# Jacob Puliyel vs Union Of India on 2 May, 2022

## Author: L. Nageswara Rao

## Bench: B. R. Gavai, L. Nageswara Rao

Reportable

IN THE SUPREME COURT OF INDIA
CIVIL ORIGINAL JURISDICTION
Writ Petition (Civil) No. 607 of 2021

JACOB PULIYEL ….PETITIONER

Versus

UNION OF INDIA & ORS. ….RESPONDENTS

JUDGMENT

L. NAGESWARA RAO, J.

1. The Petitioner was a member of the National Technical Advisory Group on Immunization (NTAGI) and was advising the Government of India on vaccines. He has filed this Writ Petition in public interest seeking the following reliefs:

> "(a) 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; and
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> (b) Direct the respondent No 2 to disclose the detailed minutes of the meetings of the Subject Expert Committee and the NTGAI with regard to the vaccines as directed by the 59th Parliamentary Standing Committee Report and the members who constituted 1 | Page the committee for the purpose of each approval meeting; and
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> (c) Direct the respondent No.2 to disclose the reasoned decision of the DCGI granting approval or rejecting an application for emergency use authorization of vaccines and the documents and reports submitted to the DCGI in support of such application; and
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> (d) Direct the respondents to disclose the post vaccination data regarding adverse events, vaccinees who got infected with Covid, those who needed hospitalization and those who died after such infection post vaccination and direct the respondents to

widely publicize the data collection of such adverse event through the advertisement of toll free telephone numbers where such complaints can be registered; and

(e) Declare that vaccine mandates, in any manner whatsoever, even by way of making it a precondition for accessing any benefits or services, is a violation of rights of citizens and unconstitutional; and

(f) Pass any other orders as this Hon'ble Court deems fit."

2. In the Writ Petition, the Petitioner highlighted the adverse consequences of emergency approval of vaccines in India, the need for transparency in publishing segregated clinical trial data of vaccines, the need for disclosure of clinical data, lack of transparency in regulatory approvals, minutes and constitution of the expert bodies, imperfect evaluation of Adverse Events Following Immunisation (AEFIs)

2 | Page and vaccine mandates in the absence of informed consent being unconstitutional. The Petitioner further stated in the Writ Petition that coercive vaccination would result in interfering with the principle of informed self-determination of individuals, protected by Article 21 of the Constitution of India.

3. Notice was issued in the Writ Petition on 09.08.2021. An additional affidavit was filed by the Petitioner on 03.09.2021 raising additional grounds. It was averred in the additional affidavit that natural immunity is long-lasting and robust in comparison to vaccine immunity and that vaccines do not prevent infection or transmission of COVID-19. The Petitioner further stated that vaccines are not effective in preventing against infection from new variants of COVID-19. The Petitioner relied on news articles on the fourth nationwide serological survey conducted by Indian Council of Medical Research (ICMR) in June and July, 2021, according to which up to two-thirds of the Indian population above the age of 6 years had already been infected with COVID-19 and had antibodies specific to the SARS-CoV-2 virus. The Petitioner relied upon other news articles and research studies conducted to state that there had been breakthrough infections even amongst vaccinated people. Urging that 3 | Page research has shown that vaccinated people also transmit the virus, the Petitioner contended that vaccine mandates are meaningless.

4. The Petitioner filed an Interlocutory Application seeking a direction to restrain all authorities and institutions, public and private, from mandating the vaccine in any manner whatsoever, on a precondition of accessing any service or on pain of any penalty. The Petitioner has drawn the attention of this Court to various restrictions that were placed by State Governments, other employers and educational institutions on unvaccinated individuals. The Petitioner contended that mandating vaccination for access to resources, public places and means of earning livelihood would be in violation of their fundamental rights, especially so, when scientific studies have shown that unvaccinated persons do not pose more danger of transmission of the virus when compared to vaccinated persons.

5. Respondent No. 1, the Union of India, has raised a preliminary objection regarding the maintainability of the Writ Petition. The Union of India has further contended that the serious threat posed by the unprecedented pandemic which had devastating effects on the entire world called for emergency measures. It is accepted world over that 4 | Page vaccination for COVID-19 is necessary to avoid infection. India was one of the few countries in the world which succeeded in manufacturing vaccines for protection from COVID-19, one of which was COVAXIN, India's indigenous vaccine and the other being COVISHIELD, which was manufactured by Serum Institute of India with technology transfer from AstraZeneca / Oxford University. The country started one of the largest inoculation programmes in the world in larger public interest, while tackling challenges of vaccine hesitancy, effect of the second wave of the pandemic and other such adverse circumstances. The Union of India expressed serious doubts about the intention of the Petitioner in filing this Writ Petition. As we have not seen the end of the pandemic caused due to the COVID-19 virus, any interference with the steps taken by the Union on the basis of the advice given by the NTAGI and other expert bodies would provide impetus to the already prevailing vaccine hesitancy in certain sections of the society. In their counter-affidavit, the Union of India reminded us that decisions of domain experts should not normally be interfered with in judicial review and that this Court should not sit in appeal over a scientific process undertaken by domain experts on a subject which is not the expertise of any judicial forum. The long-

5 | Page drawn procedure for making applications for issuance of licenses for manufacturing vaccines and the statutory regime governing the same have been referred to in the counter- affidavit to emphasize that the Union of India has not been remiss in grant of emergency licences. There is a detailed procedure for approval with checks at every stage which has been followed for grant of emergency approval. In so far as disclosure of clinical trial data is concerned, the Union of India referred to the National Ethical Guidelines for Biomedical and Health Research involving Human Participants published by the ICMR, which require privacy and confidentiality of human participants to be maintained. Accordingly, the Union of India contended that such details pertaining to identity and records of the participants in the clinical trial data cannot be disclosed to the public as per the prevailing statutory regime. It was asserted by the Union of India that the remaining data has already been made available in the public domain.

6. On the subject of monitoring of AEFIs, the Union of India brought to our attention established procedures and protocols in place for surveillance of AEFIs established under the National Adverse Event Following Immunisation Surveillance Guideline. Further, the multi-tier structure 6 | Page comprising AEFI Committees at the state and national levels, providing guidance, carrying out investigation and causality assessment was elaborated upon. Details of the procedures followed in accordance with globally accepted practices were highlighted in the counter-affidavit. According to the Union of India, all cases of serious and severe AEFI, including reported deaths, are subjected to scientific and technical review process with causality assessments done at the state and national levels by trained experts to ascertain whether a particular AEFI can be attributed to the vaccine. In the counter-affidavit, it was also made clear that COVID-19 vaccination is voluntary and that the Government of India encourages all individuals to take vaccination in the interest of public health, as the individual's ill health has a direct effect on the society. It was also made clear that COVID-19 vaccination is not linked to any benefits or services.

7. Counter-affidavits have been filed by other Respondents as well. The vaccine manufacturers, i.e., Respondents Nos. 4 and 5, have brought to the notice of this Court that approval to their vaccines was granted after strict compliance of the procedure prescribed. The States of Tamil Nadu, Maharashtra, Delhi and Madhya Pradesh have also filed counter-affidavits, justifying the restrictions that were 7 | Page placed on unvaccinated persons in public interest. The details of the restrictions have been discussed later.

8. We have heard Mr. Prashant Bhushan, learned counsel for the Petitioner, Mr. Tushar Mehta, learned Solicitor General of the Union of India, Mr. S. Guru Krishnakumar, learned Senior Counsel for Respondent No. 4, Mr. Amit Anand Tiwari, learned Additional Advocate General for the State of Tamil Nadu, Mr. Rahul Chitnis, learned counsel for the State of Maharashtra, Ms. Mrinal Gopal Elker, learned counsel for the State of Madhya Pradesh and Ms. Shyel Trehan, learned counsel for Respondent No. 5.

Preliminary Issues I. Maintainability

9. The learned Solicitor General raised a preliminary objection as to the maintainability of the Writ Petition which is filed in public interest. He stated that this Writ Petition, if entertained, would harm public interest, as any observation made by this Court against vaccination would result in potential threat of vaccine hesitancy.

10. The Petitioner is a paediatrician, who was a member of the NTAGI earlier. It has been stated in the Writ Petition that he has a number of publications in internationally peer- reviewed medical journals to his credit. The Petitioner 8 | Page strongly believes that there cannot be coercive vaccination, especially of inadequately tested vaccines, which amounts to an intrusion into the individual's personal autonomy. He is also of the firm opinion that an individual is deprived of the opportunity to give informed consent in the absence of availability of segregated data of clinical trials of the vaccines. He has also aired further grievances pertaining to poor evaluation and reporting of AEFIs.

11. This Court is entitled to entertain a public interest litigation moved by a person having knowledge in the subject-matter of the lis and, thus, having an interest therein, as contradistinguished from a busybody, in the welfare of people1. The Union of India has objected to the maintainability of the Writ Petition on the ground that the questions raised by the Petitioner may result in raising doubts in the minds of the citizenry about the vaccination, adding to the already existing vaccine hesitancy in the country. The consequence would be a debilitating effect on public health and therefore, the petition cannot be said to be in public interest. In other words, the maintainability of the Writ Petition is raised on the ground that the sensitive issue of vaccination should not be dealt with by this Court, as it 1 Indian Banks' Association, Bombay v. Devkala Consultancy Service (2004) 11 SCC 1 9 | Page has the propensity of fuelling doubts about the efficacy of the vaccines.

12. From the rejoinder affidavit submitted by the Petitioner, we note that a petition had been filed by the Petitioner earlier, during his tenure as a member of the NTAGI, with respect to the Rotavac

vaccine claiming that adequate data from the clinical trials had not been provided to the NTAGI. The rejoinder affidavit further states that the petition was dismissed by this Court, on the ground that the Petitioner could not have filed the said petition while being a member of the NTAGI. The enthusiasm of the Petitioner in approaching this Court has not gone unobserved. However, as the issues raised by the Petitioner have a bearing on public health and pertain to the fundamental rights of the country's populace, we are of the opinion that they warrant due consideration by this Court. Therefore, we are not inclined to entertain the challenge mounted by the Union of India to the maintainability of the Writ Petition. II. Judicial review of executive decisions based on expert opinion

13. Yet another ground taken by the Union of India is that this Court has to yield to executive decision and action in the matter of administration of drugs / vaccines. The existence 10 | P a g e of any other possible view cannot enable this Court to interfere in matters relating to opinion of domain experts by sitting in appeal over such decisions, while adjudicating a writ petition filed under Article 32 of the Constitution. The learned Solicitor General supported the stand of the Union of India with reference to the law laid down by this Court in Academy of Nutrition Improvement v. Union of India 2, G. Sundarrajan v. Union of India 3 and Shri Sitaram Sugar Company Ltd. v. Union of India 4. Further, the learned Solicitor General relied upon the judgments of the Supreme Court of the United States (hereinafter, the "US Supreme Court") in Henning Jacobson v.

Commonwealth of Massachusetts5, Zucht v. King6 and in Docket No. 21A240 titled Joseph R. Biden v. Missouri dated 13.01.2022 and the judgment of the Supreme Court of New South Wales (hereinafter, the "NSW Supreme Court") in Kassam v. Hazzard; Henry v. Hazzard 7 to bolster his submissions that courts should not lightly interfere with matters of policy concerning the safety and health of the people and it is not the court's function to determine the 2 (2011) 8 SCC 274 3 (2013) 6 SCC 620 4 (1990) 3 SCC 223 5 197 US 11 (1905) 6 260 US 174 (1922) 7 [2021] NSWSC 1320 11 | P a g e merits of the exercise of power by the executive. The learned Solicitor General was joined by Mr. Amit Anand Tiwari, learned Additional Advocate General for the State of Tamil Nadu, in emphasising the limited scope of judicial review in matters of policy framed on the basis of expert opinion.

14. In opposition, the Petitioner argued that matters of public importance involving invasion of fundamental rights of individuals cannot be brushed aside by this Court on the ground that they are beyond the jurisdiction of this Court. This Court has a duty to safeguard the fundamental rights of individuals and issues raised herein are of seminal importance which ought to be decided after assessing the relevant material placed before this Court by both sides. Mr. Bhushan referred to the judgement of the High Court of New Zealand in Ryan Yardley v. Minister for Workplace Relations and Safety8 in support of his submission that the scientific data and evidence that was produced before the High Court of New Zealand was assessed to adjudge the efficacy of vaccines in preventing transmission of the COVID- 19 virus.

8 [2022] NZHC 291 12 | P a g e

15. It was further argued by Mr. Bhushan that the judgments relied upon by the Union of India are not applicable to the facts of this case. He relied upon the judgments of this Court in Delhi Development Authority v. Joint Action Committee, Allottee of SFS Flats 9, Directorate of Film Festivals v. Gaurav Ashwin Jain 10 and an order of this Court in Distribution of Essential Supplies and Services During Pandemic, In re 11 and submitted that policy decisions taken by the executive are not beyond the scope of judicial review, if they are manifestly arbitrary or unreasonable.

16. Before examining the parameters of judicial review in this case, it is profitable to refer to judgments from beyond our borders which have dealt with the scope of judicial review in matters relating to public health and vaccinations, in particular. Compulsory vaccination against small pox was the subject-matter of Jacobson (supra) decided in 1905. The US Supreme Court was of the opinion that the mandate of the local government for compulsory vaccination was binding on every individual. The safety and health of the people has to be protected by the government and the judiciary is not 9 (2008) 2 SCC 672 10 (2007) 4 SCC 737 11 (2021) 7 SCC 772 13 | P a g e competent to interfere with decisions taken in the interest of public health. The Court can interfere by way of judicial review of legislative action in matters of public health only when there is no real or substantial relation to the object of the legislation or when there is plain, palpable invasion of rights secured by fundamental law and thereby, give effect to the Constitution.

17. In the wake of the COVID-19 pandemic, restrictions on attendance at religious services in areas classified as 'red' or 'orange' zones were imposed by an executive order issued by the Governor of New York. The said restrictions were challenged on the ground that they violate the free exercise clause of the First Amendment of the Constitution of the United States. By a majority of 6:3, the US Supreme Court in Roman Catholic Diocese v. Cuomo12 granted injunctive relief on being satisfied that the executive order struck at the very heart of the First Amendment's guarantee of religious liberty. While doing so, the US Supreme Court observed that the members of the Court are not public health experts and they should respect the judgment of those with special expertise and responsibility in this area. However, the Constitution cannot be put away and forgotten even in a 12 141 S. Ct. 63 (2020) 14 | P a g e pandemic. Gorsuch, J., who wrote a concurring opinion, observed that Jacobson (supra) hardly supports cutting the Constitution loose during a pandemic. Jacobson (supra) was distinguished by Gorsuch, J., who held that the Court did not interfere with the challenged law in Jacobson (supra) only because it did not " contravene the Constitution of the United States" or "infringe any right granted or secured by " it. A word of caution sounded by Gorsuch, J. is to the effect that the Court cannot stay out of the way in times of crisis, when the Constitution is under attack. In his dissent, Roberts, C.J. held that the injunction sought would not be in public interest, especially when it concerns public health and safety needs which calls for swift government action in everchanging circumstances. He relied upon the earlier order passed by the US Supreme Court in South Bay United Pentecostal Church v. Newsom 13 wherein it was recognised that courts must grant elected representatives broad discretion when they undertake to act in areas fraught with medical and scientific uncertainties.

