IN THE HIGH COURT OF JUDICATURE AT MADRAS

Reserved on	Pronounced on
07.08.2024	29.08.2024

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THE HONOURABLE MR. JUSTICE M.DHANDAPANI

W.P. NO. 3346 OF 2021
AND
W.M.P. NO. 3824 OF 2021

Asif Riaz .. Petitioner

- Vs -

1. Government of India
Rep. By its Secretary
Ministry of Health & Family Welfare
Nirman Bhavan, New Delhi 110 011.

2. Drugs Controller General of India
Central Drugs Standard Control Organization
Directorate General of Health Services
Ministry of Health & Family Welfare
Government of India
FDA Bhavan, ITO Kotla Road
New Delhi 110 002.

3. Director General, ICMR
Indian Council of Medical Research
Ansari Nagar, New Delhi 110 029.

4. CEO

Serum Institute of India Pvt. Ltd.
212/2, Hadapsar, Off : Soli Poonawalla Road
Pune 411 028.

5. CEO, Astra Zeneca UK
1 Francis Crick Avenue
Cambridge Biomedical Campus
Cambridge CB2 0AA, United Kingdom.

6. The Chairman
Ethics Committee
Sri Ramachandra Higher Education &
Research (Deemed University)
No.1, Ramachandra Nagar
Porur, Chennai 600 116. .. Respondents

Writ Petition filed under Article 226 of the Constitution of India praying this Court to issue a writ of Declaration declaring that the severe side effects and the hospitalization of the petitioner from 11th October to 26th October was a "serious adverse event" as defined in Rule 2 (ff) read with Sub-rule (a) of Rule 41 of The New Drugs and Clinical Trial Rules, 2019 and it was due to the administration of trial vaccine COVIDSHIELD manufactured by the 4th respondent Serum Institute of India Private Limited which the petitioner took as a volunteer on 1st October, 2020 and as a follow up to declare that COVIDSHIELD vaccine is not safe and consequently direct the 3rd and 4th respondents to pay the petitioner

a compensation and damage of Rs.5 Crores (Rupees Five Crores only) or any other amount as decided by this Hon'ble Court (including the medical and legal cost) for all the suffering and trauma that the petitioner and his family went through and going through with no end in sight for complete recovery.

For Petitioner : Mr. N.G.R.Prasad, for
M/s.Row & Reddy

For Respondent : Mr. V.Chandrasekaran, SPC for
RR-1 & 2
Mr. V.Arun C.Mohan for R-4
RR-3 & 6 – No Appearance
R-5 – No Representation

ORDER

The side effects caused by the vaccine "COVIDSHIELD" for which the petitioner, as a volunteer, stood for human trial, and resultantly suffered neurological complications of the said vaccine resulting in adverse effects on the daily life of the petitioner, has led to the filing of the present writ petition for declaration to declare the said vaccine "COVIDSHIELD" as unsafe for humans and also for compensation for the damage caused to the petitioner.

2. It is the case of the petitioner that he is an independent business consultant and is married with two kids, aged 12 and 17 respectively. It is the further averment of the petitioner that as a socially conscious individual, the devastative effect of COVID-19 Pandemic was followed by the petitioner and on coming to know of the vaccine developed by the 4th respondent, viz., COVIDSHIELD, based on the permission granted by the 2nd respondent to conduct human trial to find out the safety and efficacy of the said vaccine, the trial of which was conducted at the 6th respondent University, the petitioner volunteered to take the vaccine on trial. It is the further averment of the petitioner that he approached the 6th respondent and the Principal Investigator informed him that the trial vaccine is found to be safe and, therefore the petitioner acceded to participate in the clinical trial after going through the participant information sheet, in which there was a categorical assertion about the safety of the vaccine. The petitioner gave his consent to be a volunteer and the vaccine was administered on 1.10.2020.

3. It is the further case of the petitioner that there was no adverse reaction for the first 10 days. However, on 11th October, 2020, the petitioner

developed severe headache and was admitted at the 6th respondent Hospital, where he was put in ICU and he lost his memory. Various tests were done to find the cause, which tests returned a negative result, which clearly revealed that the adverse neurological disorder was on account of the vaccine administered to the petitioner on 1.10.2020.

