

GUJARAT HIGH COURT

Hon'ble Judges: Bhaskar Bhattacharya and J.B.Pardiwala JJ.

Ashok Naik Versus Union Of India

Writ Petition No. 159 of 2011 ; *J.Date :- MAY 3, 2013

- [CONSTITUTION OF INDIA](#) Article - [226](#)
- DRUGS AND COSMETICS ACT, 1940

Constitution of India - Art. 226 - Drugs and Cosmetics Act, 1940 - Public Interest Litigation - Blood Banks - distribution channels - alleged trading in blood or its components or selling blood - petitioner seeking directions to inquire into distribution channels of all blood banks and take steps against such blood banks found involved in said acts - held, every licensee dealing with whole blood is required to collect the whole blood and thereafter, supply the same in same form as per Schedule "F", Part XII-B, Chapter-III, Part-E[4], Fresh frozen plasma, in Drugs and Cosmetics Rules, 1945 - plasma has to be stored at minus 30 degree centigrade and same could be preserved for a period of not more than a year - thereafter, it should be discarded or sent for any other purpose by blood bank - blood banks to furnish necessary information as to quantity of plasma separated every month, quantity of plasma supplied to patients every month and quantity of plasma sent for further fractionation every month - surplus plasma lying with blood banks separated from whole blood is not only permitted but is encouraged by Government to be used for further fractionation rather than allowing it to go waste to be destroyed - a few years ago, patients relatives were asked to donate blood against blood taken by patients, owing to some problems of professional/commercial blood donation, need of voluntary blood donation was felt by blood banking faculty to improve quality of blood - as regards problem of profiteering from plasma, it may be mentioned that to establish and maintain a blood bank with component facilities, is a very expensive affair - process of fractionation is a complex and capital intensive process - hence, this court proposes to consider question of passing direction for taking immediate steps for full utilisation of blood collected from donation of public so that dearth of sufficient quantity of blood is not felt at any point of time, not to speak of time of summer when collection of blood appears to be insufficient - interim order passed for maintenance of proper supply of blood during summer - directions issued accordingly - petition disposed of.

Imp.Para: [[3](#)] [[9](#)] [[13](#)] [[14](#)] [[15](#)]

Equivalent Citation(s):

2015 (2) DrugsCases(DC) 169 : 2013 AJEL_HC 236572

JUDGMENT :-

Bhaskar Bhattacharya, J.

1 By this Public Interest Litigation, the petitioner has, in substance, prayed for the following three reliefs:

"A. That the Hon'ble Court be pleased to issue a writ of mandamus or a writ in the nature of mandamus or any other appropriate writ, order or direction, directing respondent nos. 2, 3 and 5 to inquire into the distribution channels of all the blood banks and take steps against such blood banks which are found to be trading in blood or its components or are found to be selling blood or its components for any purpose other than clinical use;

B. That the Hon'ble Court be pleased to appoint a committee for investigating and preparing a report on the demand for blood or its components for clinical use at various hospitals in the State, the supply of blood or its components to the various hospitals in the State, the quantum of collection of blood by various blood banks, the end use of blood/its components collected/manufactured by the blood banks, the prices at which blood or its components are made available by the blood banks and for all matters connected with distribution of the blood collected by blood banks;

C. That the Hon'ble Court be pleased to direct respondent no. 2 and 5 to monitor public blood donation camps and prohibit all blood banks supplying blood or its components to M/s. Celestial Biological Ltd. or M/s. Lambda Therapeutic or any other organisation for non-clinical use and prohibit such blood banks from holding public donation camps;"

2 The grievance of the writ-petitioner may be summed up thus:

A. In spite of a clear mandate under the policy to take adequate regulatory and legislative steps for monitoring and evaluation of blood transfusion services and to take steps to eliminate profiteering in the blood banks, there is no effective regulation or implementation of the policy in this regard.

B. Fresh licenses to stand-alone blood banks in private sector cannot be granted under the policy. The renewal of licenses of such blood banks is

required to be subjected to thorough scrutiny and shall not be renewed in case of non-compliance of any of the conditions of the license. The respondent authorities have not undertaken any scrutiny with respect to the working and operations of the blood banks to which licenses have been granted.

