

LAW

COMMENT

The vaccine mandates judgment: Some reflections

S SRINIVASAN

Abstract

This paper scrutinises the Supreme Court Judgment of May 2, 2022, in a vaccine mandate-related petition. The Hon'ble Court's Order reasserts the primacy of right to privacy and Articles 14 and 21 of the Constitution of India. However, in the interest of protection of communitarian health, the Court felt that 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. However, such mandatory vaccination directives with preconditions cannot invade an individual's right to personal autonomy and right to access means of livelihood, and must meet the threefold criteria laid down in K.S.Puttaswamy, a landmark judgment of 2017. This paper examines the validity of the arguments adopted in the Order and suggests certain infirmities therein. Nevertheless, the Order is a balancing act, and worth celebrating. The paper concludes that a cup that is "a quarter full" is a victory for human rights and a safeguard against unreasonableness and arbitrariness in medico-scientific decision-making that takes the citizen's compliance and consent for granted. If the State runs amok by way of mandatory health directives, this Order may come to the rescue of the hapless citizen.

Keywords: Mandatory Covid vaccination, right to privacy, bodily autonomy

This paper attempts to understand and reflect on the judgment of May 2, 2022, in a vaccine mandate-related petition in the Supreme Court of India [Writ Petition (Civil) No. 607 of 2021, Jacob Puliyel (Petitioner) vs Union of India and Others (Respondents)] [1].

Reliefs sought by the Petitioner

The reliefs sought by Petitioner Jacob Puliyel, paediatrician and former member of the National Technical Advisory Group

Author: **S Srinivasan** (chinusrinivasan.x@gmail.com), All-India Drug Action Network (AIDAN); and LOCOST Vadodara, Gujarat, INDIA.

To cite: Srinivasan S. The vaccine mandates judgment: Some reflections. *Indian J Med Ethics*. 2023 Apr-Jun; 8(2) NS: 134-140. DOI: 10.20529/IJME. 2022 056

Published online first on July 29, 2022.

Copyright and license

©Indian Journal of Medical Ethics 2022: Open Access and Distributed under the Creative Commons license (CC BY-NC-ND 4.0), which permits only non-commercial and non-modified sharing in any medium, provided the original author(s) and source are credited.

on Immunisation (NTAGI), through his counsel Prashant Bhushan, were in relation to Covid-19 vaccines, their approval, trials, mandates, etc. Specifically, they were to:

- 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
- b) Direct the respondent No 2 to disclose the detailed minutes of the meetings of the Subject Expert Committee and the NTAGI with regard to the vaccines as directed by the 59th Parliamentary Standing Committee Report and the members who constituted the committee for the purpose of each approval meeting; and
- c) Direct the respondent No.2 to disclose the reasoned decision of the DCGI [Drugs Controller General of India] 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
- d) Direct the respondents to disclose the post vaccination data regarding adverse events, vaccinees who got infected with Covid-19, 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 tollfree telephone numbers where such complaints can be registered; and
- 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.

The Honourable Court's final Order denied the Petitioner reliefs — in effect — in (a) to (c) above, and (d) partly if not substantially — as we shall see below [1: Conclusion, Para 89]. Parts of the Order related to Relief (e), whichever way you look at them, have broken new ground.

Vaccine mandates and fundamental rights

We try to understand how the Hon'ble Court arrived at its



Order on the issue of vaccine mandates and fundamental rights. As emphasised during the course of his arguments, the Petitioner was not opposed to the vaccination programme and did not challenge the vaccination drive of the Government of India. His opposition was only to "coercive vaccination through vaccine mandates, which place unjustifiable restrictions on those who wish to not be vaccinated" [1: paras 27 and 39].

The Union of India submitted that the Government's Covid-19 vaccination directives and policies were voluntary and not mandatory. We argue that while they may have been notionally voluntary, there was, at the peak of Covid-19, a pervasive atmosphere of persuasion, even coerciveness, through advisories, advertisements, and publicity material. It was difficult to demarcate clearly where the voluntariness/mandatoriness of government directives began, ended, and overlapped. For instance, the lockdown and the forced march on foot of the poor working class back to their rural homes was not voluntary by any means — but some may opine that is not a directly related vaccine mandate.