4. It is the further averment of the petitioner that neither the 4th respondent nor the 6th respondent contacted him after his discharge from the hospital and the neurological disorder was on account of the adverse effect of the vaccine administered by the 4th respondent. Hence, the petitioner caused a legal notice dated 21.11.2020 to the 4th respondent claiming a sum of Rs.5 Crores as compensation and damages for the trauma suffered by him and his family due to the said vaccine. It is the further averment of the petitioner that he came to know that the 2nd respondent had formed an expert committee to look into the issue and the expert committee had submitted a report stating that the severe adverse reaction was not related to vaccine. Without hearing the petitioner, the expert committee has given its report, which is in violation of principles of natural justice. Hence, the petitioner was constrained to file the present writ petition

alleging that the administration of the study vaccine and the after effects suffered by the petitioner was a serious adverse event as defined u/s 2 (ff) of the New Drug and Clinical Trial Rules (for short 'Rules, 2019') and, the present petition has been filed for the relief supra.

5. Learned counsel appearing for the petitioner contended that prior to the trial vaccine being given to the petitioner, all tests were done to the petitioner, which did not result in any adverse result, prompting the petitioner to be found fit for taking the trial of the vaccine. It is the further submission of the learned counsel that the petitioner had, on the basis of the participant information sheet accepted to be a volunteer, as the4th respondent had made a categorical assertion that the vaccine was safe to be tested for human trial. In fact, the participant information sheet has detailed that the side effect of the vaccine will be very mind.

6. It is the further submission of the learned counsel that for the first 10 days the petitioner did not face any adverse reaction, however, the adverse reaction started from the 11th day, which carried on for 16 days and, in fact, even

after the 16 days, the petitioner had not fully recovered as is evident from the discharge summary provided by the 6th respondent hospital.

7. It is the further submission of the learned counsel that all the tests that were done to the petitioner returned a negative result, meaning thereby that there was no factor, which had induced the symptoms suffered by the petitioner, but for the vaccine taken by the petitioner. In this regard, learned counsel placed reliance on the discharge summary, in which it has been mentioned that the petitioner is affected with "Acute Encephalopathy", but the reason as to which caused the same is not traceable, inspite of all tests having been done and the results returned negative.

8. It is the further submission of the learned counsel that even after two months of being discharged from the hospital, the 4th respondent did not get in touch with the petitioner except calling the petitioner during December, 2020 for a safety test, which the petitioner undertook. Neither the 2nd respondent nor the 4th respondent got in tough with the petitioner to examine the severe adverse reaction of the test vaccine, which clearly proves that the whole cause of the

petitioner's deteriorating health was the vaccine, which the petitioner had taken on trial.

9. Placing reliance on Rule 2 (ff) and Rule 41 of the Rules, 2019, it is the further submission of the learned counsel that the ailment suffered by the petitioner is a "serious adverse event", which squarely falls u/s 2 (ff), which is a direct result of the clinical trial of the COVIDSHIELD vaccine and resultantly, Rule 41 would stand attracted to hold that the injury suffered by the petitioner is a direct off-shoot of the effect of the investigational product. It is therefore the contention of the learned counsel that the petitioner, being a healthy person and even during hospitalisation post the taking of the vaccine, no negatives have been noted in any of the reports of the petitioner, the medical complications suffered by the petitioner could be attributed only to the vaccine, which had caused the problems and, therefore, it is unsafe to use the vaccine and for all the detriments suffered by the petitioner, the petitioner is entitled to compensation.

10. Learned counsel, to emphasis the point submitted before the Court, placed reliance on the decisions of the Apex Court in the case of ***Sanjay Gupta &***

Ors. – Vs – State of UP & Ors. (2022 (7) SCC 203) and also brought to the notice of this Court the effects of the vaccine as detailed in the various journals relating to health and medicine and sought to impress upon the court that the health issues suffered by the petitioner is directly associated with the vaccine, which was given at the time of trial to the petitioner and, therefore, the petitioner is bound to be compensated for the health injury faced by him, which is having a detrimental effect on the everyday life of the petitioner.

