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IN THE SUPREME COURT OF INDIA
CIVIL ORIGINAL JURISDICTION
VIKRAM NATH; J., SANDEEP MEHTA; J.
MARCH 10, 2026
WRIT PETITION (CIVIL) NO.1220 OF 2021
RACHANA GANGU & ANR. *versus* **UNION OF INDIA & ORS.**

Constitution of India – Article 21 – Right to Life and Health – COVID-19 Vaccination – Adverse Events Following Immunization (AEFI) – Compensation Policy – The Supreme Court directed the Union of India to formulate a "no-fault" compensation framework for serious adverse events or deaths resulting from COVID-19 vaccinations - held that while the state-led vaccination program was a vital public health intervention, the State bears a positive obligation under Article 21 to ensure that families suffering grave harm are not left without an accessible mechanism for redress.

Constitution of India – Articles 14 and 21 – Judicial Review of Executive Policy – Separation of Powers – While acknowledging the executive's competence in drafting health policies, Supreme Court maintained that the separation of powers cannot prevent judicial intervention when fundamental rights are violated due to the absence of a structured relief framework in exceptional circumstances.

No-Fault Liability – Principle and International Precedent – Supreme Court emphasized that requiring proof of negligence through civil courts or consumer fora imposes an "onerous burden" on families in complex scientific matters - Relying on the principle of no-fault liability (similar to Section 164 of the Motor Vehicles Act, 1988), Supreme Court noted that global jurisdictions, including Australia, the UK, and Japan, have implemented dedicated COVID-19 vaccine injury compensation schemes - Supreme Court declined to appoint an independent medical board, finding the existing National and State AEFI Committees adequate for scientific assessment - it reaffirmed the state's duty to maintain transparent surveillance and ensure AEFI data is accessible in the public domain. *[Relied on Jacob Puliyel v. Union of India (2022 SCC OnLine SC 533); In re: Distribution of Essential Supplies and Services During Pandemic (2021 SCC OnLine SC 372); Gaurav Kumar Bansal v. Union of India (W.P.(C) No. 539/2021); Paras 27-37]*

WITH SLP(C) No. 16452 OF 2023) AND T.P.(C) No. 1716 OF 2023 AND T.P.(C) Nos. 2289-2294 OF 2024

For Petitioner(s): Mr. Colin Gonsalves, Sr.Adv. Mr. Manik Gupta, Adv. Mr. Satya Mitra, AOR Mr. Amrish Kumar, AOR Mr. Raj Bahadur Yadav, AOR Mr. Sudarshan Lamba, AOR

For Respondent(s): Mr. Tushar Mehta, Solicitor General 20:06:00 IST Reason: Ms. Aishwarya Bhati, A.S.G. Mr. Rajat Nair, Adv. Mr. Ishaan Sharma, Adv. Mr. Digvijay Dam, Adv. Ms. Tanvi Dubey, Adv. Mr. Arvind Kumar Sharma, AOR Mrs. Aishwarya Bhati, A.S.G. Mr. Raj Bahadur Yadav, AOR Mr. Ishaan Sharma, Adv. Mr. Rajat Nair, Adv. Mr. Padmesh Mishra, Adv. Mr. Vijay Awana, Adv. Dr. Arun Kumar Yadav, Adv. Ms. Aishwarya Bhati, ASG Ms.Riddhi Jad, ADv. Ms. Shivika Ma Ms. Aishwarya Bhati, ASG Mr. Ketan Paul, Adv./AOR Ms. Riddhi Jad, Adv Ms. Shivika Mehra, Adv. Mr. G.S. Makker, AOR Mr. S.P. Chaly, Sr. Adv. Ms. Anu B., AOR Mr. Shivam Sharma, Adv. Mr. Bibhuti Krishna, Adv. Mr. Vaibhav Choudhary, Adv. Mr. Prashant Bhushan, AOR Mr. Shiyas Kr, Adv. Ms. Ria Yadav, Adv. Mr. Prabhu K N, Adv. Mr. Sureshan P., AOR Mr. Nishe Rajen Shonker, AOR Mrs. Anu K Joy, Adv. Mr. Alim Anvar, Adv. Mr. Santhosh K, Adv. Mr. Adolf Mathew, Adv. Ms. Meenu George, Adv. Mr. Shishir Pinaki, AOR Mr. C. Unnikrishnan, Adv. Mr. Pranav Krishna, AOR Mr. Aljo K. Joseph, Mr. Rajnish Kumar, Adv. Mr. Rajesh Kumar, Adv. Mr. Mohammed Sadique T.A., AOR Mrs. Devika A.I., Adv. Ms. Monisha Mane Bhangale, Adv. Ms. Bijal Vora, Adv. Mr. Utkarsh Vatsa, Adv. Mr. Udit Bajpai, Adv. Ms. Prachi Dhingra, Adv. Mr. Ayush Raj, Adv. Mr. Pranav Sarthi, AOR Mr. Chandragupta Patil, Adv. Mr. Ramesh Babu M. R., AOR Mr. Vijay Kumar, Adv.