Some of the respondent states, like Tamil Nadu, Maharashtra, Delhi and Madhya Pradesh [1: para 27], did accept before the Bench that some of their executive actions and restrictions were not "truly" voluntary and tried to explain away their vaccine mandates. For instance:

"The Delhi Disaster Management Authority, in a meeting held on 29.09.2021, decided to ensure 100 percent 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 virus..." [1: para 33].

Such mandatory directives were lauded, at the time, by many powerful and influential people in government and non-government circles. Governments were criticised for their laxity and inability to help people access vaccines.

Vaccine mandates and the right to privacy

The Order finally zeroes in on this proposition (hereafter, Proposition A, for brevity) as valid — a proposition put forth by the Petitioner several times during his arguments and not contested by the Union of India — that the risk of transmission of the virus from unvaccinated individuals is almost on par with that from vaccinated persons.

As long as this reading of the situation (as one of no difference between a vaccinated group of individuals and that of an unvaccinated group of persons concerning risk of transmission of the virus) is considered valid, insisting on compliance with vaccine mandates, with preconditions like denial of services or benefits to the unvaccinated, is tantamount to a denial of fundamental rights per Article 21 and per the threefold criteria enumerated in, the landmark *Puttaswamy* judgment by a nine-judge bench in August 2017 [2].

The judgment in *Puttaswamy* asserted that the right to privacy flowed from Article 21, the right to life. The right to privacy encompasses the right to bodily integrity and personal autonomy and the right to access means of livelihood. Therefore, any vaccine mandate, including mandatory vaccination with preconditions, violates the right to privacy and Article 21. A mandatory vaccination requirement that seems to invade an individual's right to personal autonomy and right to access means of livelihood must meet "the threefold requirement as laid down in *K.S.Puttaswamy*, 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." [1: para 89 (iii)]

The Puttaswamy judgment included many judicial expressions of intent like:

"... privacy also entails negative autonomy to not do a specific act." "Like all fundamental rights, privacy too has its limitations. There must be identified depending upon the nature of privacy interest claimed. Courts must be guided by the standard of just, fair and reasonable legislation as applicable to Article 21. The strictest scrutiny standard of compelling State interest must be used." a

But here is what follows when the right to privacy is deemed not absolute:

"....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 health concerns by imposing certain limitations on individual rights that are reasonable and proportionate to the object sought to be fulfilled." [1: para 49]

Therefore, in its concluding part of the Order, the Hon'ble Judges assert that at the same time when there is a clear risk for unvaccinated individuals, "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 ... " [1: para 89 (iii), italics ours].

That is, hereafter, if there is a breakthrough variant or a pandemic needing a vaccination-related mandatory requirement of any sort, including mandatory vaccination per se, the Government has to show, on being challenged, that it meets the *Puttaswamy* criteria for temporary



suspension of the right to privacy. And if the Court does not agree that these criteria are met, the Government will have to withdraw mandatory vaccination requirements and/or vaccine mandates of any kind as a precondition. This is not a "no," in this writer's opinion, to vaccine mandates, but if there happens to be a vaccine mandate hereafter, the occasion has to be an extraordinary emergency to entail temporary suspension of the right to privacy.

Flowing from this Order, one may also question the legal sanctity, subject to the threefold *Puttaswamy* criteria, of mandatory wearing of helmets and seat belts, prohibition on consuming narcotic drugs, etc., but one may not be able to question, successfully, the prohibitions on driving under the influence and speed limits while driving. One may not be able to successfully challenge immunisation against diphtheria, as diphtheria is infectious, but can possibly successfully challenge mandatory tetanus shots.

Proposition A in the light of Doctrine of Classification

The binary classification of vaccinated and unvaccinated groups of individuals, with respect to risks from virus transmission in Proposition A is too simplistic considering there is a range of possibilities of risk from the status of the vaccinated and unvaccinated, to extent of acquired immunity of a person due to having contracted/not contracted the disease, having been vaccinated/not vaccinated, proximity to persons with viral load shedding in the first few days of contracting the virus, immunity status of persons who have had Covid-19 but asymptomatically, status due to single dose/ double dose/booster dose, status of comorbid persons, elderly, poor, economically challenged, etc, and there is also the question of efficacy of the vaccine/s after the arrival of newer variants of concern. The Bench has not considered these complexities as classificatory issues even though some of these have been narrated by the Union of India and summarised in para 29, para 56, inter alia. Explicit cognisance of the doctrine of classification with respect to some of the above issues, may have led to a different final Order. A bare binary classification as in Proposition A, as a basis for the examination of the plausibility and legality of vaccine mandates, seems to go against the test of equality and nonarbitrariness that is based on the doctrine of classification. Proposition A seems to be a case of treating unequal groups equally at the expense of neglecting complexity. An unwarranted simplification in the analysis of complex issues is itself a precursor to manifest arbitrariness. Rarely does nature give us the luxury of deriving cosmic complexity from relatively simple formulations like Newton's three laws or Einstein's postulates of General Theory of Relativity. Simple one liner explanations in vaccinology as much as in law seem to be the exception rather the rule.