11. Per contra, learned Special Panel Counsel appearing for the 1st and 2nd respondents submitted that the petitioner, who is a hale and healthy individual, submitted himself for clinical trial, knowing fully well about the risk involved. It is the further submission of the learned counsel that the alleged side effects developed by the petitioner consequent to administration of the vaccine, he was subjected to clinical examination under the 6th respondent, the cost of which was borne by the 4th respondent and during the clinical examination and discharge of the petitioner, it was held that the vaccine was not the reason for the alleged complaint developed by the petitioner. It is the further submission of the learned counsel that notwithstanding the treatment given to the petitioner, an expert

committee was also constituted to examine the serious adverse event of injury and the committee submitted a report that the serious adverse event was not relatable to the vaccine. In this backdrop, it is the submission of the learned counsel that the present writ petition involves disputed questions of facts and, therefore, the present writ petition is not maintainable.

12. It is the further submission of the learned counsel that the serious adverse event noticed with regard to the petitioner, inspite of the fact that the 6th respondent had held that the medical complication suffered by the petitioner was not relatable to the vaccine, however, an expert committee was constituted to find out the reason for the complications developed and the expert committee perused the various documents related to the investigational produce, disease for which the investigational product was indicated, patient condition, treatment and the assessment made by the investigator, sponsor and the ethics committee and after due deliberation opined that the reported serious adverse event was not related to the investigation/new drug clinical trial.

13. It is the further submission of the learned counsel that Rule 42 of Rules, 2019 provides the Central Licencing Authority to constitute an independent committee for the purpose of ascertaining the reason for the cause of the injury for the purpose of arriving at the reason for the serious adverse event and there is no such provision specified in the Rules, 2019, to afford/conduct any personal hearing or clinical examination to the trial subject, as the deliberation is based on documents and not on the basis of any interaction with the trial subject.

14. Further, merely because the clinical trial subject, viz., the petitioner was not granted an opportunity of personal hearing, as the same is not mandated under Rules, 2019, the said committee report cannot be said to be vitiated. It is the further submission of the learned counsel that there is no provision under Rules, 2019 to provide for a copy of the recommendation of the Expert Committee to the trial subject, viz., the petitioner herein.

15. It is the further submission of the learned counsel that as per rule 42 r/w 40 of Rules, 2019, the Central Licensing Authority had passed order dated

1.12.2020 to the sponsors of the clinical trial to provide necessary free medical management to the trial subject as long as reqpured as per the opinion of the investigator or till such time the injury is not related to the clinical trial or bioavailability or bioequivalence study, but the petitioner having got himself discharge on his own volition, as could be evidenced from the discharge summary issued by the 6th respondent, no further compensation can be sought for by the petitioner. Therefore, the severe adverse event having been held to be not relatable to the vaccine, the compensation sought for by the petitioner is wholly erroneous and the non-grant of opportunity to the petitioner before the Expert Committee cannot said to have vitiated the enquiry and, therefore, sought for dismissal of the present petition.

16. Learned counsel appearing for the 4th respondent, while concurred with the submission of the learned counsel for respondents 1 and 2 in sum and substance, further submitted that the severe adverse event is not related to the effects of the vaccine. It is further submitted by the learned counsel that though certain articles have been placed before this Court to substantiate the case of the petitioner that the severe adverse event suffered by the petitioner, viz., acute

neuro encephalopathy" was a direct consequence of taking the trial vaccine, however, the said articles do not form the basis for coming to the conclusion that the adverse event suffered by the petitioner is relatable to the vaccine, as the said cases, in the absence of any clear medical finding that the side effects are relatable to the vaccine, the mere opinion voiced out in the said articles cannot be the basis to hold that the medical complication suffered by the petitioner is attributable to the vaccine.

