(2002) 12 NCDRC CK 0067

In the National Consumer Disputes Redressal Commission

SHEFALI BHARGAVA — APPELLANT

Vs

INDRAPRASTHA APPOLLO HOSPITAL — RESPONDENT

Date of Decision : 16-12-2002

Acts Referred:

Citation : 2003 1 CPJ 216 : 2003 3 CLT 402 : 2003 3 CPR 58

Hon'ble Judges : J.K.Mehra , Rajyalakshmi Rao , B.K.Taimni J.

Final Decision : Complaint allowed

Judgement

1. THIS complant is filed by the complainant Miss Shefali Bhargava, a monor aged 17 years, through her father and natural guardian, Mr. D.C. Bhargava, alleging medical negligence on the part of Indraprastha Apollo Hospital, respondent No. 1 and Dr. Pratap Reddy, Chairman of the hospital (Respondent No. 2). At a later stage Dr. S. Chandra, Senior Consultant of the same hospital has been added as respondent No. 3 During the pendency of this case, Miss Shefali Bhargava attained majority and impleaded herself as the complainant. The complainant''s case is that the respondent hospital gave her transfusion of improperly tested blood products from its Blood Bank thereby giving her an infection of a very serious disease Hepatitis C virus which has ruined her life and the treatment of which is difficult and very expensive.

2. THE brief facts of the case are as follows : 2.1. THE complainant Shefali Bhargava was 17 years and 10 months old when she was admitted in the Apollo Hospital, New Delhi on the evening of 22nd June, 1997, with a complaint of 1040F high malarial fever. THE respondent No. 3 who examined her got her blood tests done, which showed a Platelet count of 59,000 (as against the normal range of 1,50,000). He thought that the complainant needs to be given a transfusion of blood Platelets and advised her mother to get her blood tested so that her blood could be used for transfusion. On 23rd at about 11.00 a.m. the complainant was however given 5 units of blood Platelet concentrate prepared in the Blood Bank from five different donors. Ultrasound of the complainant was done on 24th June which showed the liver to be normal. On 25th her blood was

tested for HCV (Hepatitis C) anti-bodies and HB antigens and both were found to be negative. THE fever subsided and on 26th June the complainant was discharged from the hospital, with the advice that she should continue using the prescribed anti-malarial drugs. During her stay in the hospital, her blood was tested for liver enzyme tests, and the parameters were normal (consistent with the anti-malarial drugs being given). She was advised to carry out these tests again on the 4th July and with these results she again saw respondent No. 3 Dr. S. Chandra, on 5th July who found the parameters normal (her SGPT count was 57) and advised her to continue taking the anti-malarial drugs for a period of 3 months. He also advised her to repeat the blood tests for HB and SGPT after a period of one month. 2.2. THE complainant avers that she continued taking the drugs for the prescribed 3 months period. She however, did not get the tests done after one month as advised by respondent No. 3 THEse tests however were got done at Dr. Lal''s Lab on 13th September, i.e. after 2 months. THE test showed that an extremely abnormal result for SGPT (Liver Enzyme Test). THE normal SGPT should have been in the range of 0-31, but the test showed 1334, showing that her liver got diseased. Perturbed by this, the complainant was got examined at Dr. Kataria''s Lab on 17.9.1997; at LNJP Hospital on 18.9.1997 and at Dr. Lal''s Pathology Lab on 22.9.1997. THEse tests, which included a biopsy of her liver, revealed that she got an acute attack of Hepatitis C infection. She is convinced that infection came from the use of improperly tested and stale blood products (Platelet Concentrates) given to her at the Apollo Hospital. THE normal gestation period for Hepatitis C virus is 8 to 12 weeks, and the virus revealed itself in the 11th week after the gestation. Further medical experts confirm that the severity of the infection in this case is such that the infection must have come only from the improperly tested blood products given to her. She has been under treatment in LNJB Hospital for Hepatitis C and has already spent a huge amount on her treatment. She gave a legal notice to responent No. 1 on 10.10.1997 and thereafter filed the complaint before us alleging gross negligence on the part of the respondents and claiming : (a) Rs. 10 lakhs for the present course of treatment including cost of interferon injections ribavarine medicine, blood test and investigations which have already been done and then further prescribed in the coming months and years; (b) any such amount which the complainant may have to incur over and above the said Rs. 10 lakhs for her treatment in future, due to the lapses or serious complications; (c) pay damages of Rs. 50 lakhs as compensation for her present and future mental agony, physical suffering, depression and loss of education career and earning capacity which should have had under job in which she could have been employed keeping in view the education, background and status of the parents.

