

IN THE SUPREME COURT OF INDIA
CIVIL ORIGINAL JURISDICTION
(UNDER ARTICLE 32 OF THE CONSTITUTION OF INDIA)
WRIT PETITION (CIVIL) No. _____ OF 2019

IN THE MATTER OF:

Association of Rural Surgeons of India & Ors Petitioners

Versus

Union Of India and Ors. ...Respondents

PAPER BOOK

(Index Inside)

I.A. Of : Application seeking permission to file lengthy
2019 synopsis and list of dates.

SYNOPSIS

1. This Public Interest Litigation petition highlights the absence of access to blood for transfusion purposes for all patients in India whose lives are at risk in emergency health situations. The petition prays *inter alia* for orders to strengthen and regulate blood banks and blood storage units across the nation, especially in the priority districts under Categories A, B and C as identified by the National AIDS Control Programme- III (hereinafter “NACP III”) under the National Aids Control Organization (hereinafter “NACO”).
2. A well-organized Blood Transfusion Service (BTS) is vital to any health care delivery system. An integrated Blood Safety Strategy is required to eliminate transfusion related infections and to safely and adequately provide BTS to the people. The main components of an integrated strategy include the collection of blood only from voluntary, non-remunerated blood donors; screening for all transfusion related infections; and reduction of unnecessary blood transfusions.

The Government’s Failure in Providing Ready Access to Blood

Transfusion Services in Rural Areas

3. Health care in our society is deeply unequal. Geography, economic status and dubious public institutions dictate one’s ability to access quality health care and achieve good health. Moreover, availability, cost, quality and safety of health services raise difficult technical and ethical questions which have yet to be adequately resolved.
4. Blood Transfusion Services (BTS) in India are highly decentralized and lack many vital resources needed to make them effective including

adequate manpower, infrastructure and financial support. The main issue plaguing blood banking systems however are fragmented management. Standards of care and supplies of blood vary from state to state, city to city and centre to centre. Despite the existence of government health infrastructure, many large hospitals (such as district hospitals) and nursing homes in rural areas lack their own blood banks. This has led to the proliferation of stand-alone private blood banks out of which many are not registered. The Major failures of blood banks and BTSs in India include:

I. The low number of licensed and registered blood banks.

The number of registered and licensed blood banks in India is extremely low with only 1700 (ERAKTKOSH) blood banks across India, which comes to less than 3 blood banks per 10 lakh population. Although the annual blood collection has increased from 2013 – 2014 to 2016 – 2017 by 12%, it is still less than the projected requirement by 15%.

II. Lack of access to blood in rural areas is unaddressed. The 1996 judgment of the Hon'ble Supreme Court of India in *Common Cause v. Union of India &Ors.* [Writ Petition (Civil) 91 of 1992] regulated the means of blood transfusion and held that blood could *only* be collected, stored and tested, and components made and issued for transfusion, after first being cross matched from a licensed blood bank. This decision of the court brought to a halt the unregulated blood business, rampant profiteering, the practice of poor testing or not testing at all and the practice of encouraging professional donors. However, lack

of access to blood was not mentioned because the voluntary sector continued to use blood bags available in the market in the absence of any blood banks in small towns and rural areas. Donors (voluntary or family) were used as donors when the need arose for transfusion.

- III. **Non-implementation of laws and guidelines for BSUs and First Referral Units.** Lack of access to blood in rural areas was raised when the government, in response to Common Cause v. Union of India, announced an amendment to the Drugs and Cosmetics Act, 1940. The amendment required blood storage units to be established in areas where blood banks were not present and the requirement for blood was likely to be less than 2000 units per year. All First Referral Units (hereinafter FRUs) were mandated to have Blood Storage Units (hereinafter BSUs) and all District Hospitals as per IPHS norms were to have blood banks. Although Guidelines for BSUs were published in 2007, to date only a fraction of FRUs have the infrastructure for BSUs and only a miniscule percentage actually function to any significant extent, approximately transacting and using less than 100 units of blood per yr.
- IV. **High maternal mortality rates in India due to inaccessibility of blood.** Around the world, over 5 lakh women die annually during childbirth. One-third of these deaths happen in India. Obstetric Hemorrhaging (PPH and APH) is by far, the largest cause of these maternal deaths, the situation being compounded by rampant anemia, especially among the rural poor.

- V. **Proximity of facilities to one another.** Nearly 50,000 deaths could have been averted had there been a well-resourced and functioning facility within 50 kms of the health facilities in both public and non-governmental sectors.
- VI. **Strict enforcement of replacement donations even in emergency situations.** Most blood banks, especially those in the public sector (government) rely heavily on ‘replacement’ donations and often refuse issuing blood even in emergency situations where no replacement donor is available.
- VII. **Detrimental reliance on replacement donations.** The NBTC has called for a complete phase-out of replacement donations by 2020. The focus on replacement donations rather than voluntary, non-remunerated donations (VNRDs) means that district hospitals (otherwise known as the mother banks) which are intended to feed the BSUs underneath them (usually 4 – 5 in number) will never be self-sustaining enough to spare any blood as they themselves have a hand-to-mouth existence. Consequently, most BSUs have hardly any blood units and are non functional.
- VIII. **Lack of functioning blood banks or BSUs.** At least 81 districts across India lack a single functioning blood bank or BSU. A district hospital caters to a population often as large as 25 Lakh spread over hundreds of kilometers and is often the only hope for this population. Such district hospitals, even those sufficiently staffed (having at least one anesthetist, gynecologist, and surgeon) will rightfully refuse to perform

caesarean sections or deal with other obstetric or surgical emergencies in the absence of blood. This blood shortage however often results in needless referrals and more complications including the needless deaths of these young women.

- IX. **Unregulated cost of blood processing equipment.** The blood processing equipment is unregulated and the price of being a part of Essential Drugs List needs to be regulated through the drug price control order.
- X. **Shortage of medical specialists. There is a huge shortage trained health professionals in the field of transfusion medicine** (80 – 85% shortage of specialists). There is a need for the government to map these inadequacy and make the Blood Banks functional

The National Blood Policy

1. The National Blood Policy and National Blood Programme were formed to modify and change the BTS and ensure implementation of the Supreme Court's directives in Common Cause v. Union of India & Ors.
2. The blood banking system consists of certain government bodies, all of which come under the Ministry of Health Services. The National Blood Transfusion Council (NBTC) is the policy formulating apex body in relation to all the matters pertaining to operation of blood centres. The National AIDS Control Organisation (NACO) allocates a budget to NBTC for strengthening Blood Transfusion services. NBTC must

ensure involvement of other ministries and other health programmes for various activities related to blood transfusion services. NBTC is charged to develop guidelines to define NGO run blood centres to avoid profiteering in blood banking.

3. State Blood Transfusion Councils (SBTCs) are responsible for implementation of the blood programme at the state level. As per the recommendations of the National Blood Transfusion Council, SBTCs are supposed to organise blood transfusion service through the network of regional blood transfusion centres, Indian Red Cross Society and NGO run blood centres and monitor their functioning.

Blood Transfusion Services in India

4. BTSs are an integral part of health care provisioning, particularly because blood has no substitute; it cannot be replaced by any other drug or clinical intervention.
5. Blood cells are made in the bone marrow. The bone marrow is the spongy material in the center of the bones that makes all types of blood cells. There are other organs and systems in our bodies that help regulate blood cells. The lymph nodes, spleen, and liver help regulate the production, destruction, and differentiation (developing a specific function) of cells. The production and development of new cells in the bone marrow is a process called hematopoiesis. Blood cells formed in the bone marrow start out as a stem cell. A *stem cell* (or hematopoietic stem cell) is the initial phase of all blood cells. As the stem cell matures, several distinct cells evolve, such as the red blood cells, white blood cells, and platelets. Immature blood cells are also called blasts. Some

blasts stay in the marrow to mature. Others travel to other parts of the body to develop into mature, functioning blood cells.

6. The components of human blood are:
 - a. Plasma: The liquid component of the blood in which the following blood cells are suspended.
 - b. Red blood cells (erythrocytes): These carry oxygen from the lungs to the rest of the body
 - c. White blood cells (leukocytes): These help fight infections and aid in the immune process.
 - d. Platelets (thrombocytes): These help in blood clotting.
7. The availability of blood in emergency situations is often the difference between life and death. Nevertheless, blood is a fluid that can transmit serious and potentially fatal infections like HIV, hepatitis B and C, syphilis, malaria and gram-negative bacteria. Blood therefore needs to be screened and confirmed as safe and free from disease before it is given to a needy person. This screening must conform to the fundamental principle of medicine, *primum non nocere*, meaning “above all, do no harm.”

World Health Organization Resolution WHA63.12

8. Resolution WHA63.12 of the World Health Organization was passed during the Sixty-third World Health Assembly and recognized that achieving self-sufficiency in the supply of safe blood is an important national goal needed to prevent blood shortages and meet transfusion needs of the patient population. Blood and blood components (whole blood, red blood cells (RBCs), platelets and fresh frozen plasma) were

added to the 18th edition of the core list of the WHO Model List of Essential Medicines in 2013. Self-sufficiency in this context means that the national needs of patients for safe blood and blood components, as assessed within the framework of the National health system, are met in a timely manner, and the patients have equitable access to safe blood for transfusion, and that this can be accomplished by promoting voluntary non-remunerated blood donation. Defining blood and blood components as EMs (that is, as biological therapeutic products or simply “therapeutics”) could also contribute to self – sufficiency by:

- a. drawing attention to the role of national governments in providing the necessary organizational and other support required for assuring a safe and adequate blood supply; and
- b. Encouraging countries to develop and ensure compliance with safety and quality standards, as well as good practices, in product preparation for transfusion.”

Maternal Mortality Caused Due to Lack of Access to Blood

9. The National Blood Policy (2007) mandates that India have a network of norm based and licensed blood banks, which in turn should nourish certified blood storage centres that will address those health care facilities that provide emergency childbirth (First Referral Units). How far these legal, technical and operational prescriptions, are able to help patients especially the rural poor, is something that requires careful and in-depth consideration.
10. According to The World Health Statistics – Monitoring Health for the SDG, published in 2016, the major cause of maternal deaths is Post-Partum Haemorrhage (PPH), which is often defined as the loss of more

than 500-1,000 ml of blood within the first 24 hours following childbirth.

“In 2015, the maternal mortality ratio (MMR)- defined as the number of maternal deaths per 100,000 live births- was estimated at 216 globally. This translates into approximately 830 women dying every single day due to the complications of pregnancy and childbirth. Almost all these deaths occurred in low- resources settings, and most could have been prevented.

The primary causes of maternal deaths are hemorrhage (mostly bleeding after childbirth), hypertension during pregnancy (pre-eclampsia and eclampsia), sepsis or infections and indirect causes mostly due to interaction between preexisting medical conditions and pregnancy.”

11.The WHS further establishes the Maternal Mortality Rate of India at 174/100,000 as of 2015 (at Annexure P-). The global estimates for causes of maternal mortality primarily include the following:

Cause	Percentage(%)
Pre- existing medical conditions exacerbated by pregnancy.	28%
Severe Bleeding	27%
Pregnancy included High Blood Pressure	14%
Infections (mostly after childbirth)	11%

Obstructed Labour and other direct causes	9%
Abortion Complications	8%
Blood Clots	3%

12.To address India’s shamefully high Maternal Mortality Rate (MMR), the Central Government introduced the National Rural Health Mission (NRHM) in 2005 to provide health care to poor women and children and rural populations of India, with a primary focus on addressing India’s high rate of maternal and infant mortality. But the rural areas covered mostly through government’s Community Health Centres and Non Profit/ charitable hospitals are facing a severe crisis in the availability of blood, which in effect is causing an increase in maternal mortality and deaths from accidents or other forms of medical emergency.

Standard of Care for Blood Banks

13.Standards for blood banking have evolved in response to problems observed in the past. Donors need to be free of syphilis, hepatitis, and human immunodeficiency virus (HIV) and from a host of other diseases as well. Methods for cleaning the arms of donors should work. Blood bags should contain the appropriate solutions and be sterile. Systems for the identification of donors and patients, for the determination of antigens on their blood cells and the antibodies in their sera, and for the

procedures and processes used to gather and maintain this information should be robust.

14. Blood transfusion is a secondary health care technology. Using this technology as a case in point, we examine the idea of what constitutes appropriate or acceptable technology. While affirming that any technology has to pass muster on a litmus test of acceptability, we discuss the difference between ideal and acceptable but less than ideal technology. Lastly, we briefly discuss the dynamic push and pull between the urge to specialize and regulate and restrict use of skills by all versus the need to de-specialize and communities' technology using some examples in health care.

15. As a result of developments in medical science it is possible to preserve blood and store blood after it has been collected and tested. There are blood banks which undertake the task of collecting, testing and storage of whole blood and its components and its components and make the same available when needed.

16. That for the purposes of regulating its collection, storage and supply, blood is treated as a "drug" under the Drugs and Cosmetics Act, 1940. The Drugs and Cosmetics Rules, 1945 made under the Act contains provisions regarding equipment, blood collection supplies, and emergency equipment of the blood donor room required for a blood bank.

17. Blood banking is a medical logistic activity. It attempts to bring the potentially life-saving benefits of transfusion to the patients who need them by making blood components available, safe, effective and cheap. Blood banks try to maximize delivering getting blood from the right

donors to the right patients in a timely manner. The easiest way to assure the timely availability of blood is to have an appropriate inventory on the shelf at all times.

18.The primary problem faced with keeping an intact inventory on the shelf at all times is that the Mother Blood Bank, usually the one in District hospitals, that feeds the blood storage units in the district only collects through replacement donation and not through blood donation camps. As a result, the deficit in the number of blood bags is always high.

19.Considering the minimum standards set out by the World Health Organization and Lancet Journal, the petitioners with the intention to understand the deficit in blood supply in various states compared the actual number of blood bags available to the minimum requirement as set out by WHO and the Lancet Report. The deficit in numbers and percentage as of April, 2019 for six states is reiterated as under:

22.1: New Delhi

District	WHO requirement	Lancet requirement	Available Blood Bags	Percentage Deficit According to WHO
New Delhi	1420	7100	38	97.32394366
North Delhi	887978	44,398,9	8	99.99909908

North				
West				
Delhi	36565.39	182,826,95	14	99.96171243
West				
Delhi	25432.43	127.162	24	99.9056323
South				
West	22929.58	114,647,9	0	100
South	2731929	13659645	670	99.9754752
Central	58232	2.911	58	99.90039841
North				
East	2241624	112081	0	100
East Delhi	1709346	85467	106	99.9937988

22.2: Jharkhand

District	WHO requirement	Lancet requirement	Available Blood Bags	Percentage Deficit According to WHO
Ranchi	29142.53	145712.65	304	98.95685104
Ramgarh	9494.43	47472.15	0	100
Latehar	7269.78	36348.9	8	99.8899554

Dhanbad	26844.87	134224.35	346	98.71111315
Gumlah	10252.13	51260.65	0	100
Kodarma	7162.59	35812.95	47	99.34381278
Chatra	10428.86	52144.3	0	100
Palamu	19398.69	96993.45	6	99.96907008
PurbiSingbh um	22939.19	114695.95	86	99.62509574
Giridih	24454.74	122273.7	15	99.9386622

22.3: Chhattisgarh

District	WHO requirement	Lancet requirement	Available Blood Bags	Percentage Deficit According to WHO
Bastar	14131.99	70659.95	20	99.85847711
Bijapur	255.23	1276.15	4	98.43278611
Bilaspur	26636.29	133181.45	208	99.21911047
Durg	33438.72	167193.6	70	99.79066184

JanjgirChampa	16197.07	80985.35	20	99.87652088
Mahasamund	10327.54	51637.7	17	99.83539158
Narayanpur	139.82	699.1	0	100
Raipur	40638.72	203193.6	209	99.48571215
Surguja	23598.86	117994.3	114	99.51692582
Kanker	7489.41	37447.05	20	99.73295627

22.4: Tamil Nadu

District	WHO requirement	Lancet requirement	Available Blood Bags	Percentage Deficit According to WHO
Chennai	46467.32	232336.6	301	99.35223292
Coimbatore	34580.45	172902.25	175	99.49393371
Karur	10644.93	53224.65	119	98.88209692
Ramanathapuram	13534.45	67672.25	33	99.75617775
Tirunelveli	30772.33	153861.65	135	99.56129419
Vellore	39363.31	196816.55	160	99.59353012
Salem	34820.56	174102.8	116	99.66686349

Erode	22517.44	112587.2	9	99.96003098
Namakkal	17266.01	86330.05	112	99.35132668

22.5: Assam

District	WHO requirement	Lancet requirement	Available Blood Bags	Percentage Deficit According to WHO
Dhubri	19492.58	97462.9	0	100
Nagaon	28237.68	141188.4	0	100
Bongaigaon	7388.04	36940.2	6	99.91878766
Tinsukia	13279.29	66396.45	0	100
Goalpara	10081.83	50409.15	13	99.87105516
Darrang	92.85	464.25	0	100
Dima Hasao	2141.02	10705.1	0	100
Kamrup metropolitan	12539.38	62696.9	3	99.97607537
Sivasagar	11510.5	57552.5	0	100
Barpeta	16936.22	84681.1	0	100

22.6: Gujarat

District	WHO requirement	Lancet requirement	Available Blood Bags	Percentage Deficit According to WHO
Surat	60813.22	3040661	0	100
Kheda	23907.76	1195388	0	100
Dohad	21270.86	1063543	0	100
Amreli	1514.19	757095	53	96.5
Tapi	8070.22	403511	8	99.9
PanchMahal	23907.76	1195388	43	99.82
Rajkot	38045.58	1902279	15	99.94
Vadodara	41656.26	-	12	99.97
Patan	13437.34	671867	111	99.17
Narmada	5902.97	2951485	28	99.53

20.A simple perusal of the data from only 6 states shown in the tabular charts clearly shows that the deficit in the availability of blood across these states is extremely high. The same becomes even more apparent with the fact that while the current population of India is approximately 1.37 Billion, the availability of blood bags as shown under the e-raktkosh website run and updated by the Ministry of Health and Family Welfare, Union of India is only 30,000+ (at Annexure P-).