17. It is the further submission of the learned counsel that the cases, which are referred to in the said articles are not even miniscule, when compared to the extent to which the vaccine had been used, that too during the critical period when COVID-19 was surging and there being no clear evidence pointing out that the complications, which were found in a miniscule of persons, as detailed in the article is related to the vaccine, through proper medical evidence, the mere opinion of the author cannot form the basis to hold that the severe adverse event suffered by the petitioner and persons similarly placed, whose cases were discussed in the articles, were the result of administering of the vaccine cannot be put against the petitioner.

18. It is the further submission of the learned counsel that based on the directions of the Central Licensing Authority the 4th respondent had provided all the medical treatment to the petitioner and the petitioner had got himself discharged and the discharge summary reveals that the medical complications were not attributable to the vaccine taken by the petitioner, the compensation sought for at the hands of the 4th respondent is wholly erroneous and the further declaration to treat COVIDSHIELD vaccine as unfit for being administered to humans is wholly erroneous and no relief as sought for could be granted to the petitioner and, accordingly, prays for dismissal of the present writ petition.

19. This Court gave its careful consideration to the submissions placed on behalf of the petitioner and the contesting respondents and also perused the materials available on record, as also the decision and articles relied on by the petitioner.

20. There is no confrontation with the fact that the petitioner, on his own volition, after scrupulously going through the “Participant Information Sheet”,

voluntarily participated in the administration of the vaccine. In para-5 of the petition, the petitioner has made a clear averment as under :-

> *"5. I submit that Covid-19 Pandemic has had devastating effect on the poor and disadvantaged sections of the population not only in India but all over the world. I have been carefully following all the events of Covid-19 Pandemic since its start, I wanted to help, in any small way I could, in the larger effort to find a solution to the dismal situation because of Covid-19. I submit that when I came to know that there was a call for volunteers for Phase-III of the clinical trial pertaining to the COVIDSHIELD vaccine of the 4th respondent, Serum Institute Private Limited, I as a volunteer got the details of Phase-III before making final decision. The Phase-III clinical trial was conducted in Sri Ramachandra Institute of Higher Education and Research, Chennai (SRMC). It was the trial site and Dr. S.R.Ramakrishnan was the Principal Investigator. I submit that when I approached SRMC, the Principal Investigator informed me that it was a randomized controlled study to determine the safety and immunogenicity of COVIDSHIELD in the Health of Indian adults."*

21. From the above averment, it is clear that the petitioner, with open eyes, with an open mind and with a clear intent to help the poor, clearly knowing about the intricacies in the testing of vaccines and after reading the Participant

Information Sheet, has, on his own volition, undertaken to be a volunteer to the randomized controlled study to determine the safety and immunogenicity of the vaccine, COVIDSHIELD.

22. Further, it is to be pointed out that the petitioner was provided with the Participant Information Sheet wherein it has been stated that Oxford University has developed the vaccine and that it has been previously tested in around 500 healthy adults of 18 to 55 years and found to be safe and that currently three large clinical trial in thousands of healthy adults are ongoing with this vaccine in UK, Brazil and South Africa. Reading the above, the petitioner had undertaken to be a volunteer for testing the vaccine.

23. Further, the Participant Information Sheet also lists out the possible reactions that might occur after vaccination. Though it is the case of the petitioner that the symptoms and difficulties faced by the petitioner are of a greater magnitude and that according to the 4th respondent, any allergic reaction after vaccination is an extremely rare possibility. In fact, there is a clear mention in the Participant Information Sheet that in addition to the reactions, which have

been listed as could be undergone by a volunteer taking the vaccine, in addition there could be other side effects that have not been foreseen.

24. From the above, it is clear that not only the petitioner was made aware of what to be expected of the vaccine, COVIDSHIELD, but in addition, it was prompted to the petitioner that there could be other side effects that have not been foreseen. Reading all the above carefully, the petitioner had taken the conscious decision to be a volunteer for the said trial vaccination.

25. All the above are admitted facts and neither the petitioner nor the respondents are disputing the same. However, the whole emphasis is laid on Rule 2 (ff) and Rule 41 of the Rules, 2019, by the petitioner to submit that the complication developed by the petitioner is a serious adverse event, as provided for u/r 2 (ff) and, therefore, the petitioner is entitled to compensation, as the said serious adverse event has materially impacted the life and livelihood of the petitioner, which is controverted by the respondents.