The complainant''s case essentially is that : (i) there was no need to give Platelet transfusion to her at the time it was given according to accepted medical practice and that it was unnecessarily rushed; (ii) even if there is a case for Platelet transfusion, such transfusion should have been given from her mother''s blood, as originally contemplated by respondent No. 3 and it was risky to have given

the transfusion from other donors'' blood; (iii) that the donors'' blood was improperly and inadequately tested and that the records relating to blood transfusion maintained by Apollo Hospital are defective; and (iv) in the circumstances of her case, the Hepatitis C infection could have come only from the infected blood transfusion and not from any actions either before her admission to the Appollo Hospital or from actions after her discharge from the said hospital. These and other points of her argument are elaborated below : (i) There was no need at all for the doctors to give Platelet transfusion at the time it was given, i.e. on 23rd June. The Platelet count on that day was 50,000 and according to standard medical texts, no transfusion was necessary at that level of Platelet count, unless the patient is also bleeding. It is agrued that the Platelet count at the time of admission on 22nd was 59,000. The general blood test done at 6 a.m. on 23rd showed the Platelet count as 35,000. However, the Pathologist himself wrote on the report that the test should be repeated to confirm Platelet count. The repeated and confirmed Platelet count on 23rd was 50,000. This confirmed test of Platelet count of 50,000 was not taken into account by the respondents instead, depending on this single and unconfirmed figure of 35,000, the respondents rushed with transfusion. Medical authorities [Lanzkowsky''s Manual of Hematology Exhibit W-9 (page 251)] are quoted to show that transfusion is indicated only when Platelets are persistently less than 20,000 - 15,000 if there is no bleeding. It is argued that in fact recent studies have fixed the threshold for Platelet transfusion at 5,000 to 10,000 in uncomplicated cases (Gruchy''s Clinical Hematology) it is argued that by 23rd morning (i.e. even before the transfusion) itself, recovery symptoms had started showing in terms of Total Leucocyte Count (TLC). The TLC, which was 1700 at the time of admission on 22nd, had improved to 3800 on 23rd morning. Fever which was 1040F at admission came down to 990F with prothonim bleeding time (2 mts.). Hence there was no question of any precipitous fall in Platelet count nor any question of potential bleeding in future. Thus it is argued that from every angle, transfusion was not justified and that the respondents rushed with an unnecessary haste in Platelet transfusion which should have been considered only as a last resort.

(ii) Even if the Platelet transfusion was necessary, the blood of the mother of the complainant, Smt. Ritu Bhargava should have been used as originally planned by respondent No. 3. As a matter of fact necessary blood tests were carried out on Smt. Ritu Bhargava''s blood on 23rd morning after recovering a payment of Rs. 2,210/- and she was asked to deposit another Rs. 8,000/- for carrying out the process of separation of Platelets (called automated platelet apherisis). Smt. Ritu Bhargava''s husband, i.e. the complainant''s father in fact rushed to the Bank to withdraw Rs. 8,000/- from his account. But by the time he came back to the hospital, the Platelet transfusion on the complainant was being carried out from the blood obtained from Blood Bank. The doctors carried out the transfusion of Platelet concentrates from other donors in an unholy hurry.

(iii) The donor''s blood which was used for Platelet transfusion is contaminated

with Hepatitis C virus which showed up in the blood of the complainant after the normal incubation period of 8 -12 weeks. Though the medical records of Apollo Hospital show that all relevant tests including tests for Hepatitis C virus were carried out when the donors'' blood was received, the argument of the complainant is that these records of the hospital cannot be relied upon for the following reasons : (a) Blood of five donors have been used in extracting the Platelets. The hospital records show that the blood of all these five people were collected on 20th after carrying out all tests. However, as far as the process of Platelet concentration was concerned, the records of two donors show that the Platelet concentrate was carried out on the 18th i.e. two days even before collection of blood. It is, therefore, argued that the records regarding blood collection and tests carried out cannot be relied upon. (b) It is argued that in one of the Platelet concentrates the date of preparation and the date of expiry shown are the same, namely the 20th June. If the date of expiry is indeed 20th, then what has been given in transfusion to the complainant is an expired blood product. If the date shown is due to an inadvertent mistake as argued by the respondents, it shows their carelessness in maintaining vital and important records relating to blood leading to the conclusion that their records cannot be trustworthy.

