IN THE SUPREME COURT OF INDIA

(CIVIL ORIGINAL JURISDICTION)

WRIT PETITION (CIVIL) NO._____ OF 2016

(PUBLIC INTEREST LITIGATION)

IN THE MATTER OF:

S. SRINIVASAN … PETITIONER

VERSUS

UNION OF INDIA & OTHERS ... RESPONDENTS

PAPERBOOK

(KINDLY SEE INSIDE FOR INDEX)

ADVOCATE FOR THE PETITIONER**: PRASHANT BHUSHAN**

SYNOPSIS AND LIST OF DATES

The petitioner herein is filing 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. The petitioner at this stage is not casting aspersions on the efficacy of the said vaccine but is only asking for complete segregated data to be provided. 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. The instant petition is asking for the data to be provided to the petitioner or made available in the public domain.

Facts of the Case

On 26th March 2016, the Ministry of Health officially launched Rotavirus vaccine to combat deaths in infants caused due to diarrhea. Before the launch of the vaccine, a clinical trial (phase III) was conducted between 2011 and 2013 at three centres namely Delhi, Pune and Vellore to gauge the efficacy and safety of the said vaccine. Under this clinical trial, 6799 infants were administered the said vaccine to ensure its safety in terms of the number of intussusceptions in the 2-year trial period. Intussusceptions are intestinal obstructions that may need an urgent surgery to prevent death among infants, and is diagnosed by ultra sound examination. The trial was done as per protocol to test the risk of this potentially fatal side-effect of the vaccine over an observation period of 2 years. Multiple trial sites were

included to ensure different geographic areas to include a wider range of population groups with allows comparison of results among centers and increases the generizability of the study..

The aggregated results of the study published in UK Journal “Vaccine” issue dated August, 2014 raised certain questions about the efficacy of the vaccine and the risks associated with it. Through these aggregated results, an expert member of the National Technical Advisory Group on Immunization (NTAGI), which is the apex advisory body of the Government of India on immunization, Dr. Jacob Puliyel deduced that the number of cases of intussusceptions in the infants who were administered ‘rotavirus’ vaccine in Vellore centre were the highest and there was a huge difference in the number of cases of intussusceptions between result in Delhi and Vellore. As a member of NTAGI, Dr. Puliyel considered it his duty to study the segregated results of the clinical trial data from all the three centres to ascertain if a certain population was more susceptible to the side effects of the said vaccine. However, the respondents did not publish the centre-wise results of the said trial.

In his capacity as the member of NTAGI, Dr. Puliyel repeatedly made requests for the said results but the results were not provided to him. Dr. Puliyel made several representations to the Director, CMC Vellore requesting for the data for Vellore limb of the study. His request was not acceded to. He also wrote to the NTAGI by writing emails addressed to Dr. Vijaya Raghavan, Chairperson of Standing Technical Sub-Committee (STSC) of NTAGI (and copying to all members of NTAGI) requesting for the disaggregated data from Vellore in the format provided by him as a member of NTAGI. However, the results from Vellore were not provided.

It is submitted that not providing complete results of clinical trials involving human beings is in violation of ethics of medical research and global norms governing clinical trials. Raising this issue, journal

Vaccine published a detailed letter dated 06.10.2014 asking for segregated centre-wise results of the clinical trial to be published. As a result of the letter many newspapers through their science correspondents tried to get the information directly from the Principal Investigator but the respondents did not provide the said data from the three centres.

In the mean time, an NGO also filed an RTI application seeking information on a.) the number of cases of intussusceptions diagnosed as 'Possible intussusception' (meaning exhibiting clinical evidence of intussusception diagnosed by the trial doctor as described in the study protocol) and numbers with ultrasound evidence of intussusception in the 1000 infants given the rotavirus vaccine in Vellore limb of study over the period of 2 years and, b.) what is the corresponding figure for the 500 who were placebo recipients. But no reply was given to the RTI application by the respondents.

In response to Dr. Puliyel letter to the Prime Minister dated 16.06.2015, the Prime Minister's Office made a request to the Subject Expert's Committee to look at the data from Vellore. As per the minutes of the meetings of SEC dated 29.07.2015, the same has not yet been complied with. This shows that not only the NTAGI but even the Subjects Expert Committee has not examined the Vellore data even after a reference for the same by the PMO.