26. Therefore, the appreciate the above, Rule 2 (ff) of Rules, 2019, which defines “serious adverse event” requires to be adverted to, which provides as under :-

> *“2 (ff) : “Serious Adverse Event” means an untoward medical occurrence during clinical trial resulting in death or permanent disability, or hospitalization of the trial subject where the trial subject is an outdoor patient or a healthy person, prolongation of hospitalization where the trial subject is an indoor-patient, persistence or significant disability or incapacity, congenital anomaly, birth defect or life threatening event.”*

27. There could be no doubt that the complications suffered by the petitioner are serious in nature but what is material to be seen is whether the serious adverse event, as pointed out by the petitioner is directly attributable to the intake of vaccine taken by the petitioner during the clinical trial.

28. The petitioner was subjected to clinical trial by administration of the vaccine on 1.10.2020. Till 10.10.2020, the petitioner did not suffer any side effects. Even on the day of administration of the vaccine the petitioner did not suffer any side effects. However, the petitioner developed complications on

11.10.2020, prompting in his hospitalisation. There is no quarrel with the fact that pursuant to the complications suffered by the petitioner, the Central Licensing Authority issued directions to the sponsor/his representation to provide free medical management to the subject as long as required as per the opinion of the investigator and pursuant to the said directions, the petitioner, being the subject of clinical trial, has been provided with free medical management till the period of his hospitalisation.

29. The petitioner as well as the respondents have placed before this Court the treatment given to the petitioner pursuant to his hospitalisation. In fact, there is no quarrel with the treatment given to the petitioner by the 6th respondent. In this regard, a perusal of the counter filed by the 1st and 2nd respondents reveals that pursuant to the hospitalization of the petitioner, an independent expert committee was constituted for due deliberation and the said expert committee, after perusing the reports of the hospital, the treatment given, assessment made by the investigator and patient condition, opined that the reported serious adverse event was not related to the investigation/new drug.

30. The whole case of the petitioner hinges on non-providing of opportunity during the evaluation by the independent expert committee and not providing a copy of the report of the committee.

31. In this regard, it is the stand of the 1st and 2nd respondents that Rules, 2019 do not envisage providing of opportunity to the petitioner to make his case before the expert committee and also do not provide for providing the evaluation report of the expert committee to the petitioner. In this regard, emphasis is laid on the discharge summary of the petitioner in which it has been held that the serious adverse event was not relatable to the vaccine administered to the petitioner.

32. It is to be pointed out that the petitioner has not challenged the discharge summary and the findings rendered therein till date. When the experts in the medical field have given their opinion that the effects suffered by the petitioner are not directly relatable to the vaccine administered to the petitioner and that the serious adverse event was not on account of the vaccine, this Court

cannot substitute its views to that of the experts to hold otherwise. True it is that the petitioner has placed the opinion of few other medical professionals based on the discharge summary issued and the treatment given to the petitioner. However, the opinion of the medical professionals cannot form the basis for this Court to hold that the medical complications suffered by the petitioner are directly attributable to the trial vaccine taken by the petitioner.

33. True it is that the vitals of the petitioner were held to be normal and no complications were found while the petitioner was under hospitalization and all the tests returned a negative result. However, from the same, it cannot be inferred that the complications suffered by the petitioner are directly relatable to the trial vaccine administered to the petitioner. Further, the petitioner had voluntarily partaken to have the clinical trial of the vaccine after reading the Participant Information Sheet, in which there is a clear statement in Page-8 that there could be other side effects that have not been foreseen. Only to that end, to find out whether the side effects of a volunteer are directly attributable to the vaccine, the Central Licensing Authority had mandated the sponsor to take care of the medical management of the volunteers to find out whether the side

effects are attributable to the vaccine. However, as stated above, the discharge summary clearly reveals that the side effects, though were severe, were not directly related to the vaccine taken by the petitioner. Even the expert committee had opined that the severe adverse event suffered by the petitioner was not related to the vaccine. Such being the case, merely because the petitioner has developed complications post taking the vaccine, it cannot be held that the complications were directly relatable to the vaccine, when the expert body has opined that the complications are not directly relatable to the vaccine.