18. Biden v. Missouri (supra) related to vaccine mandates for healthcare providers. The Secretary of Health and Human Services issued a rule on being convinced that vaccination of 13 140 S. Ct. 1613 (2020) 15 | P a g e healthcare workers in facilities in the Medicare and Medicaid Programs against

COVID–19 was "necessary for the health and safety of individuals to whom care and services are furnished". The said rule was challenged and the US District Courts for the Western District of Louisiana and the Eastern District of Missouri each entered preliminary injunctions against its enforcement. The appeals filed against the said injunction were rejected by the Fifth Circuit in Louisiana and the Eighth Circuit in Missouri. Aggrieved thereby, the Government moved the US Supreme Court seeking for a stay on the preliminary injunctions passed by the US District Courts. While granting stay of the preliminary injunctions, by its plural opinion the US Supreme Court held that the role of courts in reviewing decisions taken by the executive should be to ensure that the executive " has acted within a zone of reasonableness".

19. Having been aggrieved by certain orders of the Minister for Health and Medical Research that required people working in the construction, aged care and education sectors to be compulsorily vaccinated, Al-Munir Kassam and three others, along with Natasha Henry and five others, approached the NSW Supreme Court challenging the 16 | P a g e constitutional validity of the decision. While considering the grounds of challenge, the NSW Supreme Court in Kassam v. Hazzard (supra) was of the view that "it is not the Court's function to determine the merits of the exercise of the power by the Minister to make the impugned orders, much less for the court to choose between plausible responses to the risks to the public health posed by the Delta variant ". The NSW Supreme Court further observed that it is not the court's function to conclusively determine the effectiveness of some of the alleged treatments for those infected or the effectiveness of COVID-19 vaccines, especially their capacity to inhibit the spread of the disease, which are all matters of merits, policy and fact for the decision maker and not the court. The NSW Supreme Court emphasised that its only function is to determine the legal validity of the impugned orders. The said view of the NSW Supreme Court was approved by the New South Wales Court of Appeal in Kassam v. Hazzard; Henry v. Hazzard14.

20. The Minister for Workplace Relations and Safety passed COVID-19 Public Health Response (Specified Work Vaccinations) Order 2021, by which it was determined that work carried out by certain police and defence force 14 [2021] NSWCA 299 17 | P a g e personnel could only be undertaken by workers who have been vaccinated. Three police and defence force workers who did not wish to be vaccinated sought judicial review of the said order before the High Court of New Zealand (hereinafter, the "NZ High Court"). While adjudicating the dispute, the NZ High Court in Ryan Yardley (supra) expressed its opinion that the choices made by governments on their response to COVID-19 involve wide policy questions, including decisions on the use of border closures, lockdowns, isolation requirements, vaccine mandates and many other measures, which are decisions for the elected representatives to make. The NZ High Court made it clear that the Court addresses narrower legal questions and the Court's function is not to address the wider policy questions. While referring to the evidence of experts, the NZ High Court stressed on the institutional limitations on the Court's ability to reach definitive conclusions but clarified that the Court must exercise its constitutional responsibility to ensure that decisions are made lawfully. While relying upon a judgment of the Court of Appeal of New Zealand in Ministry of Health v. Atkinson15, the NZ High Court held that the Crown has the burden to demonstrate that a limitation of a fundamental 15 [2012] NZCA 184 18 | P a g e right is demonstrably justified. We have come to know that in the time since the judgment in this matter was reserved, the decision of the NZ High Court in Ryan Yardley

(supra) has been appealed by the Government of New Zealand before the New Zealand Court of Appeal.

21. We shall now proceed to analyse the precedents of this Court on the ambit of judicial review of public policies relating to health. It is well settled that the Courts, in exercise of their power of judicial review, do not ordinarily interfere with the policy decisions of the executive unless the policy can be faulted on grounds of mala fide, unreasonableness, arbitrariness or unfairness etc. Indeed, arbitrariness, irrationality, perversity and mala fide will render the policy unconstitutional16. It is neither within the domain of the courts nor the scope of judicial review to embark upon an enquiry as to whether a particular public policy is wise or whether better public policy can be evolved. Nor are the courts inclined to strike down a policy at the behest of a petitioner merely because it has been urged that a different policy would have been fairer or wiser or more scientific or more logical17. Courts do not and cannot act as 16 Ugar Sugar Works Ltd. v. Delhi Administration (2001) 3 SCC 635 17 Villianur Iyarkkai Padukappu Maiyam v. Union of India (2009) 7 SCC 561 19 | P a g e appellate authorities examining the correctness, suitability and appropriateness of a policy, nor are courts advisors to the executive on matters of policy which the executive is entitled to formulate. The scope of judicial review when examining a policy of the Government is to check whether it violates the fundamental rights of the citizens or is opposed to the provisions of the Constitution, or opposed to any statutory provision or manifestly arbitrary 18.

22. This Court in a series of decisions has reiterated that courts should not rush in where even scientists and medical experts are careful to tread. The rule of prudence is that courts will be reluctant to interfere with policy decisions taken by the Government, in matters of public health, after collecting and analysing inputs from surveys and research. Nor will courts attempt to substitute their own views as to what is wise, safe, prudent or proper, in relation to technical issues relating to public health in preference to those formulated by persons said to possess technical expertise and rich experience19. Where expertise of a complex nature is expected of the State in framing rules, the exercise of that power not demonstrated as arbitrary must be presumed to 18 Directorate of Film Festivals v. Gaurav Ashwin Jain (2007) 4 SCC 737 19 Academy of Nutrition Improvement v. Union of India (2011) 8 SCC 274 20 | P a g e be valid as a reasonable restriction on the fundamental right of the citizen and judicial review must halt at the frontiers. The Court cannot re-weigh and substitute its notion of expedient solution. Within the wide judge-proof areas of policy and judgment open to the government, if they make mistakes, correction is not in court but elsewhere. That is the comity of constitutional jurisdictions in our jurisprudence. We cannot evolve a judicial policy on medical issues. All judicial thought, Indian and Anglo-American, on the judicial review power where rules under challenge relate to a specialised field and involve sensitive facets of public welfare, has warned courts of easy assumption of unreasonableness of subordinate legislation on the strength of half-baked studies of judicial generalists aided by the ad- hoc learning of counsel. However, the Court certainly is the constitutional invigilator and must act to defend the citizen in the assertion of his fundamental rights against executive tyranny draped in disciplinary power.20

23. There is no doubt that this Court has held in more than one judgment that where the decision of the authority is in regard to a policy matter, this Court will not ordinarily interfere since decisions on policy matters are taken based 20 Pyarali K. Tejani v. Mahadeo Ramchandra Dange (1974) 1 SCC

167 21 | P a g e on expert knowledge of the persons concerned and courts are normally not equipped to question the correctness of a policy decision. However, this does not mean that courts have to abdicate their right to scrutinise whether the policy in question is formulated keeping in mind all the relevant facts and the said policy can be held to be beyond the pale of discrimination or unreasonableness, bearing in mind the material on record.21 In Delhi Development Authority (supra), this Court held that an executive order termed as a policy decision is not beyond the pale of judicial review. Whereas the superior courts may not interfere with the nitty- gritty of the policy, or substitute one by the other but it will not be correct to contend that the court shall lay its judicial hands off, when a plea is raised that the impugned decision is a policy decision. Interference therewith on the part of the superior court would not be without jurisdiction as it is subject to judicial review. It was further held therein that the policy decision is subject to judicial review on the following grounds:

a) if it is unconstitutional;

b) if it is dehors the provisions of the Act and the regulations;

21 Union of India v. Dinesh Engineering Corporation (2001) 8 SCC 491 22 | P a g e

c) if the delegatee has acted beyond its power of delegation;

d) if the executive policy is contrary to the statutory or a larger policy.

24. During the second wave of COVID-19 pandemic, this Court in Distribution of Essential Supplies & Services during Pandemic (supra), to which one of us was a party (L Nageswara Rao, J.), dealt with issues of vaccination policy, pricing and other connected issues. While doing so, this Court held that policy-making continues to be the sole domain of the executive and the judiciary does not possess the authority or competence to assume the role of the executive. It was made clear that the Court cannot second guess the wisdom of the executive when it chooses between two competing and efficacious policy measures. However, it continues to exercise jurisdiction to determine if the chosen policy measure conforms to the standards of reasonableness, militates against manifest arbitrariness and protects the right to life of all persons.

25. There can be no ambiguity in the principles of law relating to judicial review laid down by this Court. A perusal of the judgments referred to above would clearly show that this Court would be slow in interfering with matters of policy, 23 | P a g e especially those connected to public health. There is also no doubt that wide latitude is given to executive opinion which is based on expert advice. However, it does not mean that this Court will not look into cases where violation of fundamental rights is involved and the decision of the executive is manifestly arbitrary or unreasonable. It is true that this Court lacks the expertise to arrive at conclusions from divergent opinions of scientific issues but that does not prevent this Court from examining the issues raised in this Writ Petition, especially those that concern violation of Article 21 of the Constitution of India.

26. Identifying the issues in the present matter, they can be divided as follows:

I. Vaccine mandates being violative of Article 21 of the Constitution of India.

II. Non-disclosure of segregated clinical trial data in public domain.

III. Improper collection and reporting of AEFIs.

IV. Vaccination of children.

I. Vaccine Mandates

A. Submissions

27. Mr. Bhushan submitted that there is nothing wrong in the Government encouraging the people to get vaccinated.

However, coercive vaccination from the pain of denial of essential services is plainly unconstitutional, being violative 24 | P a g e of the principle of bodily autonomy and the right to access one's means of livelihood. Though the Union of India has made a categorical submission that vaccines are voluntary, the State Governments have been placing restrictions on unvaccinated people by denying them access to public places and services. He referred to: (i) an order passed by the Government of NCT of Delhi on 08.10.2021 by which government employees, including frontline workers and healthcare workers, as well as teachers and staff working in schools and colleges were not to be allowed to attend their respective offices and institutions without the first dose of vaccination with effect from 16.10.2021; (ii) a directive issued by the Government of Madhya Pradesh on 08.11.2021 stating that it was mandatory to be vaccinated with two doses of the vaccine to get food grains at fair price shops;

(iii) an order passed by the Government of Maharashtra dated 27.11.2021 requiring persons to be fully vaccinated if they are connected with any program, event, shop, establishment, mall and for utilising public transport; (iv) an order issued by the Government of Tamil Nadu dated 18.11.2021 permitting only vaccinated people into open, public places, schools, colleges, hostels, boarding houses, factories and shops; and other instances where students in 25 | P a g e the age group of 15 to 18 years were not permitted to appear for their examinations without being vaccinated.

28. Mr. Bhushan contended that there is need to balance individuals' rights with public interest concerning health. According to him, vaccine mandates can be on the basis of efficacy and safety of vaccination and prevention of transmission. He submitted that there is sufficient evidence to the effect that natural immunity acquired from a COVID-19 infection is long-lasting and robust in comparison to vaccine immunity. Studies also indicate that vaccines do not prevent infection from the virus or transmission amongst people. Vaccines are also ineffective in preventing infection from new variants. According to serological studies, 75 per cent of the Indian population has already been infected and is seropositive and, therefore, they have better immunity to infection than what is provided by the vaccines. The vaccines which are being administered in this country are only authorised for emergency use and the procedure for clinical trials of such vaccines has not been fully complied with. In view of the lack of transparency in disclosure of trial data resulting in absence of

informed consent, any vaccine mandate would be unconstitutional. Mr. Bhushan contended that every individual has personal autonomy and cannot be 26 | P a g e forced to be vaccinated against his will. For the said proposition, he relied on the judgments of Common Cause (A Registered Society) v. Union of India 22, Aruna Ramachandra Shanbaug v. Union of India 23 and K. S. Puttaswamy v. Union of India24. Imposing restrictions on the rights of persons who are unvaccinated is totally unwarranted as there is no basis for discriminating against unvaccinated persons. He relied upon scientific studies, opinions of experts and news articles to contend that vaccinated people are also prone to infection and there is no difference between a vaccinated individual and an unvaccinated person with respect to transmission of the virus. As there is no serious threat of spread of the virus by an unvaccinated person in comparison to a vaccinated person, placing restrictions on unvaccinated persons is meaningless.

29. Per contra, the learned Solicitor General of India contended that more than 180 crore doses had been administered, resulting in a substantial number of individuals in the country being vaccinated. He submitted that the vaccines have proved to be effective and safe and any indulgence by this Court would result in vaccine hesitancy. 22 (2018) 5 SCC 1 23 (2011) 4 SCC 454 24 (2017) 10 SCC 1 27 | P a g e The Government had taken extra care to appoint various committees to examine the efficacy, safety, immunogenicity, pharmacodynamics of the vaccines before granting approvals. Some of the material placed before this Court to bolster the Union of India's submissions have been listed below:

> (a) 'Science Brief: SARS-CoV-2 Infection-induced and Vaccine-induced immunity' of the United States Centers for Disease Control and Prevention (CDC) updated as on 29.10.2021, which in its conclusion states that:
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> "Numerous immunologic studies and a growing number of epidemiologic studies have shown that vaccinating previously infected individuals significantly enhances their immune response and effectively reduces the risk of subsequent infection, including in the setting of increased circulation of more infectious variants. Although the Delta variant and some other variants have shown increased resistance to neutralization by both post-infection and post-vaccination sera in laboratory studies, observed reduction in effectiveness has been modest, with continued strong protection against hospitalization, severe disease and death."

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(b) A study conducted by researchers of Christian Medical College, Vellore25, wherein it has been concluded as follows: "Among symptomatic COVID-19 patients, prior vaccination with either Covishield™ or Covaxin® impacted the severity of illness and reduced mortality when compared with unvaccinated patients. Full vaccination conferred a substantially higher protective effect over partial vaccination." The results of the study also indicate that compared with unvaccinated patients, partially vaccinated patients had milder disease, reduced requirement of oxygen, hospital admission, ICU admission and mortality. Again, when fully vaccinated patients were compared with unvaccinated individuals, full vaccination was associated with significantly less disease severity, requirement of respiratory supports, hospital admission, ICU admission and mortality. The study

further showed that majority of the patients screened who required hospitalisation were unvaccinated.