Why is it important to disclose centre-wise data

The petitioner submits that there is a need for disclosure of the segregated data of Vellore Centre in order to ascertain whether a certain section of the population is more susceptible to adverse effects. This was the very objective of the multi-centre clinical trial. So far the respondents have shown complete secrecy in the matter and have not disclosed segregated (meaning dis-aggregated) data from all the centres and have only released aggregated data i.e. the results of all three centres clubbed together. Concealing of this vital data does

severe injustice to the thousands of infants who participated in this study, the researchers who painstakingly conducted the trials and the medical/scientific community who depend on this data for their work. It is even more crucial to study the segregated data because the respondents have now launched the vaccine in 4 states in the country where lakhs of infants might be administered the vaccine. It is submitted that informed consent requires the disclosure of safety data, and it would be unethical to proceed with immunisation without informing the public of any risks observed with previous use of the vaccine, and not informing them what adverse effects to look out for.

Earlier Petition seeking the same relief

Aggrieved by the attitude and callousness on the part of the respondents, Dr. Jacob Puliyel filed Writ Petition No.6913 of 2015 before the Hon'ble High Court of Delhi praying for the ethical disclosure of the disaggregated data of all the centres where the study was conducted. In the said matter, *Vide* order dated 14.10.2015, the Hon'ble High Court had dismissed the said writ petition on the ground that segregated trial result of all the three centres was available with the National Technical Advisory Group on Immunization (NTAGI) of which the petitioner is a member and that it was on the basis of this data that the NTAGI approved the said vaccine.

The Hon'ble High Court failed to appreciate the fact that the segregated results of the clinical trial were not made available to members of the NTAGI in spite of written requests for the same by Dr. Puliyel. Aggrieved by the order, Dr. Puliyel was constrained to filed an SLP (Civil) No.2532 of 2016 against the Order dated 14.10.2015 of the Hon'ble High Court of Delhi. On 05.02.2016 the Hon'ble Court while keeping all questions open expressed its inability to entertain the said SLP on the ground that the petitioner therein, who was a member of the NTAGI, cannot maintain a public interest petition. The Hon'ble Court in the said order dated 05.02.2016 in SLP (C) No.2532 of 2016 stated as under:

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.

Therefore, the petitioner herein has filed the instant writ petition espousing the same cause of ethical and complete disclosure of clinical trial conducted on human beings. Since the High Court has already expressed its views in the matter, the petitioner herein seeks the intervention of this Hon'ble Court to set aside the Order dated 14.10.2015 of the High Court of Delhi and to direct the respondents to disclose and publish the segregated results of the clinical trial of Rotavac vaccine conducted on 6799 infants in the period between 2011-2013 at Delhi, Pune and Vellore. The petitioner also seeks an interim direction that the segregated results from all the three centres be placed before the NTAGI, which is the expert body on immunization policy, for examination and scrutiny.

List of Dates

Dates	**Events**
11.03.2011	Department of Biotechnology, Ministry of Science and Technology, Government of India conducted a Phase III randomized, double-blind, placebo-controlled trial, hereinafter "the clinical trial", of 116E rotavirus vaccine. The study was conducted at three centres namely Pune, Delhi and Vellore.
October 2013	Revised version of Declaration of Helsinki is adopted which states that *"Every research study involving human subjects must be registered in a publicly accessible database before recruitment of the first subject."* and 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”.

05.11.2013 The above mentioned clinical trial was completed.

March 2014 *Lancet* published a paper on the said study. However the paper did not provide segregated data for different centres of the clinical trial.

August 2014 Questions about the efficacy and the risk associated with the rotavirus vaccine were raised in a paper authored by John and colleagues published in journal *Vaccine* titled *‘Active surveillance for intussusception in a phase III efficacy trial of an oral mono-valent rotavirus vaccine in India’*

06.10.2014 The *Vaccine* published a detailed letter dated 06.10.2014 asking for this data to be published but the Principal Investigator has not responded to this scientific appeal. March 2015 The Prime Minister launched Rotavirus vaccine Rotavac, developed by Hyderabad-based Bharat Biotech. The said vaccine has been ostensibly approved by the government after a clinical trial conducted to gauge its efficacy and safety

14.04.2015 World Health Organization (WHO) released a strong statement advocating for public disclosure of all clinical trial results. According to it, when data is not released it means that doctors, patients and medical regulators cannot make informed decisions about which treatments are best. Non-disclosure of complete clinical trial results means that hundreds of thousands of patients have volunteered to take part in clinical trials where results have been kept hidden or are only selectively disclosed.