J U D G M E N T

VIKRAM NATH, J.

1. Leave granted in SLP(C) No. 16452/2023.

2. The COVID-19 pandemic was an unprecedented period of suffering and disruption, which brought grief and hardship to countless families across the country. Many lives were lost, and many households were left to bear sorrow that cannot easily be expressed in words. The present proceedings arise in the aftermath of that difficult time. The Court approaches the issues raised with a deep sense of empathy for the human loss endured during the pandemic, while remaining mindful that the questions before it must be examined with care and within the constitutional limits of judicial determination.

3. At the outset, it is relevant to note that a writ petition under Article 32 of the Constitution, registered as W.P.(C) No. 1220 of 2021 (Rachana Gangu & Anr. v. Union of India & Ors.), was instituted before the Supreme Court by parents of young individuals who had received COVID-19 vaccination and are stated to have died thereafter. The petition sought, *inter alia*, the constitution of an independent expert medical board to inquire into such deaths, the formulation of protocols for early detection and treatment of adverse events following immunization (AEFI), and the grant of compensation.

4. Subsequent thereto, writ petitions raising similar grievances came to be filed before the High Court of Kerala. One such petition was Sayeeda K.A. v. Union of India & Ors. (W.P.(C) No. 17628 of 2022, High Court of Kerala), wherein the petitioner sought directions for recognition of a death allegedly following COVID-19 vaccination as an AEFI case and for the grant of compensation to the dependants of the deceased. By an interim order dated 01.09.2022, the Kerala High Court directed the Ministry of Health and Family Welfare and the National Disaster Management Authority to formulate, within a stipulated period, a policy for identification of AEFI cases and for compensating the families of such deceased persons.

5. Aggrieved by the aforesaid interim directions, the respondents approached this Court in SLP(C) No. 16452/2023 challenging the interim order passed by the High Court in Sayeeda K.A. v. Union of India & Ors.. A Transfer Petition TP(C) No.1716/2023 was also field seeking transfer of proceedings from the High Court to this Court as the same issue was pending adjudication.

6. With respect to W.P.(C) Nos. 13487/2022, 13573/2022, 11276/2022, 35180/2022, 37055/2022 and 38961/2022 pending before the Kerala High Court where similar prayers of compensation were made by the petitioners, the respondent Union of India filed T.P.(C) Nos. 2289-2294/2024 seeking transfer of these proceedings before this Court. Consequently, the Article 32 writ petition, the proceedings arising from the Kerala High Court, and the connected matters were listed together for consideration. For ease of convenience, W.P.(C) No. 1220 of 2021 is taken as the lead case. The disposal of this writ petition shall govern the disposal of all connected matters.