25 Abhilash, Kundavaram Paul Prabhakar et al. "Impact of prior vaccination with CovishieldTM and Covaxin® on mortality among symptomatic COVID-19 patients during the second wave of the pandemic in South India during April and May 2021: a cohort study." Vaccine vol. 40,13 (2022): 2107-2113 29 | P a g e

(c) A study conducted by researchers of All India Institute of Medical Sciences (AIIMS), New Delhi26, which states that:

> "We evaluated the association between COVID-19 vaccination status (the number of vaccine shots received and time interval since the last dose) and the vaccines' clinical efficacy in India in preventing the disease and its severity. This study has several noteworthy findings.
>
> Firstly, both the Indian vaccines provided a significant protective role in preventing the disease among people who had a clinical suspicion of COVID-19. Secondly, These vaccines protected from progression to a severe form of the disease among the patients who turned RT-
>
> PCR positive despite getting vaccinated. The probability of hospitalisation was about eight times less, and ICU admission/death was about fourteen times lesser among fully vaccinated patients in comparison to unvaccinated RT-PCR positive patients. Thirdly, the protective efficacy of the vaccines had a dose-dependent effect. The effectiveness is maximum among individuals who 26 Aakashneel Bhattacharya, Piyush Ranjan, Tamoghna Ghosh, Harsh Agarwal, Sukriti Seth, Ganesh Tarachand Maher, Ashish Datt Upadhyay, Arvind Kumar, Upendra Baitha, Gaurav Gupta, Bindu Prakash, Sada Nand Dwivedi, Naveet Wig "Evaluation of the dose-

effect association between the number of doses and duration since the last dose of COVID-19 vaccine, and its efficacy in preventing the disease and reducing disease severity: A single centre, cross-sectional analytical study from India" Diabetes & Metabolic Syndrome: Clinical Research & Reviews Volume 15, Issue 5 (2021), 102238 30 | P a g e received both doses of vaccination at least two weeks before the onset of their symptoms."

(d) A study conducted by researchers of AIIMS, Patna 27, which concludes as follows: "COVID-19 vaccination was found to be effective in infection prevention. One out of two and four out of five individuals were found to be protected against SARS-CoV-2 infection following partial and full vaccination, respectively. The vaccinated individuals had lesser LOS compared to unvaccinated ones. Additionally, the fully vaccinated individuals were less likely to develop severe disease. " LOS herein refers to the length of hospital stays.

30. On behalf of the State of Tamil Nadu, Mr. Amit Anand Tiwari, learned Additional Advocate General, submitted that the restrictions placed by way of the circular dated 18.11.2021 are within the competence of the State in exercise of its powers under the Disaster Management Act, 2005 (hereinafter, the "DM Act") and the Tamil Nadu Public Health Act, 1939. Section 76(2)(b) thereof empowers the State Government to make vaccinations compulsory, in the event of a declaration by the Government of an outbreak of a 27 Singh C, Naik BN, Pandey S, et al. "Effectiveness of COVID-19 vaccine in preventing infection and disease severity: a case-control study from an Eastern State of India." Epidemiology and Infection. 2021;149:e224 31 | P a g e notified disease. He submitted that the restrictions placed by the circular dated 18.11.2021 are in larger public interest and cannot be said to be unreasonable restrictions, as these were an essential facet of the precautionary approach adopted by the State of Tamil Nadu in dealing with the unprecedented pandemic. According to Mr. Tiwari, these restrictions were in furtherance of the State realising the importance of curtailing the spread of COVID-19. The unchecked spread of the virus could lead to further dangerous mutations. While referring to opinions of experts in the field of health, including that of the World Health Organization (WHO), the United Nations International Children's Emergency Fund (UNICEF) and the Oxford Vaccine group, as well as scientific studies published in the New England Journal of Medicine, the Lancet and the International Journal of Scientific Studies, it was submitted on behalf of the State of Tamil Nadu that vaccination prevents severe disease and significantly reduces hospitalisation and mortality and that vaccines continued to be highly effective in preventing severe disease and death. The measures were justified on the ground that they were not only aimed for the safety of a particular individual but also served a greater purpose of ensuring safety of the community at large.

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31. Mr. Rahul Chitnis, learned counsel appearing for the State of Maharashtra, referred to the information provided by the WHO to contend that vaccines save infected individuals from "life threatening complications, ... and consequential untimely death" and therefore, vaccine mandate issued by the State of Maharashtra is in the interest of general public. The restrictions that are imposed are reasonable and cannot be said to "manifestly arbitrary" as they are issued only for a temporary period with exclusions and are reviewed periodically by the State to assess if relaxations can be granted. He submitted that there is no compulsion to get vaccinated, however, in view of the serious threat that not being vaccinated poses to the right of life and personal liberty of the larger population, certain unavoidable restrictions have been imposed, especially given that strict adherence to social distancing and masking is significantly compromised in bigger cities.

32. The complaint of the Petitioner in relation to prevention of access to essential resources in the State of Madhya Pradesh pertains to ration not being provided to unvaccinated persons through the public distribution system. We were informed by the learned counsel for the State of 33 | P a g e Madhya Pradesh that the order dated 08.11.2021, by which vaccination was made mandatory for receiving ration from fair price shops, was not implemented and was eventually withdrawn on 07.01.2022.

33. In the counter-affidavit filed on behalf of the Government of NCT of Delhi, it was submitted that the order dated 08.10.2021 was issued by the Delhi Disaster Management Authority after due application of mind, to control the spread of COVID-19 and mitigate its effects. Under Section 6(2)(i) of the DM Act, the National Disaster Management Authority has been issuing orders from time to time directing State Governments and Union Territories, amongst other authorities, to take effective measures to prevent the spread of COVID-19, and in furtherance of this, also permitted States to impose further local restrictions. The Delhi Disaster Management Authority, in a meeting held on 29.09.2021, decided to ensure 100 per cent vaccination of all Government employees, frontline workers, healthcare workers as well as teachers and staff working in schools and colleges, on the advice of medical and other experts. It was considered necessary as these individuals have frequent interaction with the general public and vulnerable sections of the society and therefore, pose greater risk of spreading the 34 | P a g e virus. While an individual may have a right to decide against getting vaccinated, the State, however, has a statutory duty to regulate the interaction of unvaccinated persons within the society in the interest of public health.

34. In his rejoinder, Mr. Bhushan, while reiterating his submissions, took exception to the contradictory stand taken by the Union of India on COVID-19 vaccination being voluntary and not mandatory. On one hand, the Union of India made it clear in the counter-affidavit that vaccination is voluntary and on the other, a series of advisories and material had been filed by the Union of India, supporting the claim of vaccination being mandatory. Mr. Bhushan submitted that the Union of India has not provided any material to the Court contrary to what has been supplied by the Petitioner furthering his scientific and legal contention that unvaccinated people pose no greater danger than vaccinated individuals in the matter of transmission of the COVID-19 virus, and therefore, there is no public health rationale in vaccine mandates. In addition to the various points raised in his submissions, the learned counsel for the Petitioner relied upon the opinion of Dr. Aditi Bhargava, who is a professor at University of California, San Francisco and a molecular biologist with 33 years of research experience, 35 | P a g e from her presentation made before the US Senate on 02.11.2021. Her opinion is to the effect that vaccines do not prevent infection and transmission. She is of the further belief that natural immunity is the gold standard. According to Dr. Bhargava, there has been no documented case of a naturally immune person getting reinfected with severe disease or hospitalised, despite the first case reported nearly two years ago, whereas, there have been thousands of cases of severe infection, hospitalisation, and deaths in fully vaccinated people. Mr. Bhushan concluded by submitting that any restrictions placed on personal autonomy of individuals would be violative of Article 21, unless the criteria laid down in K. S. Puttaswamy (supra) is met. B. Evolution of COVID-19 and vaccines

35. COVID-19 emerged in late 2019. The WHO officially declared the novel coronavirus outbreak as a pandemic on 11.03.2020. The virus was detected in the country in the last week of January, 2020 and spread rapidly. As the threat of infections from the virus loomed large, an unprecedented national lockdown was announced on 24.03.2020, which extended for a few months, with restrictions being removed thereafter in a phased manner. India was not alone in this;

36 | P a g e several countries imposed lockdowns to arrest the spread of the deadly disease, which has led to a drastic loss of human life worldwide and presented a threat of extraordinary proportions

to public health, food systems, economic and social conditions. Scientific studies and research for manufacture of vaccines to prevent severe infections were undertaken on an emergency basis. Towards the end of 2020, emergency vaccines came to be administered in the western part of the world. However, by then, the spread of COVID-19 around the globe was considerable. Around the same period, a variant called B.1.1.7 was found in the United Kingdom. The said variant was renamed as Alpha, as per the naming scheme recommended by the expert group convened by the WHO, which also includes scientists from the WHO's Technical Advisory Group on Virus Evolution (TAG- VE). Another variant, called B.1.351 and later renamed as Beta, was found to be linked to a second wave of infections in South Africa. Both these variants were identified as Variants of Concern (VOC) by the WHO on 18.12.2020, meaning that they were variants with genetic changes that would affect virus characteristics such as transmissibility, disease severity or immune escape and through a comparative assessment, are found to be associated with an 37 | P a g e increase of transmission or increase in virulence or decrease in effectiveness of public health measures such as vaccines, therapeutics etc. Soon thereafter, the highly transmissible variant called Gamma was found in Brazil and was identified as a VOC by the WHO on 11.01.2021.28

36. In the first half of 2021, the Delta variant was identified as the predominant variant in India and was believed to be 60 per cent more transmissible than the Alpha variant. Thereafter, Delta rapidly spread beyond the borders to other countries. Another variant, Omicron, surfaced in November, 2021, whose spread was much more accelerated than earlier variants, including that of Delta. On the basis of the evidence available as on 21.01.2022, the WHO was of the opinion that the Omicron has a significant growth advantage over Delta, leading to rapid spread in the community with higher levels of incidence than previously seen in the pandemic. It was further observed that despite a lower risk of severe disease and death following infection, the very high levels of transmission nevertheless have resulted in significant increases in hospitalisation and continue to pose overwhelming demands on health care systems in most 28 Tracking SARS-CoV-2 variants, World Health Organization, available at https://www.who.int/en/activities/tracking-SARS-CoV-2-variants/ (last accessed on 01.05.2022) 38 | P a g e countries. It was found that because of the 26-32 mutations that it has in the spike protein, Omicron has infected even those who have been previously infected or vaccinated. 29 Though the infections and transmission from Omicron at present within the country are not as serious as they were in the first two months of 2022, expert opinion is to the effect that Omicron might not be the last of the variants, as we have since witnessed.

37. The WHO established the Technical Advisory Group on COVID-19 Vaccine Composition (TAG-CO-VAC) in September, 2021. According to the statement made by the said group on 11.01.2022 in the context of circulation of the Omicron variant, the group reviews and assesses the public health implications of emerging VOCs on the performance of COVID- 19 vaccines and provides recommendations on COVID-19 vaccine composition. The said group is developing a framework to analyse the evidence on emerging VOCs in the context of criteria that would trigger a recommendation to change COVID-19 vaccine strain composition and will advise the WHO on updated vaccine compositions, as required. The group has spelt out in their statement that at present, with 29 Statement by Dr Hans Henri P. Kluge, WHO Regional Director for Europe, 11.01.2011, available at https://www.euro.who.int/en/media-

centre/sections/statements/2022/statement-update-on-covid-19-omicron-wave-threatening-to-overcome-health-workforce (last accessed on 01.05.2022) 39 | P a g e the available COVID-19 vaccines, the focus is on reducing severe disease and death, as well as protecting health systems. According to the TAG-CO-VAC, vaccines, which have received WHO Emergency Use Listing across several vaccine platforms, provide a high level of protection against severe disease and death caused by VOCs. The group takes note of data which indicates that vaccine effectiveness will be reduced against symptomatic disease caused by the Omicron variant but at the same time, it was of the opinion that protection against severe disease is more likely to be preserved. Along with the Strategic Advisory Group of Experts on Immunization (SAGE) and its Working Group on COVID-19 vaccines, TAG-CO-VAC has recommended COVID- 19 vaccines for priority populations worldwide to provide protection against severe disease and death globally and, in the longer term, to mitigate the emergence and impact of new VOCs by reducing the burden of infection.30

38. With the outbreak of the devastating pandemic, as many as 5,23,843 lives have been lost in this country, as per the latest data available on the website of the Ministry of 30 Interim Statement on COVID-19 vaccines in the context of the circulation of the Omicron SARS-CoV-2 Variant from the WHO Technical Advisory Group on COVID-19 Vaccine Composition (TAG-CO-VAC), 11.01.2022, available at https://www.who.int/news/item/11-01-2022-interim-statement-on-covid-19-vaccines-in-the-context-of-the-circulation-of-the-omicron-sars-cov-2-variant-from-the-who-technical-advisory-group-on-covid-19-vaccine-composition (last accessed on 01.05.2022) 40 | P a g e Health and Family Welfare (MoHFW). Initially, efforts made by the Government of India were to protect people by arresting serious infection. With treatment protocol and clinical management protocol for COVID-19 being revised periodically as more and more data and research on the virus came to be known, persons affected by the virus were treated with the information that was available at the point. Using whatever little was known about the virus in the initial stages, dedicated efforts have been made to save countless lives in this country. With the approval of vaccines on an emergency basis in January, 2021, there was some hope about preventing infections from the virus. Inoculation, which commenced slowly in view of the non-availability of sufficient doses of vaccines, gained pace with the increase in manufacture by Respondent Nos. 4 and 5. With the Government embarking upon extensive awareness drives encouraging vaccination, more than 189 crore doses of vaccine have been administered within the country till date, as per the data available on the website of the MoHFW.

39. With the introduction of vaccines, it was understood that vaccines would aid in preventing infections. To protect their populace from infection, countries worldwide promoted 41 | P a g e vaccination as, needless to say, an uninfected person will not transmit the disease. Thereafter, with the mutation of the virus eventually resulting in multiple VOCs, breakthrough infections were noticed. Vaccinated people were found to be infected with the virus and could also act as carriers, transmitting the virus to others. Even in such a situation, there is no question of whether vaccination for COVID-19 should be continued. The recommendations of the WHO's TAG-CO-VAC and SAGE make it amply clear that vaccines, which have received emergency use approvals, provide strong protection against serious illness, hospitalisation and death and getting vaccinated is one of the most crucial steps towards protecting oneself from COVID-19, stopping new variants from

emerging and helping end the pandemic. It should be noted that the advice of the WHO with respect to COVID-19 has been consistent since the time vaccines became available, even after recognising that it was still possible to get infected and spread the infection to others despite being vaccinated, as is evident from the latest version of the WHO's 'COVID-19 advice for the public:

> Getting vaccinated' as of 13.04.2022 31. The Union of India has placed considerable material on record in terms of 31 Available at https://www.who.int/emergencies/diseases/novel-coronavirus-

2019/covid-19-vaccines/advice (last accessed on 01.05.2022) 42 | P a g e scientific briefs and published studies which stand testimony to the significance of vaccination as a crucial public health intervention in this pandemic and its continued benefits to individual health as well as public health infrastructure. Vaccination of a majority of the population of this country has undoubtedly been instrumental in preventing severe disease, hospitalisation and deaths, and benefited the community at large, especially those members with co-morbidities, the elderly and sick persons. Even the Petitioner is not opposed to the vaccination programme and does not challenge the vaccination drive of the Government of India, as has been reiterated by him during the course of his arguments. Exception to the vaccination programme taken by the Petitioner is only to coercive vaccination through vaccine mandates, which place unjustifiable restrictions on those who wish to not be vaccinated.