(iv) It is argued that according to authorities on medicine, confirmed transmission of Hepatitis C virus takes place only through three routes, namely (a) inoculation, (b) transfusion, and (c) Hemo Dialysis. (Medical literature also lists two other modes, namely (i) sexual, and (ii) maternal/neonatal through which transmission of Hepatitis B and D are known to take place, but Hepatitis C is rarely transmitted through these routes). In support of this, the complainant filed a chart from M/s. Schering and Plough, reputed manufacturers of Interferon injections (the essential treatment for HC virus) (Exhibit P. 160). She also filed extracts of "Robins Pathologic" Basis of Disease (Exhibit K-P. 163) which says that "Most important routes of spread (of Hepatitis C virus) are blood transfusion and blood products, with an incubation period of 8 to 12 weeks". Hemo Dialysis is obviously not applicable in the case of the complainant. It is agreed by the complainant that a few days prior to admission to the Appollo Hospital, the complainant did attend the reputed S.D.S Medical Centre at Greater Kailash Part-II on 19-20, June as an outdoor patient with complaint of fever when one sample of blood was taken from her for tests; it is argued by the respondents that the infection could have come from an unsterilized needle. It is the contention of the complainant that the medical centre is a reputed place and that they only use sterilized disposable syringes with needle. When this one blood sample was taken on 19th the complainant''s elder sister who is herself a doctor was also personally present and testified that sterilized disposable syringe with needle was used. The infection therefore, could not have come from this source.

(v) After treatment in Apollo Hospital, the complainant did not undergo any other treatment till 19th September when she got the blood tests for SGPT and HB (as suggested by Apollo Hospital itself) done from Dr. Lal''s Pathology Lab on

13.9.1997 when she realised that her liver function tests were extermely high compared to the normal. Subsequently, further tests only to confirm these results were got done in reputed hospitals like LNJP and GB Pant Hospitals. These tests have no relevance to the question of getting infected with Hepatitis C virus.

(vi) The severity and suddenness of appearance of the Hepatitis C virus which showed up in the 11th week after the normal incubation period of 8-12 weeks after the treatment in Apollo Hospital, clearly reveals that the infection was because of the transfusion of contaminated blood Platelet concentrates and from no other source.

(vii) Respondents have not revealed the particulars of donors whose blood was used and the state of their present health.

As against the above arguments, the arguments of the respondents are essentially that, (a) Platelet count rapidly fell by 14,000 from 59,000 (on 22nd evening) to 35,000 (on 23rd morning) and if there was further fall, it could have led to potential bleeding and danger to life and hence Platelet transfusion was necessary; (b) separation of Platelets from blood of complainant''s mother is time consuming; (c) the hospital carries out all sophisticated tests, including a test for Hepatitis C, which is not mandatory under Government procedure; (d) that the blood Platelets used in transfusion were not defective or infected; and (e) that the complainant must have got the Hepatitis C from some other source outside the hospital either before admission in the hospital or after discharge from the hospital. We need to examine these arguments in more detail.

3. HOWEVER, at the outset we would like to say that the defence put up by the respondents is rather weak and unconvincing. Except for general statements that super speciality hospital follows sophisticated and ultra modern tests, and that preparing the Platelets from the mother''s blood would have taken time, no specific details have been furnished. Though a large amount of medical literature is produced by the complainant that Platelet transfusion was not necessary unless the count is between 15,000-20,000, we are inclined to give benefit of doubt to the respondents, and feel that it is the respondent No. 3''s discretion to decide as to whether the patient required transfusion of Platelets concentrate on 23rd June. We cannot question his discretion nor his bona fides. But the defence of the respondents fails at least on two other counts. Firstly, there is no satisfactory explanation as to why the mother''s blood which matched the patient''s and which was contemplated to be used earlier in the day and when all payments (Rs. 8,000/-) asked to be made to make the Platelet concentrate were made and yet it was not used. Had that been used, there would have been no complication in this case. No proper explanation is offered as to why such an urgent transfusion with Platelet concentrates from the Blood Bank became necessary when the Platelet concentrates from mother''s blood was decidedly much safer option and could have been done at a short notice, with modern equipment the Platelets can be separated at much faster rate. One argument advanced is that the mother''s blood would have given only one unit of Platelets

