



W.P(MD)No.19081 of 2015

BEFORE THE MADURAI BENCH OF MADRAS HIGH COURT

DATED : 26.09.2023

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THE HONOURABLE MR.JUSTICE G.R.SWAMINATHAN

W.P(MD)No.19081 of 2015

R.Rajendran

... Petitioner

Vs.

- 1.The Secretary, Medical Council of India,
Sector – VIII, Pocker – 14, Dwarka, New Delhi.
- 2.The Registrar, Tamil Nadu Medical Council,
New No.914, Old No.569, Poonamalli High Road,
Arumbakkam, Chennai.
- 3.The Drugs Controller General (India),
FDA Bhavan, CHEB Campus,
Kotla Road, New Delhi.
- 4.Vitreo Retinal Technologies Inc.,
No.2, Venture Drive,
Suite 430, Irvine, CA 92618.
- 5.The Associate Director (Chemical Project),
SIRO Clinpham (P) Ltd., Dil Premises, 2nd Floor,
Swami Vivekanand Road, Ghodbunder Road,
Thane (West), Mumbai – 400 610.
- 6.The Chairman, Aravind Eye Hospitals &
P.G.Institute of Ophthalmology,
No.1, Anna Nagar, Madurai – 20.



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7.Dr.Kim Ramasamy, Chief Medical Officer,
Aravind Eye Hospitals P.G.Institute of Ophthalmology,
No.1, Anna Nagar, Madurai – 20.

8.Dr.Somnath Chakraborty, Aravind Eye Hospitals &
P.G.Institute of Ophthalmology,
No.1, Anna Nagar, Madurai – 20.

9.Dr.Dharmalingam, Chairman,
Institutional Review Board,
Sr.Professor & Head,
School of Biotechnology,
Madurai Kamaraj University,
Madurai – 21.

10.Dr.S.R.Rathinam, Institutional Ethics Committee,
Aravind Eye Hospitals &
P.G.Institute of Ophthalmology,
No.1, Anna Nagar, Madurai – 20.

11.The Commissioner of Police,
Madurai City, Madurai.

12.The Inspector of Police,
E3, Anna Nagar Police Station,
Anna Nagar, Madurai.

...Respondents

Prayer: Writ Petition filed under Article 226 of the Constitution of India praying to issue a Writ of Certiorarified Mandamus, to call for the records pertaining to the impugned report of the third respondent dated 04.06.2013 and to quash the same and to pass an order directing the third respondent to take appropriate action against the respondents 6 to 8 for the loss of eye-sight to the petitioner in clinical trial conducted by the sixth respondent through the respondents 7 and 8 and to take appropriate civil and criminal proceedings against the respondents 4 to 9.



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For Petitioner : Mr.D.R.Raghunath

For Respondents : M/s.Shubaranjani Ananth
Standing Counsel for R.1

Mr.D.Gandhiraj
Special Government Pleader for R.2

Mr.K.Govindarajan
Deputy Solicitor General of India for R.3

Mr.B.Prasanna Vinoth for R.6

Mr.R.R.Kannan for R.7 to R.10

Mr.A.Albert James
Government Advocate for R.11 & R.12

ORDER

Heard the learned counsel appearing for the writ petitioner, the learned Standing Counsel appearing for the first respondent, the learned Special Government Pleader appearing for the second respondent, the learned Deputy Solicitor General of India appearing for the third respondent, the learned counsel appearing for the sixth respondent, the learned counsel appearing for the respondents 7 to 10 and the learned Government Advocate appearing for the respondents 11 and 12.

2. The writ petitioner had some issues in his right eye. He approached Aravind Eye Hospital, Madurai for treatment. This was in October 2007. He



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was periodically consulting the said Institute. According to the petitioner, on 04.02.2008, a suggestion was given to him that if he is willing to participate in a clinical trial to test a new eye drop by name “Vitreosolve”, his eye problem would be cured and that the treatment would be given free of cost. The petitioner states that even though he was not willing, he was persuaded subsequently by the Hospital staff to subject himself to the said clinical trial.

3. The petitioner was administered the said drug on 30.04.2008. However, the petitioner developed serious complications. The petitioner states that he lost his vision in the right eye on 05.05.2008. The petitioner lodged complaint with the hospital authorities and that the petitioner was admitted as an inpatient on 05.05.2008 and discharged on 13.05.2008. According to the petitioner, the vision was not restored. He suffered serious adverse impact as a result of the trial and that the hospital authorities are to be blamed for the same. His complaint before the Tamil Nadu Medical Council was rejected and the rejection order was also sustained by the Medical Council of India. His complaint before the Drugs Controller General who granted approval for the clinical trial also does not elicit any response. Hence the petitioner moved the Central Information Commission which directed the third respondent to conduct enquiry. The third respondent called upon the petitioner to appear for



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enquiry on 24th and 25th May 2013. The petitioner objected to the venue of

enquiry. It was agreed that the enquiry will be conducted in a neutral venue.