40. In light of the virulent mutations of the COVID-19 virus and advice of experts from the WHO as well as common findings of several studies on this subject, the vaccination drive that is being undertaken by the Government of India in the interest of public health cannot be faulted with. C. Personal autonomy and public health 43 | P a g e

41. Before dealing with the issue of coercive vaccination, it is necessary to consider whether the right of privacy of individuals can override public health, more so, when the submission on behalf of the Respondents is that steps taken to restrict the rights of individuals are in the larger interest of public health. It is true that to be vaccinated or not is entirely the choice of the individual. Nobody can be forcefully vaccinated as it would result in bodily intrusion and violation of the individual's right to privacy, protected under Article 21 of the Constitution of India. Personal autonomy was read into Article 21 by this Court in Common Cause (supra), by placing reliance on National Legal Services Authority v. Union of India 32, and Aruna Ramachandra Shanbaug (supra). This Court, in Common Cause (supra), emphasized the right of an individual to choose how he should live his own life, without any control or interference by others. It recognised the right of an individual to refuse unwanted medical treatment and to not be forced to take any medical treatment that is not desired. In view of the categoric statement of the Union of India that vaccination of COVID-19 is voluntary, the question of any intrusion into bodily integrity does not arise for consideration in this case. 32 (2014) 5 SCC 438 44 | P a g e However, the Petitioner has asserted that limitations placed on access to public places and public resources for unvaccinated persons result in coercive vaccination, and therefore, limit the right of unvaccinated persons to refuse medical treatment.

42. Disclosure of data of a patient suffering from AIDS was the subject matter of a decision of this Court in X v. Hospital 'Z'33. Placing reliance on Kharak Singh v State of U.P.34, Gobind v. State of M.P.35 and a judgment of the US Supreme Court in Jane Roe v. Henry Wade36, this Court held that though non-disclosure of medical information of an individual can be traced to the right to privacy protected under Article 21, it is not absolute and is subject to action lawfully taken for protection of health or morals or protection of rights and freedoms of others.

43. In Association of Medical Super Speciality Aspirants and Residents v. Union of India 37, to which one of us was a party (L Nageswara Rao, J.), this Court, while considering validity of service bonds to be executed at the time of admission to postgraduate and superspeciality courses in medical science, held as follows:

> 33 (1998) 8 SCC 296 34 (1964) 1 SCR 332 35 (1975) 2 SCC 148 36 410 US 113 (1973) 37 (2019) 8 SCC 607 45 | P a g e "33. The above discussion leads us to the conclusion that right to life guaranteed by Article 21 means right to life with human dignity. Communitarian dignity has been recognised by this Court. While balancing communitarian dignity vis-à-vis the dignity of private individuals, the scales must tilt in favour of communitarian dignity. The laudable objective with which the State Governments have introduced compulsory service bonds is to protect the fundamental right of the deprived sections of the society guaranteed to them under Article 21 of the Constitution of India. The contention of the appellants that their rights guaranteed under Article 21 of the Constitution of India have been violated is rejected."

44. Strong reliance was placed by the Petitioner on the judgment of the High Court of New Zealand in Ryan Yardley (supra). The principal contention of the applicants therein was that the impugned order, requiring police and defence force personnel to be vaccinated, placed unjustified limitation on the rights protected by the New Zealand Bill of Rights Act 1990 (hereinafter, the "NZ Bill of Rights"), particularly the right to refuse to undergo medical treatment, the right to manifest religion, the right to be free from discrimination and other rights under Section 28 of the said Act (including the right to work, and of minority groups to enjoy their culture and practice their religion). The purpose of 46 | P a g e the order, as clarified by the Minister by way of an amendment order in February, 2022 is as below:

> "(a) avoid, mitigate, or remedy the actual or potential adverse effects of the COVID-19 outbreak (whether direct or indirect); and
>
> (b) ensure continuity of services that are essential for public safety, national defence, or crisis response; and
>
> (c) maintain trust in public services."
>
> 45. Considering the submissions of the applicants therein that the order placed unjustified limitations on fundamental rights protected by the NZ Bill of Rights, the

> NZ High Court held that the impugned order limits the right of affected workers to refuse to undergo a medical treatment as well as the right (or significant interest) to retain employment. While examining the question of whether the limitation of the said rights was justified, the NZ High Court noted that the order mandating vaccinations for the police and defence personnel was imposed to ensure the continuity of services that are essential for public safety, national defence, or crisis response, and to promote public confidence in those services, rather than to stop the spread of COVID-19. The NZ High Court further took note of the fact that by October, 2021, 83.1 per cent of police personnel had received at least one or more doses of the vaccination, and 70.1 per cent had received both doses. By the time the order took effect on

47 | P a g e 17.01.2022, there were only 164 unvaccinated staff members in an overall workforce of 15,682 staff. It was found that the position within the New Zealand Defence Forces (NZDF) was similar. From a total of 15,480 NZDF personnel, 3,048 are civil staff. As on 01.02.2022, 99.2 per cent of the regular forces were fully vaccinated, leaving aside 75 members and 98.7 per cent of the civil staff were fully vaccinated, leaving 40 who were not. The NZ High Court was of the view that the relatively low number of unvaccinated police and NZDF personnel impacted by the order may not, by itself, mean that the order was not a reasonable limit on rights that can be demonstrably justified, if there was evidence to establish that the presence of unvaccinated personnel, even in small numbers, created a materially higher risk to the remaining workforce. While observing that the evidence on this issue is sparse, the NZ High Court referred to the evidence of Dr. Petrovsky, who deposed that vaccination has potential benefit in reducing the severity of disease, even with the Omicron variant. However, in his view, mandatory vaccination did not assist in preventing workers in affected roles from contracting COVID- 19, or transmitting it to others. The NZ High Court further considered the evidence of Dr. Town, the Ministry's Chief 48 | P a g e Science Adviser, who, according to the NZ High Court, did not directly respond to Dr. Petrovsky's analysis of the effectiveness of the vaccine to inhibit the spread of COVID-19 in a workforce, but instead provided his more generalised opinions. In his evidence, Dr. Town stated that vaccines show reduced effectiveness compared with Delta in terms of becoming infected with and transmitting Omicron.

46. After weighing the evidence, the NZ High Court was of the view that vaccination may still be effective in limiting infection and transmission, but at a significantly lower level than was the case with the earlier variants. It was further concluded that vaccination does not prevent persons contracting and spreading COVID-19, particularly with the Omicron variant. The NZ High Court referred to an earlier judgment in Four Aviation Security Service Employees v. Minister of COVID-19 Response 38, where the precautionary principle had been applied, to make the point that even a modest vaccination protection on a modest number of personnel needs to be considered in the context of potential effects of a pandemic. The NZ High Court referred to a judgment of the Federal Court of Ontario in 38 [2021] NZHC 3012 49 | P a g e Spencer v. Attorney General of Canada 39 to elaborate on the precautionary principle, as "a foundational approach to decision-making under uncertainty, that points to the importance of acting on the best available information to protect the health of" the citizens. In Four Aviation Security Service Employees (supra), which dealt with restrictions placed on aviation security workers, the NZ High Court held

that even though the applicants therein were not being forcibly treated, they were required to be vaccinated as a condition of their employment, refusal of which led to termination. Observing that a right does not need to be taken away in its entirety before it is regarded as having been limited, the NZ High Court opined that the level of pressure in that case was significant and amounted to coercion, and therefore, the applicants' right to refuse to undergo medical treatment was limited. However, the said limitation was held to be justified. From the evidence adduced before the NZ High Court, it concluded that the vaccine was effective at reducing the transmission of the earlier variants of the virus and that it was also effective at reducing symptomatic infection and detrimental effects of the Delta variant. As the applicants were border workers 39 [2021] FC 361 50 | P a g e interacting with international travellers who may be carrying the virus and given the likelihood of vaccines contributing to preventing the risk of transmission, the NZ High Court held that a precautionary approach, in doing everything that can be reasonably done to minimise risk of the outbreak or spread in strong public interest, is justified. Further, the curtailment of the right to refuse to undergo medical treatment was found to be proportionate to the objective, as the applicants, who worked as aviation workers, were situated in a key location where COVID-19 might enter New Zealand.

47. In Ryan Yardley (supra), the NZ High Court held that the principle in Four Aviation Security Service Employees (supra) is not directly applicable as the order was not promulgated to contain the spread of the virus but for the purpose of ensuring continuity of, and confidence in, essential services. Additionally, there was no evidence of a threat to the continuity of the police and NZDF services, which would enable the NZ High Court to give the benefit of the doubt to the New Zealand Crown in imposing measures to address that risk. Placing reliance on the evidence adduced as well as the public health advice which was to the 51 | P a g e effect that vaccine mandates were not considered necessary for addressing the risk of the outbreak or spread of COVID- 19, the High Court made it clear that while vaccination significantly improved the prospects of avoiding illness and death even with the Omicron variant, given the variant's propensity to break through vaccination barriers, it concluded that there was no real threat to the continuity of these essential services that the impugned order sought to address. Further, finding that suspension of the unvaccinated would address any potential problems, the terminations arising from the order in light of the temporary, albeit significant, period of peak impact of the infection, were found to be disproportionate and unjustified. While the Petitioner has sought support from this judgment to demonstrate how courts in other jurisdictions have struck down vaccine mandates taking into account Omicron's impact on the effectiveness of vaccines in addressing spread, we believe that this judgment may not be of much assistance to us for determining the issue at hand for two reasons. First, the judgment expressly recognised that the impugned vaccine mandate was not brought about to suppress the spread of the virus but to ensure continuity of, and confidence in, essential services, such as the police and the 52 | P a g e defence personnel, which we are not concerned with in the present case. Second, while the NZ High Court looked into depositions of expert witnesses to come to its own conclusion on efficacy of vaccines vis-à-vis the Omicron variant, the scope of our review does not entail assessment of competing scientific opinions, as the judiciary is not equipped to decide issues of medical expertise and epidemiology.

48. The crucial point that requires to be considered by us is whether limitations placed by the Government on personal autonomy of an individual can be justified in the interest of public health in the wake of the devastating COVID-19 pandemic. As stated, personal autonomy has been recognized as a critical facet of the right to life and right to self-determination under Article 21 of the Constitution, by this Court in Common Cause (supra). In K.S. Puttaswamy (supra), this Court laid down three requirements to be fulfilled by the State while placing restraints on the right to privacy to protect legitimate State interests. It was held:

> "310. ... The first requirement that there must be a law in existence to justify an encroachment on privacy is an express requirement of Article 21. For, no person can be deprived of his life or personal liberty except in accordance with the procedure established by law. The 53 | P a g e existence of law is an essential requirement. Second, the requirement of a need, in terms of a legitimate State aim, ensures that the nature and content of the law which imposes the restriction falls within the zone of reasonableness mandated by Article 14, which is a guarantee against arbitrary State action. The pursuit of a legitimate State aim ensures that the law does not suffer from manifest arbitrariness. Legitimacy, as a postulate, involves a value judgment. Judicial review does not reappreciate or second guess the value judgment of the legislature but is for deciding whether the aim which is sought to be pursued suffers from palpable or manifest arbitrariness. The third requirement ensures that the means which are adopted by the legislature are proportional to the object and needs sought to be fulfilled by the law. Proportionality is an essential facet of the guarantee against arbitrary State action because it ensures that the nature and quality of the encroachment on the right is not disproportionate to the purpose of the law. Hence, the threefold requirement for a valid law arises out of the mutual interdependence between the fundamental guarantees against arbitrariness on the one hand and the protection of life and personal liberty, on the other. The right to privacy, which is an intrinsic part of the right to life and liberty, and the freedoms embodied in Part III is subject to the same restraints which apply to those freedoms." While the judgment is in context of the right to privacy, the analysis with respect to the threefold requirement for curtailment of such right is on the anvil of the protection guaranteed to fundamental freedoms under Article 21, and 54 | P a g e therefore, would also be the litmus test for invasion of an individual's bodily autonomy under Article 21.

49. The upshot of the above discussion leads to the following conclusions:

> a) Bodily integrity is protected under Article 21 of the Constitution of India and no individual can be forced to be vaccinated.
>
> b) Personal autonomy of an individual involves the right of an individual to determine how they should live their own life, which consequently encompasses the right to refuse to undergo any medical treatment in the sphere of individual health.

c) Persons who are keen to not be vaccinated on account of personal beliefs or preferences, can avoid vaccination, without anyone physically compelling them to be vaccinated. However, if there is a likelihood of such individuals spreading the infection to other people or contributing to mutation of the virus or burdening of the public health infrastructure, thereby affecting communitarian health at large, protection of which is undoubtedly a legitimate State aim of paramount significance in this collective battle against the pandemic, the Government can regulate such public 55 | P a g e health concerns by imposing certain limitations on individual rights that are reasonable and proportionate to the object sought to be fulfilled.

50. The submission made on behalf of the Petitioner is that the Delta and Omicron variants have shown breakthrough infections and it is clear from the scientific data that, an unvaccinated person does not pose a greater risk than a vaccinated person in terms of transmission of the infection. While this submission has been dealt with subsequently, we believe that as long as there is a risk of spreading the disease, there can be restrictions placed on individuals' rights in larger public interest. Further, extensive material from experts has been placed before this Court, which extol the benefits of vaccination in tackling the severe and life- threatening impact of the infection, specifically in terms of reduction in oxygen requirement, hospitalisation, ICU admissions and mortality, thereby easing the disproportionate burden from the upsurge of severe cases on the health infrastructure, which has already been witnessed by the country during the second wave of the pandemic where resources were woefully inadequate to stem the impact of the Delta variant on a then scarcely vaccinated population. We hasten to add that restrictions that are 56 | P a g e placed by the Government should not be unreasonable and are open to scrutiny by constitutional courts. It is difficult for us to envisage the myriad situations in dealing with the evolving pandemic that may call for restraint on individual rights in larger public interest and therefore, as and when such limitations are challenged, they can be assessed by constitutional courts to see whether they meet the threefold requirement laid down in K.S. Puttaswamy (supra). D. Assessment of the vaccine mandates imposed by State Governments

51. The grievance of the Petitioner pertains to the vaccine mandates imposed by various State Governments and private organisations, resulting in restrictions on fundamental freedoms of persons who have chosen not to be vaccinated. The Petitioner has alleged duality in the stand of the Respondents, as on one hand, the Union of India has categorically stated that vaccines are voluntary and on the other, the State Governments have imposed and defended restrictions on access to public places and resources for persons who are unvaccinated. The Petitioner contested the vaccine mandates on the following grounds:

57 | P a g e

(a) Natural immunity acquired from COVID-19 infection is more long-lasting and robust as compared to vaccine immunity.