7. A brief summary of facts giving rise to each case is as follows:

i. *Rachna Gangu & Anr. v. Union of India & Ors., W.P.(C) No. 1220 of 2021*

Petitioner's younger daughter, aged 18 years, received the first dose on 29.05.2021. Her platelet count dropped, she had severe headache, and had a tingly and numb feeling in her fingertips. Her condition worsened and the petitioner was informed that her daughter had been diagnosed with CVST- Cerebral Venous Sinus Thrombosis. She passed away on 19.06.2021

Petitioner's elder daughter, aged 20 years, received the first dose of vaccine on 08.06.2021. She had high fever, arthralgia, headache and myalgia. In the following days, she developed Multisytem Inflammatory Syndrome (MIS- C/A) She lost her life on 10.07.2021.

ii. *Sayeeda K.A. v. Union of India & Ors.* in *W.P.(C) 17628/2022 before Kerala High Court*

Husband Abdul Nazeer M.H. who was otherwise in good health received his first dose of vaccine on 08.06.2021. On the same day at 03.03 p.m., he was declared dead. The post-mortem report did not reveal a definite reason as to the cause of death, however it was noted that the possibility of death due to Heart Pathology following COVID-19 cannot be ruled out.

iii. *Renjith R v. Union of India & Ors.* in *W.P.(C) No. 13487/2022* before Kerala High Court

Petitioner's wife Mahima aged 31 years, received the vaccine on 06.08.2021 and passed away on 20.08.2021. She was pregnant with twins at that time. She died of Thromobocytopenia. The cause of death as classified by the respondent was AEFI.

iv. *Jean George v. Serum Institute of India Limited & Ors.* in *W.P. (C) No. 13573/2022* before Kerala High Court

Nova Sabu, aged 19 years, was the only daughter of the petitioner. She took the vaccine on 28.07.2021. She passed away on 12.08.2021. The cause of her death as mentioned in the post-mortem report was 'intra cranial bleeding of brain'. She had no history of neurological illness.

v. *Rajagopalan K v. Union of India & Ors.* in *W.P. (C) No. 11276/2022* before Kerala High Court

Petitioner took the first dose of vaccine on 08.02.2021. Following that, he developed fever and his situation worsened. He was ultimately diagnosed with limbic encephalitis along with 'systematic inflammatory state in the form of deranged coagulation parameter. It was diagnosed as a probable auto immune encephalitis following post COVID-19 vaccination.

vi. *Ginu G Kumar v. Serum Institute of India Ltd. & Ors*. in *W.P.(C) No. 35180/2022* before Kerala High Court

Petitioner's wife, aged 37 years, was vaccinated on 02.08.2021. She was declared dead on 23.08.2021 and the cause of her death was 'intra cerebral haemorrhage'. The medical report revealed she had thrombosis with thrombocytopenia syndrome, which is a complication of Covishield vaccine, although rare.

vii. *Ansaria AK v. Union of India & Ors.* in *W.P. (C) No. 37055/2022* before Kerala High Court

Petitioner's husband took the vaccine on 13.03.2021. He developed a high fever after that and the doctors could not pinpoint the exact cause for the problem. He eventually suffered from paralysis. Neurologist's report arrived at the conclusion that patient had been paralyzed due to the administration of Covishield vaccine.

viii. *Narayan`an MV & Anr. v. Serum Institute of India Ltd. & Ors.* in *W.P. (C) No. 38691/2022* before Kerala High Court

Petitioner's elder daughter, aged 18 years, received the vaccine on 26.10.2021. She developed a mild fever and continuous headache following it. She was admitted to the hospital. She ultimately passed away on 06.11.2021. Thrombotic Thrombocytopenia was identified as the cause of her death.

8. It is in this factual and procedural backdrop that the Court is called upon to examine the legality and propriety of the interim directions issued by the Kerala High Court, as well as the extent to which judicial intervention is warranted in matters touching upon adverse events following immunization, compensation, and public health policy.

Submissions

9. The submissions advanced on behalf of the appellants are summarised hereunder.

9.1 Learned counsel for the appellants have argued at length highlighting the Union Government's failure to ensure transparency, informed consent and postvaccination surveillance, thereby constituting a violation of Article 21 of the Constitution. They allege that deaths caused after the administration of COVID-19 vaccines expose structural defects in India's vaccine governance regime.

