IN THE SUPREME COURT OF INDIA

CIVIL ORIGINAL JURISDICTION

WRIT PETITION (CIVIL) NO. OF 2016

PUBLIC INTEREST LITIGATION

IN THE MATTER OF:

S.Srinivasan …… Petitioners

Versus

Union of India …… Respondent

REJOINDER AFFIDAVIT ON BEHALF OF THE PETITIONER

I, S.Srinivasan, aged years, S/o Shri , Managing Trustee of LOCOST (Low Cost Standard Therapeutics), Vadodara, (INSERT PINCODE) Gujarat, presently at New Delhi do hereby solemnly state and affirm as under:

1. That I am the Petitioner in the aforementioned writ petition and being familiar with the facts and circumstances of the case, I am competent and fully authorized to swear this Affidavit.

2. The petitioner herein has filed the instant writ petition in public interest under Article 32 of the Constitution of India for the enforcement of rights under Article 14 and 21 of the citizens seeking a writ directing the respondents to make public the segregated data (center-wise results) of the Rotavac clinical trial (phase III) that was conducted on 6799 infants at three centres namely Delhi, Pune and Vellore between 2011-2013 to gauge the safety and efficacy of the said vaccine.

3. The segregated data is crucial to know if the vaccine is safe in all areas or if some groups are more susceptible to adverse events from

the vaccine. The very raison d'etre of such multicenter trials is to compare results among centers. This data should have been examined by the National Technical Advisory Group on Immunization (NTAGI) in public interest but such is the secrecy surrounding it, it has not been provided even to this apex body.

4. The instant petition is asking for the data to be provided to the petitioner or made available in the public domain. The petitioner has so far not cast aspersions on the efficacy of the said vaccine but is only asking for complete segregated data to be provided.

5. The Union of India (Respondent No.1) in their affidavit has repeatedly asserted that various bodies have looked at the vaccine data and have cleared it as safe and efficacious. The petitioner submits that the same is only a half-truth because the Subject Expert Committee and the NTAGI were not provided the said data on vaccine safety at Vellore and the counter affidavit itself bears testimony to this.

6. Further more the Union of India that the Data Safety Monitoring Board (DSMB) merely monitors the trial in progress deciding whether to terminate a trial prematurely. Once the trial is complete the role of the DSMB is complete. The vaccine is evaluated finally after the trial is complete and the DSMB plays no role here. It is a half truth to say the DSMB approved the vaccine as safe.

7. In the same way the Intussusception Case Adjudicating Committee looks at each case of intussusception reported during the trial This committee is blinded to whether the particular case of intussusception had received the vaccine or was the child who received the dummy vaccine as control. The Union of India is misleading the court by suggesting that this committee can vouch for the safety of the vaccine.

8. The Drug Controller, the NTAGI and the SEC are the only committees who could have looked at the safety of the vaccine. Of these three we know that the data has not been shared with the NTAGI nor with the SEC.

9. The petitioner submits that the Subject Expert Committee (SEC) was asked by the PMO to look at the Vellore intussusception data in response to the Letter sent to the PMO in this regard by a member of NTAGI. The minutes of the meeting of the SEC specifically state that the Vellore data was not looked at. The SEC stated it was waiting for an order from the Delhi High Court to look at the data (which the PMO had specifically asked them to examine). The minutes of the meeting of the SEC is provided in the accompanying writ petition.

10. In their counter affidavit, the respondents state that the National Technical Advisory Group on Immunization (NTAGI) set up by the Government to advise it on safety and efficacy of vaccines and immunization approved the drug. The respondents also state that one member of the NTAGI, Dr Jacob Puliyel had objected to the approval by NTAGI without the NTAGI being shown the data from Vellore.

11. The counter affidavit says about the NTAGI meeting:

"No one raised concerns about the safety and efficacy of Rota vac other than Dr Jacob Puliyel who is himself is a member of the NTAGI."

It is clear that the expert committee member of the Government of India on the NTAGI Dr Jacob Puliyel raised the issue of the absence of the segregated data. It seems to be implied in the counter affidavit that he (Dr Puliyel) was not supposed to ask questions but to pass the vaccine *because* he was a member of the NTAGI.

12. As per its own affidavit on page 22 this particular trial was only powered for efficacy and not for safety of the vaccine. Yet in their counter affidavit, the respondents have listed names of a number of organisations which have approved the safety of the drug. The petitioner submits that all these agencies had approved the safety where there was no data that suggested the vaccine was safe (study was not powered to look at safety). The organisations mentioned should not have pronounced a vaccine safe knowing the study was too small and not powered to look for safety of the vaccine. Other organizations and experts on the issue such as NTAGI and SEC were not even provided with segregated data in order for them to approve it or disapprove it.

13. The respondents also state that the study has been “published in large number of journals and approved to be safe.” The petitioner submits that this assertion is misleading and only a half-truth because no safety approval is ever given by journals that publish scientific articles. The petitioner states that the segregated Vellore data requested is not provided in any of the journals quoted in the counter affidavit.

14. The respondents in their counter affidavit state that Writ Petition (Civil) No. 6913 of 2015 has already been dismissed on the ground that the petition was misconceived and motivated with private interest and the petition does not deserve to be taken cognizance as a PIL. The counter also states that the petitioner herein is trying to mislead the Hon’ble Supreme Court of India and obstruct the functioning of the Government of India. In this regard it is submitted that the petitioner in

the present petition has not filed any other petition about Rotavirus vaccine in any other court. In fact, it was a member of NTAGI itself who had filed a petition in High Court and an SLP in Supreme Court in this regard.