(b) Serological studies show that more than 75 per cent of the Indian population has already been infected and is seropositive and therefore, has better immunity to the infection than that which can

be provided by the vaccine.

(c) Vaccines do not prevent infection from or transmission of COVID-19 and are especially ineffective in preventing against infection from new variants.

52. In support of the above grounds, other than on the aspect of transmission of the virus, the Petitioner has relied on individual opinions of doctors and other advisors, news articles and findings from research studies, some of which are preprints meaning they have not been peer-reviewed and report new medical research which has yet to be evaluated and therefore, should not be used to guide clinical practice, as explained by medRxiv, a platform where several preprint articles in the field of health sciences are published. Some of the material relied on by the Petitioner has been listed below:

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(a) An article in the scientific journal Nature40, which states that "studies have shown that memory plasma cells secreted antibody specific for the spike protein encoded in SARS-CoV-2 even 11 months after the infection and further that, immune memory to many viruses is stable over decades, if not for a lifetime".

(b) A study published in the European Journal of Epidemiology41, which has analysed data from 68 countries available as of 03.09.2021 and has found that "at the country level, there appears to be no discernible relationship between percentage of population fully vaccinated and new COVID-19 cases". It is further stated therein that in fact higher percentage of population fully vaccinated have higher COVID-19 per 1 million people.

(c) The United Kingdom's COVID-19 vaccine surveillance report, Week 40, which appears to indicate negative efficacy against infection amongst all ages above 30 years, on the basis of data between week 36 and week 39 in 2021.

40 Andreas Radbruch and Hyun-Dong Chang, "A long-term perspective on immunity to Covid" Nature 595, 359-360 (2021) 41 Subramanian, S.V., Kumar, A. "Increases in COVID-19 are unrelated to levels of vaccination across 68 countries and 2947 counties in the United States" Eur J Epidemiol 36, 1237–1240 (2021) 59 | P a g e

53. While we are aware that courts cannot decide whether natural immunity is more resilient as compared to vaccine- acquired immunity and we do not seek to substitute our own views in matters of differences in scientific opinion, we cannot help but notice that in the first article referred to above, published in Nature, it has been noted that immunity in convalescent individuals (i.e., those who have recovered from COVID-19) can be boosted further by vaccinating them after a year. According to the said article, this results in the generation of more plasma cells, together with an increase in the level of SARS-CoV-2 antibodies that was up to 50 times greater than before vaccination. In the second article referred to above, published in the European Journal of Epidemiology, it has been mentioned therein that the interpretation of the findings should be as

follows: " The sole reliance on vaccination as a primary strategy to mitigate COVID-19 and its adverse consequences needs to be re- examined, especially considering the Delta (B.1.617.2) variant and the likelihood of future variants. Other pharmacological and non-pharmacological interventions may need to be put in place alongside increasing vaccination rates." We do not see how these conclusions and interpretations are in favour of an argument that natural 60 | P a g e immunity has proven to be better in protection against COVID-19 infection, as compared to vaccine-acquired immunity.

54. In any event, what we have to assess, in accordance with the law laid down by this Court, is whether the Union of India has taken note of scientific and medical inputs and research findings in putting together its policy advocating vaccination for the entire eligible population. Article 47 of the Constitution of India imposes an obligation on the Union of India to improve public health. It is the obligation of the State to ensure the creation and the sustaining of conditions congenial to good health. From the several obligations of the State enshrined in Part IV of the Constitution, maintenance and improvement of public health rank high as these are indispensable to the very physical existence of the community.42

55. It should be noted that the submission made on behalf of the Petitioner championing natural immunity is from the perspective of a healthy person. Even the Petitioner does not dispute the fact that the same standard is not applicable to persons with co-morbidities, the sick and elderly people. A cursory glance at the data recorded in the India Fact Sheet 42 Vincent Panikurlangara v. Union of India (1987) 2 SCC 165 61 | P a g e on the basis of the National Family Health Survey – 5 (2019-

21) shows that (i) in the age group of 15-49 years, 57 per cent of women and 25 per cent of men are anaemic, (ii) amongst individuals aged above 15 years, 13.5 per cent of women and 15.6 per cent of men have high or very high blood sugar level or take medicines to control blood sugar level, (iii) amongst individuals aged above 15 years, 21.3 per cent of women and 24 per cent of men have hypertension or elevated blood pressure or take medicines to control blood pressure. Further, as per the 75 th Round National Sample Survey (NSS), conducted from July 2017 to June 2018, the average age of the elderly population in India was 67.5 years, with 67.1 per cent of India's elderly living in rural areas. A study was conducted 43 on the basis of the data from the NSS, aiming to highlight the vulnerability of the aged amidst the COVID-19 pandemic. According to the study, out of every 100 elderly, 27.7 persons reported ailments during the previous 15 days, with cardiovascular conditions including hypertension (32.0%), endocrine conditions including diabetes (22.5%), musculoskeletal conditions (13.9%), infectious diseases (10.0%), and 43 Ranjan, A., Muraleedharan, V.R. "Equity and elderly health in India: reflections from 75th round National Sample Survey, 2017–18, amidst the COVID-19 pandemic" Global Health 16, 93 (2020) 62 | P a g e respiratory ailments (7.3%) being the top five conditions for seeking outpatient care among the elderly in the preceding 15 days. The Constitution, through Article 41, mandates the State to make available to the elderly the right to live with dignity and to provide the elderly, ill and disabled with assistance, medical facilities and geriatric care 44.

56. Surely, the Union of India is justified in centering its vaccination policy around the health of the population at large, with emphasis on insulating the weaker and more vulnerable sections from the

risk of severe infection and its consequences, as opposed to basing its decision keeping in mind the interests of a healthy few. Given the considerable material filed before this Court reflecting the near-unanimous views of experts on the benefits of vaccination in dealing with severe disease, reduction in oxygen requirement, hospital and ICU admissions and mortality and stopping new variants from emerging, this Court is satisfied that the current vaccination policy of the Union of India, formulated in the interest of public health, is informed by relevant considerations and cannot be said to be unreasonable. Whether there is contrasting scientific opinion supporting the argument of natural immunity offering better protection 44 Ashwani Kumar v. Union of India (2019) 2 SCC 636 63 | P a g e against infection from COVID-19 and whether these scientific opinions can be substantiated are not pertinent for determination of the issue before this Court.

57. We now come to the crux of the challenge against coercive vaccine mandates, with respect to which the Petitioner has argued that they amount to restrictions on the fundamental rights of unvaccinated individuals and cannot be said to be proportionate, as according to the Petitioner, with the prevalence of the Omicron variant, unvaccinated people pose no greater danger to the transmission of the virus in comparison to vaccinated persons. It was claimed by the Petitioner that even if the vaccines reduced the severity of the disease, it was up to the individual to decide whether they wanted to be the beneficiary of vaccines. The State's lookout was the protection of larger public health and with both the vaccinated and unvaccinated posing nearly equal risks in transmission of the infection to others around them, the State cannot impose restrictions targeting only the unvaccinated and impeding their right to access public resources. The Petitioner has thus, alleged discrimination against the unvaccinated, who in the present situation, are placed more or less on the same footing as vaccinated individuals with respect to the transmission of the virus. In 64 | P a g e support of his submissions, the Petitioner has relied on scientific studies and reports, some of which are listed below:

> (a) A letter published in the Lancet, Regional Health45, which states: "In the UK it was described that secondary attack rates among household contacts exposed to fully vaccinated index cases was similar to household contacts exposed to unvaccinated index cases (25% for vaccinated vs 23% for unvaccinated). 12 of 31 infections in fully vaccinated household contacts (39%) arose from fully vaccinated epidemiologically linked index cases.

Peak viral load did not differ by vaccination status or variant type….The US Centres for Disease Control and Prevention (CDC) identifies four of the top five counties with the highest percentage of fully vaccinated population (99.9–84.3%) as "high" transmission counties. Many decisionmakers assume that the vaccinated can be excluded as a source of transmission. It appears to be grossly negligent to ignore the vaccinated population as a possible and relevant source of transmission when deciding about public health control measures." 45 Gunter Kampf, Letter titled "The Epidemiological relevance of the COVID-19 vaccinated population is increasing" Lancet Regional Health Vol. 11, 100272, December 01, 2021 65 | P a g e

(b) A study conducted on breakthrough infection in Massachusetts in July, 2021 and reported in the Morbidity and Mortality Weekly Report46, which investigated 469 COVID-19 cases that had been

identified among the Massachusetts residents who had travelled to a town where multiple large public events had been held and 346 cases, i.e., 74 per cent of the infections occurred in fully vaccinated individuals. Findings from the investigation suggest that even jurisdictions without substantial or high COVID-19 transmission might consider expanding prevention strategies, including masking in indoor public settings regardless of vaccination status, given the potential risk of infection during attendance at large public gatherings that include travelers from many areas with differing levels of transmission.

The Petitioner has also cited various news articles reporting instances of breakthrough infections in fully vaccinated people, carrying as much virus as those who were unvaccinated, abroad as well as within India. 46 Brown CM, Vostok J, Johnson H, et al. "Outbreak of SARS-CoV-2 Infections, Including COVID-19 Vaccine Breakthrough Infections, Associated with Large Public Gatherings — Barnstable County, Massachusetts, July 2021". MMWR Morb Mortal Wkly Rep 2021;70:1059-1062 66 | P a g e

58. We have already referred to the material placed by the Union of India and the States appearing before this Court. While there is abundant data to show that getting vaccinated continues to be the dominant expert advice even in the face of new variants, no submission nor any data has been put forth to justify restrictions only on unvaccinated individuals when emerging scientific evidence appears to indicate that the risk of transmission of the virus from unvaccinated individuals is almost on par with that from vaccinated persons. To put it differently, neither the Union of India nor the State Governments have produced any material before this Court to justify the discriminatory treatment of unvaccinated individuals in public places by imposition of vaccine mandates. No doubt that when COVID-19 vaccines came into the picture, they were expected to address, and were indeed found to be successful in dealing with, the risk of infection from the variants in circulation at the time. However, with the virus mutating, we have seen more potent variants surface which have broken through the vaccination barrier to some extent. While vaccination mandates in the era of prevalence of the variants prior to the Delta variant may have withstood constitutional scrutiny, in light of the data presented by the Petitioner, which has not been 67 | P a g e controverted by the Union of India as well as the State Governments, we are of the opinion that the restrictions on unvaccinated individuals imposed through vaccine mandates cannot be considered to be proportionate, especially since both vaccinated and unvaccinated individuals presently appear to be susceptible to transmission of the virus at similar levels.

59. Details of the vaccine mandates passed by the States of Maharashtra, Tamil Nadu, Madhya Pradesh and Delhi have been discussed earlier. It has come to our knowledge that since the judgment in this matter was reserved, the National Disaster Management Authority took a decision that there may not be any further need to invoke provisions of the DM Act for COVID-19 containment measures, taking into consideration the overall improvement in the situation. Further, the States of Maharashtra and Tamil Nadu, taking into account the present situation in which near-normalcy has been restored, have rolled back the restrictions placed on unvaccinated persons. The State of Madhya Pradesh had withdrawn the restrictions imposed on unvaccinated individuals in terms of withholding distribution of food grains from fair price shops and had notified this Court of the same during the hearing. Till the infection rate and spread 68 | P a g e remains low, as it is

currently, and any new development or research finding comes to light which provides the Government due justification to impose reasonable and proportionate restrictions on the rights of unvaccinated individuals in furtherance of the continuing efforts to combat this pandemic, we suggest that all authorities in this country, including private organisations and educational institutions, review the relevant orders and instructions imposing restrictions on unvaccinated individuals in terms of access to public places, services and resources.

60. While we appreciate that it is the domain of the executive to determine how best to encourage vaccination without unduly encroaching into the fundamental rights of unvaccinated individuals, we wish to highlight the mechanism of the "health pass" employed in France, as an apt example of a proportionate measure intended to cope with the perils of the spread of the virus. We understand that a "health pass" may take the form of either the results of a viral screening test not concluding that a person has been infected with COVID-19, or proof of vaccination status, or a certificate of recovery following an infection. In a referral by the Prime Minister to review the law on managing the public health state of emergency, the Constitutional 69 | P a g e Council in France, in Decision no. 2021-824 DC dated 05.08.2021, determined that the "health pass" did not infringe the right to personal privacy guaranteed by Article 2 of the Declaration of Human and Civic Rights of 1789 as the requirement did not introduce an obligation to vaccinate.

61. Having expressed our opinion on the vaccine mandates in the prevailing context, we reiterate that vaccines effectively address severe disease arising from COVID-19 infections, are instrumental in reducing oxygen requirement, hospital and ICU admissions and mortality and continue to be the solution to stopping new variants from emerging, as per the advice of the WHO. Since the time arguments were heard in the matter, we have come to know of more variants that have now come into circulation. Given the rapidly- changing nature of the virus and the clear purpose served by the approved vaccines in terms of restoration and protection of public health, our suggestions with respect to review of vaccine mandates are limited to the present situation alone. This judgment is not to be construed as impeding, in any manner, the lawful exercise of power by the executive to take suitable measures for prevention of infection and transmission of the virus in public interest, which may also take the form of restrictions on unvaccinated people in the 70 | P a g e future, if the situation so warrants. Such restrictions will be subject to constitutional scrutiny to examine if they meet the threefold requirement for intrusion into rights of individuals, as discussed earlier.