However, such an enquiry was never conducted in the neutral venue as promised. A false report exonerating the Hospital was given by the third respondent. Challenging the same, the present writ petition came to be filed.

4. The learned counsel appearing for the petitioner reiterated all the contentions set out in the affidavit filed in support of the writ petition and called upon this Court to set aside the report and grant relief as prayed for.

5. He pointed out that even though approval was given for conducting clinical trial only for 25 patients, the number was actually 30. Even though Dr.Kim Ramasamy had personally undertaken to conduct the clinical trial under his personal supervision, injection of the drug was administered by one Dr.Somnath Chakraborty who it is alleged that did not have proper training. The next contention is that even though antibiotic should have been administered three days prior to the administration of the drug, it came to be given only a day earlier. He would point out that insurance coverage was not taken. He further stated that the respondents have come out with a false case



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that vision in the right eye was more or less normal. He drew my attention to the report given by the Eye Department of Government Rajaji Hospital, Madurai in this regard. He called upon this Court to grant relief as prayed for.

6. The seventh respondent has filed counter affidavit and the learned counsel took me through its contents. He strongly denied the allegations made by the writ petitioner that there was negligence on the part of the seventh respondent personally or on the part of the Hospital.

7. The learned Deputy Solicitor General of India appearing for the third respondent called upon this Court to sustain the impugned order. The learned counsel appearing for the first respondent took the stand that since the issue pertains to clinical trial, the issue would fall in the province of the third respondent. The respondents submitted that the writ petition deserves to be dismissed.

8. I carefully considered the rival contentions and went through the materials on record.



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9. The sequence of events deserves to be taken note of. The petitioner was administered the drug in question on 30.04.2008. On 05.05.2008 an adverse development had taken place. The petitioner was admitted in Aravind Hospital as inpatient and discharged on 13.05.2008. Complaint for the first time was lodged only on 12.11.2008. The petitioner addressed a letter to the Chairman of Aravind Hospital. The complaint was lodged before the Ministry of Health and Family Welfare on 04.03.2010. The petitioner had also moved the Police authorities. The petitioner thereafter sent a complaint to the Central Information Commission wanting to know the status of the complaint given by him on 04.03.2010. The Central Information Commission directed the Drugs Controller General of India to conduct enquiry and submit report. The Drugs Controller General of India conducted enquiry and submitted report on 25.05.2013. Copy of the same was enclosed along with the communication dated 04.06.2013 addressed to the Central Information Commissioner. That is impugned in this writ petition.

10. The petitioner wants this Court to quash the report and direct the the learned Drugs Controller General of India to take action against the Hospital authorities.



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11. At the very outset, I must observe that the petitioner has come to this Court with gross exaggeration. The prayer in this writ petition is for taking action against the Hospital for loss of eye sight to the petitioner in clinical trial. When the matter was taken up in the last occasion, the petitioner appeared in person. He gave an impression that he was misled into participating in the clinical trial and that his consent was obtained under compulsive circumstances. It is beyond dispute that the petitioner had signed in the consent form. The petitioner was working in labour wing in Kaleeswari Fire Works Limited, Sivakasi. The manner in which the petitioner has prosecuted his complaint also improbablises his allegation that he was not a willing participant in the clinical trial.

12. The first allegation is that even though permission was granted only for 25 persons, 30 persons had taken part in the clinical trial. I do not find much force in this contention. In any event, this is a matter that should be taken note of only by the third respondent. The petitioner cannot be said to have suffered any prejudice merely because 30 persons had taken part in the clinical trial. Whether the number was 25 or 30, that will not make any difference as far as the petitioner is concerned.



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13. The second contention is that the injection was administered by Dr.Somnath Chakraborty and that Dr.Kim Ramasamy did not personally supervise. Even though learned counsel appearing for the petitioner repeatedly draw my attention to the terms of approval given by the third respondent, I am again not persuaded by the submissions. The Drugs Controller General of India had expressed their no objection to the fifth respondent conducting clinical trial with Vitreosolve drug under the supervision of the investigators mentioned in their letter dated 01.11.2007.

