VOLUME - I

INDEX PAGES

(PLEASE SEE CONTINUE OF VOLUME –II)
(PAGES NO.263-541)

IN THE SUPREME COURT OF INDIA

CIVIL ORIGINAL JURISDICTION

WRIT PETITION (CIVIL) No. 289 of 2016

IN THE MATTER OF

S. Srinivasan ... Petitioner

Versus

Union of India and Others ... Respondents

COUNTER AFFIDAVIT ON BEHALF OF THE RESPONDENT No. 1

I, Dilip Kumar Sahu, aged, 43 years S/o Shri. Lt. C. B. Sahu, R/o 7/3 Minto Road Complex New Delhi-110002, do hereby solemnly affirm and state as under:-

1. That, I am working as Under Secretary (Immunization) in Ministry of Health and Family Welfare and as such, I am well conversant with the facts and records of the case and competent to swear this Affidavit.

2. That, I have read over and understood the Synopsis, List of dates and events and grounds

urged in the instant Writ Petition and I am well aware of the contents stated therein. At the outset, I deny all the averments, submissions, statements and allegations made therein except those that are specifically admitted hereinafter to be true and correct.

3. PRELIMINARY SUBMISSIONS:-

That, before adverting to Para-Wise Reply, the Respondent begs to submit the following: -

[A] The safety profile of Rotavac has been of paramount importance throughout clinical development which commenced in the year 2000. Various Expert Committees have reviewed the data from the clinical trials of Rotavac vaccine and have approved it. The deponent craves leave of this Hon'ble Court to place the below mentioned reports as part of "Convenience Compilation."

(i) An independent Data Safety Monitoring Board (DSMB) comprising of national and international experts from

the field of Paediatrics, Ethics, Biostatistics and former professionals from World Health Organization reviewed the data during the Rotavac trial for safety and efficacy of the vaccine and scientific integrity of the study.

(ii) An independent Intussusception Case Adjudication Committee comprising of experts from the field of Paediatrics, Paediatric Surgery and Radio diagnosis was constituted specifically to review all cases of Intussusceptions during the trial. This Committee reviewed the data during the study and found no association of the vaccine with intussusception.

(iii) The data from the clinical trials was reviewed by the New Drug Approval Committee (NDAC) comprising of leading physicians, Paediatricians and

Pharmacologists from all across the country. Vide Minutes of the Meeting dated 02/08/2013, the Committee recommended to allow the new drug - Rotavac. Thereafter, on the basis of the recommendation of New Drug Approval Committee (NDAC), license was granted by Drug. controller general of India (DCGI) in January, 2014. True copy of the recommendation of New Drug Approval Committee (NDAC), licence was granted by Drug Controller General of India (DCGI) dated January, 2014 is annexed herewith as ANNEXURE R-1. Pg. 40-43

[B] It is very much pertinent to mention herein that the World Health Organization's Global Advisory Committee on Vaccine Safety (WHO-GACVS) also reviewed the data from the Phase-III Rotavac clinical trial and stated that the lack of temporal relationship argues strongly against a causative relationship

between Rotavac and intussusception and since most vaccine attributable cases are expected to occur within the first week following vaccination. True copy of reviewed of World Health Organization's Global Advisory. Committee on Vaccine Safety (WHO-GACVS)' the data from the Phase-III Rotavac clinical trial is annexed herewith as ANNEXURE R-2. Pg. 44-89 . No such case has been reported within the first week.

[C] It is noteworthy to mention herein that the National Technical Advisory Group on Immunization (NTAGI) reviewed the data on disease burden and safety, immunogenicity and efficacy of all Rotavirus vaccines, including Rotavac and recommended it to be introduced in the universal immunization programme. True copy of recommendation/ letter dated of national Technical Advisory Group on Immunization (NTAGI) dated 30.06.2014 : is annexed herewith as ANNEXURE R-3. Pg. 90-121

[D] The results of the Rotavac clinical trials in India have been published in large number of prestigious journals and are approved to be safe. The deponent craves leave of this Hon'ble Court to . place the below mentioned Reports as part of "Convenience Compilation." True copy of Article of published by prestigious journals are annexed herewith as ANNEXURE R-4. Pg. 122-262

(i) A Dose-Escalation Safety and Immunogenicity Study of Live Attenuated Oral Rotavirus Vaccine 116E in Infants: A Randomized, Double Blind Placebo-Controlled Trial(available at http://iid.oxfordiournals.org/- published in August 2009).