34. Further, when Rules, 2019, do not mandate providing an opportunity of hearing to the petitioner, more so, it shields the name of the volunteer, who had taken the clinical trial by referring to the volunteer by means of a subject ID. When there is no provision for providing opportunity to the petitioner under rules, 2019, the principles of natural justice cannot be imported to such clinical trial, as it is purely within the domain of the experts to decide the reason for the severe adverse event on the basis of the materials available before them and it is not for the person, who has had the severe adverse effect to speak about the same before the expert committee, as the expert committee would be guided by

the materials placed before it as it is drawn by the medical experts in the field and it is not guided by the personal deposition of the subject, who had underwent to the medical complications.

35. In fact, in the affidavit, the petitioner had placed reliance on Page-8 of the Participant Information Sheet, where the safety of the vaccine had been reinforced, wherein it has been specifically stated as under :-

> *"..... In another ongoing study of the ChAdox 1Ncov-19 vaccine in U.K., safety reviews were carried out after 2 participants who received the vaccine developed unexplained neurological symptoms, including changes in sensation or limb weakness. After review by independent experts, these symptoms were either considered unlikely to be associated with the vaccine or there was not enough information to say for certain that the symptoms were or were not related to the vaccine. In each of these cases, after considering the information, independent reviewers recommended that the vaccine should continue. ....."*

36. From the above, it is evident that the present case is not the only case where there were certain side effects, which were held to be not attributable to the vaccine as even before, in similar situation, on similar vaccine, the

participants suffered certain complications, which, after thorough examination, was held to be not relatable to the vaccine.

37. Likewise, in the present case, the petitioner, being a recipient of the trial vaccine, had developed complications for which he was hospitalized and had was provided with treatment at the instance of the 4th respondent and while discharging the petitioner, the 6th respondent had held that the side effects faced by the petitioner were not resultantly due to the vaccine, which stand of the 6th respondent was reinforced by the evaluation by the expert committee, which also held that the complications suffered by the petitioner were not attributable to the vaccine.

38. Though very many medical journals in which certain adverse effects relating to the vaccine have been published, which have been placed before this Court, nevertheless, the said articles are stray incidents, which have been published pointing to certain precautionary measures to be taken while administering the vaccine. In none of the articles, the adverse event was directly held to be due to the intake of the vaccine. There are no positive materials to

suggest that the intake of the vaccine had directly resulted in the severe adverse event in the said patients. Merely because some volunteers have faced severe adverse event while partaking in the clinical trial by getting administered with the vaccine, that cannot be the basis to hold that the vaccine is unfit for human administration. When worldwide, the vaccine had been accepted and had been administered to millions of persons to combat the onslaught of the pandemic, stray incidents like the present case, where certain severe adverse events have come to be noted, but not directly attributed to the vaccine, cannot be the basis to hold the vaccine to be unfit for human administration. Further, in case the severe adverse effects are held to be on the basis of the vaccine, Rules, 2019, provides in-built safeguards for the volunteers against the said effects putting the sponsors to strict adherence to the safeguards mentioned therein. In the absence of any concrete proof establishing that the severe adverse events are directly attributable to the vaccine, the articles published in the said medical journals cannot be the basis for this Court to render any finding in favour of the petitioner.

39. Decision in *Sanjay Gupta case (supra)* has been relied on by the learned counsel for the petitioner to drive home the point that where life and personal liberty have been violated, absence of any statutory provision for compensation in the statute is of no consequence. Para-21, where the Supreme Court has propounded the said ratio, as quoted hereunder, has been relied heavily by the petitioner :-

> *"21. The contentions raised by Mr.Bhushan are substantially same as were raised before the Delhi High Court in Uphaar Tragedy Victims Association, which were not accepted. This Court in appeal had accepted the view of the High Court exept to the extent of finding of negligence against certain respondents. We are in complete agreement with the findings recorded by this Court in appeal that :-*
>
> > *"98. ....where life and personal liberty have been violated, the absence of any statutory provision for compensation in the statute is of no consequence. Right to life guaranteed under Article 21 of the Constitution of India is the most sacred right preserved and protected under the Constitution, violation of which is always actionable and there is no necessity of statutory provision as such for preserving that right. Article 21 of the Constitution of India has to be read into all public safety statutes, since the prime object of public safety legislation*

is to protect the individual and to compensate him for the loss suffered. Duty of care expected from the State or its officials functioning under the public safety legislation, is, therefore, very high. ....."