Classification, we may recall, is a two-step process: classification should be based on objective criteria and should have a rational nexus to the object to be achieved. If any one of these is not met it would be arbitrary, discriminatory, and violative of Article 14.^b

In the current binary classification of Proposition A, we submit, though based on intelligible differentia as classification of vaccinated and unvaccinated groups of people can be objectively achieved, there is no rational nexus to the objective to be achieved. If the objective is to prevent the transmission of disease, then the classification is inappropriate, as both vaccinated and unvaccinated (asymptomatic or symptomatic) individuals can transmit the disease. It is admitted that the Covid-19 vaccines do not prevent infection but they can reduce infectiousness and death, and mitigate the severity of the disease.

Proposition A — a done deal?

Now we turn to the scientific validity and acceptability of Proposition A itself. Proposition A is, at the cost of repetition, that the risk of transmission of the virus from unvaccinated individuals is almost on par with that from vaccinated persons.

A careful perusal of studies like these [3-7], may suggest, as it did to this writer, that Proposition A itself does not appear to be cast in stone, and is not a done deal so to speak [See also 8]. This is so, even though there was no contestation from the Union of India controverting the material put forth by the Petitioner in support of Proposition A. And in the words of the Bench: "... 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." [1: para 58]

In exchanges by this writer with practitioners and thinkers (cited in the Acknowledgements), their degree of agreement with Proposition A was mixed. A few were quite clear that Proposition A was by and large acceptable. Gagandeep Kang, virologist, had this to say in response to a query about the validity of Proposition A from the author: "Objectively, the variants, the vaccine history and the infection history (particularly time between exposures) all matter in determining level of protection from infection. Prior exposure to a vaccine or infection will change susceptibility to a lesser or greater degree depending on the factors described above, as well as others, including immune status, co-morbidities, etc. Therefore, I do not agree with the 'almost on par' part of the statement, because it depends very much on the variant and needs to be qualified as such... One situation where proposition A may be said to apply is for tetanus toxoid vaccination in the general non-pregnant population, where the proportion of vaccinated will not decrease tetanus. Yet the vaccines protect the individual and vaccinating mothers protects their babies. While I do not agree with Proposition A as stated above and with all the context discussed in my mails, I do not think vaccine mandates are justified as a measure for the general population. However, for specific populations, a requirement for vaccination may be a requirement to protect especially vulnerable individuals within the group."d



There is no reason for the Court not to examine issues around the doctrine of classification and vaccination/immunity status and related issues alluded to above.

Interestingly, the Hon'ble Justices remarked: "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." [1: para 53]

A recent statement on hybrid immunity (a "mix" of infection-induced immunity and vaccine-induced immunity) from the World Health Organization (WHO) says: When more evidence is available, advice on if and how hybrid immunity should be considered in national vaccination policies will be updated [9].

The Bench seems to have taken pains at every step to emphasise "... we do not seek to substitute our own views in matters of differences in scientific opinion," or equivalent phrases. But that does not seem to have happened in this Order — especially when the Bench has given considerable weightage to Proposition A in its logic that builds up to the Order. By doing so, we submit that the Hon'ble Justices have exercised their judicial discretion on a scientific issue, contrary to their considered thinking elaborated inter alia in paras 13 to 26 on judicial review, and contrary also to their position outlined in para 53 cited above.

