVID Vaccines show that the vaccines have serious and significant adverse effects on them, which outweighs the adverse effects due to the COVID infection itself

31. In a paper published in Toxicology Reports titled "Why are we vaccinating children against COVID-19?" the authors undertake a detailed examination of the issues related to COVID-19 inoculations for children. They state that the bulk of the official COVID-19

attributed deaths per capita occur in the elderly with high comorbidities, and the COVID-19 attributed deaths per capita are negligible in children.

"The bulk of the normalised post inoculation deaths also occur in the elderly with high comorbidities, while the normalised post-inoculation deaths are smalls, but not negligible in children. Clinical trials for these inoculations were very short terms (a few months), had samples not representative of the total population, and for adolescents/children, had poor predictive power because of their small size…most importantly, the clinical trials did not address long-term effects that, if serious, would be borne by children/adolescents for potentially decades…the risk of death from COVID-19 decreases drastically as age decreases, and the longer term effects of the inoculations on lower age groups will increase their risk-benefit ratio, perhaps substantially."

The paper details the various short and long term adverse effects of the vaccination on children.

"What are the potential mid- and long-term adverse health effects from the COVID-19 inoculation on children specifically, taking into account that they will be exposed not only to the spike protein component of the SARS-CoV-2 virus but also to the toxic LNP encapsulating-shell? This toxic combination will have bypassed many defensive safeguards (typically provided by the innate immune system) through direct injection [62]. <u>As we have shown, the main reasons why we believe the spike protein could be harmful to children even though they don't seem to get sick from exposure to SARS-CoV-2 are 1) the bypassing of the innate immune system by inoculation, 2) the larger volume of spike protein that enters the bloodstream, and 3) the additional toxic effects of the encapsulating LNP layer."</u>

(A copy of the paper "Why are we vaccinating children against COVID-19?" published in Toxicology Reports is annexed as Annexure _____At Page _____to _____).

32. According to a paper published in the Lancet titled ***'COVID-19 herd immunity by immunisation: are children in the herd?'*** dated 19.04.2021, stated that using the same approach for delivering vaccines to adults and children will exacerbate hyperinflammatory conditions in children and ethically violates the risk-benefits principle:

"...Current vaccines that are authorised for emergency use, approved or in development, do not have a safety or immunogenicity profile in children. In the absence of a better understanding of the pathogenesis of this condition, ***using the same approach for delivering vaccines as in adults could exacerbate the incidence of this hyperinflammatory condition.***

Second, from a public health perspective, it will be necessary to immunise children if they are a major source of SARS-CoV-2 transmission and if the candidate vaccines block transmission. However, epidemiological reports up to now suggest that young children have a high likelihood of developing COVID-19 via household transmission, once a family member tests positive for COVID-19.1 There is little evidence of secondary infection from children to others in the transmission pathways of COVID-19. Although emerging data suggest that some candidate vaccines can block transmission, vaccinating children cannot be justified if it is to give direct protection despite minimal burden of disease or to help to block transmission if children do not constitute a substantial reservoir for transmission.

Third, from an ethical perspective, there is a balance between risk and benefit in offering a COVID-19 vaccine to children that will offer minimal or no direct benefit to the recipient, no benefit to the public, and as yet, unknown medium-term and long-term risks to the recipient…"

(A copy of the paper published in the Lancet titled 'COVID-19 herd immunity by immunisation: are children in the herd?' dated 19.04.2021 is annexed as **Annexure ___ (Page _____to_____)**.

33. A paper published in the New England Journal of Medicine discusses the increased incidence of myocarditis in young male recipients after two dose of the vaccine and also concludes that the incidence of was higher than in the unvaccinated persons.

"The incidence of myocarditis, although low, increased after the receipt of the BNT162b2 vaccine, particularly after the second dose among young male recipients. The clinical presentation of myocarditis after vaccination was usually mild…

On the basis of data from an Israeli national database, the incidence of myocarditis after two doses of the BNT162b2 mRNA vaccine was low but higher than the incidence among unvaccinated persons and among historical controls. The risk of myocarditis was driven primarily by the increased incidence after the second dose of vaccine and in young male recipients."

(A copy of the paper in the New England Journal of Medicine titled "Myocarditis after BNT162b2 mRNA Vaccine against Covid-19 in Israel" is annexed as Annexure _____At Page _____to _____).