12.05.2015	One of the largest online campaigning communities called Avaaz.org starts a campaign requesting the Director, CMC Vellore to release the clinical trial data. As of now campaign has 442 signatories from the world over but no response has been received so far from CMC Vellore. The online petition can be accessed at: *https://secure.avaaz.org/en/petition/To_The_Director_Christian_Medical_College_Vellore_632004_Release_Indian_Rotavirus_Vaccine_Trial_Data/*.
21.05.2015	Dr. Puliyel made representations to Mr. Sunil Chandy, Director of CMC Vellore requesting the for the data for Vellore limb of the study. His request was not acceded to.
26.05.2015	An NGO filed an RTI application seeking information on the number of cases of intussusceptions in Vellore limb of study. No response has been received for the same.
28.05.2015	Dr. Puliyel, as a member of NTAGI wrote a letter to Dr. Vijaya Raghavan, Chairperson of Standing Technical Sub-Committee (STSC), NTAGI and copied to all members of NTAGI requesting for the disaggregated data from Vellore in the format provided by him as a member of NTAGI on or before the meeting of the STSC that was scheduled for June 10. However, his request was not acceded to.
30.05.2015	The Hindu published an article stating that the Government now plans to study the vaccine in 100,000 infants, without providing evidence of safety in the 1000 children already studied in Vellore.
16.06.2015	Dr. Puliyel wrote letter to the Prime Minister apprising him of the situation and requesting him to enquire into the matter.

22.06.2015	The Prime Minister's Office (PMO) made a reference (PMO ID No. 4219998//2015 dated 22.06.2015) forwarding the concerns over the SAE of intussusception in children in recently launched indigenous Rotavirus vaccine (Rotavac).
07.2015	Writ Petition (Civil) No. 6913 of 2015 was filed at the Hon'ble High Court of Delhi praying for the segregated trial research from all the three centres.
29.07.2015	Minutes of the Meeting of Subject Expert Committee (SEC) – Vaccine show that even after the PMO reference dated 22.06.2015, the SEC did not review the data with respect to Vellore limb of the study and gave its opinion based on the already published data in the journal *Vaccine.*
14.10.2015	The Hon'ble High Court of Delhi dismissed Dr. Puliyel's petition on the ground that the entire data was in fact available with NTAGI despite the fact that the petitioner therein was himself a member of NTAGI and was never provided the disaggregated data.
12.01.2016	Dr. Puliyel thereafter preferred SLP (C) 2532 of 2016 against the impugned order dated 14.10.2015 of the division bench of the Hon'ble High Court of Delhi at New Delhi.
05.02.2016	The Hon'ble Court in SLP (C) 2532 of 2016 stated its inability to entertain the said SLP on the ground that the petitioner therein, who was a member of the NTAGI, cannot maintain a public interest petition. The Hon'ble Court in its order dated 05.02.2016 in SLP (C) No. 2532 of 2016 stated as under: *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.

26.03.2016	Rotavac vaccine is launched in four states in the country with plans to include it in the Universal Immunization Policy of the government of India
23.04.2016	The petitioner herein Mr. S. Srinivasan files the instant Writ Petition

IN THE SUPREME COURT OF INDIA

CIVIL ORIGINAL JURISDICTION

WRIT PETITION (CIVIL) NO. OF 2015

IN THE MATTER OF:-

S. SRINIVASAN

.... PETITIONER

VERSUS

1. THE UNION OF INDIA
   THROUGH ITS SECRETARY
   MINISTRY OF HEALTH & FAMILY WELFARE
   NIRMAN BHAWAN, NEW DELHI-110001

2. THE UNION OF INDIA
   THROUGH ITS SECRETARY
   DEPARTMENT OF BIO-TECHNOLOGY
   MINISTRY OF SCIENCE AND TECHNOLOGY
   6TH-8TH FLOOR, BLOCK 2
   CGO COMPLEX, LODHI ROAD
   NEW DELHI - 110 003