(ii) Efficacy of a monovalent human-bovine (116E) rotavirus vaccine in Indian infants: a randomized, double-blind, placebo-controlled trial (available at

www.thelancet.com - published in June 2014).

(iii) Efficacy of a monovalent human-bovine (116E) rotavirus vaccine in Indian children in the second year of life (Available at www.iournals.elsevier.com/vaccine published in August 2014 -open access article under the CC BY-NC-ND license)

(iv) Active surveillance for intussusception in a Phase III efficacy trial of an oral monovalent rotavirus vaccine in India (Available at www.iournals.elsevier.corn/vaccine published in August 2014 -open access article under the CC BY-NC-ND license).

[E] As per Good Clinical Practice Guidelines of the Central Drugs Standard Control Organization, it is inappropriate to conduct site specific analysis of segregated data in a trial that is not designed for it. Such analysis of segregated data on safety when

not specified in the protocol may lead to misinterpretation of data and spread of disinformation about the vaccine. True Copy of Good Clinical Practice Guidelines of the Central Drugs Standard Control Organization is annexed herewith as ANNEXURE R-5. Pg. 263-541

[F] The Petitioner has picked up only piece of information from the paper authored by John et al published in journal Vaccine titled "Active surveillance for intussusception in a phase 3 efficacy trial of an oral mono-valent rotavirus vaccine in India" (Annexure P/1 @ pages 18-24). Though the said paper says that overall incidence of intussusception identified on "Ultrasound" was 28/100,000 child year in Delhi and 581/100,000 child year in Vellore, it is pertinent to mention that 50% of these cases resolved spontaneously and did not require any medical intervention and were similar in vaccine & placebo arm. So as asserted by

petitioner that Intussusception rate in Vellore is almost 20 times the rate in Delhi, is false / misleading/incorrect.

As also noted by Global Advisory Committee on Vaccine Safety (GACVS), this paper concludes that rotavac was unlikely to have caused intussusception.

[G] It is pertinent to mention herein that since the introduction of Rotavac vaccine in 4 states (Andhra Pradesh, Himachal Pradesh, Odisha and Haryana), 9,82,961 doses of Rotavac vaccine have been administered till July, 2016. No case of intussusception following Rotavirus vaccination has been reported till date.

[H] 5 Judges bench of this Hon'ble Court in 1990 (2) SCC 715 Para 47(K) has held:-

> "(K) That a dispute raised by an application under Article 32 of the Constitution must be held to be barred by principles of res judicata including

the rule of constructive res judicata if the, same has been earlier decided by a competent court by a judgment which became final."

[I] It is humbly submitted that in the instant case and for the identical reliefs as sought for in the present Writ Petition under article 32, one Dr. Jacob Puliyel had filed Writ Petition under article 226 of the Constitution of India before the Hon'ble Delhi High Court. Vide detailed Order and Judgment dated 14/10/2015; the Hon'ble Delhi High Court was pleased to dismiss the said Writ Petition (Annexure P/12 @ pages 71-75).

SLP preferred against the aforesaid Judgment and order of the Delhi High Court before this Hon'ble Court was dismissed as withdrawn by this Hon'ble Court Vide Order dated 05/02/2016 (Annexure P/13 @ pages 76). Thus, the Judgment of the Hon'ble Delhi High Court attained finality and the instant

Writ Petition under article 32 raising identical issues is barred by principles of res judicata including the rule of constructive res judicata as it has already been adjudicated upon and decided by the Hon'ble Delhi High Court vide its detailed Order and Judgment & order dated 14/10/2015.