34. A recent paper titled 'The Ethics of Drug Research in Children' by T.F. Ackerman suggests that clinical trials on children are justified only when the risk-benefit ratio is at least favourable:

> *"A second component of justice focuses on the fair distribution of the benefits of research participation. This feature is pertinent to the use of therapeutic research procedures. Involvement of children in these procedures is justified only when the risk-benefit ratio is at least as favorable as any alternative treatments available outside the research context."*

(A copy of the paper titled 'The Ethics of Drug Research in Children by T. F. Ackerman' (2001) available on doi:10.2165/00128072-200103010-00003' is annexed as **Annexure ___ (Page _____to_____)**

Children are not capable of legal consent to the vaccines and the parents who give consent on their behalf are incapable of giving informed consent in the absence of studies and data about the benefits and adverse effects of the vaccines on children

35. There are deeply disturbing reports that government and health advisory groups are calling out in the media for the COVID-19 vaccine in children to enable schools reopening, contact sports or for admissions, etc. Any sort of such coercion of children or their parents to accept the COVID -19 vaccines that are still at research stage and about which no medium or long term side effects are known and against a disease which presents no material risk to children, is unethical and irresponsible. It violates the principles of medical freedom, informed consent and bodily autonomy which are to be preserved and protected, especially while dealing with vulnerable populations such as children.

36. Informed consent is the cornerstone of ethical medical practice. Introducing vaccinations especially for children in the absence of informed consent is unconstitutional and violates principle of informed self determination and bodily autonomy which flows from Article 21. Unless factually accurate information is made available, detailing risks as well as

benefits, it is not possible for anyone, let alone children, to make a fully informed decision and give informed consent

37. Various disturbing news reports and orders have been issued which directly or indirectly have the effect of coercing children to get vaccinated. It appears to be a part of the public policy of the Union and State Governments to maximize the number of people receiving Covid 19 vaccines in as short a duration as is possible even without putting all 'information' in the public domain, enabling a citizen to make an 'informed' choice. This is unethical and has serious implication if this coercion is extending to vaccinating children.

38. In Master Hridaan Kumar Minor v. Union of India W.P.(C) 343/2019 & CM No. 1604/2019 & 1605/2019 (or "the Measles-Rubella case"), in order dated 15.01.2019, the Delhi High Court made it clear that parents must have information as to contra-indications before consent in any manner can be obtained:

> *"5. Before proceeding to examine whether consent in this manner can be obtained. It is clear that all parents must have full information as to (a) the particulars of the vaccine proposed to be administered; (b) contra indications and side effects of such a vaccine; (c) the date on which such vaccine would be administered to their wards/children; and (d) the personnel who would administer the same."*

(A copy of the order dated 15.01.2019 judgement in Master Hridaan Kumar Minor v. Union of India W.P.(C) 343/2019 & CM No. 1604/2019 & 1605/2019, is annexed as **Annexure_____(Page _____to _____)**

39. In the Measles-Rubella case (Supra) the Hon'ble High Court of Delhi also made it mandatory to advertise the contra-indications of the Measles-Rubella vaccine:

> *"15. In view of the above, it is directed as under:*
> *(1) Directorate of Family Welfare shall issue quarter page advisements in various newspapers as indicated by the respondents, namely, The Hindustan Times, The Times of India, The Hindu, The Pioneer, The Indian Express, Delhi Tribune, Mail Today, The Asian Age, Navbharat Times, Dainik Jagran, Punjab Kesari, Hindustan, Amar Ujala, Navodaya Times, Hamara Samaj, Pratap, Daur-e-*

Jadeed, Jathedar, Jan Ekta. The advertisements shall also indicate that the vaccination shall be administered with Auto Disable Syringes to the eligible children by Auxiliary Nurse Midwifery. ***The advertisement shall also clearly indicate the side effects and contraindications as may be finalised by the Department of Preventive Medicine, All India Institute of Medical Sciences.***
(2) The Head of Department of Preventive Medicine, All India Institute of Medical Sciences is directed to finalise the list of contraindications and risks associated with the vaccine being included in the aforesaid advertisements. Advertisements in two of the newspapers (one in English and the other in Hindi language) will also indicate the dates on which MR vaccine will be administered in respective schools. The website of DoE shall also clearly set out the above information…."

40. In the case of **Kemp v. New Jersey 687 A.2d 715** (N.J. 1997), the plaintiff was a high school student, vaccinated for rubella while pregnant, and her infant, born with congenital rubella syndrome; Because the rubella vaccine is contraindicated in early pregnancy, and a health care worker, even a family physician, may not know that a teenage girl is pregnant, the process of obtaining the girl's informed consent and warning her about the risk to the fetus may provide the only incentive for the girl to reveal her condition or the possibility of her pregnancy. Under these circumstances, informed consent provides an opportunity for an appropriate individualized assessment of risk and prevents vaccine-related injuries.