Need for Regional Blood Banks as Hubs

26. Medical colleges, which cater to urban areas have highly sophisticated facilities with infrastructural capabilities that are capable of serving not only urban but also rural populations. Blood banks in these facilities should have greater storage that can then be supplied to district hospitals and then to blood storage centers in CHCs.

Unbanked Directed Blood Transfusion

21. The other method of transfusion mostly used in emergency situations and due to lack of readily available blood is Unbanked Directed Blood Transfusion (hereinafter referred to as “UDBT”). UDBT is most commonly described as Blood of a particular donor if collected to be given to a particular patient and transfused to that patient only without storing or banking after doing proper grouping, cross-matching and mandatory tests for TTIs (HIV, Hbs Ag, VDRL, MP).

22. Drawing blood from voluntary donors when a sick person needs blood urgently, testing it for infections and compatibility, and then transfusing it to the person, of course without banking, has been a continued practice even post-1998. Described as Unbanked Directed (to a specific patient needing blood) Blood Transfusion (UDBT), a term coined by Dr. Ravindranath Tongaonkar of the Association of Rural Surgeons of India, it is practiced in many parts of the world where ready access to blood banks is a problem. While the American Red Cross and the New York Blood Centre welcomed directed but banked donation, Medicine Sans Frontiers recommends Unbanked Directed Transfusions in situations in which blood banks are not available. It is ironic and

noteworthy that the practice of UDBT is not recognized by any publication of the WHO, nor by the National AIDS Control Organization (NACO), or by any other developing country, even though it is highly probable that it is in widespread use.

23. UDBT is not “Manufactured,” “Offered for sale,” “Stocked” or “Distributed” a drug and therefore did not come under the purview of Drugs & Cosmetics Act 1940 and the Rules thereunder. Moreover it was exempted under “Schedule K” of the same Act. However, after the 5th April 1999 amendment to the Drug and Cosmetics Act 1940 & Rules 1945 the definition of Blood Bank was changed and even mere collection of blood required a license needed by the blood bank. The chemists were instructed not to give blood collection bags to doctors doing UDBT.

24. The Govt. of India amended the Drugs & Cosmetics Act 1940 & Rules 1945 again on 4 April 2001, exempting the Armed Forces Medical Services under the schedule K (Sub section No.30) of the Act from obtaining a license to operate a Blood Bank but allowing the Armed Forces Medical Services to collect, process and transfuse blood in emergent situations, which require lifesaving emergency surgeries/or transfusions. This exemption seemingly places a higher value on armed forces lives than those of people in rural areas suffering from the same emergency situations that require immediate blood transfusion.

25. Some of the reasons for the need for “Emergency Blood Transfusion” in Rural areas are enumerated below:

- a. Severe falciparum malaria, a condition in which the hemoglobin falls less than 5 grams/dL and leads to shock;

- b. Sickle cell crisis especially CNS, acute chest syndrome, vaso occlusive crisis;
- c. Post partum hemorrhage due to uterine atony and retained placenta;
- d. Road Trauma with shock due to massive blood loss;
- e. Acute abdominal emergency needing emergency surgery and where Hb < 7 gram %;
- f. Antepartum hemorrhage due to placenta previa, ectopic pregnancy, or accidental hemorrhage with severe anemia;
- g. Severe pneumonia with Hb < 7g per dl;
- h. Obstructed labour due to ruptured uterus with shock;
- i. Upper GI hemorrhage due to variceal bleed with hypotension;
- j. A sick new-born with anemia and hypo perfusion.

26. It is pertinent to mention here that while it is difficult to estimate the actual requirement of blood, available, Government statistics which show a huge deficit for the country at 31% (116 lakh units required annually against 80 lakh available) do not tell the whole story. The disaggregated data for rural / urban areas are not available. For the State of Chhattisgarh, which is 84% rural, this deficit is an appalling 81%. Even in the advanced states of Gujarat and Maharashtra, the government blood banks could provide only 13% and 31% respectively of blood transfused in the state.

27. That various RTIs and other reports reveal serious loopholes in the nation's blood banking system. In the last five years, over 28 lakh units of blood and its components were discarded by banks across India. When calculated in liters, the 6% cumulative wastage translates to more

than 6 lakh liters of blood – which is enough to fill 53 (add size or type of tankers) tankers.

28. The reality is, when emergency situations arise at hospitals in rural areas, such as unavailability of blood due to lack of right amount of blood banks, lack of transportation or electricity etc., obstetricians and surgeons are forced to use UDBT illegally in order to save the life of their dying patient. Therefore, at many times they are forced to choose between law and humanity.

29. The Hon'ble Supreme Court of India in State of Punjab v. Mohinder Singh Chawla [1997 (2) SCC 83] established that the right to health is an integral part to the right to life under Article 21 of the Constitution of India, and the Union of India has a constitutional obligation to provide adequate health facilities.

30. The Government of India has committed to making CHCs, fully functional first referral units with fully functional blood storage units. Thousands of women of rural areas are dying due to lack of blood during post-partum hemorrhage, and other obstetric emergencies as the functional Blood Banks and the Blood Storage Units are primarily located only in the urban areas.

31. The petitioners wish to bring to the attention of the honorable court that in this manner, women and girls have suffered, and continue to suffer, violations of their rights in contravention of Article 21 (Protection of Life and Liberty) and Article 14 (Right to Equal Protection of the Law) of the Constitution of India. The States have also impermissibly derogated from their legal obligations under binding international

human rights treaties to respect, protect and fulfill the reproductive and health rights of women and girls.

32. That Unbanked Directed Blood transfusion if used by trained and certified health care teams meets the ethical standards necessary for any appropriate technology and is likely to be an important component of satisfying emergency need of blood in rural health care. When a litmus test of beneficence, non-maleficence, and ability to foster justice and Swarajis applied to several health related technologies, several presently used ones will pass muster on appropriateness, even if they are not ideal. It is contended that UDBT is an appropriate technology.

33. In emergency cases UDBT was declared the only feasible and safe option in India's National Health Policy 2015 draft, and should be legally supported in that context.

Diagnostic Accuracy of Rapid Tests

34. Rapid HIV testing differs from conventional HIV testing in that it allows results of the test to be ready in 5 to 30 minutes; and testing, counseling, and referrals to be done in one visit. These tests are highly reliable according to studies from UNICEF and the WHO. Also, many tests do not require refrigeration and are therefore particularly suitable for remote and rural areas and other sites without a constant electricity supply.

35. UNICEF has published an article on the diagnostic accuracy of HIV rapid test kits in which it stated the following in part:

“HIV testing occurs in a variety of settings outside of the laboratory. The settings where testing will likely to occur during an era of expansion of services include: Testing & Counseling

Centers (T & C), Antenatal Clinics (ANC), Blood Banks, Surveillance programs, tuberculosis (TB) clinics, hospitals, and Sexually Transmitted Infections (STI) Clinics while all settings where testing occurs can triage persons to treatment and care, TB clinics and hospitals will be the primary venues for providing anti-retroviral treatment to HIV infected persons, and for providing care to HIV affected persons. T&C, ANC, Blood Banks, and surveillance are the primary venues for providing prevention programs.

Advantages of Rapid tests	Disadvantages of Rapid tests
<p><i>HIV rapid tests have the following advantages:</i></p> <ul style="list-style-type: none"> • Increases access to prevention (VCT) and interventions (PMTCT) • Number of tests performed Suitable for individual and small volume testing, e.g. 1- 40 samples per day: Supports increased number of testing sites • Minimal or no equipment required Most require no refrigeration Shelf-life 12 months or longer , None or one reagent (a substance used in a chemical reaction to detect or produce other substances , Minimal waste and waste disposal • Minimum technical skill, Easy to interpret <p>Visual interpretation of results, usually without equipment, Stable end-reading point, Same-day diagnosis and counseling, Test time under 30 minutes, Robust and easy to use</p> <p>? Accuracy</p> <p>High sensitivity >99%, High specificity >99% and High reproducibility* >98%</p> <p>? Specimen type</p> <p>Preferably for use on whole blood (finger-prick samples) for ease of collection</p> <p>? Low cost Mostly</p>	<p><i>HIV rapid tests also have a few disadvantages:</i></p> <ul style="list-style-type: none"> ✗ Small numbers for each test run • Quality Assurance/Quality Control at multiple sites • Test performance varies by product • Refrigeration required by some products, e.g., Capillus • Reader variability in interpretation of results • Limited end point stability of the results, i.e., reading should be done in a short time window

Image 35 a: Accuracy (sensitivity and specificity)

36. The accuracy of the test can be described in terms of the degree to which people with and without HIV infection are correctly categorized. The sensitivity of a test is its capacity to correctly identify individuals who are not

infected with HIV. The specificity of a test is its capacity to correctly identify individuals that are infected with HIV. Alternatively, the accuracy of a test can be expressed as the extent to which being categorized as positive predicts the presence HIV-infection (positive predictive value). Similarly, the negative predictive value of a test is the proportion of people with a negative test result who are uninfected. The predictive values are the factors most relevant to the decision as to whether a given test or testing algorithm be employed. The determinants of predictive values are the specificity and sensitivity of the test and the prevalence of HIV in the population concerned.

37. Even with a very accurate test (high sensitivity and high specificity), in settings with a low HIV prevalence (e.g. <1%) the positive predictive value of a test may not be sufficiently high (Table below). In general, the higher the prevalence of HIV infection in the population, the greater is the probability that a person testing positive is truly infected. It is necessary to conduct a second or supplemental test if the first test is reactive, as this markedly increases the positive predictive value.

38. In settings with a low-level HIV epidemic⁴, tests with a sensitivity or specificity greater than 99% should be used in order to achieve satisfactory positive predictive values. In all HIV testing services it is essential that the results given to individuals be reliable. The rapid tests that can be obtained through the WHO Bulk Procurement Scheme they have been evaluated and have met preset criteria. The levels of sensitivity and specificity of these rapid tests are greater than or equal to 99%.”

39. Hence this Petition.

LIST OF DATES AND EVENTS

Date	Event
1992	<p>An organization called Common Cause, files a PIL, in the Supreme Court of India highlighting the serious deficiencies and shortcomings in the matter of collection, storage and supply of blood through the various blood centres operating in India. The petition prayed that the Union Territories be required to ensure that proper, positive and concrete steps be immediately initiated in a time bound programme to obviate the malpractice, malfunctioning and inadequacies in the blood banks across India, and to place before the Court a specific action plan to overcome the deficiencies in blood bank operations.</p>
22.01.1993	<p>Vide Gazette reports that the Union Government has revised the rules in the Drugs and Cosmetic Act (First Amendment) Rules, 1982, and in doing so, has redefined “Blood Bank” with the effect of excluding UDBT from the preview of the Act 1940 and the Rules thereunder.</p>
1996	<p>In a landmark judgement on 4 January 1996, the Supreme Court issues an order requiring all blood banks to be licensed within two years, outlawing professional blood donations—donations given in exchange for money—and ordering the establishment of a National Blood Transfusion Council to oversee and strengthen policies and systems governing blood transfusion in the country. (Common Cause v Union of India and ors (1996) 1 SCC 763).</p>

	<p>During the pendency of the petition, the government revises the rules for licensing and operating blood banks in the Drugs and Cosmetic (1st Amendment) Rules, 1982 requiring all blood banks to seek licensure or cease operating. Though the intentions around this move were no doubt good, the changes to the law made it difficult for physicians in rural areas to procure blood bags and get on with the business of transfusing blood and saving lives.</p>
15.12.1997	<p>Ministry of Health and Family Welfare issues a draft of the Drugs and Cosmetics (Amendment) Rules seeking to change the definition of “blood bank” such that even the mere collection of blood drawn from donors would require a blood bank to have a license.</p>
26.05.1998	<p>Association of Rural Surgeons of India (ARSI) issues objections and suggestions to the proposed Rules. The key objection was that the proposed Rules should not apply to “‘a Village Blood Transfusion Centre’ where – a qualified medical graduate working in a small village or peripheral areas, collects Blood from a voluntary/replacement donor, performs all the necessary tests & transfuses the blood to his own patient, immediately, without storing the Blood (Unbanked Directed Blood Transfusion).”</p>
11.12.1998	<p>Ministry of Health and Family Welfare responds to ARSI rejecting their objections and suggestions, stating that</p>

	<p>“Government Hospitals which do not have a licensed blood bank, may procure the blood required by them from the nearest Government licensed blood bank, preserve it in the cold storage in their own hospital and transfuse to the needy patient. The proposal of unbanked directed Blood Transfusion system was not accepted.”</p>
1998	<p>Professional donors banned from donating blood by the Supreme Court amendment to Rules.</p>
1998	<p>Statistics from the Registrar General of India show the main causes of maternal death in rural India were largely blood related. They included: anemia (24%), bleeding in pregnancy and puerperium (23%), abortion (12%), eclampsia and toxemia (10%), puerperal sepsis (10%), malposition of child leading to death of the mother (7%) and unclassified symptoms (14%).</p>
04.04.1999	<p>Proposed Rules are made official, changing the definition of blood bank such that even the mere collection of blood required a blood bank to have a license. UDBT was disallowed and chemists were instructed not to give blood collection bags to doctors doing UDBT. This change created a serious conflict for physicians in rural areas who until then had been using UDBT to save patients’ lives in emergency situations where there was no access to banked blood.</p>
04.04.1999	<p>In accordance with the Supreme Court order, blood bank legislation is been extensively revised to include Good</p>

	<p>Manufacturing Practices, Standard Operating Procedure and validation of equipments etc. Part XII- B was added to Schedule- F appended to the 1945 Rules. Part XII- C of Schedule- F to the 1945 Rules prescribes in detail the requirements before blood products can be manufactured. Unbanked Directed Blood Transfusions are made illegal, costing countless lives of rural people in emergencies and placing doctors in the untenable position of having to choose between breaking the law and saving patient lives when emergency blood transfusions are necessary. Even mere collection of blood now required license needed for the blood bank</p>
<p>Sept. 1999</p>	<p>The Programme Evaluation Organization for the Government of India issues a report entitled “Functioning of Community Health Centres (CHCs)” which evaluated the functioning and effectiveness of CHCs in making specialized health care accessible to rural people. The report’s findings provided a sobering perspective on the failure of CHCs. The findings suggest that CHCs have not made any significant contributions towards realization of the intended objectives even after about two decades of their establishment.</p>
<p>04.01.2001</p>	<p>The government amends the Rules in the Drugs and Cosmetics Act to allow Armed Forces Medical Services in Border Areas to conduct UDBT in case of emergencies. Physicians in rural areas see the exemption as the government valuing the lives of soldiers</p>

	<p>over those of ordinary men, women and children in rural areas.</p> <p>Their hope is the government will consider permitting them to resume saving lives with UDBT in emergency situations which are no different than those for the armed forces.</p>
29.01.2001	<p>The second Amendment of Drugs and Cosmetics Rules, 1945 vide GSR 40(e)[5] published on 29 January 2001, states that Hepatitis C virus antibody testing was mandatory w.e.f 01 June 2001.</p>
28.03.2001	<p>The third Amendment of Drugs and Cosmetics Rules, 1945 vide GSR 218(e)[6] published on 28 March 2001, states that Blood Donation Camps shall be substituted by the Indian Red Cross Society or a licensed blood bank run by voluntary or charitable organization.</p>
12.02.2004	<p>Former president of the Association of Rural Surgeons of India, Dr. R. R. Tongaonkar issues a letter to the Hon'able President Justice Shri. A. S. Anand, chairman of the National Human Rights Commission entitled "<u>Denying Right to Life: Can a Rural Surgeons or Gyneocologists deny 'Right to Life' to the Rural Civillian population by with-holding life-saving 'Blood Transfusions' because of Recent Amendment of Drugs & Cosmetics Act?</u>" The email explains the benefits and necessity for UDBT in rural areas during emergencies and requests the court to "study the problems of Village Blood Transfusion and direct Govt. of India to include small mid-zonal & peripheral</p>