9.2 It is submitted that the respondents' contention that vaccination was entirely voluntary is incorrect. According to them, public communication and administrative measures created an atmosphere of effective compulsion. It is urged that restrictions were imposed upon unvaccinated individuals, including limitations on travel and access to certain public spaces and services, thereby pressuring citizens to undergo vaccination irrespective of their autonomy or informed consent.

9.3 Appellants contend that a significant body of scientific evidence had emerged linking AstraZeneca vaccine, of which Covishield is a version, to fatal blood clotting disorders (VITT/TTS). By March-April 2021, around 18 European countries had suspended or restricted its administration, limiting its use to older age groups due to multiple vaccine-induced deaths. It is alleged that the Government, despite having exclusive possession of facts essential for decision making, did not either publish causality assessments or maintain a publicly accessible portal, which is in clear violation of the expectation recorded by this Court in *Jacob Puliyel v. Union of India*. This control by the Government over AEFI data, combined with non-disclosure of serious adverse events, deprived citizens of information crucial to make an informed decision.

9.4 The appellants further allege that, despite possessing relevant information regarding potential adverse effects, the respondents failed in their duty to adequately warn users, caregivers, and the medical community about known serious side effects. It is specifically contended that the Drug Controller General of India publicly stated on 04.01.2021 that the vaccines were "110% safe," which, according to the appellants, contributed to a false sense of absolute safety and undermined informed consent.

9.5 They ultimately highlight that the non-disclosure of voluntariness, lack of truthful risk communication, investigative lapses in monitoring AEFI, denial of access to medical records, absence of diagnostic protocols and non-publication of causality assessments has led to the violation of Articles 14, 19(1)(a) and 21 of the Constitution. It was argued that many individuals had lost their lives, and many families their sole breadwinners. For the large number of similarly placed vaccine-injured citizens, it was submitted, formation of a policy which ensures grant of fair and timely compensation would secure a life of dignity.

10. Per contra, leaned counsel for the respondents have strongly opposed the submissions made on behalf of the appellants and made the following submissions:

10.1 That the safety of COVID-19 vaccines and their regulatory approval was in accordance with the statutory procedure prescribed under the law and the same was examined in detail by this Court in *Jacob Puliyel.* The vaccine was given marketing approval by the CDSCO (Central Drugs Standard Control Organisation). Following that, NTAGI (National Technical Advisory Group of Immunization), which is the apex advisory body on immunization, compiled the scientific evidence on the vaccine, and the same was sent to the COVID-19 Working Group. In order to oversee all aspects of vaccine administration, the Government constituted the National Expert Group on Vaccine

Administration for COVID-19 (NEGVAC), which provided the final layer of expert review for recommendations related to the vaccine. This is a testament to the fact that the vaccines have gone through a rigorous regulatory approval process with multifarious approval processes including reviews by independent experts. They also averred that this Court has found the approval of COVID-19 vaccines to be in accordance with law.

10.2 That the system of AEFI surveillance, monitoring and investigation is administered by leading scientific and medical experts. The AEFI Committees are created at the State and Central level to provide guidance to the program and carry out documentation, investigation and causality assessment. An AEFI can be reported by any person, on the CoWIN portal or otherwise to the District Immunization Officer (DIO). For all severe and serious AEFI cases, causality assessment is conducted by trained medical experts of the State or National AEFI Committee. It was also submitted that considering the novel nature of the virus, the Committee was expanded to include cardiologists, neurologists, respiratory medicine specialists and other medical specialists. With respect to the causality assessment, it was submitted that result of the same was made public and was available on the website of Ministry of Health and Family Welfare (MoHFW). The Operational Guidelines shared with the States and the Union Territories clearly recommended that the vaccine beneficiaries should be informed about the benefits and side-effects alike. Posters with information on the risks involved were also prepared in English and Hindi, which were to be displayed in all vaccination centres across the country.

10.3 That the occurrences of Thromboemolic events (TTS), which were identified as an AEFI, were very miniscule. It was submitted that in India, as compared to other European countries, occurrence of TTS was a rare event since different populations react differently to different vaccines due to genetic variations. In India, the reporting rate of TTS was 0.001 per one lakh doses, making it an extremely rare occurrence. It was further submitted that the existing mechanism for monitoring, investigation and analysis of AEFIs is adequate, effective and transparent. It was strongly urged that if an independent review of AEFI is allowed, then that would plant a seed of doubt in the existing regulatory system and harm public interest.