3. CHRISTIAN MEDICAL COLLEGE
   THROUGH ITS DIRECTOR
   CMC VELLORE, 632004
   TAMIL NADU ...RESPONDENTS

.To,

The Chief Justice of the Hon'ble Supreme Court of India and his companion Justices of the Supreme Court of India:

MOST RESPECTFULLY SHOWETH:

1. The petitioner herein is filing 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 (result) of the Rotavac clinical trial (phase III) involving 6799 infants, that was conducted at three centres namely Delhi, Pune and Vellore to gauge the safety and efficacy of the said vaccine.

2. The Petitioner is Mr. S. Srinivasan. He is the Managing Trustee of (Low Cost Standard Therapeutics), Vadodara, Gujarat. The petitioner is an expert and has been active for over 35 years in the field of health care, low cost medicine manufacture, transfer of pharmaceutical technology to LDCs, issues of disadvantaged children and human rights, and relief in disaster situations. He is an active member of the Medico Friend Circle and AIDAN (All-India Drug Action Network) among others. Mr. S. Srinivasan is a graduate and postgraduate of IIT Kharagpur and IIM Bangalore. His recent books include *A Lay Person's Guide to Medicine* (2000/2006 and 2012 in Hindi), *Impoverishing the Poor: Pharmaceuticals and Drug Pricing in India* as well as several articles pharma policy, drug pricing and related issues in the *Economic and Political Weekly* as well as contributed chapters in books. The petitioner, through LOCOST, has previously filed petitions in the Supreme Court on *inter alia* irrational medicines, drug pricing policy, vaccine PSUs closure and HPV vaccine related deaths.

3. The petitioner 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 results of the Rotavac clinical trial (phase III) conducted between 2011 and 2013 at Delhi, Pune and Vellore. The clinical trial involved administering the rotavac vaccine to 6799 infants with an objective of ascertaining

and ensuring the safety and efficacy of the said vaccine at all the three centres. The petitioner herein is also seeking the intervention of this Hon'ble Court to is also seeking a relief in the form of a direction from this Hon'ble Court to direct the respondents to place before the NTAGI the entire clinical trial results in segregated manner so that the NTAGI may examine and scrutinize the results of the said vaccine.

4. NTAGI is the country's apex advisory committee that provides guidance to the national policy makers on immunization. Members of NTAGI include officials from MoHFW; representatives from immunization action partners such as WHO, UNICEF, the Indian Academy of Pediatrics and the Indian Medical Association ; and leading independent experts from diverse fields such as clinical medicine, public health, immunology, vaccinology, immunization program etc.

Facts of the Case

5. On 26th March 2016, the Ministry of Health officially launched Rotavirus vaccine to combat deaths in infants caused due to diarrhea. Before the launch of the vaccine, a clinical trial (phase III) was conducted between 2011 and 2013 at three centres namely Delhi, Pune and Vellore to gauge the efficacy and safety of the said vaccine. Under this clinical trial, 6799 infants were administered the said vaccine to ensure its safety in terms of the number of intussusceptions in the 2-year trial period. Intussusceptions are intestinal obstructions that may need an urgent surgery to prevent death among infants, and is diagnosed by ultra sound examination. The trial was to test the risk of this potentially fatal side-effect of the vaccine.

6. The aggregated results of the study published in UK Journal 'Vaccine' issue dated August, 2014 raised certain questions about the efficacy of the vaccine and the risks associated with it. A paper

authored by John and colleagues published in journal *Vaccine* titled *'Active surveillance for intussusception in a phase III efficacy trial of an oral mono-valent rotavirus vaccine in India'* showed that the intusseption rate in Vellore was almost 20 times the rate in Delhi. A copy of the said paper published in journal Vaccine by John & Colleagues is annexed as **Annexure P1 (Pages_____to ____).**

7. Through these aggregated results, Dr. Jacob Puliyel of the National Technical Advisory Group on Immunization (NTAGI), which is the apex advisory body of the Government of India on immunization, came to know that the number of cases of intussusceptions in the infants who were administered rotavac vaccine in Vellore centre were the highest.