	<p>hospitals in ‘Civilian’ areas also under the said exemption of the Act applicable to Armed Forces Medical Services & allow the civilian doctors working in these hospitals to collect & transfuse the whole human blood in emergent situations which require life saving emergency surgeries or transfusions.”</p>
2005	<p>The Central Government introduces the National Rural Health Mission (NRHM) in 2005 to provide health care to poor women and children and rural populations of India, with a primary focus on addressing India’s high rate of maternal and infant mortality. Despite this initiative, rural areas which are covered mostly through government Community Health Centres (CHCs) and non-profit/charitable hospitals continue to suffer a severe blood shortage.</p>
2007	<p>A true typed copy of Guidelines for Setting Up Blood Storage Centres issued by National Blood transfusion Council and NACO, 2007.</p>
2007	<p>The National Blood Policy is drafted by the National Blood Transfusion Council. The policy aims to ensure easily accessible and adequate supply of safe and quality blood and blood components collected / procured from a voluntary non-remunerated regular blood donor in well-equipped premises, which is free from transfusion transmitted infections, and is stored and transported under optimum conditions. Transfusion under supervision of trained personnel for all who need it</p>

	irrespective of their economic or social status through comprehensive, efficient and a total quality management approach is intended to be ensured under the policy.Guidelines For Setting up Blood Storage Centres issued by NBTC and NACO.
2009	Latest version of National Blood Policy mandates a 100% voluntary donor blood collection by 2020, with no replacement or professional blood donation at all
2009	Study published showing that Maharashtra is only able to provide 31% of total blood and Gujarat only 13% of total blood required to meet need.
2011	Ministry of Health of Family Welfare by amending the Drugs and Cosmetics act (2 nd amendment) Rules, 2011 has stated that the blood donors can be in the age group of 18 to 65 years.
2011	Blood and blood components, being an essential life-saving drug, is included in the National List of Essential Medicines, 2011 although its price is yet to be fixed under the Drug Price Control Order.
2012	World Health Organisation (WHO) publishes a report noting that only nine million units of blood are collected in India annually, while the need is for 12 million units and out of this only half of the blood units are being obtained by voluntary

	<p>blood donors. The WHO also notes that there is a 31% deficit of available blood in India on a national level while in rural areas where over 70% of the Indian population lives and in backward districts like Chhattisgarh the deficit is approximately 80%.</p>
	<p>Guidelines for District Hospitals, 2012, published by Indian Public Health Standards explain that DHs must be equipped with sophisticated diagnostic and investigative facilities to provide curative, preventive and promotive healthcare services to those within the district.</p>
2013	<p>RTI report filed noting the significant wastage of blood in India and stating that that 1938 units of blood were thrown away (1 unit of blood= 450 ml), while the government medical college and hospital wasted 1140 units of blood (LODS).</p> <p>In another RTI filed by a doctor in Mumbai in 2013, the prestigious St. George hospital in Fort has also admitted of wasting blood units due to mismanagement. As per the news report in mid-day between January 2012 and August 2013, 44.45 liters of whole blood and 918 liters of plasma (plasma is procured from red blood cells within 6 hours of blood collection) was not used by the hospital and languished beyond its expiry date.</p>
02.04.2013	<p>An article in the Indian Express entitled “Blood banks sell plasma, make a killing” outlines how a lack of mechanism for what happens to blood after it is donated leads to corrupt</p>

	<p>hospitals extracting plasma out of blood and selling it to the pharma companies, who in turn make pure profits running into crores of rupees. Some hospitals will sell donated blood units for as high as Rs. 8000 to 15000 a piece.</p>
23.06.2013	<p>The Hindu publishes “No Staff to run Blood Storage centres”</p>
	<p>LiveMint published a paper from Delhi entitled “Direct Donor-Patient Blood Transfusion to Be Legalized” in which it announced that the Drug Technical Advisory Board (DTAB) indicated it would legalize the direct transfer of blood to a patient from a suitable donor in India. A promise which was never followed through on by the Drug Controller General of India (DCGI) G.N. Singh who confirmed the decision.</p>
13.02.2014	<p>News Report published in Money Life: News and Views in Your Interest, noting that between January 2012 and August 2013, 44.45 litres of whole blood and 918 litres of plasma went unused by St. George hospital and languished beyond its expiry date.</p>
July 2014	<p>Common health and Jan Swasthya Abhiyan published “Dead Women Talking: A civil society report on maternal deaths in India.”</p>
2015	<p>National Health Policy, 2015 declares in emergency cases UDBT is the only feasible and safe option. By this statement the government acknowledges the vital need for UDBT in emergency contexts in rural areas and further recognizes that this</p>

	<p>is the most safe and feasible option in those circumstances, yet UDBT remains unlawful except in a military context.</p>
Feb 2015	<p>Updated list of Licensed Blood Bank show 2760 Blood Banks across India.</p>
08.02.2015	<p>Former president of the Association of Rural Surgeons of India, Dr. R. R. Tongaonkar issues a letter to the editor of the Times of India later published in the same, explaining UDBT is safer than banked blood because the treating doctor takes more care given he is directly responsible for any mishap; the donor is known either to the doctor if he calls a donor from voluntary organizations like Rotarians, Lion club members or similar clubs or NGOs, or known to the patient if he/she arranges for the donor through a relative or friend; All the mandatory tests, including HIV are done as per WHO guidelines on the donor blood sample using WHO endorsed rapid test kits which have 99.9% effectiveness before bleeding the donor; Unlike with banked blood, there is no concern of mishaps occurring due to storage or not maintaining cold chain during transport; and so far there have been no reported cases of HIV after UDBT.</p>
26.02.2016	<p>Press release from the Ministry of Health and Family Welfare states that 81 districts in India lack a blood bank.</p>
06.05.2016	<p>Press Release published by Government of India on Maternal and Child Mortality Rate.</p>

02.06.2016	The Hindu published “A lifeline that Rural India cannot do without.”
2017	NFHS 4 (2015-2016) shows increased percentage of maternal mortality and infant mortality rates. According to National Family Health survey, the rate of blood transfusion in women who had a caesarean section during labour was 0.49%, whereas in women who had a vaginal delivery or elective caesarean section it was 0.28% and 0.23%, respectively. The most common direct medical causes of maternal death around the world are hemorrhage, obstructed labor, infection (sepsis) and hypertensive disorders related to pregnancy, such as eclampsia.
31.03.2017	Data from the central government reports that there was a huge shortfall of surgeons (86.5%), obstetricians and gynecologists (74.1%), physicians (84.6%) and pediatricians (81%) in CHCs across India. The overall shortfall of specialists to meet existing requirements was 81.6%.
14.07.2017	Publication in the International Journal of Research in Medical Sciences entitled “Patterns of voluntary and replacement blood donors in a tertiary care center: a retrospective study” states that family/replacement donors still provide more than 45% of the blood collected in India.
04.04.2018	The Hindu publishes “Blood banks running without licences, facing staff shortage”

21.07.2018	Former president of the Association of Rural Surgeons of India and current president of the International Federation of Rural Surgery, Dr. R. R. Tongaonkar publishes a document entitled “Unbanked Directed Blood Transfusion: Some Facts and Figures” outlining the need for access to safe blood in rural India and the benefits of UDBT.
08.01.2019	Letter issued from the Dr. Tongaonkar Sub-district Hospital to the M.O. Sub-district Hospital requesting the immediate need for a bag of blood for a patient in need of an immediate blood transfusion that evening.
08.01.2019	Response from the M.O. Sub-district Hospital stating they had no available blood bag.
	Hence this petition.

IN THE SUPREME COURT OF INDIA
CIVIL ORIGINAL JURISDICTION
(UNDER ARTICLE 32 OF THE CONSTITUTION OF INDIA)
WRIT PETITION (CIVIL) No. _____ OF 2019

MEMO OF PARTIES

IN THE MATTER OF:

1. Association for Rural Surgeons of India

Through the Secretary,

Dr. Tongaonkar Hospital, Dondaicha,

Dist. Dhule, PIN-425408

Maharashtra

... Petitioner No. 1

2. Jan Swasthya Sahayog

Through Secretary

Ganiyari, Bilaspur District

... Petitioner No. 2

Chhattisgarh 495112

3. Shaheed Hospital

Through the Director

Shaheed Hospital Dalli Rajhara, Ward No-

14, Post-Dalli Rajhara,

District- Balod,

Chhattisgarh, Pin-491228

... Petitioner No. 3

Versus

1. Union of India

Through Ministry of Health and Family

Welfare,

Near Udyog Bhawan Metro Station,

Maulana Azad Rd, New Delhi,

Delhi 110011

...Respondent No.1

2. National Blood Transfusion Council,

Toll Plaza, DND Flyway, Opposite

Sector 15A, Noida,

Uttar Pradesh 201301

...Respondent No.2

3. National Aids Control Organization

Department of Health & Family Welfare,

Government of India

6th & 9th Floor, Chanderlok Building

36, Janpath, New Delhi,

India .Pin:- 110001.

...Respondent No. 3

4. Andaman & Nicobar Island

Through Commissioner-Cum Secretary

Health & Family Welfare

Andaman & Nicobar Administration

Secretariat

Port Blair 744101

... Respondent No. 4

5. State Of Arunachal Pradesh

Through Principal Secretary

Health & Family Welfare

... Respondent No. 5

Directorate Of Health Services

Government Of Arunachal Pradesh

Naharlagun, Arunachal Pradesh

6. State Of Assam

Respondent No. 6

Through Additional Chief Secretary

Health And Family Welfare

3rd Floor, Block-F, Secretariat Dispur

Guwahati 781006

7. State Of Bihar

Respondent No. 7

Through Prinicipal Secretary

Health And Family Welfare

Government Of Bihar

Vikas Bhawan, New Secretariat

Patna 800015

8. State Of Chhattisgarh

...Respondent No. 8

Through The Secretary

Department Of Health And Family Welfare

Mantralaya, Mahandi Bhawan

New Raipur 492002

9. State Of Andhra Pradesh

...Respondent No. 9

Through The Commissioner

Health & Family Welfare

Dm&Hs Campus, Sultan Bazar

Hyderabad 500095

10 State Of Punjab

...Respondent No. 8

Through The Commissioner-Cum Secretary

Health & Family Welfare

4th Floor, Ut Secretariat

Delux Building, Sector 9

Chandigarh 160017

11 State Of Goa

...Respondent No. 9

Through Chief Secretary

Health & Family Welfare

Porvorim, Goa 403521

12 Nct Of Delhi

...Respondent No. 12

Through Principal Secretary

Health & Family Welfare

Room No. A-907, A Wing, 9th Level

Delhi Secretariat, I.P. Estate

New Delhi 110002

13 State Of Gujarat

...Respondent No. 13

Through The Principal Secretary

Health & Family Welfare

Block – 7, Floor No. 7

Department Of Health & Family Welfare

Sachivalaya, Gandhinagar

Gujarat 382010

14 State Of Haryana

...Respondent No. 14

Through Principal Secreatry

Health & Family Welfare

Government Of Haryana

R. No. 39-A, 7th Floor

Mini Secretariat Building, Sec-1

Changidharh 160017

14 State Of Himachal Pradesh ...Respondent No. 15

Through Prinicipal Secretary

Health & Family Welfare

Hp Secretariat

Shimla 171002

16 State Of Jammu & Kashmir ...Respondent No. 16

Through Principal Secretary, Health

Health & Medical Education Department

Government Of Jammu & Kashmir

Civil Secretariat, Mini Block, Jammu

17 State Of Jammu & Kashmir ...Respondent No. 17

Through Principal Secretary, Health

Health & Medical Education Department

Government Of Jammu & Kashmir

Civil Secretariat, Mini Block, Jammu

18 State Of Jharkhand ...Respondent No. 18

Through Secretary (Health)

Department Of Health & Family Welfare

Government Of Jharkhand

Nepal House, Doranda,

Ranchi 834002

19 . State Of Karnataka

...Respondent No. 19

Through Principal Secreatry

Health And Family Welfare Department

Room No. 105, 1st Floor

Vikas Soudha, Bangalore 560001

20 State Of Kerala

...Respondent No. 20

Through Secretary (Health & Family
Welfare)

Department Of Health & Family Welfare

Government Of Kerala

Secretariat Building

Thiruvananthapuram 695001

21 State Of Maharashtra

...Respondent No. 21

Through The Principal Secretary

Health And Family Welfare

Government Of Maharashtra

Room No. 110, 1st Floor Main Building

Mantralaya

Mumbai 400032

22 State Of Manipur

...Respondent No. 20

Through Secretary, Health & Family
Welfare

Department Of Health & Family Welfare

R. No. 223, Old Secretariat

Government Of Manipur

Imphal 795001

23 State Of Meghalaya

...Respondent No. 20

Through The Additional Secreatry Health

Department Of Health & Family Welfare

Government Of Meghalaya

Room No. 315, Additional Secretariat

Building

Shillong 793001

24 . State Of Mizoram

...Respondent No. 24

Through Chief Secretary (Health & Family
Welfare)

Sad Social Welfare & Health Department

Government Of Mizoram

Secretariat, Aizwal 796001

25 State Of Madhya Pradesh

...Respondent No. 25

Through Secretary, Health & Family
Welfare

Government Of Madhya Pradesh

Room No. 408, Mantralaya (Vallabh
Bhawan)

Area Hills, Bhopal 462004

26 State Of Nagaland

...Respondent No. 26

Through Commissioner & Secretary

Family Welfare,

Department Of Health & Family Welfare

Government Of Nagaland, Secretariat

Kohima 797001

27 State Of Orissa

...Respondent No. 27

Through The Commissioner

Health And Family Welfare

Government Of Orrissa Secretariat Building

Bhubaneshwar 751009

28 Puducherry

...Respondent No. 28

Through Principal Secreatry (Health)

Government Of Puducherry

Cheif Secretariat Building

Beach Road

Puducherry 605001

29 State Of Rajasthan

...Respondent No. 29

Through The Principal Secretary

Health And Family Welfare

Room No. 5213, Government Secretariat

Main Building

Jaipur 302005

30 State Of Sikkim

...Respondent No. 30

Through The Commissioner-Cum Secretary

Dept. Of Health Care, Human Services, And

Health

Government Of Sikkim, Tashiling

Gangtok 737102

31 State Of Tamil Nadu ...Respondent No. 31

Through Principal Secretary

Health & Family Welfare

Government Of Tamil Nadu

Fort St. George, Secretariat

Chennai 600009

32 State Of Telangana ...Respondent No. 32

Through The Principal Secretary

Health & Family Welfare

Telangana Secretariat

Khairatabad, Hyderabad,

Telangana

33 State Of Tripura ...Respondent No. 33

Through Principal Secretary,

Health & Family Welfare

Department Of Health & Family Welfare

Government Of Tripura, Civil Secretariat

Agartala 799001

34 State Of Uttar Pradesh, ...Respondent No. 34

Through The Principal Secretary

Health & Family Welfare

Government Of Uttar Pradesh, 5th Floor

Room No. 516, Vikas Bhawan, Janpath

Market

Vidhan Sabha Road, Hazrat Gnaaj

Lucknow 226001

34 State Of Uttarakhand

...Respondent No. 35

Through The Principal Secretary

Health & Family Welfare

Room No. 19, State Bank Building

Sector 4b, Subhash Road,

Dehradun 248001

36 State Of West Bengal

...Respondent No. 33

Through The Principal Secretary

Health & Family Welfare

Department Of Health & Family Welfare

Government Of West Bengal

Swasthya Bhawan, 4th Floor, B Wing

Gn-29 Sector-V, Bidhan Nagar

Kolkata 700091

WRIT PETITION UNDER ARTICLE 32 OF THE
CONSTITUTION FOR RAISING AWARENESS ABOUT
UNAVAILABILITY OF BLOOD SPECIALLY IN RURAL AREAS FOR
ALL PATIENTS IN EMERGENCY HEALTH SITUATIONS AND
PRAYING INTER ALIA FOR ORDERS FOR THE LEGALIZATION
OF UNBANKED DIRECTED BLOOD TRANSFUSION (UDBT).

To

THE HON'BLE CHIEF JUSTICE OF INDIA AND

HIS COMPANION JUSTICES OF THE

HON'BLE SUPREME COURT OF INDIA

THE HUMBLE PETITION OF THE
PETITIONER ABOVE NAMED

MOST RESPECTFULLY SHOWETH:

1. This Public Interest Litigation petition highlights the absence of access to blood for transfusion purposes for all patients in India whose lives are at risk in emergency health situations. The petition prays inter alia for order to strengthen and regulate blood banks across the nation, especially in the priority districts under Categories A, B and C as identified by the National Aids Control Programme- III (hereinafter "NACP-III) under the National Aids Control Organization (hereinafter "NACO").
 - 1A. The Petitioners have not approached the concerned authorities for similar reliefs.
2. The petitioner no.1 is a voluntary non-profit registered society of health professionals running a low-cost, effective, health program. ARSI aims to take appropriate surgery to the doorsteps of the rural population. Since ARSI believes that basic surgery can be learnt by MBBS doctors and specialists of allied surgical branches like the Obstetricians & Gynaecologists, Orthopaedic surgeons, ENT surgeons etc, the membership has been opened to them. MBBS doctors who have been practicing surgery for five or more years are eligible for membership. The PAN Card number of the petitioner organization is AAATT2438F. The email address of the petitioner organization is rajeshtongaonkar@gmail.com. The contact

number of the petitioner no.1 is 9422286134. The annual income of the Petitioner no.1 is around 3 lakhs.