Let us explain. Consider this passage in the final Order [1: Para 89 (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..." (italics ours)e

The phrase in italics above — especially "which appears to indicate ... restrictions on unvaccinated individuals imposed through various vaccine mandates by State Governments / Union Territories cannot be said to be proportionate..." — suggests to us, what the Hon'ble Justices themselves may categorise, as an "easy assumption of unreasonableness of subordinate legislation, etc." This is notwithstanding their attempt in the current Order to assert the citizen's "fundamental rights against executive tyranny draped in disciplinary power." (Pyarali K. Tejani v. Mahadeo Ramchandra Dange (1974) 1 SCC 167, cited in Para 22 of the current Order). A possibly more logical directive from the Bench could have been to ask the Respondent Union of India to produce data to refute Proposition A, and till then withdraw the mandates.

Absence of evidence submitted to controvert Proposition A does not mean no evidence exists.

As future mandatory restrictions related to at least some vaccines, will be subject to Constitutional scrutiny, any concerned person who feels any new restriction is not proportionate, may go to Court holding the State in contempt of the current Order. The State on its part will have to articulate a water-tight case for restricting the right to privacy, bodily integrity, and personal autonomy. Only approaching the Court may be a practical challenge for many.

Court's response to "emergency approval" of vaccines and data transparency

As of today in India, there are those, like the Petitioner, who, in good faith, believe in the scientific rigor of modern medicine, who would want to verify independently that tenets and the rigor of their discipline (say of epidemiology and definition of efficacy, cure and effectiveness, and related posers of causality and association and correlation) are indeed being followed in practice. But the researcher or student is frustrated in the process of seeking such access. This is a common enough experience, be it from the private or the public sector. Details regarding clinical trial data and adverse events following vaccination (AEFI) for instance are denied. The standard response is "We have put it up on the website" or "these are commercial secrets". The website itself reveals very meagre details. Such a guest for fuller data is the burden of reliefs (a) to (d) sought by the Petitioner, as mentioned earlier. In this context, the Petitioner's experience in the Rotavirus vaccine case was dismissed as irrelevant by the Bench [1: paras 69-70] whereas that experience of the Petitioner could have revealed the State's unsatisfactory response to the request for transparent sharing of data for a disease with a much smaller number of patients. Elsewhere, though Covaxin has not met the WHO standards - it is impossible to know why exactly, even if WHO says "the data, available to WHO, indicate the vaccine is effective and no safety concerns exist." [10]

The Hon'ble Judges declared that there was material compliance [1: para 76] with the relevant statutory provisions of the Drugs and Cosmetics Act and Rules, and especially with the provisions related to "accelerated approval". The Court also relied on the Subject Expert Committee (SEC) meeting minutes and declared thereafter that:

"...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.... 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...." [1: Para 76, emphasis added].

The Court has lost a golden opportunity, in our considered opinion, to open up clinical trial data — the devil does lie in the "minute detail". Currently, any concerned person who has perused the SEC minutes for any drug, let alone Covid-19 vaccines, comes back frustrated with inadequate or no explanation for decisions arrived at by the Committee. Certainly, the SEC nod for approval of Covaxin under "clinical trial mode", on Jan 2, 2021, was inexplicable. It is an understatement to say that "clinical trial mode" is a creative invention of the experts and DCGI bureaucrats, one that is not found in law. It is part of the larger assumption that Government experts and committees know best what is good for the country, and therefore, "Please believe that this much data on a need to know basis is good for you citizens". Elsewhere, the rather sweeping dismissal by the Bench of the 59th Parliamentary Committee Report as having no relevance is regrettable. The 59th Report is anything but irrelevant [11]. It is a landmark report that laid out in detail the lack of application of mind, anarchy and continuing corruption in our drug regulatory system [12], and suggested steps to regulate it. Just one example of its many recommendations relevant for the issue at hand:

"Unless there is some legal hitch, the Committee is of the view that there is no justification in withholding opinions of experts on matters that affect the safety of patients from public. Consideration should be given to upload all opinions on CDSCO [Central Drugs Standard Control Organisation] website." [12: para 7.15]

The "emergency approval" provision of a vaccine to be used on a large scale was for the first time. It gives a licence to jump certain steps in the clinical trial process. Agreed, this was an emergency. But whether post facto, that emergency approval was justified or should there be any caveats in any future use of the emergency provision can be answered only by opening up the data and the minutiae of decision making to other experts and scholars.