8. As a member of NTAGI, Dr. Puliyel considered it his duty to study the segregated results of the clinical trial data from all the three centres to ascertain if a certain population was more susceptible to the side effects of the said vaccine. The respondents while celebrating the launch of the vaccine, had not disclosed complete segregated data (centre-wise results) from these three centres where this clinical trial was conducted. In his capacity as the member of NTAGI, he repeatedly made requests for the said results but the results were not provided to him. Not providing complete results of clinical trials involving human beings is in violation of ethics of medical research and global norms governing clinical trials.

9. Raising this issue, journal *Vaccine* published a detailed letter dated 06.10.2014 asking for segregated or dis-aggregated results of the clinical trial to be published. As a result of the letter many newspapers through their science correspondents tried to get the information directly from the Principal Investigator but the respondents did not provide the said data from the three centres. A

copy of the letter dated 06.10.2014 published in journal *Vaccine* is annexed as **Annexure P2 (Pages_____to_____).**

10. Dr. Puliyel made several representations to the Director, CMC Vellore requesting for the data for Vellore limb of the study. His request was not acceded to. A copy of his email correspondence between 21.05.2015 and 28.05.2015 with Mr. Sunil Chandy, Director, CMC Vellore is annexed as **Annexure P3 (Pages_____to_____).**

11. He also wrote to the NTAGI by writing emails addressed to Dr. Vijaya Raghavan, Chairperson of Standing Technical Sub-Commitee (STSC) of NTAGI (and copying to all members of NTAGI) requesting for the disaggregated data from Vellore in the format provided by him as a member of NTAGI. However, the results from Vellore were not provided. A copy of the email dated 28.05.2015 written by the petitioner to the Chairperson STSC, NTAGI and copied to all members of NTAGI is annexed herewith as **Annexure P4 (Page_____ to _____).**

12. In the mean time, an NGO also filed an RTI application seeking information on a.) the number of cases of intussusceptions in the 1000 infants given the rotavirus vaccine in Vellore limb of study over the period of 2 years and, b.) what is the corresponding figure for the 500 who were placebo recipients. But no reply was given to the RTI application by the respondents. A copy of the RTI application dated 26.05.2015 is annexed herewith as **Annexure P5 (Pages_____to _____).**

13. Dr. Puliyel wrote a letter addressed to the Prime Minister apprising him of the situation and requesting him to enquire into the matter. A copy of the letter dated 16.06.2015 written to the Prime Minister about

theneed for disclosure of the data is annexed herewith as **Annexure P6 (Pages_____ to _____).**

14. In response to the letter to the Prime Minister dated 16.06.2015, the Prime Minister's Office made a request to the Subject Expert's Committee (SEC) to look at the data from Vellore. As per the minutes of the meetings of SEC dated 29.07.2015, the same has not yet been complied with. This shows that not only the NTAGI but even the Subjects Expert Committee has not examined the Vellore data even after a reference for the same by the PMO. Minutes of the Meeting of Subject Expert Committee (SEC) – Vaccine show that even after the PMO reference dated 22.06.2015, the SEC did not review the data with respect to Vellore limb of the study and gave its opinion based on the already published data in the journal *Vaccine.* A copy of the minutes of the meeting held on 29.07.2015 of Subjects Expert Committee is annexed herewith as **Annexure P7 (Pages_____to _____).**

Why is it important to disclose centre-wise data

15. The petitioner submits that there is a need for disclosure of the segregated data of Vellore Centre in order to ascertain whether a certain section of the population is more susceptible to adverse effects. This was the very objective of the clinical trial. So far the respondents have shown complete secrecy in the matter and have not disclosed segregated (meaning dis-aggregated) data from all the centres and have only released aggregated data i.e. the results of all three centres clubbed together.