10.4 That a claim for compensation for an AEFI related death does not lie under writ jurisdiction. It was contended that a claim can be made at two stages- first, during the clinical trial stage, where the vaccine manufacturer is under a legal obligation to provide treatment to the trial participant in case of an injury or death; second, at the vaccine administration stage, in case of an untoward incident, appropriate remedies are available in law to the vaccine beneficiary or their family. This includes approaching consumer courts seeking damages for negligence, malfeasance or misfeasance, which is determined on a day-to-day basis. It was brought to our attention that unlike other countries where vaccine manufacturers have legal immunity from such claims, the manufacturers here do not have any legal immunity whatsoever. Therefore, all those aggrieved can approach the consumer courts and pursue their claims.

Issues

11. Having heard the learned counsel for the parties at length and examined the submissions placed on record, the broad issues that have arisen for our determination are as follows:

i. Whether the absence of a uniform policy governing compensation in cases of death or injury following administration of COVID-19 vaccination results in violation of Right to Life protected under the Constitution?

ii. If yes, can this Court direct the respondents to frame a policy in that regard?

Analysis

12. At the outset, we would like to reiterate that the petitions before us raise serious questions of violation of fundamental rights, more particularly that of right to life. The respondent Union of India has urged that the questions raised by the appellants traverse into a realm of scientific inquiry, and that the individuals aggrieved by the adverse outcomes have the door of private remedies open for them. The Court is conscious that questions of public health, governance, vaccine approval and element of causality involve complex technical considerations, and that the constitutional courts must exercise appropriate restraint in domains entrusted exclusively for determination by the executive branch.

13. At the same time, a closer look at the petitions reveals that the question is not just confined to the adjudication of individual cases. The grievance here is much deeper, namely, that families alleging grave harm during the course of State-led vaccination program are left without any uniform remedy to seek redressal.

Extension of the Right to Health

14. It is well settled that Article 21 is not limited to protection against unlawful deprivation; of life, but also includes within its ambit a wide range of other rights that facilitate the smooth operation of right to life. Right to health and bodily integrity, is one such right. This Court has not shied away from upholding this constitutional idea and recognizing that the State bears a positive obligation to safeguard health of its people and ensure conditions necessary for meaningful enjoyment of life.

15. In the aftermath of the unfortunate Bhopal Gas Tragedy, this Court had expressed its anguish at the plight of the affected persons and noted the absence of a coordinated and effective effort to provide timely care and redress to them. It was noted:

"*9. It is indeed a matter for national introspection that public response to this great tragedy which affected a large number of poor and helpless persons limited itself to the expression of understandable anger against the industrial enterprise but did not channel itself in any effort to put together a public supported relief fund so that the victims were not left in distress, till the final decision in the litigation."*

10. This Court, considered it a compelling duty, both judicial and humane, to secure immediate relief to the victims. In doing so, the court did not enter upon any forbidden ground. Indeed, efforts had earlier been made in this direction by Judge Keenan in the United States and by the learned District Judge at Bhopal. What this court did was in continuation of what had already been initiated."[1]

16. The jurisprudence of this Court has progressively evolved from recognising the right to health as a facet of the right to life under Article 21 in ***Parmanand Katara v. Union of India***[2] to emphasising the positive duty of the State to act as provider, facilitator, and regulator in all aspects of healthcare. In ***State of Punjab v. Mohinder Singh Chawla***,[3] this Court had reiterated that "*it is now settled law that right to health is integral to the right to life. Government has a constitutional obligation to provide health facilities*." Again, **in *State of Punjab* v. *Ram Lubhaya Bagga,***[4] this Court observed that "*the State can neither*

[1] Union Carbide Corpn. v. Union of India, (1989) 3 SCC 38.
[2] (1995) 3 SCC 248.
[3] (1997) 2 SCC 83.
[4] (1998) 4 SCC 117.

urge nor say that it has no obligation to provide medical facility. If that were so, it would be ex facie violative of Article 21".