whereas the patient required 5 such units, and hence they perforce had to use the donors'' blood. If this were true, what was the logic in asking the mother to be ready to donate the blood and make preparations for separation of Platelets. On the contrary, extracts from medical literature have been filed by the complainant [Lanzkowsky''s Manual of Hematology (Exhibit W. 9; page 251)], which show that "the number of Platelets obtained from a single donor by apheresis is approximately equal to the number of Platelets obtained from five to eight whole blood donations". This statement has not been contradicted by the respondents. Secondly, it appears to us that reliance cannot be placed on hospital records. A reference has to be made to the hospital records about the Platelet count of the complainant. The Platelet count on 22nd evening at the time of admission, was admittedly 59,000. The dispute is regarding the count on 23rd morning before the transfusion. The complainant relies on the report at Exhibit W-6 (Page 248 of the paper book) where it is shown as 35,000. There is a remark on the report "Adv : Repeat Sample to confirm Platelet count". Further, Exhibit W-7 (page 249) shows a report which according to the complainant is of 23rd (prior to the transfusion) which shows the platelet count as 50,000 and that this is the confirmed report after the test is repeated. However, according to the respondents, this report is of 24th (post-transfusion) and it is alleged that the complainants tried to alter the date to 23rd. At another place (Exhibit 1-OP) the respondents have said that this report relates to 5 p.m. on 23rd (post-tranfusion). We need not go into this question whether Ex. W-7 is of 23rd (prior to transfusion) or of 24th (post-transfusion). One thing that is clear is that on Ex. W-6, which is admittedly of 6 a.m. on 23rd, the Pathologist wrote "Repeat the sample to confirm Platelet count". Was this test repeated before the actual transfusion took place towards noon on the 23rd ? If so, where is that report ? If not, was it not gross negligence in not repeating the test, especially since the transfusion with Platelet concentrates from Blood Bank was rushed on the basis of this low count of Platelets (35,000) ? But another important aspect that arises out of this document is the credibility to be attached to the hospital records. At page 12 is a copy of the report of 23rd morning which is brought on record by the respondents. This is an exact copy of the Ex. W-6 (at page 248) except that strangely the copy at Page 12 does not contain the narration "Repeat sample to confirm Platelet count". It is unsafe to place reliance on the hospital records with such discrepancies.

4. THIRDLY, while the medical records of the hospital do show that all relevant tests have been carried out at the time when the blood was taken from the five donors, no reliance can be placed on these records since the points raised by the complainant in this regard with reference to the discrepancies in dates of drawal of blood and dates when the Platelet concentrate was made are not satisfactorily explained. Exhibits at P 193, 195, 197 and 201 shows that blood was drawn from the donors on 20th Exhibits at P. 194, 196, 198 and 200 show that these blood samples were tested on 21st. However, extracts at P. 186 and 187 show that the testing was done on 20th. Dr. (Miss) Ruby Bhargava in her affidavit at P. 234 and