3. The Petitioner no. 2 is a is a voluntary, non-profit, registered society founded by a group of health professionals committed to developing a low-cost and effective health program that provides both preventive and curative services in the tribal and rural areas of Bilaspur district of Chhattisgarh state in central India. Till date about, 8 lac consultations have been provided to more than 350,000 patients from the OPD. The inpatient services with 100 beds and an operation theatre complex (including 3 major operation theatres, 1 minor OTs and a labour room) has provided high-quality surgical services to more than 30,000 patients and over 25,000 inpatients have been admitted for serious illnesses. At the same time, through the village based programme which is based among 40,000 people in 72 villages, we have been able to implement primary health care in its detail and spirit, and in the process draw lessons for the country's marginalized rural population. . The PAN Card number of the petitioner organization is AAATJ0614R. The email address of the petitioner organization is janswashya@gmail.com. The contact number of the petitioner no.1 is 07743244997. The annual income of the Petitioner no.1 is nil.
4. The petitioner no. 3 is a 120 bedded hospital serving a catchment area of more than 100 km around. It provides all-round health facilities like medicine, surgery, obstetrics and gynecology, dentistry, pediatrics and physical medicine at a very reasonable cost serving the population with humble livelihood. It runs an updated pathological laboratory and outpatient services are open 6 days in a week. It also houses the ICTC

centre under National AIDS Control Organization and a DOT centre for tuberculosis. Shaheed Hospital is a champion of providing services to poor people under Rashtriya Suraksha Bima Yojana. The PAN Card number of the petitioner organization is AAPTS4285A. The email address of the petitioner organization is shaheedhospital@gmail.com. The contact number of the petitioner no.1 is 07748285869. The annual income of the Petitioner no.1 is around Rs.5,22,90,166/-

Introduction

5. Blood is an essential life-saving drug which the law requires must always be available. Each year, blood transfusions save millions of lives in both routine and emergency situations. Patients requiring blood transfusions have the constitutional and fundamental human right to expect enough blood will be available to meet their needs and to receive the safest blood possible. Nevertheless, many patients in rural areas still die or suffer unnecessarily because they do not have access to safe blood transfusion.
6. Blood for transfusions can be obtained through services of Blood Banks which store units of blood or directly taken from a donor and given to the patient without “banking” or “storing” after first doing proper grouping, cross-matching and the mandatory tests (e.g. HIV, Hepatitis B, etc.). This latter process is known as unbanked directed blood transfusion (UDBT).
7. UDBT is a common practice around the world and in the United States which historically and still today is used to save lives in cases of emergencies where banked blood is not readily available. In rural areas of India where there are no blood banks, UDBT is the only means available to fulfill the required need for blood. Regrettably however, the 1999

amendments to the Drugs & Cosmetics Act, 1940 and Rules, 1945 have made UDBT unlawful in India, costing countless lives of rural people in emergencies and placing doctors in the untenable position of having to choose between breaking the law and saving patient lives when emergency blood transfusions are necessary.

8. In lieu of UDBT the Central Government has instituted Community Health Centers in rural areas, which are meant to serve as first referral units and Blood Storage Centers for rural populations where banked blood can be accessed when necessary. These facilities are meant to obtain blood from nearby blood banks, usually in district hospitals. This system has proven to be a fundamental failure however at the expense of the health and mortality of rural people.
9. There are nearly 3000 licensed blood banks in India and most of them are in cities. A remarkable 81 districts in India have no blood bank. The national government defines a blood bank as “a place or organization or unit or institute or other arrangements made by such organization, unit or institution for carrying out all or any of the operations for collection, apheresis, storage, processing and distribution of blood drawn from donors and/or for preparation, storage and distribution of blood components.”
10. The operation of a standard blood bank requires an air-conditioned environment with round the clock power supply, specially designed refrigerators, other expensive sophisticated equipment and management by a medical officer and full-time technical staff. Even though this may be a possibility in urban areas small towns and rural areas struggle to meet these requirements for various reasons including:
 - i. Non-availability of blood in emergency situations

- ii. Non availability of blood banks in rural areas
- iii. Time taken to obtain and deliver blood from blood banks
- iv. The cost to the recipient of blood from blood banks is between Rs.500/- and 1000/- per unit. This includes the blood bag and testing kits for TTIs.
- v. Problems regarding transportation; 24-hour availability, distance and cost incurred in carrying blood from distant blood banks.
- vi. Need for insulated containers to avoid spoilage of blood carried from blood banks.
- vii. Variable quality/purity of blood bank products.

11. The blood storage centers advocated by the government are too far in distance, too few in number and most of them are dysfunctional and do not carry blood. These shortfalls undercut the critical lifesaving moment for a patient in need of immediate blood transfusion known as the “golden hour.” The “golden hour” refers to the period following a traumatic injury during which there is the highest likelihood that prompt medical and surgical treatment such as receiving a blood transfusion will prevent death. Once that window is closed and those precious life-saving minutes expire, the likelihood of death is significant. Accordingly, in emergency situations where a blood transfusion is needed, saving time and performing the transfusion before the end of the golden hour is a life or death concern.

12. Despite the vast network of health care institutions in India there is a wide gap between the rural and urban areas in terms of availability and accessibility of health care infrastructure, as the urban areas are found better equipped with these facilities. Moreover, health being a state subject,

there are imbalances and variations in availability and accessibility of these services in the rural areas across the states. The lopsided emphasis on health policy in favour of urban areas has led to disparity in the health status of the rural people, as reflected in the high birth, death and infant mortality rates. For instance, the rural health indicators, such as, birth rate, death rate and infant mortality rate stood at 30.3, 10.1 and 80 respectively during 1995, which are still higher as compared to the corresponding figures of 23.1, 6.3 and 48 respectively for urban areas.

13. The WHO found in 2012 that India collects 9 million units of blood annually while the need is for 12 million units. The WHO also notes that there is a 31% deficit of available blood in India on a national level while in rural areas where over 70% of the Indian population lives and in backward districts like Chhattisgarh the deficit is approximately 80%. This shortage of blood in rural areas and the high death rate reflects the failure of the current healthcare system which prohibits UDBT. It is the direct cause of loss of life in a majority of cases.

14. Thirty percent of maternal deaths are due to hemorrhages. There are also occasions where life threatening conditions like rupture of uterus occur with severe internal bleeding and unless the surgery is done immediately the mother is certain to die within minutes or an hour or two. Overall, bleeding related to childbirth amounts to over 25% of deaths from childbirth and pregnancy. These deaths are preventable when timely blood transfusion is available. But in rural areas where there is a drought of blood and where those centers that are meant to carry blood—if having any stored units of blood at all—are too far away, there is no viable option for a timely blood transfusion besides UDBT.

15. Nineteen percent of deaths in India are due to anemia. Additionally, India has the highest number of road traffic accidents in the world. Most of these accidents occur on highways in rural areas away from cities. These victims also need immediate blood transfusions.

16. Physicians from the Association of Rural Surgeons on India who still use UDBT on humanitarian grounds argue that this blood is safer than banked blood. In a letter to the editor of the Times of India dated 8 February 2015, the former president of the ARSI, Dr. R. R. Tongaonkar explained UDBT is safer than banked blood for the following reasons:

- a. The treating doctor who is transfusing the blood to his own patient is directly responsible for any mishap or complication and therefore is much more careful than blood banks.
- b. The donor is known either to the doctor if he calls a donor from voluntary organizations like Rotarians, Lion club members or similar clubs or NGOs, or known to the patient if he/she arranges for the donor because then the donor is either a relative or friend of the patient.
- c. All the mandatory tests, including HIV are done as per WHO guidelines on the donor blood sample using WHO endorsed rapid test kits which have 99.9% effectiveness before bleeding the donor. If all tests are negative for diseases transferrable through blood, then and only then is the donor bled and blood collected for transfusion.
- d. Unlike with banked blood, there is no concern of mishaps occurring due to storage or not maintaining cold chain during transport.

e. So far there has been no reported case of HIV after UDBT.

A true typed copy of Letter to the editor of the Times of India, the former president of the ARSI, Dr. R. R. Tongaonkar, dated 8 February 2015 marked and annexed hereto as **Annexure P-1 (pages ____ to ____)**.

17. In the same letter Dr. Tongaonkar explains that though the government has made UDBT unlawful in 2001 it provided an exemption in the Drugs and Cosmetics Act which allows members of the armed services to use UDBT in emergent circumstances. This exemption is a glaring violation of Article 14 of the Indian Constitution which guarantees equal protection before the law because it allows the lifesaving practice of UDBT to save the lives of soldiers but not rural people. Consequently, physicians performing UDBT in the armed forces are protected from liability when performing the exact same procedure carried out by physicians serving rural populations where most of our country resides. The Amendment against UDBT also violates the right to life under Article 21.

18. On 16 January 2014 the LiveMint published a paper from Delhi entitled “Direct Donor-Patient Blood Transfusion to Be Legalized.” The article noted that:

“In a major step to address the shortage of blood in India, the Drug Technical Advisory Board (DTAB) will on Thursday legalize the direct transfer of blood to a patient from a suitable donor in India.

At present, the Drugs and Cosmetic Rules (1945) authorize collection of blood only by licensed blood banks, in effect

making the so-called unbanked directed blood transfusion (UDBT) illegal.

But India has only 2,545 licensed blood banks, most of which are in the cities, a factor that plays a huge role in the deaths of pregnant women and road accident victims, according to health activists and rural surgeons who have been campaigning for legalizing UDBT.

Drug Controller General of India (DCGI) G.N. Singh confirmed the decision.

“We have called a meeting and UDBT is the main agenda,” Singh said. “Everyone has agreed in principle. The issue has been flagged by the health ministry several times and we have taken this very seriously this time. The idea is that no one in India should go without blood. Since this does not require amending the Act, we are hoping to implement this rule at the earliest.”

According to the World Health Organisation (WHO), a country needs a minimum stock of blood equal to 1% of its population. This means while India needs 12 million units of blood a year, only nine million units are collected.

Indian law currently allows UDBT only for the armed forces. In 2001, the government amended the rule in the D&C Act to allow

Armed Forces Medical Services to conduct UDBT in case of emergencies.

‘We have for long argued that the life of rural woman is as precious as a soldier’s. There is a need for UDBT because our health system is not robust enough to meet demands in rural and semi urban areas,’ said Amit Sengupta, a health activist from the Jan Swasthya Abhiyaan health movement. ‘There is a need for UDBT, especially in areas where no blood bank can be accessed within an hour. This method consists of transfusing the blood from a donor, matching it after testing for pathogens and transfusing it directly to the patient. This is as safe as banked blood transfusion if all the mandatory tests (including for HIV) are done.’”

A true typed copy of Article published by LiveMint entitled “Direct Donor-Patient Blood Transfusion to Be Legalized” dated 16 January 2014 marked and annexed hereto as **Annexure P-2 (Pages _____to_____)**.

19. More than five years following this notification no action has been taken.

The “Thursday” spoken of by the Drug Controller General of India has never come and UDBT has not been legalized despite the government’s assertion from five years ago that it was taking the issue “very seriously this time.”

20. It is the humble submission of petitioners that UDBT should be legalized and strictly regulated to cater to emergency situations after proper testing

by licensed Healthcare facilities whose physician and Lab Technician have undergone appropriate short training. To prevent misuse, it should be mandatory to send blood samples of the patient and donor to the mother blood bank within 24 hours and information online. Each blood bag should be accounted for and could be pre-packed with testing kits/cards.

21. Additionally, medical hospitals which cater to urban areas should be directed to operate on a regional basis so as to cater to rural areas where access to health care services and blood banks is scarce.

Blood Procurement Methods in Blood Banks

22. Blood banking is a medical logistic activity. It attempts to bring the potentially life-saving benefits of transfusion to the patients who need them by making blood components available, safe, effective and cheap. Blood banks try to maximize delivering blood from the right donors to the right patients in a timely manner. The easiest way to ensure this timely availability of blood is to always have an appropriate inventory on the shelves. The shelf-life of donated blood however is only 35 to 42 days. Thus there is a constant need to replenish stocks in the blood banks.

23. Blood banks have three methods of procuring blood for transfusions:

- a. voluntary non-remunerated blood donation (VNRBD) where a person donates blood, plasma or cellular components freely and without payment, replacement/family donation where the patient is accompanied by a family member or friend who donates blood in exchange for the blood transfusion provided to the patient and paid donations where blood is given in exchange for money. Paid donations were made illegal in India under the National Blood

Transfusion Services Act, 2007 following a Supreme Court ruling outlawing non-volunteer donations. An article in the Indian Journal of Medical Ethics notes however that a significant portion of the blood available at NACO-supported blood banks continues to be procured from these illegal sources. A true typed copy of article published in Indian Journal of Medical Ethics entitled “Walking blood banks: an immediate solution to rural India’s blood drought”, dated – 2nd April- June, 2018, marked and annexed as **Annexure P- 3 (pages __ to __)**.

b. Blood for transfusions can also be drawn from a donor and, after doing all the tests, directly given to the patient without “banking” or storing. This method is called Unbanked Directed Blood Transfusion (UDBT). Surgeons in rural areas (where 69% of our population live) and urban areas have long used UDBT to save lives in the absence of banked blood. Until 1999, this method was entirely legal, and the blood transfusion equipment was freely available to any doctor or hospital that needed it. On April 4, 1999, however, through an amendment to the Drugs and Cosmetics Act, UDBT was made illegal.

24. The primary problem faced with keeping a regular intact inventory on the shelves is that mother banks (usually in district hospitals) that feed the blood storage units in the district only collect through replacement donations and not through blood donation camps where voluntary blood donations may be drawn. The WHO has found that systems based on replacement donation by the family and friends of patients requiring transfusion are rarely able to meet clinical demands for blood while paid or

professional “donation” poses serious threats to health and safety. As a result, the deficit in the number of blood bags is always high. A true typed copy of the relevant portion of “Towards 100% Voluntary Blood Donation: A global Framework for Action” published by WHO, 2010 dated- nil, is marked and annexed herewith as **Annexure P- 4 (Pages _____ to _____)**.

The Drugs and Cosmetics Act, 1940 and Rules, 1945

Changes Pertaining to Blood Banks

25. Blood is treated as a drug under the Drugs and Cosmetics Act, 1940 (D&C Act) to regulate its collection, storage and supply. Provisions regarding equipment, blood collection supplies, and emergency equipment of the blood donor room required for a blood bank are in the Drugs and Cosmetics Act Rules, 1945.
26. A further revision to the Drugs and Cosmetics Act, 1940, defined the term “blood bank” as “a centre/place/organization or other arrangement made by such organizational unit or institution for carrying out all or any of the operations of manufacture of human blood components, blood products or whole human blood for its collection, storage, processing, distribution from selected human donors.” Since collection of blood was necessary for transfusion, all blood transfusion was brought under the purview of the Rules (Drugs and Cosmetics Rules 1945). However, since unbanked directed blood transfusion (UDBT) was not manufacturing, offering for sale, stocking or distributing a drug, it did not come within the purview of the D&C Act, 1940 and was also exempted under Schedule K of the Act, thus enabling the life-saving practice to continue.

27. In 1992, an organization called Common Cause filed a PIL in the Supreme Court of India (Writ Petition (c) 91 of 1992) highlighting the serious deficiencies and shortcomings in the collection, storage and supply of blood in India's blood centres. The PIL prayed that the Union of India, its states and territories be required to immediately initiate a time bound programme to ensure proper positive and concrete steps for obviating the malpractices, malfunctioning and inadequacies of the country's blood banks. The PIL also prayed the Court require respondents provide it with a specific action plan to overcome the operational deficiencies in blood banks.

28. In a landmark judgment on 4 January 1996, the Supreme Court issued an order requiring all blood banks to be licensed within two years, outlawing professional blood donations—donations given in exchange for money—and ordering the establishment of a National Blood Transfusion Council to oversee and strengthen policies and systems governing blood transfusion in the country.

29. During the pendency of the petition, the government revised the rules for licensing and operating blood banks in the Drugs and Cosmetic (1st Amendment) Rules, 1982 requiring all blood banks to seek licensure or cease operating. Though the intentions around this move were no doubt good, the changes to the law made it difficult for physicians in rural areas to procure blood bags and get on with the business of transfusing blood and saving lives.

Requirements for a License as a Blood Bank under the Drugs and Cosmetics

Act, 1940 and Rules, 1945

30. The rules for setting up a licensed blood bank were—and still are—largely unattainable in rural parts of the country. For those facilities able to obtain a license, the process takes years. The requirements for licensure as a blood bank, which are still in force today, demanded that blood banks have seven rooms, of which four should be air-conditioned, with round-the-clock power supply, specially designed refrigerators and other sophisticated equipment managed by a medical officer and full-time technical staff. Poor infrastructure and limited resources in rural areas make these requirements near impossible for rural hospitals to meet.