4. REPLY TO THE SYNOPSIS AND LIST OF DATES AND EVENTS:-

That in reply to the synopsis and the list of dates and events, it is humbly submitted that the safety profile of Rotavac has been of paramount importance throughout clinical development since the year 2000 onwards. Various expert committees have reviewed the data from the clinical trials of Rotavac vaccine and have approved it and as elaborately dealt hereinabove in the Preliminary Submissions made in the preceding paragraphs.

The World Health Organization's Global Advisory Committee on Vaccine Safety (WHO-GACVS) also reviewed the data from the Phase-III clinical trials. The lack of a time-based association argues strongly against a causative relationship between Rotavac and intussusception since most rotavirus vaccine-attributable cases are expected to occur within the first week following vaccination. Based on this Global Advisory Committee on Vaccine Safety (GACVS) has published a recommendation that the Rotavac is unlikely to have caused Intussusception. It is noteworthy to mention herein that the National Technical Advisory Group on Immunization (NTAGI) reviewed the data on disease burden and safety, immunogenicity and efficacy of all rotavirus vaccines including Rotavac and recommended it to be introduced in the universal immunization programme.

The results of clinical trials of Rotavac in India have been published in large number of prestigious journals and are approved to be safe.

As per Good Clinical Practice Guidelines of the Central Drugs Standard Control Organization (CDSCO), it is inappropriate to conduct site specific analysis of segregated data in a trial that is not designed for it. Such analysis of segregated data on safety, when not in the protocol, may lead to misinterpretation of data and spread of misinformation about the vaccine.

The Petitioner has picked up only piece of information from the paper authored by John et al published in journal Vaccine titled "Active surveillance for intussusception in a phase 3 efficacy trail of an oral mono-valent rotavius vaccine in India" (Annexure P/1 @ pages 18-24). Though the said paper says that overall incidence of intussusception identified on "Ultrasound" was 28/100,000 child year in Delhi and 581/100,000 child year in Vellore, it is pertinent to mention that 50% of these cases resolved spontaneously and did not require any medical intervention and were similar in vaccine & placebo arm. So as asserted by petitioner that Intussusception rate in

Vellore is almost 20 times the rate in Delhi, is false/misleading/incorrect.

As also noted by Global Advisory Committee on Vaccine Safety (GACVS), this paper concludes that Rotavac was unlikely to have caused Intussusception.

It is pertinent to mention herein that since the introduction of Rotavac vaccine in 4 states (Andhra Pradesh, Himachal Pradesh, Odisha and Haryana), 9,82,961 doses of Rotavac vaccine have been administered till July, 2016. No case of Intussusception following Rotavirus vaccination has been reported till date.

In the instant case and for the identical reliefs as sought for in the present Writ Petition under article 32, one Dr. Jacob Puliyel had filed Writ Petition under article 226 of the Constitution of India before the Hon'ble Delhi High Court.

Vide detailed Judgment and order dated 14/10/2015; the Hon'ble Delhi High Court was pleased to dismiss the said Writ Petition

(Annexure P/12 @ pages 71-75). SLP preferred against the aforesaid Judgment and order of the Delhi High Court before this Hon'ble Court was dismissed as withdrawn by this Hon'ble Court Vide Order dated 05/02/2016 (Annexure P/13 @ pages 76).

Thus, the Judgment of the Hon'ble Delhi High Court attained finality and the instant Writ Petition under article 32 raising identical issues is barred by principles of res judicata including the rule of constructive res judicata as it has already been adjudicated upon and decided by the Hon'ble Delhi High Court vide its detailed Judgment and order dated 14/10/2015.

5. PARAWISE REPLY;-

The contents of the Preliminary Submissions may kindly be read as part of reply on merits:-

[1] The contents of this Para are denied and the Preliminary Submissions as made in the preceding Paragraphs may kindly be read as part and parcel of Reply to this Para.

[2] The contents of this Para warrant no Reply.