C. Any blood bank, found involved in trading of blood or its components in violation of the policy and/or for any purpose other than for clinical use of such blood or blood components, cannot be permitted to continue its operations in the guise of a charitable organisation. The respondent authorities have failed to take appropriate action and measures against such blood banks.

D. Blood donation, when done voluntarily, is not meant for enabling the drug manufacturers to reap benefits from the acts of charity. The donor, at the time of donation, believes that his blood will be used for saving the life of a person in need of blood and that the blood so donated or its components will be utilised clinically only. In the circumstances, it is highly unjust and unethical on the part of the blood banks which have acquired licenses in the guise of charitable work to acquire free blood and then, use it for their personal economic/commercial gain.

E. In spite of having drawn attention of the respondent authorities to the illegal activities of the blood banks with an intention to deceive the bona fide donors, no serious action has been taken for cancellation or suspension of such licenses.

F. Under Part XIIB of the Drugs and Cosmetics Act, 1940, it is mandatory that blood and/or its components shall be distributed on the prescription of a registered medical practitioner. However, in reality, number of blood banks are flouting this requirement. It is, therefore, essential that there is an inquiry into the outflow of blood or blood components from the blood banks.

G. The blood banks, registered as charitable Trusts, are enjoying tax benefits as charitable organisations. However, the blood banks, which profiteer, are not charitable organisations and do not deserve to be granted any benefits for the acts done in flagrant violation of the law and the public policy.

3 After entertaining this Public Interest Litigation and after going through the affidavits filed by the parties, this Court found that every licensee dealing with whole blood is required to collect the whole blood and thereafter, supply the same in the same form i.e. whole blood and if the license holder is having license for preparing the components, in that case, he is required to undergo the procedure for collection, separation and storage of the blood within six

hours of the collection of blood which is reflected in the Schedule "F", Part XII-B, Chapter-III, Part-E[4], Fresh frozen plasma, in the Drugs and Cosmetics Rules, 1945. It further appears that according to the provisions referred to above, the plasma has to be stored at minus 30 degree centigrade and the same could be preserved for a period of not more than a year. Thereafter, it should be discarded or sent for any other purpose by the blood bank. But at the same time, it is incumbent upon the blood banks to store it for one year for the benefit of the patients. It further appears that once the blood is collected, the plasma from the blood has to be separated and stored at minus 30 degree centigrade. But when the voluntary blood donation camps are held at a distant and far away places, the blood so collected may not reach the blood bank for separation and storage within the period of six hours which might make the plasma contained therein unfit for the purpose of storage and usage to the patients. It may also give rise to a situation wherein the blood banks are likely to take advantage by contending that as the plasma is unfit for consumption by the patients, the same has to be sent for fractionation.

4 We further noticed that according to Schedule "F", Part XII-B, Clause-L under the Drug and Cosmetics Rules, 1945, it is mandatory for all the blood banks to keep all the records for checking and functioning of the blood banks.

5 In such circumstances, this Bench, on 20th December, 2012 issued notice to all 145 blood banks, which are functioning within the State of Gujarat, to disclose to this Court whether the formalities required under the aforesaid provisions were complied with by those blood banks. We further directed those blood banks to disclose whether they were complying with the requirement of collection, separation and storage of the blood within six hours of its collection as reflected in the Schedule "F" Part XII-B Part-E[4] fresh frozen plasma, in the Drug and Cosmetic Rules, 1945. We also directed those blood banks to disclose whether they complied with the formality of storing plasma at minus 30 degree centigrade within six hours of its collection. We further directed those blood banks to furnish necessary information as to the quantity of plasma separated every month, quantity of plasma supplied to the patients every month and the quantity of plasma sent for further fractionation every month.

6 Pursuant to such directions, affidavits have been filed by several blood banks. Subsequently, we also directed all the parties who were added as respondents, to give suggestions for the purpose of resolving the issue raised in this Public Interest Litigation.