The Court may have been satisfied with the apparent compliance by the Government with the letter of the law and therefore declare there is no manifest arbitrariness — but the judicial endorsement of the Government-decreed limits to share clinical data (the paternal State deciding what is good for who), on which vaccine decisions with countrywide impact are/were based, and the Court's own unwillingness to enlarge the canvas of transparency in clinical trial and drug approval matters, are, de facto, endorsing arbitrariness at a more fundamental scientific level. One might add that this kind of meta-arbitrariness contributes to violation of right to privacy, bodily integrity, etc. It results in closing the door to critical

interrogation by experts not in Government committees (and by not only so-called "fringe" elements) on the rationale of decisions on which public policy like vaccination is based. That Governments tend to fear sunlight, openness, and transparency, is no news. That the Court, for reasons known best to it, is seen as endorsing the Government's lack of transparency is discouraging news.

"Broad-strokes challenge" and AEFI

It is in this context the Court's rejection of the Petitioner's prayer and averments characterised by the Court as "the broad-strokes challenge mounted by the Petitioner" [1: para 82] on Covid-19 related AEFI is disappointing:

"...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 [Pharmacovigilance Programme of India] 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 taken into consideration and investigated. 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..." [1: Para 83, emphasis added].

The Union of India had "painstakingly" taken the Hon'ble Court through a mass of details. However, in spite of the Hon'ble Court expressing its satisfaction, these details do not appear to address the concerns of the Petitioner. What the Petitioner was asserting, in this writer's reading, was the inadequate functionality of the system of AEFI so constructed but deemed otherwise adequate by the respondents Union of India [1: paras 77-78]. The burden of monitoring AEFIs during clinical trials and post licensure monitoring is on the manufacturer leading to doubts about data integrity of such AEFI. So far, the SAFE-VAC platform of the Government of India seems to be voluntary but not mandatory, as is the case with tuberculosis. The lack of a strong AEFI system for Covid-19, as Pulla points out [13], possibly increases vaccine hesitancy.

In hindsight, after, and probably in spite of, the recent kerfuffle [14] on the accuracy of WHO estimates on deaths in India due to Covid-19, there does seem to be cause for concern; and according to this author, there is considerable merit in the suspicion of underreporting of deaths and therefore of AEFI. Also, any number of citizens who wrote to the Government on serious adverse effects following the Covid-19 vaccine can attest to the inadequacy of the



Government's responses [15, 16], as well as the lack of transparency in the methodology of classifying adverse effects as related or not related to the vaccine.

A small important step

At least now that the worst of the pandemic seems to have abated it may be a good time to consider the long-term implications of Covid-19. Why not throw open all the minute data for experts like the Petitioner to examine? Indeed, the clinical trial process, as much as the drug approval process before marketing and manufacturing are contingent on accepting the data integrity of the manufacturer or the clinical triallist, so should we not at least allow the system to throw up devices that examine data integrity and the integrity of the approval process? That opportunity has been missed — for this round certainly. One hopes that post-marketing trial data related to the Covid-19 vaccines are thrown open to experts across the country.

In spite of these limitations, this judgment attempts to restore a semblance of balance by observing towards the end [1: Conclusion, Para 89 (viii)]:

"Recognising the imperative need for collection of requisite data of adverse events ... 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 ... 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."

A small, but important, step for India, if implemented.

Paediatric vaccination for Covid-19

On paediatric vaccination (not among the original reliefs sought), the Petitioner felt that introduction of the vaccine for children was unscientific. The Court refused —

"to sit in Judgement of leading scientific analysis relating to the safety of paediatric vaccination ... 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 [United Nations Children's Fund] and the CDC [Centers for Disease Control and Prevention] have also advised paediatric vaccination.... the scope of judicial review does not entail the Court embarking upon such misadventures. Therefore, we reject the contention of the Petitioner that this Court has to intervene in paediatric vaccination on the ground that it is unscientific." [1: para 89, (ix)]

This was a not unexpected loss for the Petitioner, considering the predominant pro-vaccine ecology among the ruling elite in India and the world at large during the Covid-19 pandemic. Still, the petitioner's arguments on the advisability and rationality of paediatric vaccination for Covid-19 deserved careful hearing, and could have thrown light on the decision-making process on such matters in India. The resulting vaccination in children will perforce have the smell and colour of undeclared mandatoriness.