15. The respondents have failed to mention that in the said Writ Petition (Civil) No. 6913 of 2015 before the Hon'ble High Court of Delhi, the Hon'ble Court was made to believe by the respondents, that the Vellore data was given to NTAGI including the petitioner therein as a member of NTAGI, whereas no data was provided to him even after his requests for the same.

16. The petitioner submits that aggrieved by the final order/judgment dated 14.10.2015 of the Hon'ble High Court of Delhi, the same petitioner filed an SLP (Civil) No. 2532 of 2016 before this Hon'ble Court. The petitioner submits that the said SLP was dismissed as withdrawn only on the ground that the petitioner therein was a member of NTAGI and therefore could not file a PIL. This Hon'ble Court in its order dated 05.02.2016 stated the following:

> *"Learned counsel for the petitioner seeks leave to withdraw this petition. This petitioner cannot maintain a petition in public interest since he was a member of the National Technical Advisory Group on Immunization which recommended the introduction of the vaccine in question.*
>
> *Leave to withdraw is granted.*
>
> *The special leave petition is dismissed as withdrawn.*
>
> *All questions are left open."*

17. The respondents have further stated that petitioner's assertion that intussusception in Vellore is more than 20 times that in Delhi is false.

The respondents have stated: "The paper said overall incidence of intussusception identified on ultrasound was 28/100,000 child year in Delhi and 581/100,000 in Vellore, 50% resolved spontaneously. So the assertion that Vellore data is almost 20 times rate in Delhi is false/ misleading/incorrect. The petitioner submits that just because 50% of the cases of intussusception got resolved, it does not imply that intussusception did not occur. The intussusceptions were all proved on ultrasound examination. .

18. The respondents have admitted in their counter affidavit that the number of infants who had intussusception diagnosed on ultrasound in Vellore was 581 and in Delhi it was 20. It is clear that Vellore incidence is more than 20 times that in Delhi. Even if one were to assume that half of the infants recovered without treatment, and the Union of India wants to count only the 50% that did not resolve by itself, it means there were 290 unresolved intussusceptions in Vellore and 10 in Delhi. Even looking at it this way, the number of intussusceptions in Vellore is more than 20 times that in Delhi.

19. The petitioner submits that in whichever way one looks at the data, the assertion made in the petition that Vellore data is almost 20 times rate in Delhi is not false or misleading or incorrect.

20. The respondents have further stated in the counter that the vaccine has been introduced in 4 states and there have been no intussusceptions in 982961 cases vaccinated. The counter-affidavit also says in para 7 that the India background rate is 19 cases per 100,000 or 1 case per 5263 children in the general population, even if no vaccine is given.

21. Given this background rate, even without vaccination there would be 186 cases of intussusception even if vaccination did not increase the number of intussusceptions. The respondents assertion that out of

982961 cases vaccinated, there were no cases of intussusception following rotavirus vaccination when 186 at least should have been detected based on the background rate itself is proof of the desultory way data is being collected. This is exactly what the petitioner fears. There is clearly very poor reporting if 186 cases which would have happened as background rate is clearly missed. Thus it is very clear that no reliance can be placed in the Governments assertion that the vaccine has not increased the intussusception rate where it has not managed to capture even the background intussusception rate. The petitioner submits that there are no controls against which intussusception in the vaccinated can be compared. This is clearly an exercise to whitewash the serious adverse events associated with the vaccine.

22. The present so called study with no controls looks at intussusception in a small window period which has no real scientific basis. *The counter affidavit states (page 25), that vaccine attributable cases are expected to occur within first week following vaccination*

23. The counter -affidavit says on Page 5 that the WHO has opined that Vaccine attributable cases expected to occur in first week following vaccination. This is an empty 'opinion' not based on clear empirical evidence.

24. The protocol of trial for which the petitioner is seeking data on the other hand has well selected Controls (who were not given vaccination and demonstrates the background rate) to look at intussusception for 2 years. It cannot be changed later to look for intussusception in 1 week.

25. The petitioner submits that in the original Rotashield trial (a vaccine that was licensed but then withdrawn due to intussusception) there were 3 additional cases of intussusceptions in the 10,000 vaccinated

and these were within 7 weeks of immunization. A copy of the paper on the same issue is annexed herewith as **Annexure P1 (pages_____to_____)**. (Reference https://web.stanford.edu/~siegelr/ShadmanRotashieldPaper.pdf*). The 1 week window is clearly deceptive and seems designed to cover up all the cases of intussusception caused by the vaccine*

26. The petitioner submits that the new so called surveillance cannot be trusted. There is a need to make public the data obtained in a well conducted randomised controlled trial. The data already obtained ought to be shared with the public whose children are to be vaccinated. If there is no risk from the vaccine the public would feel confident to take the vaccine. Concealing the data even from the expert bodies makes the public very suspicious.

27. Petitioner submits that non-disclosure of such important data violates the basic ethics of clinical research. Parents trustingly allow their babies to be experimented on. If the trial shows serious, statistically significant increase in risk of a potentially fatal complication, it will be unethical to further test the drug without informing the volunteering parents of the risks that the trial has already shown.

28. The petitioner seeks a direction from the Hon'ble Court that as the lives of innocent children could be at risk, the data requested should be provided in accordance with the 'WHO Statement on Public Disclosure of Clinical Trial Results' released on 14.04.2015 and the Declaration of Helsinki, which states unequivocally that ""Researchers have a duty to make publicly available the results of their research .... Negative and inconclusive as well as positive results must be published or otherwise made publicly available".

DEPONENT

VERIFICATION:

I, the above named Deponent, do hereby verify that the contents of the above Affidavit are true and correct to my knowledge; that no part of it is false and that nothing material has been concealed therefrom.

Verified at New Delhi on this day of October 2016.

DEPONENT