17. The Court therefore approaches the present proceedings with the limited objective of examining, whether in the exceptional context of a pandemic response, the absence of any structured framework to address serious adverse events raise constitutional concerns warranting an institutional response. In doing so, we reiterate that we are neither adjudicating upon the vaccine efficacy nor sitting in scientific review over the regulatory approval process. The question is confined to whether the State's welfare obligations require the exploration of an equitable mechanism of redressal for harm arisen in the course of a national public health intervention.

18. This Court in ***Distribution of Essential Supplies and Services*** During ***Pandemic, In re***[5] specifically talked about special duty cast on the executive in times of emergency such as this and the subsequent duty of the Court in ensuring that the executive acts within the constitutional boundaries. The relevant portion is extracted below:

"*16. Similarly, courts across the globe have responded to constitutional challenges to executive policies that have directly or indirectly violated rights and liberties of citizens. Courts have often reiterated the expertise of the executive in managing a public health crisis, but have also warned against arbitrary and irrational policies being excused in the garb of the "wide latitude" to the executive that is necessitated to battle a pandemic. This Court in Gujarat Mazdoor Sabha vs State of Gujarat,*[6] *albeit while speaking in the context of labour rights, had noted that policies to counteract a pandemic must continue to be evaluated from a threshold of proportionality to determine if they, inter alia, have a rational connection with the object that is sought to be achieved and are necessary to achieve them."*

19. This Court does not proceed on the premise that the regulatory approval process or the vaccination programme was unlawful or deficient. The measures were undertaken in extraordinary circumstances with the objective of protecting public health. As submitted by the respondents, this has already been dealt with by the Court in ***Jacob Puliyel v. Union of India.***[7] The relevant portion is extracted below:

"***117.*** *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.*

118. *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."*

20. However, the Constitution does not view the right to life solely through the lens of fault. Article 21 also embodies a positive obligation of the State to ensure that where grave harm is alleged to have occurred in the course of a Stateled public health intervention, affected families are not left without any accessible mechanism of redress. The absence

[5] 2021 SCC OnLine SC 372
[6] AIR 2020 SC 4601, para 9.
[7] 2022 SCC OnLine SC 533

of such an institutional framework raises constitutional concerns which warrant a calibrated response.

21. The Union of India has submitted that question of causality between the vaccination and the resultant deaths involve scientific assessment. They also admit that such an assessment has been conducted by them and no relation has been found between the two. This Court in ***Jacob Puliyel*** did a detailed examination of the AEFI surveillance system in India and recorded the following:

*"**132.** 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 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 medical professionals concerned 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."*

22. It has come to our notice that extensive studies conducted by Indian Council of Medical Research (ICMR) and National Centre for Disease Control (NCDC) have affirmed that there is no direct link between the vaccines and sudden deaths caused thereafter. They have concluded that the vaccines are safe with extremely rare instances of side effects.[8] This court accords due weight to such scientific findings. At the same time, the expression 'Adverse Event Following Immunization' (AEFI), as recognized by the World Health Organization (WHO) denotes any untoward medical occurrence after vaccination which does not necessarily have a causal relationship with the vaccine itself.[9]

23. This Court does not consider it either feasible or appropriate, in a writ jurisdiction, to embark upon a scientific determination of causality in individual cases. Such questions are better left to be answered by domain experts. Nevertheless, the Court's inability to undertake scientific inquiry does not exhaust its constitutional enquiry.

24. The Constitution does not conceive of the State as a distant spectator to human suffering, but as an active guardian of welfare and dignity. The Directive Principles of State Policy illuminate this vision with clarity. Article 41 speaks of public assistance in cases of sickness and disablement, within the limits of State's capacity. Article 47 declares the improvement of public health to be among the State's primary duties.

25. The vaccination program undertaken during the pandemic was itself an expression of these constitutional commitments. The State went above and beyond in order to create

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[8] *Extensive studies by ICMR and AIIMS on sudden deaths among adults post COVID have conclusively established no linkage between COVID-19 vaccines and sudden deaths*, PRESS INFORMATION BUREAU, <https://www.mohfw.gov.in/?q=en/pressrelease/extensivestudies-icmr-and-aiims-sudden-deaths-among-adults-post-covidhave>.