the complaint in her affidavit at P. 277 stated that two bags out of five bags of blood Platelets were dated 18.6.1997 and that the shelf life of these is a maximum of 5 days. This statement Dr. Ruby Bhargava has not been effectively answered at any point by the respondents. Dr. Ruby Bhargava and the complainant also stated that one of the Platelet bags have 20.6.1997 as both the date of collection and date of expiry. This has been explained by respondents as an inadvertent mistake. The least that can be said is that no proper care has been exercised in maintaining such important blood records, which have a life and death bearing on the recipient of blood. Even the particulars of the blood donors and the present health status of those has been withheld by the respondent. The respondents also seem to have realised the fact that medical opinion supports that the suddenness and the severity of the on set of Hepatitis C virus does appear to have come from contaminated blood used in transfusion. (Their argument that the complainant might have got the infection probably because of contaminated needles used in a private hospital on the 19th is too feeble and has no force). The other explanation the respondents offered is that probably a donor may be in the "Window Phase" i.e. to say that the donor''s blood may actually carry the virus, but at the time of donation of blood the donor has not developed anti-bodies. Therefore, the test will be negative. The argument is that while in such a rare case, the receiver of blood may get the infection, it cannot be construed as negligence or inadequacy on the part of respondent No. 1 hospital, since there is no control on the situation and there is no wilful default. It does not lie in the mouth of a hospital to take up such an argument without further evidence regarding the donors and their present health which has not been revealed. The party who is in a position to produce evidence and does not produce it, must suffer the adverse inference against itslf. The Court will be justified in drawing an adverse inference against that party. Apollo is claimed to be a sophisticated medical centre with updated Blood Bank. They must be maintaining complete details of the donors. Only five donors'' blood has been supplied (used in this case) and they should have produced their medical record to show that none of them has infected with Hepatitis C. In view of the fact that they have failed to produce that record even they were in a position to do so, this Commission must draw an inference against this institution. The complainant argued that firstly the chances of infection during window period are 1 in 1,00,000 (Epidemiology of Hepatitis C virus infection : A Global Perspective by J. I. Estefan - Page 323); secondly that a superspeciality hospital like Apollo should have taken care and precaution to carry out a simple SGPT enzyme test on donor blood, in addition to the anti-HCV test, to detect elevated levels of SGPT (donors with level of more than 45-60 10/L carry 50% risk of Hepatitis with transfusion of only one unit) which indicate chances of Hepatitis C weeks before detection by anti-HCV method. In support of this, the complainant relied on extracts from Harrisons Principles of Internal Medicine (Exhibit 24 page 266). We see force in the contention of the complainant. Further, however, we would have accepted these arguments of the respondent that while it is unfortunate that the complainant got the infection of Hepatitis C virus, there is no wilful

default on the part of the respondents because of this "Window Phase" period, if only the hospital had maintained meticulous records relating to the blood donation and the further processing of the blood for Platelet concentration. As we indicated above, at least in the case of two donors, complainant alleges that the Platelet concentration was made on 18th June (and this has not been satisfactorily countered) whereas the hospital records show that the blood itself was received from the donors on the 20th June which is an impossibility. The circumstances of this case clearly show that the complainant must have got the Hepatitis C infection through contaminated blood.

5. THE circumstances of this case clearly show that the Hepatitis C infection by which the SGPT count went from 57 on 4th July, 1997 up to 1334 on 13th September, 1997 i.e. after 9 weeks which coincides with the normal gestation period of 10 weeks after the transmission, could have taken place only through the transfusion of Platelets concentrates from anyone or more of the 5 donors. THE respondent No. 1 did not display the necessary care and caution in transfusing this material when a safe transfusion could have taken place from the mother''s blood. THE way the hospital blood transfusion records are maintained does not inspire confidence in them. A young life has been seriously affected by this negligence. Literature shows that more 50% of the patients with Hepatitis C develop chronic liver disease, which may be mild and slowly progresses rapidly leading to Cirrhosis of the liver and cancer in 5 to 15 years. THE treatment is long, painful and very expensive. THEre is no assurance of cure and this dormant virus can and does sometimes re-surface after some time leading to relapse and serious complications even though success has been known in some cases. Taking these factors into consideraion, we therefore, allow the complaint.

6. AS regards compensation, the complainant claimed that the cost of interferon and other injections itself amounts to Rs. 3.50 lakhs for 12 months. In addition to this, she is required to take other medicines and should go regularly for blood tests and other investigations which are very expensive. The cost of treatment in future has also to be taken into consideration because there is no permanent cure and the condition might lead to serious complications. The complainant filed a statement supported by cash memos of the cost of injections for the period from January, 2001 to July, 2001 which itself comes to Rs. 1,68,507/-. The complainant, therefore, prayed for an immediate payment of Rs. 10 lakhs to cover the costs of urgent medicines, another Rs. 10 lakhs to cover future costs and Rs. 50 lakhs as compensation for the complainant''s mental agony, physical suffering, depression, loss of education, career and earning capacity, deprival of marriage and raising a family. It is further argued that Shefali Bhargava is dependent on her father''s income, who retired in March, 1999 and it is difficult for him to financially support the daughter. Taking all these factors into account, we order payment of Rs. 10 lakhs towards costs of medical treatment incurred till now and Rs. 8 lakhs towards costs of further medical treatment which is likely to be lengthy and expensive and also for the mental agony etc. caused to the complainant. The payment should be made by respondent No. 1 within a period

of 4 weeks from the date of this order failing which interest @ 12% has to be paid on the unpaid amount. We also award Rs. 10,000/- as costs to the complainant. Complaint allowed.