7 Pursuant to such direction, many of the blood banks have given various suggestions.

8 At the time of hearing of those suggestions, it was pointed out to us that there is acute shortage of blood in the State during the summer season and, therefore, to cope with such situation, we should, before final disposal of this

application, pass some interim order for the benefit of the patients during this summer.

9 After hearing the learned counsel for the parties and after going through the materials on record, we find that once the blood is collected, it is separated into different blood components, ie, red blood cells, platelets, fresh frozen plasma [FFP]. FFP is further separated into cryo-precipitate and cryo-poor-plasma [CPP]. Thereafter, the surplus plasma, i.e FFP and CPP is sent to the Organisation having plasma fractionation facility for making additional life saving medicines such as Albumin, Immunoglobulin, Factor VIII, Factor IX and Fibrinogen. The process of fractionation is a complex and capital intensive process. Until very recent past, there did not exist any fractionation facility in India. There is only one such factory in India, run by Reliance Life Science, in comparison to more than 20 in China. The surplus plasma which can be fractionated into the above referred life saving medicines, if not fractionated within one year of its storage [storage at minus 35 degree centigrade in ultra-modern storage facility], would go waste and would have to be destroyed, as per the rules framed under the Drugs and Cosmetics Act, 1940. On account of the advancement in biotechnology, the fractionation of surplus plasma has been invented so as to manufacture life saving medicines as stated above. Moreover, manufacturing of the above stated medicines from the artificial chemicals is not only highly expensive but is also proved to be not acceptable for being infused in the blood and as such, the surplus plasma lying with the blood banks separated from the whole blood is not only permitted but is encouraged by the Government to be used for further fractionation rather than allowing it to go waste to be destroyed.

10 It, therefore, appears that the red cells are the chief component and highly in demand in our country, where Anemia (low hemoglobin) is so much prevalent. All other components, i.e. platelets, plasma and cryo-precipitates are the by-products, but they have their own indications and highly desirable in certain specific conditions. It further appears that by and large, all the blood banks utilise their stock of red cells and in fact, they fall short of the same. But platelets and plasma are utilised up to 20-30% of the stock. It further appears that due to short shelf life of 5 days only, the surplus platelets are discarded by the blood banks. The plasma has a shelf life of one year at minus 30 degree centigrade and the surplus plasma is the only source for other life saving drugs like Albumin and Factor VIII.

11 It appears from the materials on record that there are following six types of blood banks:

- A. Hospitals based blood banks in the Government hospitals.
- B. Hospital based blood banks run by the corporate hospitals.

- C. Standalone blood banks run by the Indian Red Cross Society.
- D. Standalone blood banks run by the NGOs.
- E. Standalone private blood banks.
- F. Regional blood banks.

12 The blood banks can also be categorised in the following different categories:

- a. Blood bank providing only whole blood.
- b. Blood bank providing whole blood and/or blood components.
- c. Blood bank providing whole blood and/or blood components as well as Aphaeresis services.

A. Hospital Based Blood Banks In The Government Hospitals:

These blood banks get everything from the Government including infrastructure, manpower, equipments, reagents and other consumables. Generally they give blood/BC free of cost to the patients of the Government hospitals with service charge from the patients from outside hospitals.

B. Hospital Based Blood Banks Run By The Corporate Hospitals:

These types of blood banks generally aim at maintaining the highest standards of quality even if higher amount of cost is involved. Many of the corporate hospital run blood banks maintain quality equal to developed countries.

C. Standalone Blood Banks Run By The Indian Red Cross Society:

Such blood banks generally get funding from the Government as well as from the management of the Indian Red Cross Society. They take service charge from the patients that differs from blood bank to blood bank.

D. Standalone Blood Bank Run By The Ngos.:

These blood banks also generally get funding from the Government as well as from the Trust management. They take service charge from the patients that differs from blood bank to blood bank.

E. Standalone Private Blood Banks:

These kinds of blood banks are not getting any funding from the Government or other agencies. They take service charges from the patients which differ from blood bank to blood bank.