[9] WORLD HEALTH ORGANIZATION, Causality Assessment of An Adverse Event Following Immunization, <https://iris.who.int/server/api/core/bitstreams/88d3e61d63e5-458c-8880-893f713226d1/content.>

a vaccination scheme and the same undoubtedly helped save many lives. But at the same time, as the government data itself suggests, it cannot be brushed aside that the same vaccines also led to loss of life. In such a situation, it is not appropriate that the State shrugs its responsibility in coming to aid to those affected families who have lost their near and dear ones.

26. The Union has urged that individuals aggrieved by adverse outcomes may seek remedies before civil courts or consumer fora on the grounds of negligence-based principles. While such remedies do exist, the Court is of the view that they are ill-suited as the only pathway of redress in the context of a mass immunization program. Vaccine injury claims raise questions where scientific attribution is often complex. To insist upon proof of negligence and fault in each case would impose an onerous burden upon affected families and would not be the best solution to those left affected. Further, a multiplicity of individual proceedings risks inconsistent outcomes and unequal access to relief, thereby undermining the guarantee of equality under Article 14.

27. In such a setting, the relationship between the individual and the State cannot be viewed through the prism of faultbased liability. Where the State undertakes an intervention of this scale in discharging of its duty to protect public health, the right to health under Article 21 would automatically extend to a corresponding obligation of institutional support in cases of grave outcomes, no matter how rare they are.

No-Fault Compensation

28. The principle of no-fault liability is not alien to Indian law. Section 164 of Motor Vehicles Act, 1988 stipulates a fixed liability of the owner even though the accident was caused without any fault of her own, subject to certain conditions. The rationale behind it is simple- certain categories of harm require swift relief without prolonged inquiry into fault.

29. Even across the world in many jurisdictions, no-fault vaccine injury compensation scheme is a recognized feature of a welfare-state response. Some policies are listed below:

i. Australia, which did not have a no-fault vaccine injury compensation program already in place, introduced a comprehensive policy on COVID-19 vaccination compensation called the 'COVID-19 Vaccine Claims Scheme Policy 2021'. It lays out the basis on which the government may make a grant of financial assistance to a person who submits a claim for compensation. It covers losses or expenses arising from administration of a COVID-19 vaccine or an adverse effect which is recognized as vaccine-related. The scheme recognises graded categories of injury, including death, and provides structured compensation covering medical expenses, loss of earnings, dependency benefits, and funeral costs.

ii. Similarly, the United Kingdom, which already had a no-fault compensation scheme for vaccines, incorporated COVID-19 vaccines into the scheme from 31 December 2020. The scheme is administered by the NHS Business Services Authority and funded by the government. It covers vaccine recipients, their representatives, or estates at no cost to file claims.

iii. The World Health Organization's COVID-19 Vaccines Global Access (COVAX) initiative which covered low and middle-income countries also had a No-Fault Compensation Program which provided a lump sum compensation to eligible individuals who suffered from adverse events after receiving the vaccine distributed through the COVAX Facility till 30 June 2022.

iv. Japan had a no-fault compensation scheme for vaccine related injuries since 1976, and it added COVID-19 vaccines as 'temporary vaccinations' after a 2020 amendment. It covers a wide range of adverse reactions related to COVID-19 vaccines.

30. It is evident from the policies adopted internationally that Governments have acknowledged the need to address vaccine-related injuries through dedicated compensation mechanisms. Such programmes provide an expeditious and fair avenue of relief, obviating the necessity for affected persons to be relegated to the labyrinthine processes in order to secure enforcement of their claims.