[3] The clinical trial of Rotavac was designed as a multicenter trial with a pre-defined statistical plan to analyze the combined data across the study centers. This pre-defined plan was followed and did not include stratification by site for analysis for either efficacy or safety, with data management and monitoring of global standards provided by quintiles. Data analysis was performed by independent statisticians not involved in the recruitment, vaccination & clinical management. As per Good Clinical Practice Guidelines of the Central Drugs Standard Control Organization (CDSCO), it is inappropriate to conduct site specific analysis (analysis of segregated data) in a trial that is not designed for it and such analysis is well known to throw up false trends in either direction of benefit or harm. Releasing site specific data (segregated data) on safety when not in the registered protocol

may lead to misinterpretation of data and spread of misinformation about the vaccine. The same process has been followed for Rotavirus vaccine introduced as for any other vaccine. There are 25 members in total in National Technical Advisory group on Immunization (NTAGI) other than representatives from professional organizations & international partners.

The National Technical Advisory Group on Immunization (NTAGI) reviewed the data on disease burden and safety, immunogenicity and efficacy of the Rotavac and other vaccines and in June, 2014, recommended that the rotavirus vaccine be introduced in the universal immunization programme. No one raised concerns about the safety and efficacy of Rota vac other than Dr. Jacob Puliyel who himself is a National Technical Advisory Group on Immunization (NTAGI) member.

Globally there were only 2 Rota virus vaccine manufacturers; none of them were Indian manufacturers. UNICEF procurement price of these 2 manufacturers ranges from 193.9 to 300.9 per dose.

Rotavirus vaccine (Rotavac) is the first indigenous vaccine developed from an Indian strain by an Indian company. Government of India has procured this vaccine under Immunization programme at the cost of Rs.71.82/dose.

Safety profile of Rota vac (116E) has been of paramount importance throughout clinical development since 2000 - 2014. Various expert committees have reviewed the data from the clinical trial (Refer to response for Para 8).

Referring to judgment dated 14th October, 2015 of similar PIL filed in High court vide case no. 6913/2015 wherein High Court has already dismissed the case saying "the

petition is misconceived and motivated with private interest & the petition does not deserve to be taken cognizance as a Public Interest Litigation"

Thus, it is evident that the petitioner is trying to mislead the Hon'ble Supreme Court of India and obstruct the functioning of the Government of India.

[4] The contents of this Para warrant no Reply.

[5] That with regard to the contents of paras of the writ petition, the deponent begs to state as follows:

The results of the clinical trial study have been published in prestigious peer reviewed journals. (Please refer to Para 16.)

The randomized double-blind, placebo-controlled, multicenter trial was conducted at three sites in Delhi (urban), Pune (rural), and Vellore (urban and rural) to assess the efficacy and tolerability of a monovalent

human-bovine rotavirus vaccine for severe rotavirus gastroenteritis in low-resource urban and rural settings in India.

Since the introduction of Rotavirus Vaccine in four states (Andhra Pradesh, Himachal Pradesh, Odisha & Haryana) 9,82,961 doses of Rotavirus Vaccine have been administered till July 2016. No case of Intussusception following Rotavirus vaccination has been reported in these 4 states.

[6] The contents of this Para are denied. The petitioner has submitted superfluous statements with regard to 'certain questions about the efficacy of the vaccine' and the 'risks associated with it'.

The petitioner while relying on the published article in Journal Vaccine volume 32S (2014) A104-A109 titled "Article surveillance for intussusception in phase 3 efficacy trial of an oral monovalent rotavirus vaccine in India" has made his own interpretation that

the Vellore has almost 20 times the intussusception rate as compared to Delhi.

The fact as per the paper published is "the incidence of intussusception varied across geographic locations in India with an incidence of 581 per 100,000 child years at Vellore, 178 per 100,000 child years at Pune & 27.7 per 100,000 child years at Delhi". So It is distortion of the fact.