F. Regional Blood Banks:

Big blood banks of any category passing certain criteria can take the designation of Regional Blood Bank from the Gujarat State Council of Blood Transfusion [GSCBT]. These blood banks have certain privileges and get help from the Government also. They take service charge from the patients that differs from blood to blood bank.

12.1 The Essential Requirements Of Running of The Blood Banks:

- i. To run a blood bank, a license is required from the Food and Drugs Control Administration [FDCA] Department, Department of Health and Family Welfare, Government of India.
- ii. License is valid only for 5 years, i.e. every 5 years, a blood bank has to apply for license and after inspection from the FDCA, it gets the license if it is found eligible.
- iii. There are definite rules and regulations provided by the FDCA in the form of Drugs and Cosmetic Rules which are mandatorily followed by every blood bank.
- iv. Blood bank has to take approval of all newly recruited technical staff from the FDCA.
- v. Blood bank has to inform the FDCA for leaving of any technical staff.
- vi. Blood bank has to inform the FDCA of any change in the floor plan.
- vii. Blood bank has to inform the FDCA for any change in the Constitution.
- viii. Gujarat State AIDS Control Society [GSACS] which is a State branch of the National AIDS Control Organisation [NACO], inspects the blood banks from time to time and keeps control on the blood banks by providing different guidelines. Blood banks also send monthly report to NACO through the GSACS.
- ix. Gujarat State Council for Blood Transfusion [GSCBT] which is a State branch of the National Blood Transfusion Council [NBTC], inspects the blood banks from time to time and keeps control over the blood banks by providing different guidelines. In addition to that, daily stock of

blood/blood components of all the blood banks is updated on the GSCBT website.

x. Total 12 blood banks of Gujarat [5 from the Government, 5 from the NGOs, one from private and one from corporate hospitals] are accredited from NABH [National Accreditation Board for Hospitals and Health-care Providers] which is the highest accreditation body of the Government of India. These blood banks are supervised and inspected by the NABH to retain the accreditation.

13 As regards profiteering from the blood donated by voluntary donors, if we see the blood banking system, a few years ago, the patients' relatives were asked to donate blood against the blood taken by the patients. In this system, there were some problems of professional/commercial blood donation. Thereafter, the need of voluntary blood donation was felt by the blood banking faculty to improve the quality of blood and reduce the risk of transfusion of transmissible infections. In other words, the blood donation is not a charity but a responsibility of a common man to donate blood that can be utilised by the patients. Although it is donation and not deposition, every blood bank gives coupons/assurance to the blood donors and the camp organisers that if they need blood for their family members or friends in future, blood bank will provide blood to them without asking for blood against the same. Many times, blood banks give blood free of cost also to those camp organisers for poor patients.

14 As regards the problem of profiteering from plasma, it may be mentioned that to establish and maintain a blood bank with component facilities, is a very expensive affair. Extra cost of space, expensive equipments, manpower, electricity, costly consumables make component separation expensive. It goes loss making if all the components made from whole blood are not utilised in sufficient quantity. Red cell component is the prime and most desirable component of blood and the other components are by-products. Red cell is used to the fullest extent, but the plasma and platelets are partially used. It has been seen that in most of the centres, plasma and platelets used for patients are less than 20%. For extra plasma, blood bank has choice either to throw it away or to give it to the fractionation agency to make life saving drugs from the said plasma. No blood bank wants to give any plasma for fractionation if it is required by patients as the service charge for patients is generally more than the one given by the fractionation agencies.

15 After taking into consideration that above basic facts, we now propose to consider the question of passing direction for taking immediate steps for full utilisation of the blood collected from the donation of the public so that dearth of sufficient quantity of blood is not felt at any point of time, not to speak of the time of summer when the collection of blood appears to be insufficient.