(A copy of the judgement in Kemp v. New Jersey 687 A.2d 715 (N.J. 1997), is annexed as **Annexure_____(Page _____to _____)**

41. Informed consent is necessary for medical procedures and bodily integrity is an integral part of the right to privacy flowing from Article 21 as has been settled in several judgments by the Hon'ble Supreme Court including Aarushi Dhasmana v. UOI & Ors (2013) 9 SCC 475, K. Puttaswamy v. UOI (2017) 10 SCC 1 and Common Cause v. UOI (2018) 5 SCC 1. Also, the Hon'ble Supreme Court in Kalpana Mehta & Ors. v. UOI & Ors. WP(C) No.558/2012 has framed questions on the procedure by which a vaccine (HPV vaccine, in that case) was to be administered and thus recognized the factum that prior informed consent is a necessity for vaccination.

42. The draft "Charter of Patient's Rights" as issued by the Ministry of Health and Family Affairs, for public comments, which holds 'right to informed consent' as one of the patient's legal, fundamental rights states that:

> *"4. Every patient has a right that informed consent must be sought prior to any potentially hazardous test/treatment (e.g. invasive investigation / surgery / chemotherapy) which carries certain risks. It is the duty of the hospital management to ensure that all concerned doctors are properly instructed to seek informed consent, that an appropriate policy is adopted and that consent forms with protocol for seeking informed consent are provided for patients in an obligatory manner. It is the duty of the primary treating doctor administering the potentially hazardous test / treatment to explain to the patient and caregivers the main risks that are involved in the procedure, and after giving this information, the doctor may proceed only if consent has been given in writing by the patient / caregiver or in the manner explained under Drugs and Cosmetic Act Rules 2016 on informed consent.*
>
> *a) Participation of patients in clinical trials must always be based on informed consent, given after provision of all relevant information. The patient must be given a copy of the signed informed consent form, which provides him / her with a record containing basic information about the trial and also becomes documentary evidence to prove their participation in the trial."*

(A copy of the Charter of Patient's Rights" as issued by the Ministry of Health and Family Affairs, is annexed as **Annexure_____(Page _____to _____)**

COVID-19 Vaccine Mandates for Children

43. In an order no. DMC-SPO-2020/14198, Haryana State Disaster Management Authority, Government of Haryana notified that vaccinations of eligible persons (more than 15 years) is mandatory.

(A copy of the order no. DMC-SPO-2020/14198 dated 1st January 2022 by the Haryana State Disaster Management Authority, Government of Haryana is annexed as **Annexure____(Page _____to_____)**

44. In a letter dated 1st January 2022 by the District Educational Officer, YSR District, Kadapa, Andhra Pradesh, issued instructions to mandatorily vaccinate all children. The relevant parts of the same are reproduced below:

> *"In pursuance of the instructions issued by the Joint Collector (V, WS & D), YSR District in the reference cited, all the Deputy Educational Officers and Mandal Educational Officers in the district are requested to inform all the Headmasters of High Schools and Principals of Junior Colleges/AP Model Schools and Special Officers of KGBVS under their jurisdiction to complete vaccination (Covid-19) to all the students in the age group of 15-18 from 03.01.2022 to 10.01.2022 in their respective Sachivalams and see that all students are vaccinated."*

(A copy of the letter dated 1st January 2022 by the District Educational Officer, YSR District, Kadapa, Andhra Pradesh is annexed as **Annexure____(Page _____to_____)**

45. A Deccan Herald article dated 4th January 2022 and titled 'Parents fume after some Karnataka schools make Covid-19 vaccinations mandatory', reported that schools in Karnataka were making vaccinations compulsory fueling fears that vaccinations may be compulsory to sit for board examinations despite government clarifications that COVID-19 vaccinations are voluntary:

> *"Such sentiments were also echoed by other parents that DH met after several schools made vaccination mandatory and sent out warning messages as the vaccination programme kicked off amid a Covid-19 surge. Parents revealed that some of the private unaided schools sent out messages on Sunday evening itself, mandating offline attendance for children on Monday following the vaccination session."*

(A copy of the Deccan Herald article dated 04.01.2022 and titled 'Parents fume after some Karnataka schools make Covid-19 vaccinations mandatory' has been annexed as **Annexure_____(Page_____to_____)**

46. A notice letter addressed to the 'The Principal Secretaries/Secretaries WCD/SJE (All States/UTs)' from the Ministry of Women and Child Development that vaccinations are compulsory for children:

> "F*urther, it is brought to the notice that in light of the compulsory vaccination of children against COVID-19 falling in the 15-18 age group, it is requested that all*

*District Magistrates may be directed to make appropriate arrangements on for vaccination of the Children living in CCIs as well, on pri*ority basis."