[7] Intussusception occurs in children at varying rates in different locations because of several causes & the background rate reported from Asia, in about 1 in 300 children. Whereas with the internationally licensed vaccines; a rate of 1 in 20,000 to 1 in 60,000 vaccines has been documented in many countries. In India, there is only one paper on the background rate and that was estimated at 19 per 100,000 children.

It is pertinent to note that Since the introduction of Rotavirus Vaccine in four

states (Andhra Pradesh, Himachal Pradesh, Odisha & Haryana) 9,82,961 doses of Rotavirus Vaccine have been administered till July 2016. No case of Intussusception following Rotavirus vaccination has been reported in these 4 states.

[8] The statements at Para 8 of the writ petition are denied. It is submitted that when clinical trials are designed, the analytic plan is specified a priori. This trial was not designed for site specific analysis for either efficacy or safety, and was in fact, only powered for efficacy. Therefore, it would be unscientific to conduct site specific analyses. There are specific criteria by which sub-analyses should be conducted and the results of this trial provide no indication of such a need.

Safety profile of 116E rotavirus vaccine has been of paramount importance throughout clinical development since 2000-2014.

Various expert committees have reviewed the data from the clinical trial, as given below:

a. Data Safety Monitoring Board (DSMB) was constituted to study all safety issues during the clinical trial. The members include international and national experts from the field of Pediatrics, Ethics, and Biostatistics and former professionals for World Health Organization (W.H.O.).

b. Intussusception Case Adjudication Committee was constituted only to study all cases of intussusception in the study and take appropriate action. It comprised experts of following specialties - pediatrics, pediatric surgery and radio diagnosis.

c. All the results from the study were submitted to the Drugs Controller General of India (DCGI). It was reviewed

and vaccine was licensed in January 2014.

d. The data from the clinical trials was reviewed by the New Drug Approval Committee (NDAC) constituted with leading physicians, pediatricians and pharmacologists from all across the country.

e. The World Health Organization's Global Advisory Committee on Vaccine Safety (WHO-GACVS) reviewed the data from the Ph. III clinical trials and has published a recommendation that the 116E rotavirus vaccine did not cause intussusception. World Health Organization's Global Advisory Committee on Vaccine Safety (WHO-GACVS) Quote: "The lack of a temporal association argues strongly against a causative relationship between Rota vac and intussusception since most

rotavirus vaccine-attributable cases are expected to occur within the first week following vaccination. No case has been reported within a week.

[9-13] That with regard to the contents at Para 9-13 of the writ petition, the deponent begs to state that Dr. Puliyel did publish a letter in Vaccine journal but his letter and the communications to newspapers etc. were based on a complete lack of consideration of the known risk window for intussusception for all widely tested rotavirus Vaccines. In the absence of any cases in the risk window in the phase III trial, there was no basis for his communication.

The Director, Christian Medical College (CMC) discussed the issue with the administration and the faculty who agreed that:

i) the trial was a multi-site trial with CMC as one of three sites,

ii) the trial was not sponsored by CMC and

iii) the trial data had been reviewed by the most competent regulatory and public health authorities nationally and internationally and no issues had been raised, and hence no response was required.

[14] The petitioner in Para 14 has mentioned that Prime Minister's Office made a request to Subject Expert Committee (SEC) to look in to the data of Clinical trial of Vellore.

In this regard it is submitted that Dr. Jacob Puliyel made request for these data through Prime Minister's Office. He is the same petitioner who had earlier filed petition in High Court of Delhi for making the request to get the segregated data on the phase 3 clinical trial of Vellore.

Central Drug Standard Control Organization (CD SCO) received the said

representation wherein he had raised the issue of safety of Rotavirus vaccine (Brand Name - Rotavac) indigenously developed and manufactured by M/s . Bharat Biotech, Hyderabad.