16 Our attention has been drawn to the fact that the majority of the blood donors are from the student community and the place of blood collection is the Universities and colleges which remain closed during the summer resulting in less number of blood donation camp. Such being the real reason of dearth of blood during the summer, it is the duty of the blood banks and the State Government to take special measures for holding blood donation camp during summer by inspiring the donors to come forward at the said crucial period. Various programmes can be undertaken in the presence of renowned personalities to encourage donation during the summer. The State Government and the Blood banks can think of giving some special benefits to the donors during such period, such as, the opportunity of availing free supply of blood in case of future need of the donors or their friends and relatives, in addition to the existing facilities given to the donors. The State Government can also consider whether the students donating blood during the summer can be given free supply of relevant study materials needed for the current academic session the donor is undergoing or according to his choice.

17 During the summer, the State Government should give sufficient advertisement in television, radio and news papers highlighting the scarcity of blood during the summer and also declaring the special benefits available to the donors during this period.

18 After increase of supply during the summer and appropriate storage of the blood collected, what is most required is the compliance of the formalities required under the existing law as pointed out earlier in item nos. I to IX stated in page 12 of this order in order to make healthy utilisation the blood. The State Government is directed to take special measure to see that all the blood banks licensed in this State comply with the terms of their respective licence.

19 The importance of preservation of plasma, however, cannot be overlooked. If after the utilisation of the full red cell component and preservation of the other components for the required period prescribed by law for direct patients, the plasma components are given to the drug manufacturing companies subject to the supervision of the Government agency, such components can also be utilised for the needy patients. We cannot lose sight of the fact that red cells of the blood collected can be administered only to the limited group of patients depending upon the blood groups of the donor, the plasma components can be universally utilised by all the patients irrespective of the blood group they belong. If a blood donor comes to know that after the full utilisation of red cell and other component for direct patient during the prescribed period fixed by law, the plasma portion has been utilised for preparation of medicine on payment of money to the blood banks by the drug manufacturing companies, in our view, he should not feel that he is deceived if such transfer of plasma to the drug company is controlled and regulated by the Government Agency with the assurance that the money received by the blood banks in lieu of plasma

should not be used as a profit but for the maintenance of the blood bank activity.

20 On consideration of the above aspects, we pass the following interim order for maintenance of proper supply of blood during the summer and also thereafter:

1) The State Government will immediately appeal to the public to donate blood during the summer through the mode of television, radio and news papers highlighting the scarcity of the blood during summer season. In such advertisements, the State Government will also indicate the necessity of preservation of plasma and utilisation of the unused portion of the same beyond the statutory period of one year for manufacture of drug under the guidelines to be framed by the State agency making it compulsory that money received there from are fully utilised for the purpose of maintenance and upkeep and not for profit so that the voluntary donors do not feel that they are deceived and that the Blood Banks are making profit out of their donation. Such advertisement should be given at least once in a week during summer.

2) The recognised Blood banks and the State Government will take special measures for holding blood donation camp during summer by inspiring the donors to come forward at this crucial period. Various programmes should be undertaken by the Blood banks and the State Government in the presence of renowned personalities of the society to encourage donation during the summer. The State Government and the Blood banks will think of giving some special benefits to the donors during such period, such as, the opportunity of availing free supply of blood in case of future need of the donors or their friends and relatives, in addition to the existing facilities given to the donors. The State Government will also consider whether the students donating blood during the summer can be given free supply of relevant study materials needed for the current academic session such donor is undergoing or according to his choice.

3) The State Government is also directed to take special measure to see that all the Blood banks licensed in this State comply with the terms of their respective licence and the various formalities as indicated at pages 12 and 13 of this order.

4) The Non Government Organisations and the Social Organisations working for the welfare of the people throughout the State be requested by the Government to conduct Blood Donation Camps as part of their social activity or as a special project.

5) The National Cadet Corps (NCC) and Scout guards may be requested by the Government to undertake the activity of Blood Donation Camps and through NCC and Scout guards, the public awareness should also be created among the public at large.

6) Government servants serving in various Departments should also be requested to donate blood as a special drive.

7) The Government shall put up large and visible hoardings, signboards and display boards to promote donation of blood all over the main towns and cities so as to create public awareness of this laudable social obligation during the summer.

21 Let the matter appear for further hearing on June 17, 2013.