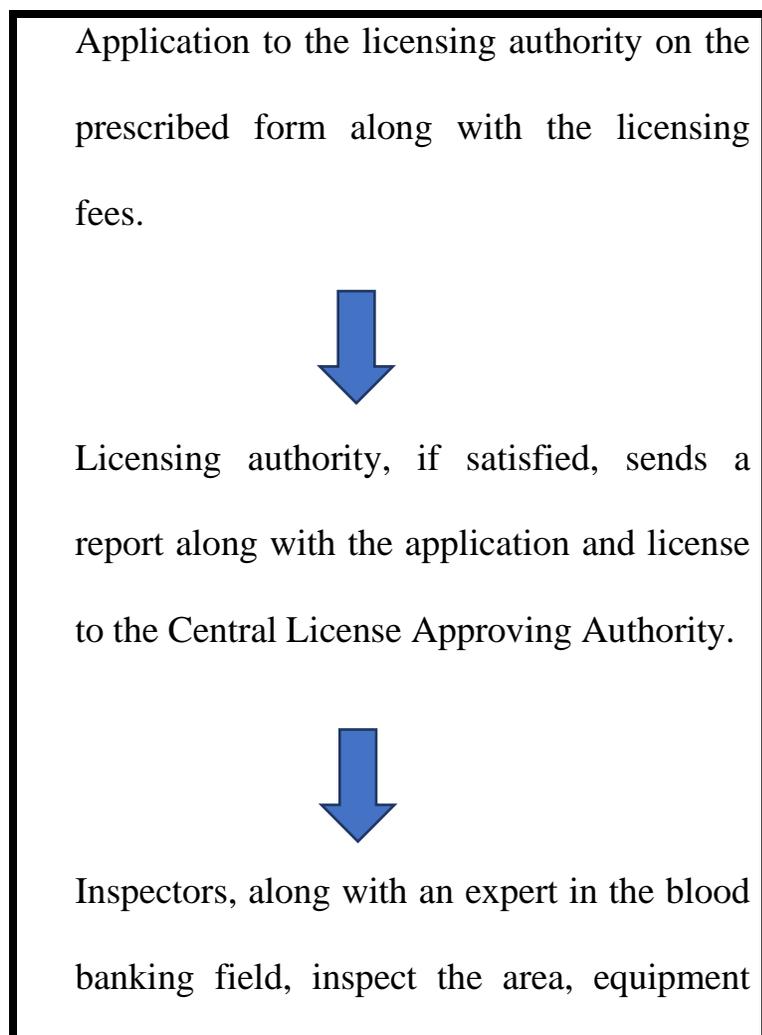
31. If a facility is somehow able to obtain the requisite infrastructure to apply for a license then and only then may such an application be sought. The prescribed form for grant of a license is included in the Drugs and Cosmetics Act, 1940. To obtain a license, the applicant must comply with certain conditions which can be summarized as follows: -

1. The licensee should be able to provide and maintain the required infrastructure for the proper operation of a blood bank.
2. The licensee should maintain the records of all the tests performed on blood and blood components. The licensee should also preserve reference samples of all the blood collected in adequate quantity for supply to the inspector for checking and for conducting the prescribed tests. There are other conditions regarding the grant of license as given in Appendix II.

32. The application requires information about the premises for the blood bank, the names and qualifications of the medical and technical staff, the time by which all the required infrastructure namely premises and

equipment will be ready. The application is submitted on the prescribed form along with a license fee of Rs 600. Before grant of license an inspection is done on the blood bank. The applicant must pay an inspection fee of Rs 1000 for this inspection. Also after a blood bank is functional, a periodic check is done twice or thrice a year to confirm whether the blood bank is complying with the Drugs and Cosmetics Act. The licensee must pay an additional Rs 500 for every inspection and for every renewal of license.

33. The licensee must submit two copies of the application form for grant of license: one to the central license approving authority and one to the state drugs controller. An application form then goes through various stages of checking and cross checking by numerous authorities. The hierarchy of officials scrutinizing the license application is as follows:



and qualification of technical staff.



If every requirement is satisfied the license is granted by the Central Licensing Approving Authority.

34. A blood bank license is valid for five years from the date it has been granted. If the applicant applies for renewal of license after the expiry date, but within six months of the expiry date, the fee payable for the renewal of license shall be Rs 6000 and inspection fee of Rs 1500 plus an additional fee at the rate of Rs 1000 per month.
35. The check performed on the licensed blood banks twice or thrice a year by drug inspectors appointed by the Drug Control Authority of the state is supposed to be a surprise check.
36. On 15 December 1997, the Ministry of Health and Family Welfare issued a draft of the Drugs and Cosmetics (Amendment) Rules which sought to change the definition of “blood bank” such that even the mere collection of blood drawn from donors would require a blood bank to have a license. As a result, UBDT performed in village blood transfusion centers, though not carrying out the operation of storage, processing or distribution of blood or blood components would nevertheless come under the definition of “blood bank” and be fully subject to the proposed draft rules and licensure requirements. Given the difficulty of obtaining a license due to infrastructural and staffing requirements, this would force many of these

small facilities serving rural populations to close their doors for failure to meet standards that ultimately make no impact on their ability to successfully function in the practice of providing lifesaving transfusions.

37. Physicians in rural areas objecting to the proposed Rules were directed by the Supreme Court to contact the Director General of Health Services or the National Council to further address their concerns. On 26 May 1998 the Association of Rural Surgeons of India issued a series of objections and suggestions to the proposed Rules. The key objection stressed by the Association was that the proposed Rules should not be applicable to “‘a Village Blood Transfusion Centre’ where – a qualified medical graduate working in a small village or peripheral areas, collects Blood from a voluntary/replacement donor, performs all the necessary tests & transfuses the blood to his own patient, immediately, without storing the Blood (Unbanked Directed Blood Transfusion).” Instead, the Association suggested separate rules may be drafted for operating village blood transfusion centers.

38. The Association noted that the licensure requirements made no sense for a village blood transfusion center performing UDBT. It stated that:

“Where blood is not stored, processed or distributed and where Unbanked Directed Blood Transfusion is done by a practicing qualified medical graduate doctor, who already has knowledge to perform all tests and collect Blood & where all well-equipped – Hospital or a Nursing Home is already existing, hardly needs any additional place or personnel & special equipment for carrying out the only operation for collection of blood drawn from donors.

Such a facility ‘does not require an area of 100 sq. feet, special air-conditioned blood collection room, specially trained medical officers, technical supervisors, registered nurses or blood bank technicians as the doctor in charge of the Village Blood Transfusion Center can do all the operations required for collection of Blood himself and at most would need an additional area of 10sq feet for a Laboratory. So also a Village Blood Transfusion Centre does not need special costly equipment required for storage of blood or blood components’”

A typed copy of the Objections and Suggestions to Proposed Rules prepared by the Association of Rural Surgeons of India dated 26 May 1998, marked and annexed hereto as **Annexure P- 5 (Pages ____ to ____)**.

39. The objections and suggestions made by the Association were ultimately rejected in a letter dated 11 December 1998 which stated that “Government Hospitals which do not have a licensed blood bank, may procure the blood required by them from the nearest Government licensed blood bank, preserve it in the cold storage in their own hospital and transfuse to the needy patient. The proposal of unbanked directed Blood Transfusion system was not accepted.” A true typed copy of letter rejecting objections and suggestions to proposed rules dated 11.12.1998 marked and annexed hereto as **Annexure P- 6 (Pages ____ to ____)**.
40. On 04 April, 1999 the proposed Rules were made official, changing the definition of blood bank such that even the mere collection of blood required a blood bank to have a license. UDBT was disallowed and chemists were instructed not to give blood collection bags to doctors doing

UDBT. This change created a serious conflict for physicians in rural areas who until then had been using UDBT to save patients' lives in emergency situations where there was no access to banked blood.

41. The government amended the Act yet again on 04 January 2001, this time to allow armed forces medical services in border areas to perform UDBT under a specific exemption in emergency situations like those previously used by doctors in rural areas. The exemption was stated as follows:

No	Class of Drug	Extent and condition of Exemption
30	Whole Human Blood Collected and transfused by centres by Armed Forces Medical Services in Border areas, small mid-zonal hospitals including peripheral hospital. Field Ambulances, Mobile medical units including blood supply units in border, sensitive and field areas.	All the provisions of Chapter IV of the Act and rules made thereunder which require them to be covered by a licence to operate a Blood Bank for collection, storage and processing of whole human blood for sale or distribution subject to the following conditions: - i) These Centres shall collect, process and transfuse blood in emergent situations, which require lifesaving emergency surgeries/or transfusion. ii) Centre shall be under the active direction and personal supervision of a qualified Medical Officer,

		<p>possessing the qualifications and experiences specified in condition (i) of Rule 122-G</p> <p>iii) Each blood unit shall be tested before use for freedom from HIV I and II antibodies, Hepatitis B surface antigen, malarial parasites and other tests specified under the monograph “Whole human Blood” in current edition of Indian Pharmacopoeia.</p> <p>iv) These Centers shall have adequate infrastructure facilities for storage and transportation of blood</p> <p>v) The blood collected and tested by such Centres shall be transfused by the Centre itself and may be made available for use of other peripheral Armed Forces hospitals or centres during operational circumstances.</p>
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42. Physicians in rural areas saw the exemption for armed forces as the government valuing the lives of soldiers over those of ordinary men, women and children in rural areas. Their hope was the government would consider permitting them to resume saving lives with UDBT in emergency situations where there is no banked blood available without fear of criminal liability given the emergency circumstances in which they had previously performed UDBT were—and are—no different than those for the armed forces.

43. In a letter dated 12 February 2004, former president of the Association of Rural Surgeons of India, Dr. R. R. Tongaonkar issued a letter to the Hon'able President Justice Shri. A. S. Anand, chairman of the National Human Rights Commission. The subject of the email was "Denying Right to Life: Can a Rural Surgeons or Gynecologists deny 'Right to Life' to the Rural Civilian population by with-holding lifesaving 'Blood Transfusions' because of Recent Amendment of Drugs & Cosmetics Act?" In this letter, Dr. Tongaonkar wrote the following:

“Honourable Sir,

In most of the rural areas in our country there are no Blood Banks & if a mother delivering a child comes to a Rural surgeon (or gynecologist) with severe bleeding on the verge of dying or a man with road traffic accident with massive bleeding, the Rural surgeon had to save them as he has taken an oath to treat and save any patient coming to him. He was saving them by giving blood immediately by what was known as 'Unbanked Directed Blood Transfusion' (UDBT) done by himself. In this procedure blood

of a voluntary donor was taken and after doing all the mandatory tests was immediately transfused to the needy patient without storing or 'Banking'. This was (and is) a common practice across the country which has saved thousands of lives.

The mandatory tests done are Blood grouping, Cross-matching. Tests for HIV, Hepatitis 'B', VDRL & malarial parasites. These tests can be done even in remote areas using Rapid Test Kits as recommended by WHO (World Health Organisation).

This type of Blood Transfusion (UDBT) was perfectly legal before the recent 1999 amendment of the Drugs and Cosmetics Act 1940 & Rules 1945 because UDBT was not coming under the purview of the law.

But after the Amendment of the Law this life saving procedure is not legally permissible and many clinicians & surgeons in rural areas have stopped transfusing blood in emergencies, as a result many patients are dying.

Now those doctors who still practice UDBT, illegally, but on 'humanitarian grounds', risk their necks only because they do not know of a better alternative to save the life of the patients, and their conscious does not permit them to allow the patients to die, even at the risk of punishment.

This is not true for their Army colleagues. Because by another amendment of the Drugs and cosmetics Act done on 04-01-2001, this type of service (UDBT) is legally allowed if done by Armed Forces Medical Services in Border areas, small mid zonal hospital including peripheral hospitals, as per the exemption No.30 under the schedule K of the said Act.

If this is so, can a 'Civilian' Rural surgeon or Gynecologist deny rural civilian population their 'Right to life' by with-holding timely blood transfusions to save their life while the life of an Army personnel is saved 'legally'?

We, therefore request your honour to study the problems of Village Blood Transfusion and direct Govt. of India to include small mid-zonal & peripheral hospitals in 'Civilian' areas also under the said exemption of the Act applicable to Armed Forces Medical Services & allow the civilian doctors working in these hospitals to collect & transfuse the whole human blood in emergent situations which require lifesaving emergency surgeries or transfusions.

Yours Sincerely,

Dr. R. R. Tongaonkar”

A true copy of the Letter of Dr. R. R. Tongaonkar entitled, “Denying Right to Life: Can a Rural Surgeons or Gyneocologists deny ‘Right to Life’ to the Rural Civilian population by with-holding lifesaving ‘Blood Transfusions’ because of Recent Amendment of Drugs & Cosmetics Act?” dated 12 February 2004 marked and annexed hereto as **Annexure P-7** (Page ____ to ____)

44. The second amendment of the Drugs and Cosmetics Rules, 1945 published on 29 January 2001, stated that Hepatitis C virus antibody testing was mandatory. The third Amendment of Drugs and Cosmetics Rules, 1945 published on 28 March 2001, stated that Blood Donation Camps where voluntary blood donations are drawn shall be substituted by the Indian Red Cross Society or a licensed blood bank run by voluntary or charitable organization.

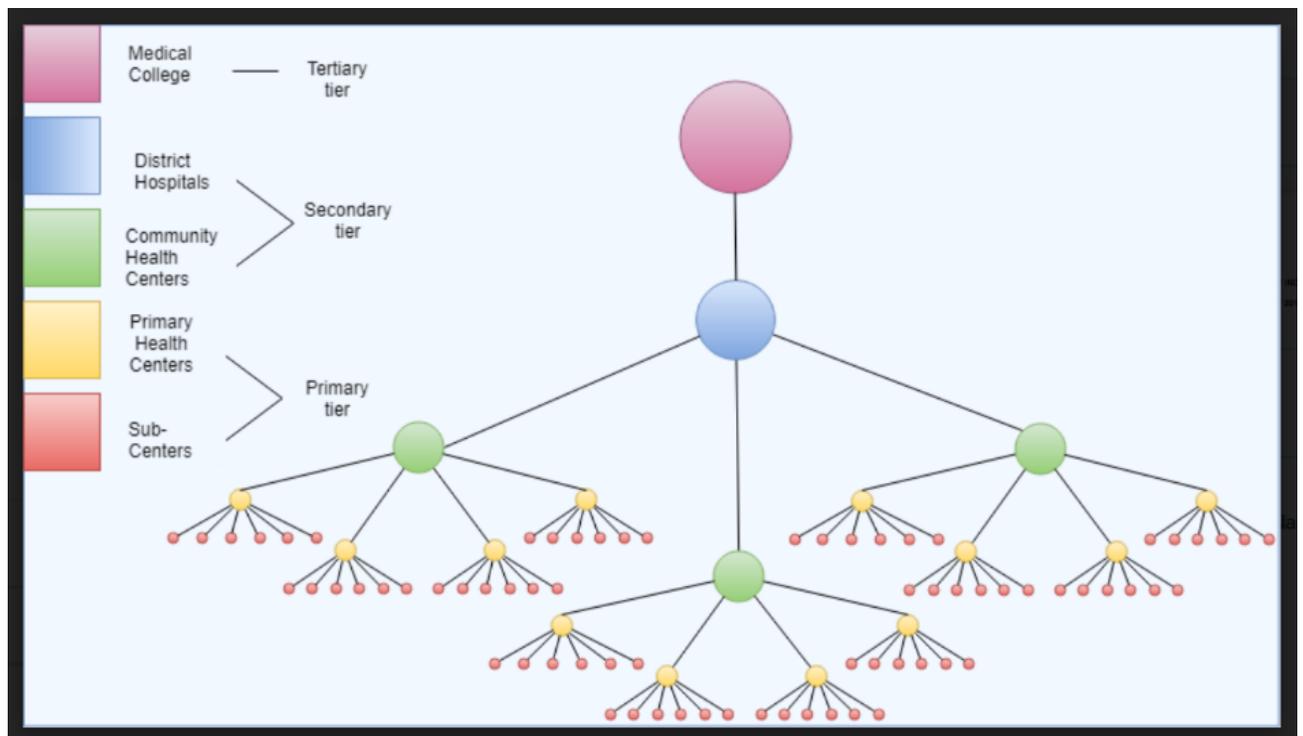
45. The National Human Rights Commission responded to Dr. Tongaonkar’s letter on 18th March 2005 declining to accept his recommendations.

46. The second amendment to the D&C Rules, 1945 published on 29 January 2001, stated that Hepatitis C virus antibody testing was mandatory effective 01 June 2001. The third Amendment published on 28 March 2001 stated that Blood Donation Camps shall be substituted by the Indian Red Cross Society or a licensed blood bank run by voluntary or charitable organization.

Structure of the Public Health System in India

47. Health care in India is delivered through a three-tier system comprising primary, secondary and tertiary health care facilities. At the primary level are sub-centers (SC) and primary health centers (PHC). At the secondary

level are community health centers (CHC) and district hospitals (DH) and at the tertiary level are medical colleges (MC). The table below demonstrates this three-tier system.



Sub-centers and Primary Health Centers—Primary Level

48. An article published in the Journal of Perinatology on 7th December 2016 entitled “Indian Health Systems” explains India’s health care system aims to make health care accessible in both rural and urban areas. To that end, the article explains sub-centers (SC) are designed to serve extremely rural areas with all expenses covered by the national government. They are established in plain areas with populations of 5000 people and in hilly/difficult to reach/tribal areas with populations of 3000.