(A copy of the notice letter dated 4th January 2022 addressed to the 'The Principal Secretaries/Secretaries WCD/SJE (All States/UTs)' by the Director to the Government of India is annexed as **Annexure____(Page _____to_____)**.

47. In a letter dated 4th January 2022, the Council for the Indian School Certificate Examinations addressed to all heads of affiliated schools, the Chief Executive and Secretary made it mandatory for children to be vaccinated to sit in examinations. The relevant parts of the letter are reproduced below:

"*Considering the above, the CISCE would like to advise you to encourage all your parents and guardians to get their children in the age group of 15-18 years vaccinated at the earliest. Vaccination against the Covid-19 virus is the best protection which can be given to children at this stage. All candidates for the ICSE & ISC Year 2022 Examinations should be vaccinated before the start of the said examinations.*"

(A copy of the notice letter dated 4th January 2022 by the Council for the Indian School Certificate Examinations is annexed as **Annexure____(Page _____to_____)**.

48. Another school, Lawrance Public Sr. Sec. School, Mohali, made it mandatory for students to be vaccinated and stated that unvaccinated children will not be allowed in offline classes.

(A copy of the notice letter dated 8th January 2022 by Lawrance Public Sr. Sec. School, Mohali is annexed as **Annexure____(Page _____to_____)**.

Regulations regarding clinical trials in Children

49. According to the First Schedule of the New Drugs and Clinical Trials Rules, 2019 children are part of "special populations" and if a safety concern exists, the studies may be initiated after post-marketing surveillance:

"GENERAL PRINCIPLES AND PRACTICES FOR CLINICAL TRIAL

….(iv) If the new drug has a potential for use in paediatric patients – paediatric studies should be conducted. These studies may be initiated at various phases of clinical development or after post marketing surveillance in adults if a safety concern exists. In cases where there is limited paediatric data at the time of submission of application, more data in paediatric patients would be expected after marketing authorisation for use in children is granted.

(v) The paediatric studies should include—

(a) clinical trials,

(b)relative bioequivalence comparisons of the paediatric formulation with the adult formulation performed in adults, and definitive pharmacokinetic studies for dose selection across the age ranges of paediatric patients in whom the drug is likely to be used. These studies should be conducted in the paediatric patient population with the disease under study…"

(A copy of the New Drugs and Clinical Trials Rules, 2019 is annexed as Annexure ___ (Page _____to_____).

50. The approval for the clinical trials which are being conducted on children are in direct contravention with the National Ethical Guidelines for BioMedical Research Involving Children. These guidelines need to be read in conjunction with the current National Ethical Guidelines for Biomedical Research involving Human Participants, Indian Council of Medical Research (ICMR):

"1.5 General guidelines for research in children

The following guidelines should be followed when conducting research in children:

• Research proposals should be scientifically sound.

• The equation between the potential benefit and the risk or potential harm should be at least as favourable for the proposed research procedure as for the alternatives available to the children.

• There should be benefit to children in general and, in most cases, to the individual child subject.

• The need for the study should be justified by a thorough review of literature.

• The research should be conducted by a team of investigators who have the requisite expertise. One or more members of the team should be a paediatrician and/or have prior experience of conducting research involving children.

• Research involving children should take into consideration the unique physiology, anatomy, psychology, pharmacology, social situation and special needs of children and their families.

• Research involving children must be conducted in a child-friendly environment, as far as possible.
• In general, drugs should be tested for safety, pharmacokinetics, and at least initial indications of efficacy in adults established before they are tested in children. It may often be appropriate to defer paediatric testing until adult testing has reached Phase III or beyond, when substantial data are available on the safety and efficacy of a drug in adults. *However, there may be situations where studies involving children would be needed without prior adult studies, for example, surfactant use in premature babies with respiratory distress syndrome."*

(A copy of the National Ethical Guidelines for BioMedical Research Involving Children is annexed as Annexure ___(Page _____to_____).

51. In an advisory by WHO published on their website last updated on 14.07.2021 and titled "COVID-19 advice for the public: Getting vaccinated", the body states that:

"Children and adolescents tend to have milder disease compared to adults, so unless they are part of a group at higher risk of severe COVID-19, it is less urgent to vaccinate them than older people, those with chronic health conditions and health workers.

More evidence is needed on the use of the different COVID-19 vaccines in children to be able to make general recommendations on vaccinating children against COVID-19."

