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* IN THE HIGH COURT OF DELHI AT NEW DELHI

+ W.P.(C) 5369/2021 and C.M. No. 18256/2021

SANJEEV KUMAR

..... Petitioner

Through: Petitioner in person.
versus

UNION OF INDIA & ORS.

..... Respondent

Through: Mr. Waize Ali Noor for Mr. Kirtiman Singh, CGSC for R-1 to R-4.

Mr. Vipin Nair and Mr. Agnish Aditya, Advs. for R-4.

CORAM:

HON'BLE THE CHIEF JUSTICE

HON'BLE MR. JUSTICE SUBRAMONIUM PRASAD

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ORDER
13.09.2022

The Petitioner before this Court has filed the present PIL praying for the following reliefs:

“(a) quash and set aside the Impugned Order dated 13/05 /2021 passed by the respondents for conducting phase II/III clinical trial of Whole Virion Inactivated Coronavirus Vaccine on healthy volunteers from the age group ranging between 2 to 18 years, and

(b) direct the respondents to place on record the details of the 525 children who will be subjected to phase II/III clinical trial of Whole Virion Inactivated Coronavirus Vaccineas also the records of vaccination of their parents/ legal guardians and family members and other persons who come in close contact of such toddlers/ children for taking their care;

(c) direct the respondents to produce the contracts under which the 525 children have been/ would be made Volunteers for the phase II/III clinical trial of Whole Virion Inactivated

Coronavirus Vaccine,

(d) direct the State to criminally prosecute the persons involved in such trials and the persons having authorized conduct of such trials in the event of any death or loss of peaceful and pleasant enjoyment of life of any toddler or a minor children;
(e) pass any other or further order as may be deemed fit and proper in the facts and circumstances of this case.”

Learned Counsel for the Union of India has straight away drawn the attention of this Court towards a judgment dated 09.08.2021 delivered by the Apex Court in Writ Petition (Civil) No. 607 of 2021 titled ***Jacob Puliyel v. Union of India & Ors.***

Paragraphs 1 and 89 of the aforesaid judgment reads as under:

“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

(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 59 th 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 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, 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. ”

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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 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 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 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 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 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.

(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 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.”

Learned counsel for the parties were fair enough in stating before this Court that the controversy involved in the present matter stands concluded in light of the aforesaid judgment and, therefore, no further orders are required

to be passed in the present case.

The petition stands disposed of in the aforesaid terms.

SATISH CHANDRA SHARMA, CJ

SUBRAMONIUM PRASAD, J

SEPTEMBER 13, 2022

N.Khanna