16. It is submitted that the revised version of Declaration of Helsinki is adopted which states that *"Every research study involving human subjects must be registered in a publicly accessible database before recruitment of the first subject."* and 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". A copy of the relevant section of the revised Declaration of Helsinki is annexed herewith as **Annexure P8 (Pages_____to _____).**

17. World Health Organization (WHO) released a strong statement advocating for public disclosure of all clinical trial results. According to it, when data is not released it means that doctors, patients and medical regulators cannot make informed decisions about which treatments are best. Non-disclosure of complete clinical trial results means that hundreds of thousands of patients have volunteered to take part in clinical trials where results have been kept hidden or are only selectively disclosed. A copy of the 'WHO Statement on Public Disclosure of Clinical Trial Results' released on 14.04.2015 is annexed as **Annexure P9** (**Pages_____ to _____).**

18. One of the largest online campaigning communities called Avaaz.org starts a campaign requesting the Director, CMC Vellore to release the clinical trial data. As of now campaign has 442 signatories from the world over but no response has been received so far from CMC Vellore. The online petition can be accessed at:

https://secure.avaaz.org/en/petition/To_The_Director_Christian_Medical_College_Vellore_632004_Release_Indian_Rotavirus_Vaccine_Trial_Data/. A copy of the online petition on avaaz.org is annexed herewith as **Annexure P10** (**Pages_____ to _____).**

19. Concealing of this vital data does severe injustice to the thousands of infants who participated in this study, the researchers who painstakingly conducted the trials and the medical/scientific community who depend on this data for their work. It is even more crucial to study the segregated data because the respondents have now launched the vaccine in 4 states in the country where lakhs of infants might be administereed the vaccine.

Earlier Petition by Dr. Jacob Puliyel seeking the same relief

20. Aggrived by the attitude and callousness on the part of the respondents a member of the National Technical Advisory Group on Immunization (NTAGI) Dr. Jacob Puliyel had earlier filed Writ Petition No.6913 of 2015 before the Hon'ble High Court of Delhi praying for the ethical disclosure of the disaggregated data of all the centres where the study was conducted. A copy of the writ petition (civil) No. 6913 of 2015 is annexed herewith as **Annexure P11 (Pages_____ to _____).**

21. *Vide* order dated 14.10.2015, the Hon'ble High Court dismissed the said writ petition filed by Dr. Puliyel on the ground that segregated trial result of all the three centres was available with the National Technical Advisory Group on Immunization (NTAGI) of which the petitioner therein was a member and that it was on the basis of this data that the NTAGI had approved the said vaccine. A copy of the order dated 14.10.2015 of the Hon'ble High Court in Writ Petition (Civil) No. 6913 of 2015 is annexed herewith as **Annexure P12 (Pages_____ to _____).**

22. The Hon'ble High Court failed to appreciate the fact that the segregated results of the clinical trial were not made available to members of the NTAGI in spite of written requests for the same by Dr. Puliyel. The details of the same are given below. Aggrieved by the order, Dr. Puliyel was constrained to filed an SLP (C) No. 2532 of 2016 against the Order dated 14.10.2015 of the Hon'ble High Court of Delhi. On 05.02.2016 the the Hon'ble Court while keeping all questions open expressed its inability to entertain the said SLP on the ground that the petitioner therein, who was a member of the NTAGI, cannot maintain a public interest petition. The Hon'ble Court in the said order dated 05.02.2016 in SLP (C) No. 2532 of 2016 stated as under:

> *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.

A copy of the said Order dated 05.02.2016 of the Hon'ble Supreme Court in SLP No. 2532 of 2016 is annexed as **Annexure P13 (Pages_____ to _____).**

23. In March 2016, the said vaccine was launched in four states - Haryana, Himachal Pradesh, Orissa and Andhra Pradesh with plans to launch it in other states in the next phase without making public the segregated results (from Pune, Delhi and Vellore) of the clinical trial of the said vaccine.

24. The petitioner herein submits that there have been many efforts on the part of the respondents to keep the segregated results of clinical trial conducted at the three centres undisclosed. This is despite the fact that all clinical trials conducted on humans must be reported entirely because such trials are done on the general public with public money and therefore the public at large has a right to know the trial results.

25. The instant Writ Petition is preferred on the ground that the said study was carried out by government funding and it is the duty of the respondents to disclose segregated data of clinical trial involving infants and not keep it under a shroud of mystery and the same is crucial to enable evaluation of the risks of the vaccine in different population groups.

26. The petitioner herein has filed the instant writ petition espousing the cause of ethical and complete disclosure of clinical trial conducted on human beings. The petitioner at this stage is not

raising aspertions on the efficacy of the said vaccine but is only asking for complete segregated data to be provided to him and to members of NTAGI as the same is in public interest.