(A copy of the WHO advisory last updated last updated on 14 July 2021 and titled "COVID-19 advice for the public: Getting vaccinated" is annexed as **Annexure P (Page _____to _____).**

52. According to the International Ethical Guidelines for Biomedical Research Involving Human Subjects issued by the Council for International Organizations of Medical Sciences, children need special consideration due to their evolving capacity to give informed consent:

"GUIDELINE 17:
RESEARCH INVOLVING CHILDREN AND ADOLESCENTS
Children and adolescents must be included in health-related research unless a good scientific reason justifies their exclusion. As children and adolescents have distinctive physiologies and health needs, they merit special consideration by researchers and research ethics committees.

However, their distinctive physiologies and emotional development may also place children and adolescents at increased risk of being harmed in the conduct of research. Moreover, without appropriate support, they may not be able to protect their own interests due to their evolving capacity to give informed consent. Specific protections to safeguard children's rights and welfare in the research are therefore necessary……
For research interventions or procedures that have no potential individual benefits for participants, two conditions apply:

- ***the interventions and procedures should be studied in adults first, when these interventions and procedures target conditions that affect adults as well as children and adolescents, unless the necessary data cannot be obtained without participation of children or adolescents; and***
- ***the risks must be minimized and no more than minimal.***

When the social value of the studies with such research interventions and procedures is compelling, and these studies cannot be conducted in adults, a research ethics committee may permit a minor increase above minimal risk."

(A copy of the International Ethical Guidelines for Biomedical Research Involving Human Subjects issued by the Council for International Organizations of Medical Sciences is annexed as Annexure ___(Page _____to_____).

53. As per the requirements of WHO's Good Clinical Trial Practices guidelines trials involving humans should be initiated only if the anticipated benefit(s) for the individual research subject and society clearly outweigh the risks:

"WHO Principles of GCP

Principle 1: Research involving humans should be scientifically sound and conducted in accordance with basic ethical principles, which have their origin in the Declaration of Helsinki. Three basic ethical principles of equal importance, namely respect for persons, beneficence, and justice, permeate all other GCP principles.
Principle 2: Research involving humans should be scientifically justified and described in a clear, detailed protocol.
Principle 3: Before research involving humans is initiated, foreseeable risks and discomforts and any anticipated benefit(s) for the individual trial subject and society should be identified. Research of investigational products or procedures should be supported by adequate non-clinical and, when applicable, clinical information.
Principle 4: Research involving humans should be initiated only if the anticipated benefit(s) for the individual research subject and society

clearly outweigh the risks. Although the benefit of the results of the trial to science and society should be taken into account, the most important considerations are those related to the rights, safety, and well-being of the trial subjects….."

(A copy of the WHO's Good Clinical Trial Practices guidelines is annexed as Annexure ___(Page _____to_____).

54. The Declaration of Helsinki states that vulnerable populations should not be included in clinical trials unless absolutely necessary:

"The Declaration of Helsinki on inclusion of vulnerable populations:
What special protections are required to enable vulnerable populations to participate in research?
For a research subject who is legally incompetent, physically or mentally incapable of giving consent or is a legally incompetent minor, the investigator must obtain informed consent from the legally authorized representative in accordance with applicable law. These groups should not be included in research unless the research is necessary to promote the health of the population represented and this research cannot instead be performed on legally competent persons." (Declaration of Helsinki)"

(A copy of the Declaration of Helsinki is annexed as **Annexure ___(Page _____to_____)**.

PRAYER

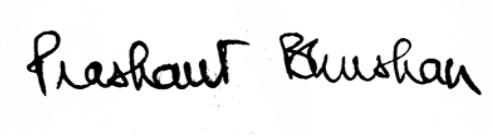
In view of the abovementioned facts and in the interest of public safety, it is respectfully submitted that this Hon'ble Court may be pleased to

a) Direct the respondents to halt the roll out of vaccines under the government immunization programme for children, till complete clinical trial data is available in the public domain for these vaccines for the trials in children as well as in adults;
b) Direct the respondents to halt the Zydus Cadila vaccine from being administered to children in India till complete trial data is available in the public domain for these vaccines;
c) Direct the respondents to release the entire segregated trial data for each of the phases of trials that have been undertaken with respect to the vaccines being administered in India for children along with the trial data for those vaccines in adults; and

d) Declare that vaccine mandates for children, in any manner whatsoever, even by way of making it a precondition for accessing educational institutions or sports facilities, is unconstitutional; and

e) Pass any other orders as this Hon'ble Court deems fit.

PETITIONER THROUGH:



(PRASHANT BHUSHAN)
COUNSEL FOR THE PETITIONER

DRAWN BY: CHERYL D'SOUZA, ADVOCATE
RIA YADAV

DRAWN ON: 10th JANUARY 2022

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