To examine the concern raised in the representation of Dr. Jacob. Puliyel, the issue was deliberated in the Subject Expert Committee (SEC) wherein Subject Expert Committee (SEC) on 30.06.15 has reviewed the submission of the indicated product related Serious adverse events (SAE) during the Phase III clinical trial and did not find the concerns of non-disclosure of Serious adverse events (SAE) of intussusception and safety from Vellore site well authenticated. Moreover, the intussusception rate was very low in the trial and statistically not different significantly in the study and placebo arms as was indicated in the letter. Further, evaluation of Serious adverse events (SAE) may be undertaken under Periodic safety

update report (PSUR) evaluation or Adverse events following immunizations (AEFI) as per rules.

Also, this was further discussed in detail in the Subject Expert Committee (SEC)-Vaccine meeting held on 29.07.2015 and Subject Expert Committee (SEC) opined the following after examination and review of the published data in the journal Vaccine (Reference given below) and as per the details tabulated in the letter of Dr. Jacob Puliyel:

1. As per the Brighton Criteria, overall the percentage of intussusception in vaccine group was 0.28% (13/4532) and 0.26% (6/2267) in the placebo group. The difference is not statistically significant.

2. None of the events of intussusception required surgical interventions and

none were fatal (Reference J. John 'et al/ Vaccine 325(2014) A104-A109).

Further review of data with respect to site at Vellore with regard to intussusceptions may be under-taken, if required, based on the observations of Hon'ble High Court of Delhi, where the matter is stated to be under trial, as informed.

A PIL vide W.P. (C) No. 6913/2015, Jacob Puliyel Vs Union of India was submitted on 21.07.2015 in the Ron Isle High Court of Delhi on the non-disclosure of Serious adverse events (SAE) of intussusception and safety data from. Vellore site. Later, as per the judgment dated 14.10.2015 of the bench of Chief Justice of the Hon'ble High Court of Delhi, the writ petition was dismissed on the subject of disclosure of segregated data in public interest with remarks reproduced below: -

"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 of public injury and that there is no personal gain, private motive or oblique motive behind filing the public interest litigation.

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 Additional Solicitor General (ASG) that

the petition is misconceived and motivated with private interest.

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

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

[15] The contents of this Para are denied and the Preliminary Submissions as made in the preceding paragraphs may kindly be read as part and parcel of Reply to this para.

[16-19] The contents at Para 16-19 are denied. The deponent begs to state that the results of the study have been published in a prestigious peer reviewed journals, listed below:

1. Article on Dose - Escalation Safety and Immunogenicity Study of Live Attenuated Oral Rotavirus Vaccine

116E in Infants: A Randomized, Double Blind Placebo-Controlled Trial(available on http://jid.oxfordjournals.org/at NERL).

2. Efficacy of a monovalent human-bovine (116E) rotavirus vaccine in Indian infants: a randomised, double-blind, placebo-controlled trial (www.thelancet.com - published online on March 12, 2014).

3. Efficacy of a monovalent human-bovine (116E) rotavirus vaccine in Indian children in the second year of life (Published in the Elsevier Journal - open access article under the CC BY-NC-ND license).

4. Active surveillance for intussusception in a Phase III efficacy trial of an oral monovalent rotavirus vaccine in India (published in 2014 in the Elsevier

Journal - open access article under the CC BY-NC-ND license).

[20-21] The contents at Para 20 of the writ petition are matter of records. Hence need no reply.

[22-28] The contents of these para's are denied and the preliminary Submissions as made in the preceding paragraphs may kindly be read as part and parcel of reply to these para's.

[5] REPLY TO THE GROUNDS:-

[A] to [R]

The contents of these para's are denied. It is humbly submitted that the safety profile of Rotavac has been of paramount importance throughout clinical development since the year 2000 onwards. Various Expert Committees have reviewed the data from the clinical trials of Rotavac and have approved it and as elaborately dealt hereinabove in the Preliminary Submissions

made in the preceding paragraphs. The World Health Organization's Global Advisory Committee on Vaccine Safety (WHO-GACVS) also reviewed the data from the Phase-III clinical trials and has published a recommendation that Rotavac was unlikely to have caused Intussusception. It is noteworthy to mention herein that the National Technical Advisory Group on Immunization (NTAGI) reviewed the data on disease burden and safety, immunogenicity and efficacy of all rotavirus vaccines, including Rotavac and recommended it to be introduced in the universal immunization programme.