Concluding remarks

The Order is a balancing act, where the Court in its wisdom appears to have concurred for the most part, with the all-is-well response of the Union of India. Nevertheless, the Order is worth celebrating as a cup that is a quarter full, as a victory for human rights and the right to privacy, and as a safeguard against unreasonableness and arbitrariness in medico-scientific decision-making that takes the citizen's compliance and consent for granted. In a future India, there could be a scenario in which the State may tend to run amok with Government's health-related mandates and directives, and thereby violate the privacy of its citizens. This current Order may then come to the rescue of the hapless citizen, if a Bench at that time sees fit.

Endnotes

- ^a For more on the Puttaswamy judgment, see:
 - i. Fundamental Right to Privacy. Judgment of the Court in Plain English (I). Supreme Court Observer. 2017. [Cited 2022 Jul 20]. Available from: https://www.s cobserver.in/reports/k-s-puttaswamy-right-to-privacy judgment-of-the-court-in-plain-english-i#:~:tex t=On%2024th%20Agust%2C%202017%20a,a%20 fundamental%20right%20to%20privacy
 - Bhandari V, Kak A, Parsheera S, Rahman F. An Analysis of Puttaswamy: The Supreme Court's Privacy Verdict. 2017. [Cited 2022 Jul 20] Available from: https:// www.ssoar.info/ssoar/handle/document/54766
- b For a discussion on arbitrariness and classification issues, see https://www.scconline.com/blog/post/2021/10/11/article-14-and-arbitrariness-vis-a-vis-legislative-action/ [Cited 2022 Jul 20], and for a readable primer on Doctrine of Reasonable Classification, see https://lexforti.com/legal-news/test-of-reasonable-classification-and-doctrine-of-arbitrariness/[Cited2022 Jul 20]
- ^c I am grateful to the lawyer reviewer for these comments.
- d Email communication dated July 19, 2022 from Kang to the author. Permission to reproduce the text has been taken from Kang by the author as per the email dated July 25, 2022.
- ^e The author thanks Anant Phadke for pointing out this particular phrase. Elsewhere in the Order too, the Court appears to have crossed the self-drawn line of neutrality on scientific matters.

Acknowledgements: The author wishes to thank Anant Phadke and Sridhar Srikantiah for discussion on especially



"Proposition A", and Jacob Puliyel on aspects of the Judgment. Special thanks are due to a lawyer reviewer and Gagandeep Kang for answering questions patiently. Errors of omission and commission are the author's alone.

References

- Supreme Court of India. Jacob Puliyel vs Union Of India on 2 May, 2022. Writ Petition (Civil) No. 607 of 2021 [Cited 2022 Jul 20]. Available from: https://indiankanoon.org/doc/17990001/
- Justice K.S.Puttaswamy (Retd) and Anr. vs Union of India and Ors, final Order dated 24 August, 2017 in the Supreme Court. [Cited on 2022 Jul 20]. Available from: https://indiankanoon.org/doc/91938676/
- Shah ASV, Gribben C, Bishop J, Hanlon P, Caldwell D, Wood R, et al. Effect of Vaccination on Transmission of SARS-CoV-2. N Engl J Med. 2021 Oct 28;385(18):1718-1720. https://doi.org/10.1056/ NEJMc2106757
- Puhach O, Adea K, Hulo N, Pascale S, Genecand C, Iten Anne, et al. Infectious viral load in unvaccinated and vaccinated individuals infected with ancestral, Delta or Omicron SARS-CoV-2. Nat Med. 2022 Jul;28(7):1491-1500. https://doi.org/10.1038/s41591-022-01816-0
- Singanayagam A, Hakki S, Dunning J, Madon KJ, Crone MA, Koycheva A, et al. Community transmission and viral load kinetics of the SARS-CoV-2 delta (B.1.617.2) variant in vaccinated and unvaccinated individuals in the UK: a prospective, longitudinal, cohort study. *Lancet Infect Dis.* 2022 Feb;22(2):183-195. https://doi.org/10.1016/S1473-3099(21)00648-4
- Wilder-Smith A. What is the vaccine effect on reducing transmission in the context of the SARS-CoV-2 delta variant? *Lancet Infect Dis.* 2022 Feb;22(2):152-153. https://doi.org/10.1016/S1473-3099(21)00690-3
- Antonelli M, Penfold RS, Merino J, Sudre CH, Molteni E, Berry S, et al. Risk factors and disease profile of post-vaccination SARS-CoV-2 infection in UK users of the COVID Symptom Study app: a prospective, community-based, nested, case-control study. *Lancet Infect Dis.* 2022 Jan;22(1):43-55. https://doi.org/10.1016/S1473-3099(21)00460-6
- World Health Organization. The Statement for healthcare professionals: How COVID-19 vaccines are regulated for safety and effectiveness. Revised March 2022. [Cited 2022 Jul 20]. Available from: https://www.who.int/news/item/11-06-2021-statement-for-