40. This Court has no quarrel with the aforesaid proposition of law laid down by the Supreme Court and in fact, this Court is in respectful agreement with the said ratio. However, the case on hand does not fall within the parameters of the said case and is wholly on a different scale. In the present case, the petitioner having read the Participant Information Sheet and understood and satisfying himself had submitted voluntarily to the clinical trial. The effects of the clinical trial cannot be foreseen by any person. Only to cater to that end, the Central Licensing Authority has provided for treatment to the clinical trials, who develop serious adverse event to find out whether the event is on account of the vaccine taken by the volunteer. In the event of it being established that the serious adverse event is due to the vaccine administered, then compensation could be sought for by the volunteer, as is provided under the Rules, 2019. However, what is to be noted here is the fact that it should stand established that the severe adverse effect suffered by the volunteer is as a

direct consequence of the vaccine that had been administered, which alone would form the basis for seeking compensation. Without establishing that the medical complications suffered were a direct consequence of the severe adverse effect that had come due to the administration of the vaccine, the claim of compensation cannot be pressed into service.

41. Once the petitioner has understood and with open eyes submitted himself to the clinical trial by accepting to take the vaccine on trial, the safety provided by Rules, 2019 would come into play and so long as the trial is taken within the four corners of Rule, 2019 and the volunteers are provided with the necessary assistance, any serious adverse event, which befalls on a volunteer, is sought to be addressed by subjecting him to medical treatment at the cost of the sponsor. The outcome of the medical treatment, so long as it is not on account of the vaccine, the sponsor cannot be made liable to pay any compensation to the volunteer. However, if the serious adverse event is directly relatable to the vaccine, if established, then necessarily the sponsor, viz., the 4th respondent herein would be duty bound to pay compensation and take care of the volunteer by providing the necessary treatment.

42. In the case on hand, the petitioner having voluntarily come forward to submit himself to the clinical trial after satisfying himself by going through the Participant Information Sheet, which had provided all the details to the petitioner and after taking the vaccine, the petitioner not having suffered any immediate complications, but suffered certain untoward complications, which is a severe adverse event, as provided for u/r 2 (ff) of Rules, 2019, but which adverse event was held to be not related to the vaccine taken by the petitioner, the decision in *Sanjay Gupta case* would not stand attracted to the case of the petitioner and, therefore, the prayer sought for by the petitioner for payment of compensation and also for a further declaration to declare the vaccine "COVIDSHIELD" as unfit for being administered on humans is wholly erroneous and the same cannot be countenanced by this Court.

43. Though this Court can sympathise with the petitioner for being inflicted with the severe adverse effect, however, the same having been held to be not relatable to the vaccine administered by the 4th respondent, no relief can

be granted to the petitioner and, therefore, there are no merits in the present petition and the same deserves to be dismissed.

44. For the reasons aforesaid, the present writ petition is devoid of merits and, accordingly, the same is dismissed. Consequently, connected miscellaneous petition is also dismissed. However, there shall be no order as to costs.

29.08.2024

Index : Yes / No

GLN

To

1. The Secretary
Ministry of Health & Family Welfare
Government of India
Nirman Bhavan, New Delhi 110 011.

2. Drugs Controller General of India
Central Drugs Standard Control Organization
Directorate General of Health Services
Ministry of Health & Family Welfare
Government of India
FDA Bhavan, ITO Kotla Road
New Delhi 110 002.

3. Director General, ICMR
Indian Council of Medical Research
Ansari Nagar, New Delhi 110 029.

M.DHANDAPANI, J.

GLN

PRE-DELIVERY ORDER IN
W.P. NO. 3346 OF 2021

Pronounced on

29.08.2024