27. Since the Hon'ble High Court has already expressed its views in the matter in the earlier petition (WPC 6913 of 2015) filed by Dr. Jacob Puliyel, the petitioner herein seeks the intervention of this Hon'ble Court to set aside the Order dated 14.10.2015 in WPC 6913 of 2015 of the High Court of Delhi and to direct the respondents to place the segregated results from all the three centres before the NTAGI, which is the expert body on immunization policy, for examination and scrutiny and also to make the said results public.

GROUNDS

A. Because the respondents have ignored the scientific appeals in peer reviewed medical journal, RTIs, online appeals of the petitioner and many others who are to gain by this scientific data and have failed to provide the said data which can affect millions of infants in this country.

B. Because if the data from Vellore shows that more children who were vaccinated had intussusceptions than the controls in Vellore, it will demonstrate that children in some areas are more susceptible to this potentially fatal side effect.

C. Because in the said clinical trial there was an excess of 11 cases of intussusception per 10,000 vaccinated. This is 5 to 10 times higher than the risk of intussusception with Rotashield vaccine (which was withdrawn from the market in the USA and nearly 70 times higher than the risk of intussusception with the current, internationally licensed vaccine - RotaTeq.

D. Because non-disclosure of such important data violates the basic ethics of clinical research that require results of clinical research studies to be published and brought to the knowledge of the medical community, participants to the research and general public.

E. Because the World Health Organization (WHO) in April 2014 has released a strong statement advocating for public disclosure of all clinical trial results.

F. Because when data is not released it means that doctors, patients and medical regulators cannot make informed decisions about which treatments are best. Non-disclosure of complete clinical trial results means that hundreds of thousands of patients have volunteered to take part in clinical trials where results have been kept hidden or are only selectively disclosed.

G. Because when researchers embark on a clinical trial, they make a commitment to conduct the trial and to report the findings in accordance with basic ethical principles. This includes preserving the accuracy of the results and making both positive and negative results publicly available. Selective reporting, regardless of the reason for it, leads to an incomplete and potentially biased view of the trial and its results. Selective reporting of clinical trial results can also lead to wrong or unnecessary allocation of public funds, which could otherwise have been used in public interest.

H. Because the Declaration of Helsinki, an international document providing ethical guidance on research states that *“Every research study involving huan subjects must be registered in a publicly accessible database before recruitment of the first subject.”* and 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".

I. Because the Government of India has now launched the vaccine in four states without making the results public and without even providing it to NTAGI members despite repeated requests.

J. Because *vide* order dated 14.10.2015 in the earlier Writ Petition WPC 6913 of 2015, the Hon'ble High Court stated that that the entire segregated result of all the trial centres was available with NTAGI and that the NTAGI approved the vaccine having examined the segregated data. However, the Hon'ble High Court failed to appreciate the fact that the segregated results of the clinical trial was not made available to the NTAGI. In fact, as a member of the NTAGI the petitioner in that writ petition Dr. Puliyel had sought the said data but was not provided the same.

K. Because Dr. Jacob Puliyel made a number of requests for disclosure of the data in a peer reviewed scientific journal, to the Chairperson, Standing Technical Sub Committee of NTAGI, to the director of CMC Vellore, to the Prime Minister and also filed an RTI seeking the segregated data from the different centers. However, it was not provided to him despite the fact that he is himself a member of NTAGI and ought to have been provided the segregated data.

L. Because the Hon'ble High Court failed in appreciating the fact that the said clinical trial has been conducted with government funding and the government owes it to the participants and the people of this country to know the complete segregated results.

M. Because the segregated data ought to not only be available to the members of NTAGI but also to the general public under the Right to Information Act.

N. Because NTAGI is the country's apex advisory committee that provides guidance to the national policy makers on immunization. Members of NTAGI include officials from MoHFW; representatives from immunization action partners such as WHO, UNICEF, the Indian Academy of Pediatrics and the Indian Medical Association ; and leading independent experts from diverse fields such as clinical medicine, public health, immunology, vaccinology, immunization program etc. The fact that the respondents cannot even trust the members of such an exemplary committee with the complete and segregated results of clinical trial conducted on thousands of infants calls for an enquiry

O. Because it is mandatory to explain to future recipients the risks that have already been seen in the Phase III trial before consent is taken from them for administration of the said vaccine.