II. Non-disclosure of segregated clinical trial data in public domain

62. It is the complaint of the Petitioner that the COVID-19 vaccines, manufactured by Respondent Nos. 4 and 5, have been given restricted emergency approval by the Drugs Controller General of India (DCGI) in a hurried and opaque manner. Mr. Bhushan argued that clinical trials in respect of the vaccines had not been completed and at present, the vaccines are only authorised for emergency use. According to the Petitioner, while clinical trials are scheduled to be completed in the year 2023, even the full dataset from the interim analysis conducted has not been made public. The disclosure of segregated data of clinical trials is essential to determine the adverse effects, if any, across various age groups and diverse populations and accordingly, enable individuals to make more informed decisions on whether to be vaccinated. Reliance was placed on an order of this Court in Aruna

Rodrigues (4) v. Union of India 47 and a 47 (2011) 12 SCC 481 71 | P a g e judgment of the Delhi High Court dated 15.01.2019 in W.P. (C) No. 343 of 2019 titled Master Hridaan Kumar (minor) v. Union of India with respect to the importance of disclosure of relevant technical data and informed consent. Additionally, the last amended version of the Declaration of Helsinki – Ethical principles from medical research involving human subjects (hereinafter, the "Declaration of Helsinki") and a statement by the WHO dated 09.04.2015 on 'public disclosure of clinical trial results' (hereinafter, the "WHO Statement on Clinical Trials") were pressed into service to establish the significance of disclosure of data of clinical trials, so as to enable the data to be assessed independently, and not only by the vaccine manufacturer who has a commercial interest in production of the vaccines. Mr. Bhushan submitted that there would be no invasion of privacy of individuals, if personal identification data and past medical history of the trial participants was redacted and the raw data pertaining to clinical trials is made public. The further grievance of the Petitioner pertained to lack of transparency in regulatory approvals, minutes of meetings and constitution of expert bodies. The Petitioner has sought for clear detailing of the information furnished before, and evidence relied on by, the expert bodies such as the NTAGI 72 | P a g e and the Subject Expert Committee (SEC), the body which sends recommendations to the Central Drugs Standard Control Organisation, while deliberating on the applications and data of the vaccine manufacturers, and the names and institutional relationships of the experts who participated in each of these meetings. Mr. Bhushan relied on the 59 th Report of the Parliamentary Standing Committee on Health and Family Welfare, in support of his submission on a need for transparency in the decision-making of the CDSCO and other regulatory authorities.

63. In response, the Union of India submitted that the procedure prescribed under the statutory regime was scrupulously followed before granting emergency approval of the vaccines manufactured by Respondent Nos. 4 and 5. As per the extant statutory regime, permission to import or manufacture new drugs including vaccines or to undertake clinical trials is granted by the Central Drugs Standard Control Organisation (CDSCO). The CDSCO, in consultation with the SEC, evaluates the applications for grant of such permission, which are to be accompanied with data as required under the Second Schedule to the New Drugs and Clinical Trials Rules, 2019 (hereinafter, the "2019 Rules") framed under the Drugs and Cosmetics Act, 1940. The SEC 73 | P a g e is a statutory body, constituted by the CDSCO under Rule 100 of the 2019 Rules, comprising group of experts with specialisation in relevant fields. According to the Union of India, the SEC looks into the details of trials and results presented before it and examines them, interacts with the developers of the vaccines and gives them appropriate directions and eventually makes recommendations in writing, by way of a resolution, reflecting the collective opinion of all the domain experts. We were informed that the trials have been registered on the database of the Clinical Trials Registry – India, which is hosted at the ICMR's National Institute of Medical Statistics. The provisions in relation to 'Accelerated Approval Process' under the Second Schedule to the 2019 Rules were pointed out to this Court, which stipulate that "accelerated approval process may be allowed to a new drug for a disease or condition taking into account its severity, rarity, or prevalence and the availability or lack of alternative treatments, provided that there is a prima facie case of the product being of meaningful therapeutic benefit over the existing treatment". It is further stated that " After granting accelerated approval for such drug, the post marketing trials shall be required to validate the anticipated clinical benefit ." It was submitted that applying these provisions on 74 | P a g e

Accelerated Approval Process, the CDSCO, in detailed consultation with the SEC and after examining the efficacy of the vaccine and its effects, granted permission for restricted emergency use of COVAXIN and COVISHIELD, as manufactured by Respondent Nos. 4 and 5, respectively.

64. As regards COVAXIN (Whole Virion Inactivated Corona Virus Vaccine), the Union of India stated that application for permission to manufacture the vaccine was made by Bharat Biotech on 23.04.2020. The CDSCO, in consultation with the SEC, granted permission to Bharat Biotech for conducting Phase I/II clinical trials on 29.06.2020 and Phase III clinical trials on 23.10.2020. Respondent No. 4 submitted interim safety and immunogenicity data of Phase I and Phase II clinical trials carried out in the country, along with safety data, including Serious Adverse Events data, of the ongoing Phase III clinical trial in the country. The data provided by Respondent No.4 from the various phases were evaluated and analysed by the SEC, which consisted of eminent experts from the fields of microbiology, medicine, pulmonary medicine, paediatrics and immunology and immunogenetics. The resolutions of the various meetings of the SEC, which also required the presence of the developer / manufacturer with the necessary information, have been put up on the 75 | P a g e website of the MoHFW at every stage. In its meeting dated 02.01.2021, observing that on receiving further updated data, justification and request for consideration of the proposal in the wake of a new mutation of the COVID-19 virus, and on recognising that the data generated till then showed that the vaccine had the potential to target mutated coronavirus strains, the SEC recommended for grant of permission for restricted use in emergency situation in public interest in clinical trial mode, as an abundant precaution. While granting such permission, Respondent No. 4 was directed to continue the ongoing Phase III clinical trial and submit data from the trial, as and when available. Approval for restricted use in emergency situation in clinical trial mode with various conditions / restrictions was granted by the CDSCO to Respondent No. 4 to manufacture COVAXIN on 03.01.2021.

65. Thereafter, Respondent No. 4 submitted the interim safety and efficacy data of Phase III clinical trial, which was reviewed by the SEC in meetings held periodically. In its meeting conducted on 10.03.2021, the SEC, after detailed deliberation on the updated interim safety and efficacy data of the phase III clinical trial, recommended omission of the condition of the use of the vaccine in clinical trial mode.

76 | P a g e However, it was recommended that the vaccine be continued to be used under restricted use in emergency situation condition. Following expansion of the Government's vaccination drive to include individuals in the age group of 18-45 years, in its meeting held on 23.04.2021, the SEC considered Bharat Biotech's proposal to unblind the trial participants in the said age group. After detailed deliberations, the SEC recommended the unblinding of the participants in the said age group, upon the request of the participants or the principal investigator after completion of two months from the second dose. Eventually, on consideration of relevant data of Phase I and Phase II clinical trials along with safety data of 6 months' Phase III clinical trial, including data of serious adverse events till the date, the SEC in its meeting dated 19.01.2022 noted that there had been no safety issues and the vaccine maintained its efficacy, specially to avoid hospitalisation and severe infections in the existing situation as well. Accordingly, the SEC recommended that the status of approval of COVAXIN from the restricted use in emergency situation to the New Drug permission

be updated, along with the condition that the firm shall continue to submit data of ongoing clinical trial and monitor AEFIs. The Union of India pointed out that 77 | P a g e Phase I and Phase II clinical trial reports were published in the Lancet Infectious Diseases Journal, which was publicly available. Further, to the knowledge of the Union of India, Phase III trial publication had been submitted to the Lancet journal by Respondent No. 4 on 02.07.2021, a copy of the manuscript of which has been provided to this Court.

66. COVISHIELD (ChAdOx1 nCoV-19 Corona Virus Vaccine (Recombinant)) manufactured by Respondent No. 5 was developed by the Serum Institute of India in collaboration with Oxford University and AstraZeneca under technology transfer. As the clinical development of the said vaccine, including Phase I clinical trial, was conducted in other countries, Phase II / III clinical trials were conducted by Respondent No. 5 in the country. Application for permission to manufacture COVISHIELD for test, examination and analysis was first made by Respondent No. 5 on 03.05.2020. The safety, immunogenicity and efficacy data of Phase II / III clinical trials of the AstraZeneca vaccine carried out in the United Kingdom, Brazil and South Africa were submitted to the SEC, along with the safety and immunogenicity data from the ongoing Phase II / III clinical trials in India. On reviewing this data as well as the approval dated 30.12.2020 granted by the United Kingdom's Medicines and Healthcare Products 78 | P a g e Regulatory Authority (hereinafter, the "UK-MHRA") for the AstraZeneca vaccine along with its conditions / restrictions, the SEC, in its meeting dated 01.01.2021, noted that the safety and immunogenicity data from the Indian study was comparable with that of the overseas clinical trial data. After detailed deliberation and taking into account the emerging situation, the SEC recommended grant of permission for restricted emergency use of the vaccine, subject to various regulatory provisions and conditions, including requirement to submit relevant data from the ongoing clinical trials nationally and internationally at its earliest. Eventually, in its meeting dated 19.01.2022, the SEC considered the request of Respondent No. 5 to grant permission to manufacture the vaccine, excluding the conditions for restricted use in emergency situation and other conditions, on the lines of Marketing Authorisation by the UK-MHRA for the parent vaccine. After detailed deliberation and consideration of safety, immunogenicity and efficacy data from Indian and overseas clinical trials, amongst other data, the SEC recommended grant of New Drug permission or regular approval, with conditions that data of ongoing clinical trials and vaccine shall continue to be supplied and AEFIs shall continue to be monitored.

79 | P a g e

67. We were directed to Rule 25 of the 2019 Rules, framed under the Drugs and Cosmetics Act, 1940, which provides that the clinical trial shall be conducted in accordance with approved clinical trial protocol and other related documents as per the requirements of Good Clinical Practices (GCP) guidelines and the other rules. The expert committee set up by the CDSCO under Rule 25(vi) in consultation with clinical experts formulated the GCP guidelines for generation of data on drugs. The 'Ethical Principles', which are part of the said guidelines, protect principles of privacy and confidentiality of human subjects of research. The learned Solicitor General also relied upon para 2.4.4 of the GCP guidelines, which require safeguarding of the confidentiality of research data that might lead to identification of individual subjects. He further referred to the important role played

by the Ethics Committee under Rule 11 of the 2019 Rules, which includes safeguarding the rights, safety and well-being of trial subjects in accordance with the said rules. The 2019 Rules also empower the Ethics Committee to discontinue or suspend the clinical trial in case it concludes that the trial is likely to compromise the right, safety or well-being of the trial subject. As per the ICMR's National Ethical Guidelines 80 | P a g e for Biomedical and Health Research involving Human Participants, the four basic ethical principles for conducting biomedical and health research are (i) respect for persons (autonomy), (ii) beneficence, (iii) non-malfeasance and (iv) justice. These four basic principles have been expanded into 12 general principles, including the 'principle of ensuring privacy and confidentiality' which requires maintaining the privacy of potential participants, her / his identity and records, with access given to only those authorised. As regards transparency of functioning of expert bodies, it was submitted by the Union of India that recommendations of the SEC in all its meetings are uploaded on the website of the CDSCO. Additionally, the detailed minutes of NTAGI meetings were already available in public domain, which can be downloaded from both the ICMR and the MoHFW websites.

68. The contention of Respondent No. 4 is that COVAXIN has undergone all clinical trials. In Phase III, trials revealed a 77.8% efficacy against symptomatic COVID-19 disease. The findings of the clinical trials have been published in reputed peer-reviewed journals and are readily available on the website of Respondent No.4. A reference was made by Respondent No. 4 to the WHO Statement on Clinical Trials, to submit that it is only the key outcomes and findings which 81 | P a g e are required to be made publicly available. It was contended that Respondent No. 4 is in compliance with the WHO Statement on Clinical Trials as the key outcomes and results of the Phase III clinical trial have been published in the Lancet. On behalf of Respondent No. 5, it was submitted that the clinical data generated during the trials had been submitted to the regulatory authorities for obtaining permissions / licences etc. Further, the peer-reviewed study of the partial clinical data of Phase II / III trials had already been published in reputed scientific journals, which included all the information necessary for safeguarding the public as well as informing them of the credibility and efficacy of the vaccine. According to Respondent No. 5, the raw data of the clinical trials served no greater public purpose than the data which was already available in the public domain. All applicable medico-legal, scientific and ethical requirements had been strictly adhered to by Respondent No. 5.

69. In rejoinder, the learned counsel for the Petitioner argued that there is no transparency in the process of approvals of vaccines and relevant data is not always placed before the NTAGI. He referred to a news article in The Wire, according to which Jayaprakash Muliyil, a member of the NTAGI had stated that the NTAGI had not recommended 82 | P a g e vaccination of children in the age group of 12-14 years. He also drew the attention of this Court to non-supply of relevant data to the NTAGI at the time of approval of the Rotavac vaccine against rotavirus. The Petitioner further complained of the haste shown in grant of emergency approval to Respondent No. 4. The Petitioner has sought support of a decision of the United States District Court for the Northern District of Texas dated 06.01.2022 in Public Health and Medical Professionals for Transparency v. Food and Drug Administration, which highlighted the need for transparency in disclosure of clinical trial data. It was reiterated by the Petitioner that privacy of individuals would not be at risk as their personal identification data can be redacted before disclosing segregated data of clinical trials.

70. It is settled law that courts cannot take judicial notice of facts stated in a news item published in a newspaper. A statement of fact contained in a newspaper is merely hearsay and therefore, inadmissible in evidence, unless proved by the maker of the statement appearing in court and deposing to have perceived the fact reported. 48 In the absence of anything on record in the present case to substantiate the statement made by Mr. Jayaprakash Muliyil, 48 Laxmi Raj Shetty v. State of Tamil Nadu (1988) 3 SCC 319 83 | P a g e member of the NTAGI, we are not inclined to take judicial notice of the news article reported in The Wire, even more so in light of the affidavit filed on behalf of the Union of India stating that the relevant data was examined by the expert bodies at all stages before granting emergency use approval to the vaccines. We are also of the opinion that the evidence relating to the approval process of the Rotavac vaccine has no relevance to the dispute in this case. On the basis of the said two incidents, it cannot be concluded that the emergency use approval to COVISHIELD and COVAXIN recommended by the SEC are not in accordance with the statutory regime.

71. At this stage, it is worthwhile to refer to the statutory regime in place. According to Rule 19 of the 2019 Rules, no person, institution or organisation shall conduct clinical trial of a new drug or investigational new drug, except in accordance with the permission granted by the Central Licensing Authority (i.e., the CDSCO) and without following the protocol approved by the Ethics Committee for clinical trial, registered in accordance with the provisions of Rule 8. Rule 19 (2) of the 2019 Rules provides that every person associated with the conduct of clinical trial of a new drug or investigational new drug shall follow the general principles 84 | P a g e and practices as specified in the First Schedule. The methodology to be adopted in a clinical trial is provided for in the First Schedule to the 2019 Rules, relevant clauses of which are as under: -

> "GENERAL PRINCIPLES AND PRACTICES FOR CLINICAL TRIAL
>
> 1. General Principles.☐(1) The principles and guidelines for protection of trial subjects as described in Third Schedule as well as Good Clinical Practices guidelines shall be followed in conduct of any clinical trial. xxx
>
> 4. Conduct of Clinical Trial.☐Clinical trial should be conducted in accordance with the principles as specified in Third Schedule. Adherence to the clinical trial protocol is essential and if amendment of the protocol becomes necessary the rationale for the amendment shall be provided in the form of a protocol amendment. Serious adverse events shall be reported during clinical trial in accordance with these Rules.
>
> xxx
>
> 6. Reporting.☐Report of clinical trial shall be documented in accordance with the approaches specified in Table 6 of the Third Schedule. The report shall be certified by the principal investigator or if no principal investigator is designated then by each of the participating investigators of the study." It is clear from the above, that there are stringent statutory requirements which have to be complied with by the manufacturers of vaccines and other participants, during different stages of clinical

trials of vaccines. Further, we also

85 | P a g e note that the GCP guidelines are statutorily required to be followed.