49. SCs are the most peripheral and first contact point between the primary health-care system and the community. Each SC must be staffed by at least one auxiliary nurse midwife (ANM)/female health worker and one male health worker. The National Rural Health Mission (NRHM) provides for one additional ANM on a contract basis.

50. Directly above SCs are primary health centers (PHC)—the first contact point between the village community and the medical officer. PHCs are state funded and exist in more developed rural areas of 30,000 or more (or 20,000 or more in remote areas). PHCs must be staffed at a minimum with one medical officer and 14 paramedical and other staff. NRHM provides for two additional staff nurses on a contract basis. Because PHCs are larger health clinics than SC each PHC acts as a referral unit for the 5–6 SCs nearest to it in cases requiring more complex treatment, though not requiring a blood transfusion.

51. Given the limited nature of the services they provide, facilities at the primary level lack the infrastructure to store blood and often also physicians qualified as transfusion medicine specialists. Thus, in an emergency where blood transfusion is necessary patients would ideally be referred to the community health center at the secondary level. As discussed below however, many CHCs in rural areas lack proper infrastructure to store blood and are empty.

Community Health Centers and District Hospitals—Secondary Level

Community Health Centers—a Problem Masked as a Solution

52. Community health centers (CHCs), known in some states as sub-district centers are state funded facilities serving 120,000 people in urban areas or 80,000 people in remote areas (the 4 PHCs nearest to them and the respective SCs there under). While CHCs are required to be staffed at a minimum with four medical specialists, including a surgeon, physician, gynecologist/obstetrician and pediatrician, and supported by 21

paramedical and other staff, minimum staff requirements continue to go unmet in nearly all CHCs.

53. This lack of adequate medical practitioners is gravely concerning because for patients at the primary level needing greater care, CHCs are intended to be first referral units (FRUs)—facilities providing emergency obstetric care including surgical interventions such as caesarean sections; care for small and sick newborns; and blood storage on a 24-hour basis.

54. The objective of having CHCs as a referral center for the primary health care institutions was to make modern health care accessible to the rural people and to ease overcrowding in district hospitals. Their shortage of adequate staff however renders CHCs virtually inoperable in their purpose. In September 1999, the Programme Evaluation Organization for the Government of India issued a report entitled “Functioning of Community Health Centres (CHCs)” which evaluated the functioning and effectiveness of CHCs in making specialized health care accessible to rural people. The report’s findings provided a sobering perspective on the failure of CHCs until that point. The findings include the following:

- a) Some CHCs have been approved without sanctioning all the posts of specialists. Only 30% of the required posts of the specialists were found to be in position. More than 70% of the sample CHCs is running either with one specialist or without any specialist.
- b) There is a mismatch between medical specialists vis-a-vis equipment/facilities/staff, leading to sub-optimal use of resources. The overall productivity of the public health services

can substantially be improved if this mismatch and thin spread of resources is avoided.

c) Only two out of 31 CHCs evaluated were being used as referral centres. As many as 11 CHCs have not attended any referral case, while the remaining 18 have been used sub-optimally with an average of 206 cases per year. The suboptimal use of CHC services is due to infrastructure inadequacies, medical and paramedical staff, and more importantly, the mismatch of various inputs.

d) Notwithstanding the existing limitations in the services delivery system, a large majority of the households expressed their strong preference for public health care system as against the private facilities. The findings tend to suggest that CHCs have not made any significant contributions towards realization of the intended objectives even after about two decades of their establishment.

A true copy of report entitled “Functioning of Community Health Centres (CHCs),” issued by the Programme Evaluation Organization for the Government of India, dated September 1999, marked and annexed hereto as **Annexure P- 8(Pages ._____to_____)**.

55.Regrettably, the functioning of CHCs has not improved since the 1999 PEO report. Consequently, rural area patients with treatable conditions have continued to suffer lower health quality and needless loss of life.

56.Data from the central government reports that as recently as 31st March 2017 there was a huge shortfall of surgeons (86.5%), obstetricians and gynecologists (74.1%), physicians (84.6%) and pediatricians (81%) in

CHCs across India. The overall shortfall of specialists to meet existing requirements was 81.6%. These monumental short falls reflect that the government's goal of having CHCs as first referral units for rural people has been a failure from the start and has contributed to the declining health and mortality of rural people for the last 4 decades. Having a first referral center that is almost or completely unstaffed is the same as having no CHC at all. It may even be worse as patients in critical condition will lose vital lifesaving time traveling to a CHC that will inevitably turn them away due to lack of resources and no blood.

Community Health Centers as Blood Storage Centers

57. CHCs not only suffer from a lack of staff but also from a shortage of blood.

Because CHCs (as intended referral units) must store blood on a 24-hour basis they are also intended to function as Blood Storage Centers (BSC). In that capacity, CHCs must procure required units of safe blood from their specified mother blood banks which are established in district hospitals or other BSCs. They are responsible for proper storage, cross-matching, transfusion and all other associated activities involving stored or banked blood.

58. Despite the aspirational objectives of blood storage units set out nearly 20 years ago by the central government, BSCs—in CHCs or otherwise—have failed as a concept leading to the deaths of countless patients in rural areas from lack of blood or access to proper health care. The key factors impacting BSC functionality are lack of adequate infrastructure and manpower in CHCs and a significant shortage of blood. A true typed copy of article published in Journal of Perinatology entitled “Indian Health

Systems” dated 7th December 2016 marked and annexed hereto as **Annexure P- 9 (Pages _____ to_____).**

59.A news article in The Hindu dated 23 June 2013, titled “No staff to run blood storage centers,” stated that the decision to start regional blood-storage centres at three government hospitals “is hanging in the balance with the delay in recruiting the required number of staff for their operations. For the past one year, the special rooms and the refrigeration facilities allotted for the project have been remaining unused.” A true typed copy of “No Staff to run Blood Storage centres” published by The Hindu, dated- 23.06.2013 is marked and annexed herewith as **Annexure P- 10 (Page No. ____ to ____).**

60.To demonstrate the issues preventing CHCs from functioning in rural areas as intended by law, petitioners submit a statement prepared by Dr. R. R. Tongaonkar, director of the Tongaonkar Hospital in the Maharashtra District of Dhule entitled, “Present Position of Blood Storage Centers in State of Maharashtra.” Dr. Tongaonkar’s statement provides the following:

“To conclude, it can be said that the basic idea of amending the Drugs & Cosmetics Act & Rules to establish ‘Blood Storage Centers’ as an alternative to Unbanked Directed Blood Transfusion (UDBT) as done in Rural areas by practicing surgeons, Gynecologist & Physicians to save their patients in emergencies has not been a successful venture. UDBT is the real answer to solve the problem of blood supply in Rural areas.”

A true typed copy of statement entitled Present Position of Blood Storage Centers in State of Maharashtra prepared and submitted by Dr. R. R.

Tongaonkar dated nil, marked and annexed hereto as **Annexure P-11** (Pages _____ to _____).

61. An article published in Scroll on 06 August 2016 entitled “Should hospitals give patients unbanked blood to save their lives” provides further clarification on the state of blood storage units and their effectiveness in resolving the blood shortage issues in rural areas. The article states in part:

“In 2002, the council allowed the setting up of blood storage centres that were allowed to keep blood from licensed blood banks (but were not authorized to collect it). These storage centres could come up in villages and towns, while the mother blood banks would usually be in the district headquarters or cities.

In Chhattisgarh, there are 60 such storage units, mostly in community health centres, many of which do not use the blood at all and direct patients to go to other healthcare facilities. For instance, the community health centre in Gaurella, attached to the Chhattisgarh Institute of Medical Sciences in Bilaspur, has never approached the storage unit for blood. “I am not even sure it [the centre] functions,” said Dr VP Singh, who is in charge of the blood storage centre in the Bilaspur college.

Patients from community health centres often make their way to Jan Swasthya Sahyog, a non-profit in Ganiyari, near Bilaspur city. “Often, we see patients who are bleeding copiously after

childbirth and are referred to us in that condition,” said Dr Yogesh Jain, one of the founders of the hospital.

Even hospitals that do use blood storage units, such as Jan Swasthya Sahyog, Shaheed Hospital in Dalli Rajahara in Chhattisgarh’s Balod district and the mission hospitals, said they get insufficient units of blood.”

A true typed copy of article published in Scroll entitled “Should hospitals give patients unbanked blood to save their lives” dated 06 August 2016 marked and annexed hereto as **Annexure P- 12 (Pages ____ to ____)**.

62. Additionally, an article published in BJM Global Health on 16 February 2017 entitled “Access to safe blood in low-income and middle-income countries: lessons from India” stated the following:

“Blood storage centres are often insufficient, especially in emergency situations. Some rural surgeons also attest that in many public hospitals, which often serve as the first point of care for many patients, blood storage centres exist only in name. These centres are reportedly rarely operational due to multiple factors, including the central blood bank requirement for a family replacement donation, preferential deferral of nearly expired or unwanted blood group units to the storage centre, and the challenges inherent to the requirement of a constant and reliable power supply to operate the blood storage refrigerator and other necessary appliances. For example, one surgeon reported that the

refrigerated vehicle meant to transport blood from the central blood bank to the storage centre has never left the blood bank. Another clinician reported that when he has attempted to retrieve blood from the blood storage centre nearest to his clinic, he was told they could not deliver blood as he was located >40 km away, effectively eliminating his supply to blood products.”

A true typed copy of article published in BJM Global Health titled “Access to safe blood in low-income and middle-income countries: lessons from India” dated 16 February 2017 is marked and annexed herewith as **Annexure P- 13 (Pages _____ to _____)**.

63. The logistical and infrastructural hurdles to maintaining round-the-clock blood in BSCs are directly felt when CHCs that have no blood experience emergencies in which their patients immediately need blood. A recent correspondence from 8th January 2019 between Dr. R. R. Tongaonkar on behalf of the Dr. Tongaonkar Sub-district Hospital (aka CHC) and the M.O. Sub-district Hospital shows the futility of a system where none of the facilities meant to store round-the-clock blood are all dry. At 9:30 p.m., Dr. Tongaonkar wrote:

“To, the M.O. Subdistrict Hospital, Dondaicha

Subject: Supply of urgent blood bag to our patient

Sir,

Our patient Rajashree Ulhas Jagtap is having severe PPH (postpartum Hemmorage). She needs urgent blood transfusion.

Her group is [A positive] (sample sent in bulb).

Please give us one bag of A [positive] blood for our patient immediately. Thank you.

Yours sincerely,

Dr. R.R. Tongaonkar”

Thirty minutes later at 10:00 p.m. the M.O. Subdistrict Hospital responded as follows:

“To, The Director

Tongaonkar Hospital,

Dondaicha District, Dhule

Thanks for referral. According to your requirement—there’s no A+ blood bag available in our Blood Storage Centre of Subdistrict Hospital Donaiche. Sorry for the inconvenience.

Thank you”

The 30 minutes lost between the initial correspondence above and the response cut the golden hour in which doctors had to save this patients life in half. Had the BSC been appropriately stored with banked blood as it was meant to be loss of life would not have been as imminent an issue. Alternatively, had it already been known that the BSC at the M.O. Sub district Hospital was empty; physicians would not have lost precious time relying on the hospital to obtain blood for their patient. A true copy of the Correspondence between Dr. R. R. Tongaonkar and the M.O. Sub-district Hospital, dated 8th January 2019 is marked and annexed hereto as **Annexure P- 14 (Pages _____ to _____)**.

64. The remarks of Dr. Tongaonkar in his written statement “Present Position of Blood Storage Centers in State of Maharashtra” shows the practical and infrastructural difficulties making it near impossible for CHCs to maintain round-the-clock fully stocked blood storage centers, Dr. Tongaonkar’s correspondence with the BSC at M.O. Subdistrict Hospital shows the hazardous consequences of this unworkable system. When the only options under the law for rural citizens to access safe blood transfusion area non-viable, countless numbers of rural people fall in immediate danger of dying from treatable conditions. Additionally, doctors are left with no legal remedy to provide their patients and must make difficult legal and ethical decisions in order to save lives.

65. In a document entitled ‘No blood bank or blood storage centre can save these patients’ Statistics of a rural hospital – One year study” Dr. Tongaonkar tracks the need for blood transfusion in his hospital over the course of a year and the complications faced acquiring safe blood to save lives during that year under the current system. Dr. Tongaonkar wrote the following:

This is a study for a period of 1 year of a rural hospital for its blood needs and how it was met.

There is no blood bank in the town. The nearest blood bank is more than 30 Kms away. A Govt. Sub-District Hospital in the town turns down the demand for blood.

The hospital is having total bed strength of 22.

4 qualified doctors, one surgeon, one gynecologist, one anesthetist & one MBBS doctor are working in this hospital.

Statistics of 1 year activities in this hospital is as under ---

Total No. of surgical procedures- 1314 (including general surgical &Gynaec& Obstetric) ---

Total No. of Deliveries- 2560

Total No. of Blood Transfusions required – 61

No. of units per patient	Number of patients	Total units used
5	2	10
4	1	4
3	3	9
2	16	32
1	6	6
Total	28	61

Indications for Blood Transfusions

Indication	No of Patients
Postpartum hemorrhage (PPH)	19
PPH needing hysterectomy	3
Ruptured uterus	1

Placenta Previa	1
Dysfunctional uterine bleeding	1
G.I. Bleeding	2
Surgical	1
Total	28

In the period of 1 year out of 28 patients who needed total 61 units of blood, 26 were females & out of them 24 were Obstetric patients who needed 54 units (89%) of blood.

Other points to be noted are—

1) Out of 61 transfusions only 6 were single blood transfusions, that was also because the bleeding which was anticipated, stopped and second transfusion was not given.

2) All the indications were emergencies to save lives, 86% of them Obstetrics.

3) In past the hospital did have a 'Licensed Blood storage centre' (copy of certificate attached). But when 2 units of each blood group was stored many of the units used expired to expire because there were no indications to use them. When one unit of each group was stored then it used to fall short because as seen from above statistics most of the patients needed more than 2 units blood to save patient's life during emergencies usually at night an blood storage enter could not fulfill this demand. There

were many other problems I running the blood storage centre (A separate letter attached.). Therefore it was closed and License forfeited.

4) Lastly it was not possible to get blood from distant blood bank in emergent situations and the only solution to save the patients' lives was to do 'Unbanked Directed Blood Transfusion' (UDBT)!

5) All the donors were voluntary donors.

6) All the mandatory tests were done on the donor's blood.

7) There was no short term or long term reactions or complications of transfusions.

Some key facts that need to be considered are as follows:

1) The Govt. Sub-district hospital in the town is having 'Blood Storage Center' but it is totally non-functioning and does not have a single unit of blood.

2) In the State there is arrangement to meet blood need in rural areas. Just dial number 104 and blood will be available in one hour! But **this facility is available only up to 40 Kms distance.**

As the above mentioned hospital is 55 kms away from District

blood bank this facility is denied to patients only because they are at a distance 15 Kms more than the prescribed limit.

So in such situations, as given above, in a busy rural hospital where there is no blood bank in the town, the doctors have to resort to UDBT to save lives.

A true typed copy of 'No blood bank or blood storage centre can save these patients'! Statistics of a rural hospital – One year study" dated nil, by Dr. R. R. Tongaonkar, marked and annexed hereto as **Annexure P- 15 (Pages _____ to _____)**.

District Hospitals

66. District Hospitals (DH) are the final referral center for primary and secondary level facilities. Every district is expected to have a DH which will be linked to specific CHCs (between 3–5 for each DH), PHCs and SCs within the district. In 2010 however, it was recorded that only 605 DHs existed despite there being 640 districts. Due to lack of manpower in district hospital blood banks many CHCs are unable to deliver. Among other things, this has caused voluntary blood donations in the country to fall from 69% to 64%.

67. The Guidelines for District Hospitals, 2012, published by Indian Public Health Standards explain that DHs must be equipped with sophisticated diagnostic and investigative facilities to provide curative, preventive and promotive healthcare services to those within the district. As such, DHs are to serve as mother blood banks for their district and be responsible for

procuring and storing blood for their own use and to feed to other healthcare facilities.

68. Blood banks in DHs are responsible for collecting blood through proper donor selection, screening units of blood, storing and preventing unnecessary transfusions and establishing an effective quality assurance system. However, the large number of maternal mortalities in India is caused by lack of timely availability of safe blood to women during or after childbirth. The mother blood banks are struggling due to problems of short supply, lack of a reliable, truly voluntary donor base and lack of any mechanism for transport of this blood maintaining the cold chain to the BSCs.

69. It was recently found out that 23 out of 68 blood banks in Delhi are running without valid licenses due to delay in processing applications for their renewal. The Comptroller and Auditor General of India found several deficiencies in management of blood banks including lack of updates on authentic information pertaining to blood/blood components in the National Health Portal, thus depriving residents of Delhi of information regarding availability of blood and its components. The report also noted the significant shortage of medical staff throughout 2012-17 in AYUSH dispensaries. Against sanctioned posts of 163 doctors and 155 pharmacists, 28 posts of doctor and 61 posts of pharmacist were vacant as of March 2017. Out of 103 homoeopathic dispensaries, only 24 have full complement of staff to ensure proper patient care. A true typed copy of "Blood banks running without licenses, facing staff shortage" published by The Hindu, dated- 04.04.2018 is marked and annexed herewith as **Annexure P- 16** (Page No. ___ to ___).