31. In contrast, as matters stand today, India does not appear to have in place any uniform or structured policy mechanism to provide redress to individuals who suffer adverse effects following vaccination. This gap cannot be lightly overlooked, particularly when vaccination programmes are undertaken as public health measures under the aegis and authority of the State itself. The concern becomes all the more pressing in the context of the COVID-19 pandemic, where immunisation was carried out on an unprecedented scale as a collective societal necessity. In such a situation, the State cannot be heard to say that those who experience serious adverse consequences must fend for themselves, without any clear or accessible avenue of relief. The absence of a coherent framework, therefore, calls for timely intervention, lest the rights of such persons remain only theoretical and without meaningful enforcement.

32. It must also be acknowledged that, from the onset of the pandemic, efforts were undertaken at every level of governance to mitigate the impact of the pandemic. This Court, at the beginning took suo moto cognizance of the situation in ***Distribution of Essential Supplies and Services During Pandemic, In re*** [10] which led to the development of a national policy, the issues of oxygen supply, drugs, administration and pricing of vaccines were also adjudicated upon. Similarly in ***Gaurav Kumar Bansal v. Union of India in W.P.(C) No. 539/2021,*** this Court had directed the National Disaster Management Authority to frame appropriate guidelines for ex-gratia assistance to families of persons who died due to COVID-19. The Court recognized that while the design of the policy lies within the executive domain, the absence of any structured framework of relief in exceptional circumstances affecting life and dignity may warrant a limited institutional response.

33. That said, this Court has time and again also reiterated that the executive, which has been democratically elected by the people of the country and is accountable for its actions to them, is vested with the competence and authority to draft policies. But at the same time, this constitutionally protected separation of powers cannot in any scenario come in the way of Judiciary when the fundamental rights of its citizens are violated due to executive policies, or by lack of them, as in this case. In such circumstances, the constitutional duty of this Court to safeguard the rights of citizens cannot be eclipsed.

34. This Court, in *Jacob Puliyel*, underscored the responsibility of the State in monitoring adverse events following immunisation. In our considered view, that responsibility cannot end at surveillance alone, but must extend to providing fair compensation to those who suffered vaccine-related injury, in light of the discussion above.

35. In addition to this, to allay the concerns of the appellants regarding the inefficiency in monitoring AEFIs, we reiterate that the Union of India shall continue to ensure that surveillance of adverse events following immunisation (AEFI) is carried out through

[10] Supra note 5.

efficient monitoring mechanisms, and that relevant data is placed in the public domain in a transparent and timely manner. This is consistent with the observation of this Court in *Jacob Puliyel* which is produced hereinbelow:

*"**144.8.** 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."*

36. With respect to the issue regarding forming an independent expert board to look into the deaths caused, we are satisfied with the submissions made by the respondent that a framework already exists consisting of National and State AEFI Committees which investigate into the deaths and injuries caused after the administration of vaccines. As discussed before, this court is not sitting in a scientific inquiry into the question of causation. In our opinion, this mechanism is adequate and there is no need to conduct any independent inquiry into the individual cases of deaths. In the absence of any material indicating that such mechanisms are nonfunctional or incapable of performing their role, it would not be appropriate for this Court, in exercise of its writ jurisdiction, to constitute a parallel body to undertake individual medical determinations.

37. In view of the foregoing discussion, and having regard to the limited constitutional concerns which arose for consideration, the Union of India, through the Ministry of Health and Family Welfare is hereby directed to expeditiously formulate and place in the public domain an appropriate no-fault compensation framework to address serious adverse events following immunisation) arising in the context of COVID-19 vaccination.

Conclusion

38. In the end, the following directions are issued:

i. The Union of India shall, through the Ministry of Health and Family Welfare, frame a no-fault compensation policy for serious adverse events following COVID-19 vaccination.

ii. The existing mechanisms for monitoring adverse events following immunisation shall continue, and relevant data shall be periodically placed in the public domain in accordance with the observations in *Jacob Puliyel*.

iii. No separate court-appointed expert body is considered necessary in view of the existing mechanisms for scientific assessment of adverse events following immunisation.

iv. It is clarified that this judgment shall not preclude any person from pursuing such other remedies as may be available in law. Equally, the formulation of the nofault framework shall not be construed as an admission of liability or fault on the part of the Union of India or any authority.

39. Accordingly, the writ petition and other connected matters are disposed of.