P. Because informed consent requires the disclosure of safety data, and it would be unethical to proceed with immunisation without informing the public of any risks observed with previous use of the vaccine, and not informing them what adverse effects to look out for. The signs and symptoms of this dreaded adverse effect (namely intussusception) are the same as with dysentery (meaning the passage of blood and mucus in the stools) and unless the public are warned before hand, they would suspect only dysentery and many deaths from intussusception will be mislabelled as dysentry.

Q. Because when data is not released it means that doctors, patients and medical regulators cannot make informed decisions about which treatments are best. Non-disclosure of complete clinical trial results means that hundreds of thousands of patients have volunteered to take part in clinical trials where results have been kept hidden or are only selectively disclosed.

R. Because the request of the Prime Minister's Office asking the Subject Experts Committee to look at the Vellore data has not been complied with in an instance of clear dereliction of responsibility by this expert committee.

PRAYER

It is most respectfully prayed that this Hon'ble Court may be pleased to:

a. Set aside final order/judgment dated 14.10.2015 of the Hon'ble High Court of Delhi in WPC 6913 of 2015

b. Issue an appropriate writ directing the respondents to provide the petitioner the complete segregated results (centre-wise data) of the clinical trial of rotavac vaccine conducted in all three centres, including the number of intussusceptions in the 2-year trial period ar each centre

c. Issue an appropriate writ directing the respondents to place before the NTAGI the complete segregated results of the said clinical trial of rotavac vaccine for examination and scrutiny

d. Issue an appropriate writ restraining the respondents from including rotavac from Universal Immunization Policy of the government of India till the complete data from the said clinical trial is not disclosed to the key stakeholders, including the petitioner.

e. Issue an appropriate writ directing the respondents to frame guidelines regarding publication of complete and segregated research results in clinical trials on humans, in accordance with the WHO statement of April 2015 on the issue.

f. Issue such other writ, direction or order, which this Hon'ble court may deem fit and proper under the facts and circumstances of the case.

Drawn By: Neha Rathi
Drawn on: 19/04/2016

FILED BY:

(PRASHANT BHUSHAN)
ADVOCATE FOR THE PETITIONER

NEW DELHI
FILED ON 23.04.2016

S. NO.	PARTICULARS	PAGES
1.	Listing Performa	
2.	Brief Synopsis and List of Dates	
3.	Writ Petition with Affidavit	
4.	**ANNEXURE – P1** A copy of the paper titled *'Active surveillance for intussusception in a phase III efficacy trial of an oral mono-valent rotavirus vaccine in India'* published in journal Vaccine by John & Colleagues in August 2014	
5.	**ANNEXURE – P2** A copy of the letter dated 06.10.2014 written by the petitioner published in the journal Vaccine	
6.	**ANNEXURE – P3** A copy of the petitioner's email correspondence between 21.05.2015 and 28.05.2015 with Mr. Sunil Chandy, Director, CMC Vellore	
7.	**ANNEXURE - P4** A copy of the email dated 28.05.2015 written by the petitioner to the Chairperson STSC, NTAGI and copied to all members of NTAGI	
8.	**ANNEXURE – P5** A copy of the RTI application dated26.05.2015	
9.	**ANNEXURE - P6** A copy of the letter dated 16.06.2015 written by the petitioner to the Prime Minister	
10.	**ANNEXURE - P7** A copy of the minutes of the meeting held on 29.07.2015 of Subjects Expert Committee	
11.	**ANNEXURE – P8** A copy of the relevant section of the revised Declaration of Helsinki of March 2013	
12.	**ANNEXURE – P9** A copy of the 'WHO Statement on Public Disclosure of Clinical Trial Results' released on 14.04.2015	
13.	**ANNEXURE – P10** A copy of the online petition on avaaz.org	
14.	**ANNEXURE - P11** A copy of the writ petition (civil) No. 6913 of 2015	

15.	**ANNEXURE - P12** A copy of the order dated 14.10.2015 of the Hon'ble High Court in Writ Petition (Civil) No. 6913 of 2015	
16.	**ANNEXURE - P13** A copy of the said Order dated 05.02.2016 of the Hon'ble Supreme Court in SLP No. 2532 of 2016	