14. According to the learned counsel appearing for the petitioner, the seventh respondent as approved investigator alone have administered the drug. In my view, the permission letter merely speaks of the overall supervision of the investigator. The investigator cannot be expected to personally administer the drug in question. In any event, Dr.Somnath Chakraborty was not a novice or a non-medical person. He is also a qualified eye surgent. In fact, his name has been associated in the entire process as a co-investigator. Administering of drug by the co-investigator cannot be cited as an instance of medical negligence.



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15. The third contention made by the learned counsel appearing for the petitioner is that the antibiotic was not given three days prior to the administration of the drug. This aspect of the matter has been dealt with in the impugned report in the following terms :

“The committee also observed that in Mr.Rajendran case the antibiotics were administered one and half days before Intra Vitreal injection instead of three days as per protocol. “According to PI this was done after checking with the medical monitor for the study as literature as proven that prophylactic antibiotics are not heldful. Only providone iodine used before the injection is beneficial and it is the standard practice everywhere.””

But this is not the basis on which I am non-suiting the petitioner. I am more on the conduct of the petitioner. As already noted, complaint was made by the petitioner only six months after the occurrence. The complaint was made to the Ministry only in March 2010. He went to the Central Information Commission only in 2013. Pursuant to the direction given by the Central Information Commission, the third respondent constituted an enquiry committee. The members of the enquiry committee are Doctors of standing. They were present in Madurai on 24.05.2013 and 25.05.2013. When they called upon the petitioner to appear for enquiry, the petitioner replied that he will not participate in the enquiry since it was proposed to be conducted in the premises



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of Aravind Eye Hospital. Thereupon, the Deputy Drugs Controller, South Zone sent a mail that they would hold the enquiry at a common place to be identified by the inspecting team and that they would also intimate the petitioner telephonically. The petitioner was requested to be present in the neutral venue between 03.00 p.m to 04.00 p.m on 24.05.2023 and if required 25.05.2023 also. In response to this mail, the petitioner replied at 08.08 p.m on the same day in the following terms:

“ I request your goodself may kindly arrange to conduct the enquiry in the proper manner, the information to be given telephonically about the venue of common place is against the procedure to be followed to conduct the enquiry the enquiry. So I am unable to comply the controversial information received from your office, so try to conduct the enquiry in a proper manner with a member of retired High Court Judge as a Chairman of the enquiry committee. ”

Thus, the petitioner had made his stand quite clear. He was not interested in extending his co-operation. In these circumstances, the third respondent after going through the materials on record and after examining the seventh respondent and other staffs come to the following conclusions:

“1.Based on our enquiry including physical checking of relevant documents and data it does not appear that the trial



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was performed with the intention of monetary gain from the sponsor.

2.The drug trial was conducted after the approval of its protocol by the DCGI as well as by the Institutional Ethics committee of Aravind Eye Hospital.

3.The PI included 30 subjects in the drug trial as the number of the subjects was not fixed for this site. It appears the investigators did not violate the guidelines.

4.Although the patient in question did develop the Serious Adverse event after Intravitreal injection (Placebo). However, Mr.Rajendran's case was reported as Serious Adverse event both to the Ethical Committee on 08.05.2008 and DCGI through Sponsor as per protocol. Endophthalmitis following intravitreal injection is a known complication. The treatment of this SAE provided by PI and his team was prompt and adequate. Finally the patient regained BCVA of 6/9.

5.All the clinical trial procedures were conducted by the authorized and competent team in the absence of PI.

6.The expert body could not examine Mr.R.Rajendran because despite repeated written and telephonic requests he failed to appear before the enquiry committee.”

I am of the view that the petitioner has to blame only himself. Having lodged a complaint and having caused an enquiry to be made, it was his bounden duty to have participated in the enquiry. When objection was taken as to the venue of



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enquiry, the inspecting team agreed to choose a neutral venue. Even that was not acceptable to the petitioner. In the impugned report it has been stated that on the said date and the next date also, the petitioner was telephonically intimated. In the affidavit filed in support of the writ petition this averment found in the enquiry report has not been denied.

16. The petitioner had also stated before this Court that the complaint was not drug related but only procedure related. The respondents have been consistently stating that the petitioner did not lose his vision in the right eye and that it was found to be 6/9, the petitioner's case is that he had lost his vision in his right eye completely. The petitioner could have very well appeared before the committee. He has not done so. In these circumstances, no case for interference has been made out.

17. This writ petition stands dismissed. There shall be no order as to costs.

26.09.2023

Index : Yes / No
Internet : Yes / No
NCC : Yes / No
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G.R.SWAMINATHAN, J.

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