- health care-professionals-how-covid-19-vaccines-are-regulated-for-safety-and-
- effectiveness#:~:text=The%20most%20commonly%2Dreported,vaccines%20from%20clinical%20trials
- World Health Organization. Interim statement on hybrid immunity and increasing population seroprevalence rates. June 01, 2022. [Cited 2022 Jul 20]. Available from: https://www.who.int/news/item/ 01-06-2022-interim-statement-on-hybrid-immunity-andincreasing-population-seroprevalence-rates
- 10. World Health Organization. Suspension of supply of COVID-19 vaccine (COVAXIN®). April 02, 2022. [Cited 2022 Jul 20]. Available from: https://www.who.int/news/item/02-04-2022-suspension-of-supply-of-Covid-19-vaccine-covaxin
- Department-related Parliamentary Standing Committee on Health and Family Welfare. Fifty-ninth Report on the Functioning of the Central Drugs Standard Control Organisation (CDSCO). Parliament of India, Rajya Sabha. 2012 May 4 [Cited 2022 Jul 20]. Available from: http://164.100.47.5/newcommittee/reports/englishcommittees/ committee%20on%20health%20and%20family%20welfare/59.pdf
- PTI. Biocon subsidiary caught offering bribe to waive off trial of new drug. The Hindu. 2022 Jun 21[Cited 2022 Jul 12]. Available from: https://www.thehindu.com/news/national/joint-drugs-controllernabbed-taking-bribe/article65546933.ece
- Pulla P. How covid-19 vaccines exposed India's adverse events reporting system. BMJ. 2022; 376:n3146. https://doi.org/10.1136/ bmj.n3146
- 14. Kaur B. No Rest for the Weary: WHO Report Says India Undercounted COVID-19 Deaths by 10x. The Wire Science. 2022 May 06 [cited 2022 Jul 16]. Available from: https://science.thewire.in/health/who-report-india-undercounted-covid-deaths-10x/
- Kaur B. The Union Government Has Lied to the Supreme Court in COVID Vaccines Case. The Wire Science. 2022 May 5 [Cited 2022 Jul 16]. Available from: https://science.thewire.in/health/union-Government-falsehoods-ntagi-approval-aefi-data-supreme-Court/
- Menghani SM. When India's Arguments Against COVID Report Left WHO Scientists 'Frustrated'. The Wire Science. 2022 May 14 [Cited 2022 Jul 16]. Available from: https://science.thewire.in/health/ jonathan-wakefield-interview-who-covid-excess-deaths-reportindia-dispute/

The FMES is supported by occasional grants from philanthropists and subscriptions to the journal.

APPEAL FOR DONATIONS TO THE FORUM FOR MEDICAL ETHICS SOCIETY

The Indian Journal of Medical Ethics (IJME) has been published for over 30 years by the **Forum for Medical Ethics Society (FMES)** since 1993. IJME is a multi-disciplinary academic journal providing a platform for original content and discussion on all aspects of healthcare ethics, as well as law, history, literature, philosophy and the humanities where they intersect with health and healthcare. We are committed to maintaining our editorial independence which is critical to safeguarding the scientific integrity of what we publish. Therefore, wider support from all those who are committed to social justice in health is essential.

FMES is registered under the Societies Registration Act, 1860 and the Bombay Public Trusts Act, 1950. Donations are eligible for tax exemption under Section 80G of the Income Tax Act, 1961. Donations are solicited only from Indian individuals and entities, as donations from foreign individual/entities are not permitted under Indian law. However, foreign readers/authors may wish to support the journal by:

- Gifting subscriptions to the print or soft PDF copies of the journal;
- · Voluntarily paying any amount for full text views of individual online articles or PDF downloads;
- Or paying a fee for article processing when submitting an article to be considered for publication
- For more details on how to support us, write to admin@ijme.in or visit our website https://ijme.in/subscribe/

SUPPORT OPEN ACCESS ACADEMIC PUBLICATIONS, DONATE TO THE FMES CORPUS FOR THE PUBLICATION OF IJME!