72. The GCP guidelines further elaborate on the role of the Ethics Committee. According to the GCP guidelines, the Ethics Committee is an independent review board or a committee comprising of medical / scientific and non-medical / non-scientific members, whose responsibility it is to verify the protection of the rights, safety and well-being of human subjects involved in a study. The independent review provides public reassurance by objectively, independently and impartially reviewing and approving the "Protocol", the suitability of the investigator(s), facilities, methods and material to be used for obtaining and documenting "Informed Consent" of the study subjects and adequacy of confidentiality safeguards. Para 2.4 of the GCP guidelines deal with ethical and safety considerations, which provide that all research involving human subjects should be conducted in accordance with the ethical principles contained in the current version of the Declaration of Helsinki, as annexed to the guidelines. Amongst the principles to be followed, the GCP guidelines require adherence to the "principles of accountability and transparency" and "principles of public domain":

> 86 | P a g e "Principles of accountability and transparency, whereby the research or experiment will be conducted in a fair, honest, impartial and transparent manner, after full disclosure is made by those associated with the Study of each aspect of their interest in the Study, and any conflict of interest that may exist; and whereby, subject to the principles of privacy and confidentiality and the rights of the researcher, full and complete records of the research inclusive of data and notes are retained for such reasonable period as may be prescribed or considered necessary for the purposes of post-research monitoring, evaluation of the research, conducting further research (whether by the initial researcher or otherwise) and in order to make such records available for scrutiny by the appropriate legal and administrative authority, if necessary.

xxx Principles of public domain, whereby the research and any further research, experimentation or evaluation in response to, and emanating from such research is brought into the public domain so that its results are generally made known through scientific and other publications subject to such rights as are available to the researcher and those associated with the research under the law in force at that time."

73. The GCP guidelines have been formulated following the Declaration of Helsinki. The relevant portion of the said Declaration is as follows: -

> "Privacy and Confidentiality
>
> 24. Every precaution must be taken to protect the privacy of research subjects and the confidentiality of their personal information.

87 | P a g e Research Registration and Publication and Dissemination of Results ...

36. Researchers, authors, sponsors, editors and publishers all have ethical obligations with regard to the publication and dissemination of the results of research.

Researchers have a duty to make publicly available the results of their research on human subjects and are accountable for the completeness and accuracy of their reports. All parties should adhere to accepted guidelines for ethical reporting. Negative and inconclusive as well as positive results must be published or otherwise made publicly available. Sources of funding, institutional affiliations and conflicts of interest must be declared in the publication. Reports of research not in accordance with the principles of this Declaration should not be accepted for publication." It is profitable to refer to the relevant portion of the WHO Statement on Clinical Trials, which is as under: -

"Reporting timeframes for clinical trials Clinical trial results are to be reported according to the timeframes outlined below. Reporting is to occur in BOTH of the following two modalities.

1. The main findings of clinical trials are to be submitted for publication in a peer reviewed journal within 12 months of study completion and are to be published through an open access mechanism unless there is a specific reason why open access cannot be used, or otherwise made available publicly at most within 24 months of study completion.

2. In addition, the key outcomes are to be made publicly available within 12 months of study completion by posting to the results section of the primary clinical trial 88 | P a g e registry. Where a registry is used without a results database available, the results should be posted on a free-to-access, publicly available, searchable institutional website of the Regulatory Sponsor, Funder or Principal Investigator."

74. The GCP guidelines are being scrupulously followed, according to the Union of India. The principles of "public domain" in the GCP guidelines provide for research, experimentation or evaluation in response to the research to be brought into the public domain. The results of the clinical trials are generally to be made known through scientific and other publications. The requirement of publication, according to the WHO, also relates to the main findings of clinical trials to be published in a peer-reviewed journal and the key outcomes to be made publicly available, within 12 months of study completion. The Petitioner complains of opaqueness in clinical trials as the general public do not have access to, and the opportunity to be aware of, all the necessary details by segregated clinical trial data (primary datasets) not being available. There is no challenge by the Petitioner to the GCP guidelines. As required by the WHO Statement on Clinical Trials and the GCP guidelines, findings of the clinical trials and the key outcomes of the trials have been published. In light of the existing statutory regime, we do not see it fit to 89 | P a g e mandate the disclosure of primary clinical trial data, when the results and key findings of such clinical trials have already been published.

75. After examining the judgment of the United States District Court for the Northern District of Texas (hereinafter, the "US District Court"), we are afraid that the said decision cannot be said to be relevant for adjudication of the dispute in the present case. The grievance of the plaintiff in the said case pertained to all data and information for the Pfizer vaccine, enumerated under the relevant provisions of the Freedom of Information Act, not being provided by the United States Food and Drug Administration. The US District Court referred to the Freedom of Information Act to hold that the citizenry has a right to be provided with the relevant information pertaining to the Pfizer vaccine and that such 'information is often useful only if it is timely'. The US District Court directed expeditious completion of the plaintiff's request after concluding that the request under the Freedom of Information Act was of paramount importance. We note that with respect to COVAXIN and COVISHIELD, results of clinical trials have been published in accordance with our statutory regime in place. Reliance placed by the Petitioner on European Medicines Agency policy on 90 | P a g e publication of clinical data for medicinal products for human use is also not relevant as the GCP guidelines relating to the disclosure of clinical trial data, framed under the 2019 Rules, currently govern the field of disclosure of clinical trial data in India.

76. An analysis of the submissions made by the learned counsel appearing for the parties and a close scrutiny of the material placed on record would show that there is a strict statutory regime in force for grant of approvals to vaccines. Specialist bodies established under the provisions of the Drugs and Cosmetics Act, 1940 and the rules framed thereunder comprise of domain experts in the relevant field, who conduct a thorough scrutiny of the material produced by the manufacturers before granting approval. The information provided on behalf of the Union of India substantiates that the data provided by the vaccine manufacturers was considered by the SEC over a period of time and several conditions were imposed at the time of recommending approvals, which have been modified or lifted subsequently on availability of further data arising from the clinical trials before the SEC, as can be seen from the minutes of the meetings of the SEC, available on the website of the MoHFW.

91 | P a g e We do not agree with the submission on behalf of the Petitioner that emergency approvals to the vaccines were given in haste, without properly reviewing the data from clinical trials. We are also of the opinion that the Parliamentary Standing Committee report relied upon by Mr. Bhushan is not relevant and the lapses pointed out therein pertain to the year 2011, which have no obvious connection to the grant of approval to Respondent Nos. 4 and 5 for the restricted emergency use of their respective vaccines. As long as the relevant information relating to the minutes of the meetings of the regulatory bodies and the key outcomes and findings of the trials are available in public domain, the Petitioner cannot contend that every minute detail relating to clinical trials be placed in public domain to enable an individual to take an informed, conscious decision to be vaccinated or not. Given the widespread affliction caused by the virus, there was an imminent need of manufacturing vaccines which would keep the infection at bay. We would like to highlight that both the vaccines have been approved by the WHO as well. A perusal of the material placed on record would show that there is material compliance with the procedure prescribed under the Drugs and Cosmetics Act, 1940 and the 2019 Rules, before grant of approval for the 92 | P a g e emergency use of the two vaccines. However, it is made clear that subject to the protection of privacy of individual subjects and to the extent permissible by the 2019 Rules, the relevant data which is

required to be published under the statutory regime and the WHO Statement on Clinical Trials shall be made available to the public without undue delay, with respect to the ongoing post-marketing trials of COVAXIN and COVISHIELD as well as ongoing clinical trials or trials that may be conducted subsequently for approval of other COVID- 19 vaccines / vaccine candidates.

III. Improper collection and reporting of AEFIs

77. The contention of the Petitioner is that there have been several adverse effects from vaccines, including deaths. The Petitioner has sought to fault the Government's mechanisms in place for handling of the adverse events. According to the Petitioner, during Phase III trials, where small controlled trials of a limited number of participants are conducted, a significant increase in adverse events may not be seen. But after licensure, when the vaccines are administered to the masses, rare reactions show up, which is why Phase IV post-marketing trials are legally mandated. It was pointed out by the Petitioner that there has been a 93 | P a g e revision of the rules by the WHO for classifying AEFIs in 2018. As per the revised mechanism, only reactions that are previously acknowledged to be caused by the vaccine are classified as vaccine-related reactions. Reactions observed during post-marketing surveillance are not considered as 'consistent with causal association with vaccine', if a significant increase in such reactions during Phase III trials had not been recorded. According to the Petitioner, this acquires significance in the context of trials conducted in this country, as the control trial in Phase III did not go on in the manner intended, with several members of the original control group prematurely unblinded and offered the vaccine. The Petitioner contends that owing to 'dilution of Phase III control trials prematurely', there are no controls to compare against, making it difficult to ascertain which adverse events are caused by the vaccine. Therefore, reactions which are not "known reactions" to the vaccine are not considered AEFIs. In light of this, it is necessary for the authorities to carefully monitor all vaccine recipients and publicly record all adverse events.

78. Taking this argument further, the Petitioner contended that the adverse events reporting system in India is not transparent, with obscure investigation and follow-up of 94 | P a g e deaths and other serious adverse events after COVID-19 vaccination. The Petitioner relied on a letter published in The Hindu on 17.03.2021, written by a group of experts in public health, ethics, medicine, law, and journalism to the Minister for Health & Family Welfare and the DCGI, appealing for "time-bound and transparent investigation" following deaths and serious adverse effects after COVID-19 vaccination. A presentation made by the National AEFI Committee in a meeting held on 31.03.2021 was referred to by the Petitioner to claim that complete documentation was not available for all the severe and serious adverse events (including deaths) that had occurred till the time. Additionally, it was contended that no data pertaining to the AEFIs already classified nor any analysis of the same had been published publicly till date. The Petitioner also drew the attention of this Court to the Vaccine Adverse Event Reporting System (VAERS) in place in the United States, which published all vaccine injury reports every Friday, received till about a week prior to the release date. It was brought to the notice of this Court that 77,314 adverse events have been reported in India as on 12.03.2022, amounting to 0.004% of the total vaccination. The Petitioner has pointed out that the percentage of adverse events 95 | P a g e reported in Europe is much larger than the percentage identified in India, which would show that correct figures are not being published by the

Government.

79. On behalf of the Union of India, the procedures and protocols for monitoring of adverse event following immunisation under the National Adverse Event Following Immunisation Surveillance Guideline were elaborated upon. The National Adverse Event Following Immunisation Surveillance Secretariat, established in the Immunisation Technical Support Unit in 2012, had staff dedicated for managing Adverse Event Following Immunisation surveillance system. It was further strengthened by the National Adverse Event Following Immunisation Surveillance Technical Collaborating Centre, comprising of experts from Lady Hardinge Medical College and Allied Hospitals in New Delhi. Adverse Event Following Immunisation Committees were formed at the national and state levels to provide guidance to the National AEFI Surveillance and carry out documentation, investigation and causality assessment, besides training and orientation of health care workers and others involved in AEFI. According to the Union of India, a foolproof protocol for reporting and causality assessment for any AEFI with Universal Immunisation Program (UIP) and 96 | P a g e Non-UIP vaccines has been established. The National AEFI Committee gets periodical reports regarding 'minor AEFIs', 'severe AEFIs' and 'serious AEFIs'. Online reporting of all serious and severe AEFIs at the district level to be communicated to relevant authorities at the state / national level is done on a web-based portal, SAFEVAC (Surveillance and Action for Events Following Vaccination). All serious and severe adverse events following vaccination even at district level are uploaded online on SAFEVAC. It was submitted on behalf of the Union of India that case details, scanned copies of reports are uploaded on SAFEVAC, which also has facilities for generating dashboards and line-lists at different levels.

80. Further, a similar feature of reporting of all AEFIs (including minor) by the vaccinator was made available on the Co-WIN portal. District Immunisation Officers (DIOs) were given the facility to report AEFI cases about which they have information from such individuals who do not have access to Co-WIN. Departmental orders and standard operating procedures have been issued for further investigations and sharing of hospital records by the DIOs through Co-WIN. The Union of India has brought to the notice of this Court that an alignment with the Pharmacovigilance Programme of India (PvPI) under Indian 97 | P a g e Pharmacopoeia Commission has been developed for receipt of information regarding AEFI cases from around 300 Adverse Drug Reaction Monitoring Centers in medical colleges and large hospitals. The Union of India has highlighted that information from the PvPI and the CDSCO are collated and studied, in case of any new, previously unknown events identified through AEFI surveillance. A press release of the MoHFW dated 17.02.2017 titled 'Maximum Possible Marks to Indian NRA in WHO Assessment' has been placed before this Court to state that the AEFI Surveillance System in India (which is in use for COVID-19 vaccination) has been approved by global experts in an assessment conducted by the WHO in 2017. Given the novel nature of the virus, membership of the National AEFI Committee has been expanded to include neurologists, cardiologists, respiratory medicine specialists and medical specialists, with even States / Union Territories requested to expand their AEFI Committees on a similar scale to strengthen AEFI surveillance for COVID-19 vaccines. Causality assessment of AEFI cases is conducted at the state and the national levels by experts trained as per the causality assessment checklist, based on the definition and algorithm developed by the WHO. Once approved by experts of the National AEFI Committee, results of causality 98 | P a g e assessment of AEFI cases are made available in the

public domain and are shared with the CDSCO, amongst other authorities, for appropriate regulatory action.

81. As regards the present status of AEFI surveillance for COVID-19 vaccination, it was submitted that as the causality assessment of reported AEFI cases is a time-consuming process, a method of rapid review and assessment had been initiated at the national level to quickly review available information in each case and look for trends in reporting of specific events or unusual cases requiring further early investigation and assessment. All cases of serious and severe AEFIs, including reported deaths, are subjected to rapid reviews, analysis and causality assessment done by a team of trained subject experts. It was clarified that mere reporting of AEFI case should not be attributed to the vaccine unless proved by the causality assessment analysis. The National Expert Group on Vaccine Administration for COVID- 19 (NEGVAC), an additional body of experts, is also involved in providing guidance on vaccine safety and surveillance, thus, aiding in the prompt identification of AEFIs for the purpose of identifying and understanding evolving trends in the disease and taking prompt action. 2,116 serious and severe AEFIs have been reported from 1,19,38,44,741 doses 99 | P a g e of COVID-19 vaccine administered till 24.11.2021. While a report of rapid review and analysis completed for 495 cases had been submitted, a further report of 1,356 serious and severe AEFI cases had been presented to the NEGVAC and the rapid review and analysis of balance cases was underway. Press releases around a report on bleeding and clotting events following COVID-19 vaccination being submitted to the MoHFW by the National AEFI Committee and on clarification on deaths following vaccination and process of causality assessment were placed before this Court. Therefore, the Union of India submitted that there was continuous monitoring and examination of AEFI cases in India and there is no basis for the allegations around AEFIs not being properly collected and lack of transparency in their investigation.