The results of the clinical trials of Rotavac in India have been published in large number of prestigious journals and are approved to be safe. As per Good Clinical Practice Guidelines of the Central Drug Standard Control Organization (CDSCO) and, as duly followed in the instant case, it is inappropriate to conduct site specific analysis of segregated data in a trial that is not designed for it. Such analysis of segregated data

on safety when not in the protocol may lead to misinterpretation of data and spread of disinformation about the vaccine.

The Petitioner has picked up only piece of information from the paper authored by John et al. published in journal Vaccine titled "Active surveillance for intussusception in a phase 3 efficacy trail of an oral mono-valent rotavius vaccine in India" (Annexure P/1 @ Pgs 18-24). Though the said paper says that overall incidence of intussusception identified on "Ultrasound" was 28/100,000 child year in Delhi and 581/100,000 child year in Vellore, it is pertinent to mention that 50% of these cases resolved spontaneously and did not require any medical intervention and were similar in vaccine & placebo arm. So as asserted by petitioner that Intussusception rate in Vellore is almost 20 times the rate in Delhi, is false/misleading/incorrect.

As also noted by Global Advisory Committee on Vaccine Safety (GACVS), this paper concludes

that Rotavac was unlikely to have caused intussusception.

It is pertinent to mention herein that since the introduction of Rotavac vaccine in 4 states (Andhra Pradesh, Himachal Pradesh, Odisha and Haryana), 9,82,961 doses of Rotavac vaccine have been administered till July 2016. No case of Intussusception following Rotavirus vaccination has been reported till date.

5 Judges bench of this Hon'ble Court in 1990 (2) SCC 715 Para 47(K) has held:-

> "(K) That a dispute raised by an application under Article 32 of the Constitution must be held to be barred by principles of res-judicata including the rule of constructive res-judicata if the same has been earlier decided by a competent court by a judgment which became final."

In the instant case and for the identical reliefs as sought for in the present Writ Petition under article 32, one Dr. Jacob Puliyel had filed Writ

Petition under article 226 of the Constitution of India before the Hon'ble Delhi High Court.

Vide detailed Order and Judgment dated 14/10/2015, the Hon'ble Delhi High Court was pleased to dismiss the said Writ Petition (Annexure P/12 @ Pgs 71-75).

SLP preferred against the aforesaid Order and Judgment of the Delhi High Court before this Hon'ble Court was dismissed as withdrawn by this Hon'ble Court Vide Order dated 05/02/2016 (Annexure P/13 @ Pg 76).

Thus, the Judgment of the Hon'ble Delhi High Court attained finality and the instant Writ Petition under article 32 raising identical issues is barred by principles of res judicata including the rule of constructive res judicata as it has already been adjudicated upon and decided by the Hon'ble Delhi High Court vide its detailed Order and Judgment dated 14/10/2015.

[6] MAIN PRAYER:-

In the light of the true factual and legal matrix as more particularly detailed above in the preceding paragraphs of the present Counter Affidavit, the Petitioner is not entitled for any relief, as being prayed for, and the present writ Petition is fit to be dismissed with costs.

[7] That no new fact has been pleaded which were not on record before the courts below.

[8] That the contents of this Counter Affidavit have been read over and explained to me and having understood the same I say that the same are true and correct to the best of my personal knowledge and belief and nothing material has been concealed there from nor any part of thereof.

DEPONENT

VERIFICATION:

I, the deponent above named do hereby verify that contents of the above affidavit are true to my knowledge and belief and based on the record, no part

of it is false and nothing material has been concealed there from.

Verified at New Delhi on this _____day of September, 2016.

DEPONENT

DRAFTED BY

SHRI A. DEB KUMAR
ADVOCATE,
SUPREME COURT OF INDIA