

* **THE HIGH COURT OF DELHI AT NEW DELHI**

Pronounced on: October 14, 2015

+ W.P.(C) 6913/2015

JACOB PULIYEL Petitioner
Through: Mr.Prashant Bhushan with Ms.Nidhi
Rathi, Mr.Sudhakar T., Advs.

versus

UNION OF INDIA &ORS. Respondents
Through: Mr. Sanjay Jain, ASG with Mr.Kirtiman
Singh, C.G.S.C., Ms.Pallavi Shali,
Mr.Vidur Mohan, Ms. Prerna Shah Deo,
Advocates for Respondents No.1 & 2

CORAM:
HON'BLE THE CHIEF JUSTICE
HON'BLE MR. JUSTICE JAYANT NATH

J U D G E M E N T

G.ROHINI, CHIEF JUSTICE

1. This petition, by way of Public Interest Litigation, is filed seeking a direction to the respondents to provide complete data of the results of the Multi Centre Clinical Trial of 'Rotavirus' Vaccine done on infants.

2. It is pleaded by the petitioner, who is a Paediatrician working in St.Stephen's Hospital, Delhi, that a Paper has been published in the Journal 'Vaccine' of August, 2014 raising several questions about the efficacy and the risk associated with the 'rotavirus' vaccine on the basis of the findings of Clinical Trial conducted in three centres in India and that from the said Paper, he came to know that the number of cases of intussusceptions in the infants who were administered 'rotavirus' vaccine

in Vellore centre were the highest. The petitioner claims that there is a need for disclosure of the segregated data of Vellore Centre so as to ascertain whether a certain section of the population is more susceptible to adverse effects. It is also pleaded that though the petitioner made an application under the Right to Information Act seeking information about the number of cases of intussusceptions in clinical trials at Vellore, there was no response. It is further pleaded that he also addressed a letter dated 16.06.2015 to the Prime Minister's Office bringing to their notice that the vaccine has been licensed for general use without releasing the segregated data on the Clinical Trials. Alleging that despite several attempts, the data relating to Vellore centre is not being shared and that without disclosing the said data the respondents are proceeding to launch Phase-IV trial of the vaccine, the present petition is filed with the following prayer:

“(i) to direct the Department of Biotechnology, Ministry of Science and Technology and Ministry of Health and Family Welfare and the Christian Medical College, Vellore to provide complete segregated data on the clinical trial conducted in 3 centres, namely, Delhi, Pune and Vellore apart from the number of intussusceptions with rotavirus vaccine in the two year trial to the key stakeholders and the petitioner.

(ii) to restrain the respondents from conducting any further trial of rotavirus vaccine in India until the complete data is disclosed to the key stakeholders and the petitioner.

(iii) to frame guidelines regarding publication of complete and segregated research results in clinical trials on humans in accordance with the norms of WHO published in April, 2015 on the issue.”

3. We have heard Shri Prashant Bhushan, the learned counsel appearing for the petitioner as well as Shri Sanjay Jain, the learned ASG who appeared on advance notice on behalf of the respondents No.1 and 2.

4. It is submitted by Shri Prashant Bhushan that though Phase-III clinical trials of the 'rotavirus' vaccine started in 2011 by the Department of Biotechnology, Ministry of Science and Technology, Government of India at three centres, namely, Pune, Delhi and Vellore, it has now come to light that complete segregated data of different centres of clinical trial has not been disclosed. It is vehemently contended by the learned counsel that Phase-IV trial of vaccine, i.e., post marketing study cannot be allowed without providing evidence of safety from the trials already made in Vellore centre.

5. Shri Sanjay Jain, the learned ASG has brought to the notice of this Court that the vaccine in question has already been approved by the Government after a clinical trial about its efficacy and safety and that the same has also been reviewed by the Global Vaccine Safety Advisory Committee of WHO in June, 2014. Pointing out that the petitioner himself is a member of National Technical Advisory Group on Immunization (NTAGI), which is the highest technical advisory body in the country on immunization and that having been satisfied with the efficacy and safety of the vaccine in question, NTAGI recommended that the same be introduced in the National Immunization Programme for all Indian children, the learned ASG contended that the allegations made by the petitioner as to the efficacy and safety of the vaccine in question are without any basis and unwarranted and that the writ petition itself is misconceived. It is also brought to our notice by the learned ASG that on the basis of the recommendations of the New Drugs Advisory Committee (NDAC) recommending grant of new drug permission for the vaccine in question, the Drugs Controller General of India (DCGI) has granted the licence in January, 2014. It is also submitted by the learned ASG that the

Indian Academy of Paediatrics - Committee on Immunization had reviewed the entire data and recommended inclusion of the said vaccine into its childhood vaccination schedule.

6. It may, at the outset, be pointed out that the petitioner is a member of National Technical Advisory Group on Immunization (NTAGI). It is not disputed before us that NTAGI is the highest technical advisory body in the country on immunization. It is also not in dispute that NTAGI, on being satisfied about its efficacy and safety, has recommended to introduce the vaccine in question for National Immunization Programme. The learned counsel appearing for the petitioner could not dispute the fact that the entire segregated data on the clinical trial conducted in all the three centres was available with NTAGI before making its recommendation. That being so, we are unable to understand the purpose for which the petitioner is insisting on public disclosure of the segregated data. It is not the case of the petitioner that before allowing Phase-IV trial, public disclosure of segregated data is mandatory under the provisions of any statute. No case is made out even to show that such disclosure is necessary in public interest. In fact, it is admitted by the petitioner himself that the clinical trial report has already been cleared by NTAGI, the highest technical advisory body in the country on immunization and, thereafter, the vaccine was approved and licence was also granted by DGCI after reviewing the entire data on the clinical trials of the vaccine in question. In the circumstances, we do not find any substance in the contention of the petitioner that in the absence of the information about the number of cases of intussusceptions in clinical trial at one of the centres, the Government cannot be allowed to proceed to take up Phase-IV study of the vaccine. It also appears to us that the

prayer in the petition virtually amounts to questioning the correctness/authenticity of the recommendation made by NTAGI to which the petitioner himself is a member.

7. As held in *State of Uttaranchal Vs. Balwant Singh Chaufal*, **(2010) 3 SCC 402**, the courts should be *prima facie* satisfied regarding the correctness of the contents of the petition and that substantial public interest is involved before entertaining a PIL. The courts should also ensure that the PIL is aimed at redressal of genuine public harm or public injury and that there is no personal gain, private motive or oblique motive behind filing the public interest litigation.

8. As mentioned above, no case of violation of any statutory provision is made out in the present petition. No case is also made out to show that disclosure of the segregated data is essential in public interest. We, therefore, find substance in the submission of the learned ASG that the petition is misconceived and motivated with private interest.

9. For the aforesaid reasons, the petition does not deserve to be taken cognizance as a Public Interest Litigation.

10. Accordingly, the writ petition is dismissed. No costs.

CHIEF JUSTICE

JAYANT NATH, J

OCTOBER 14, 2015

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