82. From the material placed before us, we note that the National AEFI Surveillance Secretariat has been functioning for 10 years and as has been pointed out, there is a well- established protocol in place for identification and monitoring of AEFIs. The website of the MoHFW carries the results of causality assessment of AEFI cases, from which the public can obtain relevant information pertaining to AEFIs. We have been informed that a thorough causality assessment analysis 100 | P a g e of AEFIs is carried out by experts and not every severe disease and death can be attributed to vaccination. Reactions are examined by experts specifically trained to undertake causality analysis before notifying such reactions as adverse events arising from vaccination. There is a well- defined mechanism for collection of data relating to adverse events that occur due to COVID-19 vaccines and the Government of India has taken steps to direct all concerned medical professionals at the ground level to report adverse events. Even medical practitioners at private hospitals are associated with reporting of adverse events. Therefore, we are not inclined to accept the broad-strokes challenge mounted by the Petitioner that the surveillance system of AEFIs in this country is faulty and the correct figures of those who have suffered any side effects, severe reactions or deaths post-inoculation have not been disclosed.

83. As regards the contention of the Petitioner on abandoning of Phase III trials, we note that unblinding of participants during the Phase III trial was done on the recommendation of the SEC. The Union of India has emphasized that at every stage, the deliberations of domain experts, which

involved discussions with the manufacturers, focused on safety and immunogenicity of the vaccines and it 101 | P a g e was only when there was consensus among domain experts that it was safe to extend the immunisation drive beyond the category of 'healthcare workers / frontline workers', the appropriate decisions were taken. In doing so, the available trial data, trajectory of the pandemic, evidence, future contingencies and several other factors have always been heeded. There is no challenge to the decision of the SEC, a body of domain experts, as being unreasonable or arbitrary, nor have we been called upon to determine whether adequate time was devoted to recognise all relevant reactions as vaccine-related reactions prior to such unblinding. What the Petitioner seeks is the monitoring of all adverse events and publication of the results of investigation. The Union of India has painstakingly taken this Court through the details of the procedure followed to closely monitor, review and escalate the incidence of AEFIs to appropriate authorities. As regards previously unknown / unidentified reactions seen during the monitoring of AEFIs at the time of vaccine administration, the Union of India has elaborated on the role of the PvPI and the CDSCO, which collate and study such reactions. We believe this adequately addresses the Petitioner's concerns, as this Court has been informed that previously unidentified events are also being 102 | P a g e taken into consideration and investigated. We trust the Union of India to have the appropriate authorities ensure that this leg of the AEFI surveillance system is not compromised with while meeting the requirements of the rapid review and assessment system followed at the national level.

84. The Petitioner had taken issue with the present system to the extent it allows only DIOs or the vaccinators to report AEFIs. According to the Petitioner, the repository of AEFIs should be as detailed as the VAERS in the United State of America. The Petitioner further submitted that individuals and doctors must be able to report adverse events, with the reporter being given a unique identification number and the reports being openly accessible. The response of the Union of India on this issue is that the DIOs have been instructed to set up a network with private hospitals to report AEFIs. Training has been provided to state officers, medical officers, private practitioners and frontline health workers on their role in AEFI surveillance. Even auxiliary nurse midwives have been instructed to notify all AEFIs. However, we are in agreement with the suggestion made by the Petitioner that there should be a mechanism by which individuals and private doctors should be permitted to report suspected 103 | P a g e adverse events. Information relating to adverse effects following immunisation is crucial for the purpose of understanding the safety of the vaccines that are being administered, apart from being instrumental in further scientific studies around the pandemic. There is an imminent need for collection of requisite data of adverse events and wider participation of people in reporting the adverse events is necessary for the purpose of gathering correct information. Thus, the Union of India is directed to facilitate the reporting of suspected adverse events by individuals and private doctors on a virtual platform and the reports so made shall be publicly accessible after being given unique identification numbers, without listing any personal or confidential data of the persons reporting. All necessary steps to create awareness of, and to navigate, this platform for self-reporting shall be effectuated by the Government, roping in and training relevant participants right from the ground level of vaccine administration.

IV. Vaccination of Children

85. The opinion of the Petitioner is that children are at almost no risk from COVID-19 and instances of previously healthy children requiring hospitalisation due to COVID-19 are exceedingly rare. While referring to articles in the Nature 104 | P a g e and the Lancet, the Petitioner contended that scientific evidence shows that risk of administering vaccines to children outweigh the benefits offered by the vaccine in children. The Petitioner further submitted that serological studies would show that a large number of children have already acquired antibodies to COVID-19. The Petitioner has highlighted the risk of myocarditis associated with the mRNA vaccines, on the basis of which, several European countries have recently stopped the use of Moderna vaccines for those under the age of 30. He has also pointed out that these risks had not been identified in the initial vaccine trials as the trial size was too small to uncover rare risks, which were discovered after mass vaccination. The Petitioner has sought for results as well as the primary data of clinical trials conducted on the paediatric population to be made public.

86. In response thereto, the Union of India contended that paediatric vaccination is advised by global agencies such as the WHO, the UNICEF and the CDC. Expert opinion in India is in tune with global consensus in favour of vaccination of children. We are informed that 8,91,39,455 doses of COVAXIN have been administered to individuals in the age group of 15 to 18 years as on 12.03.2022. The AEFIs 105 | P a g e reported are 1,739 minor complaints, 81 serious complaints and 6 severe. According to the Union of India, the said data would show that the vaccine does not pose threat to the safety of children. As regards the clinical trials, para 2.4.6.2 of the GCP guidelines were relied on to show that children are not required to be involved in research that could be carried out equally well with adults and further that, for the clinical evaluation of a new drug, study in children should be carried out after the Phase III clinical trials in adults. It has been stated that paediatric vaccination was considered at a stage where more than substantial data on safety and immunogenicity of COVAXIN in adults was available. To avoid any risks, clinical trials were also conducted on a limited number of children as per the protocol approved by domain experts. Having found no serious adverse event in the said trials, paediatric vaccination was initiated in a phased manner, starting from the eldest paediatric age group of 15 to 18 years. On 12.05.2021, on the basis of recommendations of the SEC, the CDSCO granted permission to Respondent No. 4 to conduct Phase II / Phase III clinical trials of COVAXIN for the age group of 2 to 18 years. Thereafter, Respondent No. 4 had submitted an application for grant of permission to manufacture COVAXIN paediatric 106 | P a g e vaccines for emergency use, which was subsequently granted by the CDSCO. It was argued on behalf of the Union of India that expert opinion is to the effect that paediatric vaccinations are always preventive in nature and are administered to avoid any risk of infection and of prolonged clinical symptoms.

87. This Court cannot sit in judgment of leading scientific analysis relating to the safety of paediatric vaccination. Experts in science may themselves differ in their opinions while taking decisions on matters related to safety and allied aspects, but that does not entitle the Court to second-guess expert opinion, on the basis of which the Government has drawn up its policies. The decision taken by the Union of India to vaccinate paediatric population in this country is in tune with global scientific consensus and expert bodies like the WHO, the UNICEF and the CDC have also advised paediatric vaccination. It would not only be beyond our jurisdiction but also hazardous if this Court were to examine the accuracy of such expert opinion, based on competing medical opinions. As

already stated, the scope of judicial review does not entail the Court embarking upon such misadventures. Therefore, we reject the contention of the 107 | P a g e Petitioner that this Court has to intervene in paediatric vaccination on the ground that it is unscientific.

88. With respect to results of clinical trials, we note that the Union of India has stated that the results of clinical trials of COVAXIN for paediatric population have already been published. We also note that for the age group of 12 to 14 years, Biological E's Corbevax is being administered. Keeping in line with the WHO Statement on Clinical Trials, the Declaration of Helsinki and the GCP guidelines, we direct the Union of India to ensure that key findings and results of the clinical trials of Corbevax be published at the earliest, if not already done. Neither vaccine is an mRNA vaccine and to this extent, the apprehensions of the Petitioner with respect to the associated risks of mRNA vaccines are unfounded in the present situation.

Conclusion

89. In conclusion, we have summarised our findings on the various issues considered by us, below:

> (i) Given the issues urged by the Petitioner have a bearing on public health and concern the fundamental rights of individuals in this country, we are not inclined to 108 | P a g e entertain any challenge to the maintainability of the Writ Petition.

(ii) As far as judicial review of policy decisions based on expert opinion is concerned, there is no doubt that wide latitude is provided to the executive in such matters and the Court does not have the expertise to appreciate and decide on merits of scientific issues on the basis of divergent medical opinion. However, this does not bar the Court from scrutinising whether the policy in question can be held to be beyond the pale of unreasonableness and manifest arbitrariness and to be in furtherance of the right to life of all persons, bearing in mind the material on record.

(iii) With respect to the infringement of bodily integrity and personal autonomy of an individual considered in the light of vaccines and other public health measures introduced to deal with the COVID-19 pandemic, we are of the opinion that bodily integrity is protected under Article 21 of the Constitution and no individual can be forced to be vaccinated. Further, personal autonomy of an individual, which is a recognised facet of the protections guaranteed under Article 21, encompasses the right to refuse to undergo any medical treatment in 109 | P a g e the sphere of individual health. However, in the interest of protection of communitarian health, the Government is entitled to regulate issues of public health concern by imposing certain limitations on individual rights, which are open to scrutiny by constitutional courts to assess whether such invasion into an individual's right to personal autonomy and right to access means of livelihood meets the threefold requirement as laid down in K.S. Puttaswamy (supra), i.e., (i) legality, which presupposes the existence of law; (ii) need, defined in terms of a legitimate State aim; and (iii) proportionality, which ensures a rational nexus between the objects and the means adopted to achieve them.

(iv) On the basis of substantial material filed before this Court reflecting the near-unanimous views of experts on the benefits of vaccination in addressing severe disease from the infection, reduction in

oxygen requirement, hospital and ICU admissions, mortality and stopping new variants from emerging, this Court is satisfied that the current vaccination policy of the Union of India is informed by relevant considerations and cannot be said to be unreasonable or manifestly arbitrary. Contrasting scientific opinion coming forth from certain quarters to 110 | P a g e the effect that natural immunity offers better protection against COVID-19 is not pertinent for determination of the issue before us.

(v) However, no data has been placed by the Union of India or the States appearing before us, controverting the material placed by the Petitioner in the form of emerging scientific opinion which appears to indicate that the risk of transmission of the virus from unvaccinated individuals is almost on par with that from vaccinated persons. In light of this, restrictions on unvaccinated individuals imposed through various vaccine mandates by State Governments / Union Territories cannot be said to be proportionate. Till the infection rate remains low and any new development or research finding emerges which provides due justification to impose reasonable and proportionate restrictions on the rights of unvaccinated individuals, we suggest that all authorities in this country, including private organisations and educational institutions, review the relevant orders and instructions imposing restrictions on unvaccinated individuals in terms of access to public places, services and resources, if not already recalled. It is clarified that in the context of the rapidly-evolving situation presented 111 | P a g e by the COVID-19 pandemic, our suggestion to review the vaccine mandates imposed by States / Union Territories, is limited to the present situation alone and is not to be construed as interfering with the lawful exercise of power by the executive to take suitable measures for prevention of infection and transmission of the virus. Our suggestion also does not extend to any other directions requiring maintenance of COVID-appropriate behaviour issued by the Union or the State Governments.

(vi) As regards non-disclosure of segregated clinical data, we find that the results of Phase III clinical trials of the vaccines in question have been published, in line with the requirement under the statutory regime in place, the GCP guidelines and the WHO Statement on Clinical Trials. The material provided by the Union of India, comprising of minutes of the meetings of the SEC, do not warrant the conclusion that restricted emergency use approvals had been granted to COVISHIELD and COVAXIN in haste, without thorough review of the relevant data. Relevant information relating to the meetings of the SEC and the NTAGI are available in public domain and therefore, challenge to the procedures adopted by the expert 112 | P a g e bodies while granting regulatory approval to the vaccines on the ground of lack of transparency cannot be entertained. However, we reiterate that subject to the protection of privacy of individual subjects, with respect to ongoing clinical trials and trials that may be conducted subsequently for COVID-19 vaccines, all relevant data required to be published under the extant statutory regime must be made available to the public without undue delay.

(vii) We do not accept the sweeping challenge to the monitoring system of AEFIs being faulty and not reflecting accurate figures of those with severe reactions or deaths from vaccines. We note that the role of the Pharmacovigilance Programme of India and the CDSCO, as elaborated upon by the Union of India, collates and studies previously unknown reactions seen during monitoring of AEFIs at the time of vaccine administration and we trust the Union of India to ensure that this leg of the

AEFI surveillance system is not compromised with, while meeting the requirements of the rapid review and assessment system followed at the national level for AEFIs.

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(viii) We are also of the opinion that information relating to adverse effects following immunisation is crucial for creating awareness around vaccines and their efficacy, apart from being instrumental in further scientific studies around the pandemic. Recognising the imperative need for collection of requisite data of adverse events and wider participation in terms of reporting, the Union of India is directed to facilitate reporting of suspected adverse events by individuals and private doctors on an accessible virtual platform. These reports shall be made publicly accessible, without compromising on protecting the confidentiality of the persons reporting, with all necessary steps to create awareness of the existence of such a platform and of the information required to navigate the platform to be undertaken by the Union of India at the earliest.

(ix) On paediatric vaccination, we recognise that the decision taken by the Union of India to vaccinate children in this country is in tune with global scientific consensus and expert bodies like the WHO, the UNICEF and the CDC and it is beyond the scope of review for this Court to second-guess expert opinion, on the basis of which the Government has drawn up its policy. Keeping in line with 114 | P a g e the WHO Statement on Clinical Trials and the extant statutory regime, we direct the Union of India to ensure that key findings and results of the relevant phases of clinical trials of vaccines already approved by the regulatory authorities for administration to children, be made public at the earliest, if not already done.

90. We express our gratitude to the learned counsel on either side for their able assistance in enabling this Court to reach the above conclusion.

91. The Writ Petition is disposed of accordingly.

.....J. [ L. NAGESWARA RAO ] .....J. [ B. R. GAVAI ] New Delhi, May 2, 2022 115 | P a g e