

(2016) 04 AHC CK 0041

In the Allahabad High Court

Case No : Public Interest Litigation (PIL) No. 13841 of 2016.

Deeksha Dwivedi and Others

APPELLANT

Vs

Union of India and Others

RESPONDENT

Date of Decision : 01-04-2016

Acts Referred:

Constitution of India, 1950 — Article 226

Citation : (2016) 3 AILLJ 578

Hon'ble Judges : Dr. Dhananjaya Yeshwant Chandrachud, C.J.;Yashwant Varma, J.

Bench : Division Bench

Advocate : In Person, for the Appellant; C.S.C., A.S.G.I. and Ajeet Kumar Singh, Advocate, for the Respondent

Final Decision : Disposed Off

Judgement

1. The public interest litigation has been instituted by a group of law students of the University of Allahabad who are associated with the activities of the Human Rights Law Network. Seven patients who were being treated in the department of Ophthalmology at Banaras Hindu University were administered an intra vitreal dose of Avastin. The patients had purchased the injection from a chemist ? M/s New Amar Pharma, Varanasi. Upon the administration of the injection, the patients are reported to have developed problems of diminished vision and approached the treating Doctor, Professor OPS Maurya on 29 January 2016. The patients complained that there was a loss of vision. On 2 February 2016, the Vice Chancellor constituted a six member committee to inquire into the incident. The committee recorded statements and has concluded that all the seven patients to whom the injection Avastin was administered developed complications of pain, redness and loss of vision.

2. The grievance of the patients was that they had been made to approach Doctors outside the S S Hospital by the treating Doctor. The committee noted that the five patients had experienced diminished ocular vision but has formed

the opinion that the condition was not due to the negligence of the treating Doctor but due to other associated illnesses in their eyes. In the view of the committee, the injection Avastin is normally used by medical practitioners in the field of ophthalmology for the treatment of retinal disorders. The patients were counselled before the injection was administered and the treating Doctor was found to have taken all reasonable care. Relying upon the report of Professor Gopal Nath of the Department of Microbiology, the committee has found that there was reason to believe that the possibility of the patients having been administered contaminated vial of the injection cannot be ruled out.

3. In support of the submission that the administration of the injection Avastin is not prohibited, learned counsel appearing on behalf of the BHU has placed on the record a notice dated 9/11 March 2016 issued by the Directorate General of Health Services. The notice follows upon an earlier notice dated 21 January 2016 regarding the use of the injection in ophthalmologic conditions. The notice states that earlier, an alert notice was issued as a precautionary measure in the light of incidences of blindness which were reported in Gujarat following the use of Avastin. However, it was found that WHO has recommended the administration of the injection by including it in the list of essential medicines and that the safety and the efficacy of the injection has been proven by independent studies conducted globally. The drug is stated to be forty times cheaper than other available drugs thereby reducing the financial burden on poorly resourced patients for preventing blindness. However, the notice also states that the All India Ophthalmological Society and Vitreo Retinal Society of India will formulate guidelines for safe and effective use of the drug based on written-informed consent of patients as practised globally for off-label use under appropriate environmental conditions by skilled ophthalmic surgeons based on a risk-benefit analysis.

4. First and foremost, the concern of the Court at this stage of the case must be to ensure the restoration of eye sight of the seven patients who were administered the drug. Learned counsel appearing on behalf of BHU states that it appears that subsequently, five of the patients who received follow up treatment have had their eye sight restored while two received treatment at Shankar Netralaya, Chennai and have been duly treated. Since several of the patients involved in the present case, belong to a strata of society which cannot afford expensive medical care, we are of the view that it is the bounden duty of the Court to ensure that all feasible treatment options are provided to them for the restoration of their eye sight. Without casting any aspersion on the report of the expert committee which was constituted by the Vice Chancellor, we are of the view *prima facie* that it may be proper for the Court to have an independent assessment of whether prevailing protocols were duly followed in the administration of the drug. The report of the Microbiologist does not rule out the possibility of the injection Avastin which was purchased from the open market being contaminated though it equally does dwell on the possibility of such contamination taking place in the course of the administration of the drug in the

Hospital.

5. Hence, we propose to issue an immediate direction to the effect that such of the seven patients who consent to the course of action which the Court proposes to adopt should be duly examined at an independent institute for the purpose of their treatment. We direct that the Vice Chancellor of BHU shall ensure that immediate steps are taken to contact each one of the seven patients and, subject to their consenting to receiving the benefit of the remedial order which is being passed by this Court, to make arrangements for their being examined at the Sanjay Gandhi Post Graduate Institute, Lucknow (SGPGI). The Head of the Department of Ophthalmology at SGPGI may be requested to assign these seven patients to an appropriate treating department or Doctor, as the case may be, for evaluation of their condition and for prescribing and administering the line of treatment, if any. This exercise shall be completed within a period of one week from today. We clarify that this Court cannot compel patients to seek the benefit which is being extended in terms of this order and hence, the line of action as noted above would be pursued for those of the seven patients who are ready and willing to accept the directions of the Court for being examined and treated at SGPGI at the cost and expenses which are to be borne by BHU. Arrangements for travel and stay of the patients to Lucknow and their return shall be borne by BHU at this stage.

6. We also direct that a counter affidavit be filed in the present proceedings by BHU in the meantime. The petition be listed after two weeks when the Court will consider the necessity of ordering an independent probe based on the material before the Court.

7. In the meantime, the Vice Chancellor in the interest of transparency, may also apprise the Court on the next occasion of the response of BHU to the suggestion that an independent team of experts drawn from an institution outside BHU may be constituted to submit a report on the protocol which was followed, the line of treatment which was administered and the causes if any for the diminution of vision which was suffered by the patients who were treated. The Court shall be apprised of the report of SGPGI on the next date. Since the Court has been apprised of the fact that the State Government had also ordered the constitution of a committee to look into the matter, the learned Standing Counsel shall place on the record a copy of the report of the committee on the next date. A copy of the report of the committee constituted by the State shall also be made available to the petitioners appearing in person in advance so as to enable them to assist the Court. A copy of the report which has been placed before the Court by the learned counsel for the BHU shall also be handed over to the petitioners.

8. List under the same caption on 22 April 2016.