70. Addressing these problems and increasing the spread of blood banks and BSCs must be a top priority. These efforts will require allocation of funds and aggressive creation of trained manpower in a planned way.

The Tertiary Level: Medical Colleges

71. Tertiary health care is provided by medical colleges (MC) in urban areas. MCs function as full-service hospitals and research institutions with advanced technology capable of treating complex issues. They are FRUs for urban areas, blood banks and BSCs. In order to further the goal of making health care services and specifically safe blood accessible to people in rural areas, MCs should function at a regional level to reach rural populations not just urban ones.

The Shortage of Blood Banks in India: The disparity between Urban and Rural Populations

72. India suffers from an acute disparity in access to health care. Urban residents who form only 28% of India's population get the lion's share of access to hospital beds, while the remaining 72% of the population in rural areas get only one-third. This gross disparity also extends to access to safe blood and blood banks. The nearly 3000 blood banks across India, including those run by government, charitable and private hospital blood banks are mainly located in Class A and B cities with very few in class C cities and smaller towns. Even as demand for blood increases daily, only four out of every 81 blood banks are available in rural areas, which is less than 5% of the existing blood banks in the country. Even if that number

were doubled, it would still only be 10% of blood banks in the country to serve the 72% of Indians living in rural areas.

73. This lopsided health policy has limited access to safe blood in rural areas and drastically impacted the health and death rates of people in rural areas. Moreover, health being a state subject, there are imbalances and variations in availability and accessibility of health services in rural areas from state to state. A press release from the Ministry of Health and Family Welfare issued on 26th February 2016 stated that 81 districts in India lack a blood bank. For the reference of this Hon'ble Court the lists of districts with and without blood banks as reflected in the press release are provided below:

Chart 12.1: List of Blood Banks in India

S.NO	NAME OF STATE	Public including Govt. Blood Banks	Private including charitable trust Blood Bank	TOTAL
1	Andaman & Nicobar	02	01	03
2	Andhra Pradesh	32	93	125
3	Arunachal Pradesh	09	01	10
4	Assam	37	28	65
5	Bihar	32	35	67

6	Chandigarh	03	01	04
7	Chhattisgarh	19	30	49
8	Dadra & Nagar	-	01	01
9	Daman & Diu	01	01	01
10	NCT of Delhi	22	47	69
11	Goa	03	01	04
12	Gujarat	30	106	136
13	Haryana	26	50	76
14	Himachal Pradesh	19	03	22
15	Jammu & Kashmir	20	04	33
16	Jharkhand	26	18	44
17	Karnataka	40	153	193
18	Kerala	40	140	183
19	Lakshadweep	01	00	01
20	Madhya Pradesh	54	90	144
21	Maharashtra	74	236	310
22	Manipur	04	01	05
23	Mizoram	08	02	10

24	Nagaland	05	-	05
25	Odisha	63	20	83
26	Pondicherry	02	10	13
27	Punjab	48	53	101
28	Rajasthan	48	54	102
29	Sikkim	02	01	03
30	Tamil Nadu`	102	198	300
31	Telangana	27	113	140
32	Tripura	06	02	08
33	Uttar Pradesh	100	142	242
34	Uttarkhand	20	08	28
35	West Bengal	81	39	120
Total		1024	1684	2708

Chart 12.2: List of Districts Without Blood Banks in India

S.No	State	Districts without Blood Bank with names
1	Andaman & Nicobar	2 districts (Nicobar Group, Middle & North Andaman)
2	Arunachal Pradesh	9 districts (East Kameng, West Kameng, KurungKumey, Kra Daadi, Siang, Dibang Valley, Namsai, Tirap, Longding)
3	Assam	9 districts (Udalguri, Baksa, Chirang, Kamrup (Rural), Biswnath Chariali, South Salmara&Mankasar, Hojai,vi Charaيداow, West Karbi, Anglong)
4	Bihar	5 districts (Araria, Arwal, Banka Sheohar&Supaul)
5	Chhattisgarh	11 districts (Gariyaband, Balodabazar, Balod, Bemetara, Janjgir, Surajpur, Balrampur, Jashpur, Kondagaon, Sukma, Bijapur)
6	Gujarat	1 district (Ahwa-Dang)

7	Himachal Pradesh	1 district (Lahaul&Spiti)
8.	Jammu & Kashmir	5 districts (Reasi, Samba, Shopian, Ganderbal&Bandipora)
9	Jharkhand	6 districts (Khunti, Ramgarh, Godda, Jamtara, Seraikela, Bokaro)
10	Madhya Pradesh	2 districts (Anuppur, Agar)
11	Manipur	5 districts (Tamenglong, Ukhrul, Bishnupur, Senapati and Chandel)
12	Meghalaya	8 districts (West Khasi Hills District, South-West Khasi Hills District, RiBhoi District, East Jaintia Hills District, North Garo Hills District, East Garo Hills District, South Garo Hills District, South- West Garo Hills District)
13	Nagaland	3 districts (Peren, Longleng&Kiphire)
14	Sikkim	3 districts DH, Mangan(N), Singtam(E) &Gyalsing(W)

15	Tripura	3 districts (Khowai, Sepahijala, South Tripura)
16	Uttar Pradesh	4 districts (Amethi, Hapur, Shambhal&Shamli)
17	Uttarakhand	4 districts Tehri, Rudraprayag, Champawat and Bageshwar
	Total	81

A true typed copy of the press release from the Ministry of Health and Family Welfare dated 26 February 2016 is marked and annexed herein as **Annexure P- 17**(Page ____ to ____).

74. Transportation of blood from a blood bank is another major hurdle with problems related to quick contamination of the blood due to lack of proper equipment. Surgeons, obstetricians and other qualified clinicians now available in nodal villages are greatly handicapped due to the unavailability of blood. Surgeries and treatment of critically ill patients are delayed and patients incur huge expenses and sometimes lose their lives on their way if referred to nearby bigger towns or cities and not treated in the villages or block head quarter immediately.

Blood Shortage In India

75. India not only suffers from an acute shortage of blood banks in rural areas, but also an overall shortage of blood. Statistics show that on an annual basis there are 234 million major operations in India, 63 million trauma-induced

surgeries, 31 million cancer-related procedures and 10 million pregnancy related complications, all of which require blood transfusions. Additionally, disorders including sickle cell anemia, thalassemia and hemophilia require repeated blood transfusions.

76. Importantly, the need is not only for blood but for "safe blood," which includes all that is available for transfusion. That which is unsafe should not be available for transfusion. The donated blood should ideally be checked for HIV, HBV (hepatitis B virus), HCV (hepatitis C virus) and other blood transmitted diseases prior to being made available for transfusion.

77. According to a 2012 World Health Organisation (WHO) report, only 9 million units of blood are collected in India annually, while the need is for 12 million units. Out of this only half the blood is obtained by voluntary blood donors. The rest is from replacement donations and sometimes even paid donors. The report also suggests that only 1% of eligible donors donate blood every day. Delhi NCR alone faces a shortage of 100,000 units per year. Bihar is 84% short of its blood requirements—more than any other state, followed by Chhattisgarh (66%) and Arunachal Pradesh (64%). A study in 2009 showed blood banks in Maharashtra are only able to provide 31% of total blood needed and those in Gujarat only 13%.

78. Considering the minimum standards set out by the World Health Organization and Lancet Journal, the petitioners with the intention to understand the deficit in blood supply in various states compared the actual number of blood bags available to the minimum requirement as set out by WHO and the Lancet Report. The deficit in numbers and percentage as of April 2019 for six states is reiterated as under:

22.1: New Delhi

District	WHO requirement	Lancet requirement	Available Blood Bags	Percentage Deficit According to WHO
New Delhi	1420	7100	38	97.32394366
North Delhi	887978	44,398,9	8	99.99909908
North West Delhi	36565.39	182,826,95	14	99.96171243
West Delhi	25432.43	127.162	24	99.9056323
South West	22929.58	114,647,9	0	100
South	2731929	13659645	670	99.9754752
Central	58232	2.911	58	99.90039841
North East	2241624	112081	0	100

East Delhi	1709346	85467	106	99.9937988
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22.2: Jharkhand

District	WHO requirement	Lancet requirement	Available Blood Bags	Percentage Deficit According to WHO
Ranchi	29142.53	145712.65	304	98.95685104
Ramgarh	9494.43	47472.15	0	100
Latehar	7269.78	36348.9	8	99.8899554
Dhanbad	26844.87	134224.35	346	98.71111315
Gumlah	10252.13	51260.65	0	100
Kodarma	7162.59	35812.95	47	99.34381278
Chatra	10428.86	52144.3	0	100
Palamu	19398.69	96993.45	6	99.96907008
PurbiSingbhum	22939.19	114695.95	86	99.62509574
Giridih	24454.74	122273.7	15	99.9386622

22.3: Chhattisgarh

District	WHO requirement	Lancet requirement	Available Blood Bags	Percentage Deficit According to WHO
Bastar	14131.99	70659.95	20	99.85847711
Bijapur	255.23	1276.15	4	98.43278611
Bilaspur	26636.29	133181.45	208	99.21911047
Durg	33438.72	167193.6	70	99.79066184
JanjgirChampa	16197.07	80985.35	20	99.87652088
Mahasamund	10327.54	51637.7	17	99.83539158
Narayanpur	139.82	699.1	0	100
Raipur	40638.72	203193.6	209	99.48571215
Surguja	23598.86	117994.3	114	99.51692582

				99.7329562
Kanker	7489.41	37447.05	20	7

22.4: Tamil Nadu

District	WHO requirement	Lancet requirement	Available Blood Bags	Percentage Deficit According to WHO
Chennai	46467.32	232336.6	301	99.35223292
Coimbatore	34580.45	172902.25	175	99.49393371
Karur	10644.93	53224.65	119	98.88209692
Ramanathapuram	13534.45	67672.25	33	99.75617775
Tirunelveli	30772.33	153861.65	135	99.56129419
Vellore	39363.31	196816.55	160	99.59353012
Salem	34820.56	174102.8	116	99.66686349
Erode	22517.44	112587.2	9	99.96003098
Namakkal	17266.01	86330.05	112	99.35132668

22.5: Assam

District	WHO	Lancet	Available	Percentage
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	requirement	requirement	Blood Bags	Deficit According to WHO
Dhubri	19492.58	97462.9	0	100
Nagaon	28237.68	141188.4	0	100
Bongaigaon	7388.04	36940.2	6	99.91878766
Tinsukia	13279.29	66396.45	0	100
Goalpara	10081.83	50409.15	13	99.87105516
Darrang	92.85	464.25	0	100
Dima Hasao	2141.02	10705.1	0	100
Kamrup metropolitan	12539.38	62696.9	3	99.97607537
Sivasagar	11510.5	57552.5	0	100
Barpeta	16936.22	84681.1	0	100

22.6: Gujarat

District	WHO requirement	Lancet requirement	Available Blood Bags	Percentage Deficit According to WHO
Surat	60813.22	3040661	0	100

Kheda	23907.76	1195388	0	100
Dohad	21270.86	1063543	0	100
Amreli	1514.19	757095	53	96.5
Tapi	8070.22	403511	8	99.9
PanchMahal	23907.76	1195388	43	99.82
Rajkot	38045.58	1902279	15	99.94
Vadodara	41656.26	-	12	99.97
Patan	13437.34	671867	111	99.17
Narmada	5902.97	2951485	28	99.53

79. A simple perusal of the data provided above makes it abundantly clear the deficit in availability of blood across these states is dangerously high. This is even more apparent given that while the current population of India is approximately 1.37 billion, the availability of blood bags as shown under the e-raktkosh website run and updated by the Ministry of Health and Family Welfare, Union of India is only 30,000+.

80. Blood shortage is due primarily to the rural health care system which provides infrastructural requirements that rural areas are largely unable to meet in order to secure blood bank licenses. The shortage is compounded by several aggravating factors. India lacks a central system of blood collection agency. There is an online system where the banks across the country are required to update their blood stock status real time; this feature however is not fully utilized. Many a times the blood donation

camps collect blood; more than what is required due to lack of proper data. Another problem faced by the blood banks as discussed earlier is the lack of proper storage facility. The processing charges for blood and blood components are a continuing issue that adds to the problem. Also there is an absence of a strong blood sharing network between banks and hospitals leading to failure in serving their purpose. There is a lack of processing and testing units especially in government hospitals, as such the whole blood must be transfused to patients instead of their components, which leads to wastage of blood. This is commonly prevalent in rural areas often contributing to other disease in patients. Several of these named factors are discussed further below.

Aggravating Factors Impacting the Shortage of Blood in India

Lack of Voluntary Non-Remunerated Blood Donations

81. Voluntary non-remunerated blood donors are the foundation of a safe, sustainable blood supply. The WHO has stressed that without a system based on voluntary unpaid blood donation, particularly regular voluntary donation, no country can provide enough blood for all patients who require transfusion. Most developed countries have a long history of voluntary blood donation, but several developing and transitional countries have also achieved this goal. India's failure to do so yet sets our country behind in this important regard.

82. The NBTC has called for a complete phase-out of replacement donations by 2020. The focus on replacement donations rather than voluntary, non-remunerated donations (VNRDs) means that district hospitals (a.k.a mother banks) which are intended to feed the CHC/blood storage centers

underneath them (usually 4 – 5 in number) will never be self-sustaining enough to spare any blood as they themselves have a hand-to-mouth existence. Consequently, most blood storage centers have hardly any blood units.

83. An article published in the International Journal of Research in Medical Sciences dated 14 July 2017 entitled “Patterns of voluntary and replacement blood donors in a tertiary care center: a retrospective study” stated that family/replacement donors still provide more than 45% of the blood collected in India. Such donors are supposed to be associated with a significantly higher prevalence of transfusion-transmissible infections including HIV, hepatitis B, hepatitis C, syphilis and malaria.

84. In northern India, the voluntary donor rates vary from 9.1% to 52.3% and the National AIDS Control Organization (NACO) reported that in 2007, voluntary donations in India were about 55%. Today, replacement donors still comprise a large proportion of blood donors. Some states collect voluntary blood units more than the national average, others are far below in meeting targets. The VBD in almost 13 states of the country is less than 50%. For a safe blood service in India, where comprehensive laboratory tests are neither possible nor pragmatic, it is best to switch over to 100% voluntary donations, as it is now established that voluntary non-remunerated regular donation is the safest. Thus, one of the key strategies to enhance blood safety must be to focus on motivating non-remunerated blood donors especially in rural areas and phase out replacement donors. A true copy of article published in the International Journal of Research in Medical Sciences titled “Patterns of voluntary and replacement blood

donors in a tertiary care center: a retrospective study” dated 14 July 2017 marked and annexed as **Annexure P- 18 (Pages _____ to _____)**.

85. Blood banks currently have no responsibility to maintain minimum stock of units of each group and to ensure adequate collection and issue. Minimum number of camps and a minimum number of units collected and issued each month according to the class of blood bank should be laid down. Such compliance through monthly online reports to state drug controller and accessible to the public, will encourage voluntary donation through camps.

86. Replacement of blood by a relative should not be mandatory to get blood from a blood bank or blood storage center, especially in life threatening emergencies (to be certified by treating physicians, at least 2, with valid reasons). This also conforms to NACO guidelines in their document ‘Standards for blood banks and blood transfusion services, 2007. Requiring a replacement donation may lead to delays in care—oftentimes the transfusion will not be administered to the patient in need until a family member travels to a blood bank, donates blood then returns. These delays in care can be fatal. Additionally, Professional donors may pose as a relative or friend of the patient, which is difficult for blood banks to verify.

87. The National Blood Policy, 2009, mandates a 100% voluntary donor blood collection by 2020, with no replacement or professional blood donation at all. We are far from this as can be made out from a report on this by NACO. Accordingly, decisive steps must be taken towards this goal.

Blood Wastage

88. The shelf-life of donated blood is only 35 to 42 days. Government statistics on blood banks reveal there is a massive deficit between the amount of blood collected and stored by blood banks and the amount of blood used to treat the population. The immeasurable units of banked blood wasted in urban areas due to expiration are a grave concern as those wasted units could have been used to save lives in rural areas where there are virtually no blood banks. At a national level the deficit is as high as 31% (116 lac units vs. 80 lac units). For the State of Chhattisgarh, which is 84% rural, this deficit is an appalling 81%.

89. National statistics indicate India needs 8.5 million odd units annually as against the 5 to 5.5 million units that are collected. According to an RTI report of 2013, 1938 units of blood were discarded (1 unit of blood = 450 ml), while the government medical college and hospital wasted 1140 units of blood. One of the major reasons for blood wastage has been the absence of maintaining the temperature of blood units during its shifting from blood bank to the recipient department or on receiving it back at the blood bank owing to its non-utilization. In another RTI filed by a doctor in Mumbai in 2013, the prestigious St. George hospital in Fort has also admitted of wasting blood units due to mismanagement. As per the news report in mid-day between January 2012 and August 2013, 44.45 liters of whole blood and 918 liters of plasma (plasma is procured from red blood cells within 6 hours of blood collection) was not used by the hospital and languished beyond its expiry date.

90. Lack of synergy between donors, blood banks, regulators, hospitals and receivers is leading to wastage of blood because of no takers and contrastingly severe shortage of blood in cases of emergencies like

accidents or natural disasters. In 2016–17 alone, over 6.5 lakh units of blood and its products were discarded. The worrying part is that 50 per cent of the wasted units was plasma which has a longer shelf life of one year as compared to whole blood and red blood cells that have been used within 35 days.

91. There must be transparency to ensure that all blood banks and blood storage facilities have their data on blood donations, storage, testing and issuance in the public domain. Availability of blood and components of different groups should also be available to people in real time through government portals so that optimal utilization of these can take place. Additionally, pediatric blood bags must be freely available. Currently because of their non-availability or very limited availability blood used for pediatric patients is either wasted from the full adult unit or individual doctors and healthcare facilities evolve their own protocols to reuse the blood after removing an aliquot for transfusion.

The Illegal Blood Market

92. Despite the sale of blood being unlawful, blood is often illegally sold in India and not given to patients based on critical medical conditions. This is a key contributor to blood shortages in rural areas. A true copy of the “Bloodless Ban” published with the Down To Earth, dated- 17 August 2015 is marked and annexed herewith as **Annexure P-19 (Page ___ to ___)**.

93. An article in the Indian Express from 2 April 2013 entitled “Blood banks sell plasma, make a killing” outlines how a lack of mechanism for what happens to blood after it is donated leads to corrupt hospitals extracting

plasma out of blood and selling it to the pharma companies, who in turn make pure profits running into crores of rupees. Some hospitals will sell donated blood units for as high as Rs. 8000 to 15000 a piece.

94. The article notes that Fifty-two blood banks in Gujarat had been extracting plasma from the blood collected through donation and have earned Rs 11.35 crores by selling the same to private pharmaceutical companies. It further states that several blood banks observe this practice at the cost of needy patients, especially in government hospitals. A true copy of article published in the Indian Express entitled “Blood banks sell plasma, make a killing” dated 2 April 2013 marked and annexed as **Annexure P- 20 (Pages __ to __)**.

95. Although the Drugs and Cosmetics Act was amended in 2017 to allow the transfer of human blood and blood components under prescribed storage conditions from one blood bank to another, the illicit sale of blood and blood components continues to hamper this change in laws from being fully embraced by tempting hospitals seeking to make a profit off of the blood they farm rather than providing excess blood collected at voluntary donation camps to other blood banks in rural areas experiencing blood droughts.

Processing Charges for Blood and Blood Components

96. Blood and blood components, being an essential life-saving drug, are included in the National List of Essential Medicines, 2011 although its price is yet to be fixed under the Drug Price Control Order. This should be done immediately to halt arbitrary and often exorbitant pricing, playing on the emergency needs of the patients. Unfortunately blood banking even in

NACO supported blood banks remains highly fragmented with no real checks and ensuring that guidelines and SOPs are being followed.

97. Money spent on testing of blood and storage is charged as processing fee when blood is bought from the blood banks. The government of India has prescribed rates of blood and blood products though these are optional and not mandatory. The price list is as follows:

Whole Blood	Rs 1050/ - per unit
Packed Red Cells	Rs 1050/ - per unit
Fresh Frozen Plasma	Rs 300/ - per unit
Platelet Concentrate	Rs 300/ - per unit
Cryoprecipitate	Rs 200/ - per unit

98. Most blood banks use these as rough guideline values and charges can vary, depending on the demand. Even where blood is collected for free, banks must spend for processing, storage and testing. In almost all cases, private blood banks charge more than government blood banks.

99. One of the benefits of UDBT that increases its functionality in rural areas where the cost of blood and blood components may be a significant added hurdle for facilities to meet is that these processing charges need not apply as the practice of UDBT does not require the storage of blood.

Deaths Caused from Blood Shortage

100. The scarcity of blood banks in rural areas and the unavailability of safe stored blood in reasonable time at affordable cost in villages' results in loss of many lives due to the delay caused. The "golden hour" refers to the period following a traumatic injury during which there is the highest likelihood that prompt medical and surgical treatment such as receiving a

blood transfusion will prevent death. Once that window is closed and those precious life-saving minutes expire, the likelihood of death is significant. Accordingly, in emergency situations where a blood transfusion is needed, saving time and performing the transfusion before the end of the golden hour is a life or death concern.

101. Transportation of blood from a blood bank is another major hurdle with problems related to quick contamination of the blood due to lack of proper equipment. Surgeons, obstetricians and other qualified clinicians now available in nodal villages are greatly handicapped due to the unavailability of blood. Surgeries and treatment of critically ill patients are delayed and patients incur huge expenses and sometimes lose their lives on their way if referred to nearby bigger towns or cities and not treated in the villages or block head quarter immediately.

102. Given the hurdles to accessing blood in rural areas in reasonable time many have died. The worst affected are women, as seen from statistics of UN's population fund (UNFPA), WHO, UN Children's fund and the World Bank. These statistics put India at the top of the list of high maternal mortality rates. In 1998, the main causes of maternal death in rural India were largely blood related. They included: anemia (24%), bleeding in pregnancy and puerperium (23%), abortion (12%), eclampsia and toxemia (10%), puerperal sepsis (10%), malposition of child leading to death of the mother (7%) and unclassified symptoms (14%). These statistics reveal how preventable these deaths are. The interventions required to address the leading causes of death exist and are not technically complex if accessed in time.

103. This makes the unsuccessful efforts by pregnant women in backward regions of India to obtain basic obstetric care even more tragic. Gender bias in terms of failure to acknowledge pregnant women's needs and failure to ensure accountability for women's reproductive rights and survival are crucial factors sustaining high levels of maternal mortality. A true typed copy of the article "Dead Women Talking: A civil society report on maternal deaths in India" published by Common health and Jan Swasthya Abhiyaan, dated- July, 2014 is marked and annexed herewith as **Annexure P- 21 (Page No. ___ to ___)**.

104. On 02 June 2016 the Hindu published an article entitled "A lifeline that Rural India cannot do without" in which it stated in part:

"The young lady was deathly pale and in obvious shock from the loss of blood due to a ruptured uterus. Immediate resuscitation with intravenous fluids was started, while waiting for her blood grouping report. Unfortunately, a match for her group was unavailable at the hospital's blood storage centre and her brother is asked to go to the blood bank in the district headquarters town to get three units.

What is an hour away during day takes more than three hours at that late hour. In the town, the blood bank staff insists on a replacement donation. Even though her brother offers his own blood, it is rejected as he is anaemic. A helpful bystander (read tout) directs him to a private blood bank where he gets one unit for Rs. 2,400, but without any replacement donation. He rushes back to the hospital, where his sister has already been operated

upon to remove her uterus and the dead baby. She continues to remain severely pale and in shock.

A single unit of blood is not enough to save her and she dies in the early hours of the next morning. Her mother is inconsolable, while her brother is completely drained of all emotions as he squats with his head on his knees. The doctors and the nursing staff are equally heartbroken and angry.”

A true typed copy of “A lifeline that Rural India cannot do without” published by The Hindu, dated- 02.06.2016 is marked and annexed herewith as **Annexure P- 22 (Page No. _____ to _____)**.

105. On 06 August 2016, Scroll published an article entitled “Should hospitals give patients unbanked blood to save their lives” in which it stated in part:

“In April, a woman walked into a hospital in Baitalpur in Bilaspur district of Chhattisgarh, bleeding heavily. She was in her thirties, and had ruptured her uterus while delivering a baby at home in a nearby village. She needed urgent medical attention. When a van dropped her off on the highway, she trudged two kilometers to Baitalpur Evangelical Mission Hospital – only to be turned away.

The hospital had an operation theatre and a gynecologist, but no blood.

With buses plying only once in two-three hours from Baitalpur to Bilaspur, the district headquarters, getting blood from the blood bank takes at least four to five hours, if not a day. Without a quicker way to access blood, the hospital is not equipped to handle an emergency.

‘She had a ruptured uterus and was anaemic,’ said Dr Kusum Masih, the medical superintendent of the hospital who is also a gynaecologist. ‘We could not operate without blood.’

The doctors sent her to Bilaspur about 35 km away – but she died on her way there.”

106. The same article provides the following story of a woman in Chattisgarh:

For a rural hospital in Chhattisgarh, there is just one option in case of emergencies where blood is required – to refer a patient to a bigger facility. This often means that the person reaches the hospital in a critical condition, or dies on the way, as in the Baitalpur case.

Some hospitals are countering this by opting for an illegal way of giving blood, called unbanked direct blood transfusion. Under this, the blood of a willing donor’s that matches with the recipient’s group is collected, tested for infection with a rapid blood kit and then transfused without roping in a blood bank.

Take the case of a 40-year old woman from Shahdol district in Madhya Pradesh, who had been having extremely painful menstrual bleeding for nearly four months.

'Khoongiratrahe [I was bleeding all the time],’ she said. ‘But, I would still have to work in our fields. How can I stop?’ She was also not able to eat or walk and had severe chest pain.

On June 28, she somehow made it to a rural hospital in Chhattisgarh, which shares a border with Madhya Pradesh, travelling more than 200 km by train and bus with her husband and son.

When the doctors examined her blood, they saw she had a hemoglobin count of 4.6 – the normal range for women is between 12.1 and 15.1 – which meant she needed immediate transfusion. She also required an abdominal hysterectomy, as she had a large fibroid in her uterus.

In all, she needed three units of blood.

‘I do not know how she managed to travel so far,’ said a doctor at the hospital. ‘There is barely any oxygen reaching the organs. We have patients coming in with hemoglobin count of one as well.’

We can't direct such patients to other hospitals as their condition is already critical.'

The names of the hospitals and the doctors have been withheld because it is illegal to get blood from any other establishment other than a blood bank.

In this case, her son gave one unit of blood through unbanked direct blood transfusion, while two other units were arranged legally.”

A true typed copy of Article published in Scroll entitled “Should hospitals give patients unbanked blood to save their lives” dated 06 August 2016 marked and annexed hereto as **Annexure P- 23 (Pages ____ to ____)**.

107. According to National Family Health survey, the rate of blood transfusion in women who had a caesarean section during labour was 0.49%, whereas in women who had a vaginal delivery or elective caesarean section it was 0.28% and 0.23%, respectively. The most common direct medical causes of maternal death around the world are hemorrhaging, obstructed labor, infection (sepsis) and hypertensive disorders related to pregnancy, such as eclampsia. These conditions are largely preventable and once detected, they are treatable. Complications from unsafe abortion are another common and preventable direct cause of maternal death. Statistics from the Registrar General of India show that 19% of maternal deaths in 1998 were caused by anemia.

108. The comparative data on maternal mortality in all the States as recorded under NFHS-3 and NFHS-4 is illustrated as below:

Comparison of NFHS-4 and NFHS-3 data for IMR and U5MR

	Infant mortality rate (IMR)			Under-five mortality rate (U5MR)		
	NFHS-4	NFHS-3	Points Decline (NFHS-3 and 4)	NFHS-4	NFHS-3	Points Decline (NFHS-3 and 4)
Bihar	48	61	13	58	84	26
Goa	13	15	2	13	20	7
Haryana	33	41	8	41	52	11
Karnataka	28	43	15	32	54	22
Meghalaya	30	44	14	40	70	30
Madhya Pradesh	51	69	18	65	93	28
Sikkim	29	34	5	32	40	8
Tamil Nadu	21	30	9	27	35	8
Tripura	31	27	-4	36	33	-3

Uttarakhand	40	42	2	47	56	9
West Bengal	27	48	21	32	59	27
Andhra Pradesh*	35	54	19	41	63	22
Telangana*	28	54	26	32	63	31
Puducherry	16	NA	-	16	NA	-
Andaman & Nicobar Islands	16	NA	-	22	NA	-

Chart 35.1: Comparison of NFHS-4 and NFHS-3 data for IMR and U5MR

A true typed copy of the Press Release of Government of India on Maternal and Child Mortality Rate, dated -06.05.2016 is marked and annexed herewith as **Annexure P- 23 (Page ___ to ___)**.

The need for Unbanked Directed Blood Transfusions to Save Lives in Emergencies in Rural Areas

109. Reports show that a considerable part of rural blood transfusion requirements are met through unbanked blood transfusions. In some contexts this is the only feasible and safe option. The recent Clinical Establishment Act requires the attending physician to give first-aid treatment to the emergency patient. Even if the physician wants to refer

the patient to a higher centre the patient has to be stabilized first, then only may the patient be transferred. In case of bleeding patients this “stabilization” can only be done by Blood Transfusions.

110. In rural areas with severe unavailability of blood and licensed blood banks, the only way local doctors can stabilize and save lives of patients in cases of emergency is by UDBT. This lifesaving procedure is prohibited however under the Drugs and Cosmetics Act and many clinicians and surgeons in rural areas have stopped transfusing blood in emergencies to avoid criminal liability, leading to the deaths of many patients.

111. Accordingly, a conflict exists in the laws which put physicians in an impossible position. If the treating doctor does not stabilize the patient, this will be treated as Medical Negligence and is punishable under the Clinical Establishment Act. If he stabilizes or saves the patient by giving Blood (by doing UDBT) he will be punished under the Drug and Cosmetics Act.

112. There are doctors who still practice UDBT, illegally, but on humanitarian grounds, risking their lives only because they do not know of a better alternative to save the lives of their patients, and their conscience does not permit them to allow their patients to die for want of blood, even at the risk of punishment.

113. On 04 January 2001, the government amended the rule in the Drugs and Cosmetics Act to allow Armed Forces Medical Services in Border Areas to conduct UDBT in cases of emergencies. Alternatively, for people in rural areas, the government has committed to making CHCs fully functional First referral Units with blood storage units. But as laid out in previous sections, most of these units are still to be fully functional. Thousands of

women in rural areas are dying due to lack of blood during post-partum hemorrhaging and other obstetric emergencies because physicians are not allowed to save them using UDBT.

Benefits of using UDBT

114. On 21 July 2018, former president of the Association of Rural Surgeons of India and current president of the International Federation of Rural Surgery, Dr. R. R. Tongaonkar published a document entitled “Unbanked Directed Blood Transfusion: Some Facts and Figures.” The documents set out several key facts on the benefits of UDBT and how it is viewed in countries around the world. Regarding facts concerning the benefits and importance of UDBT to save lives, Dr. Tongaonkar provides the following:

<p>IN INDIA IS THERE ANY NEED OF BLOOD IN RURAL AREAS?</p> <p>Some of the facts: -</p>
<ul style="list-style-type: none">• 69% of Indian population is living in Rural Areas
<ul style="list-style-type: none">• 30% deaths related to childbirth & pregnancy are due to bleeding (Hemorrhages). 19% deaths are due to anemia. Both these patients need immediate blood transfusions to prevent death.
<ul style="list-style-type: none">• India has highest number of road traffic accidents in the world. The road traffic accidents mainly occurring away from bigger towns & in rural areas where there are no blood banks. They need urgent blood transfusions on the spot or nearby areas to save their lives.

- As it stands today there are only 2,760 blood banks in India, most of them placed in cities and hardly any blood banks in rural areas. As per the recent statement in the parliament by the minister, there is not a single blood bank in 80 districts in India. THUS there is unavailability of safe blood in reasonable time at affordable cost in villages, sometimes taking 4 to 6 hours (& much more at night) to get blood from the Blood bank located in cities. Precious lives are lost due to delay unless they are saved by UDBT.

- There are problems associated with transportation of Blood to a distant place maintaining cold chain, Contamination etc.

- Presently in some of the states there is Govt. facility t dial phone number 104 and blood is made available in about ½ hour time. But this facility is available only up to 40KNs distance. **(We were denied blood for our patient because our hospital is 55KMs from the Govt. blood bank!)**

- Surgeons, obstetricians & other qualified Clinicians now available in nodal villages are greatly handicapped due to unavailability of blood.

- Surgeries and treatment of critically ill patients are delayed and patients incur more than double expenses if referred to near by bigger towns or cities and not treated at their doorsteps in villages.

<ul style="list-style-type: none"> • <u>All these problems can be solved by UDBT</u>
<p>WHAT ARE THE ADVANTEGES OF UDBT?</p>
<ul style="list-style-type: none"> • Blood is available immediately in life saving situations, anywhere, anytime, even in remote places. Because <u>any healthy human being is a walking blood bank!</u>
<ul style="list-style-type: none"> • No risk of spoiling of blood during transportation, storage or due to expiry
<ul style="list-style-type: none"> • Relatives were saved the trouble of traveling, the travelling expenses, loss of a day's wages for fetching blood from the nearby city
<ul style="list-style-type: none"> • The pool of voluntary donors in the villages is utilized

Safety of UDBT

115. Unbanked blood is not stored at 4°C (for the minimum 48 hours) unlike banked blood and hence Treponemes especially syphilis and Leptospira can be transmitted, when such blood is used. While syphilis can easily be tested before transfusion Leptospira is very uncommon and is likely to be excluded if donor selection is proper. There is no risk of spoiling of blood during transportation, storage or due to expiry.

116. That Gram-negative infection is also not tested for in the current regime (of licensed Blood Banks) as well, and the risk is miniscule if donor

selection is proper and collection is correctly done. Risk of graft versus host disease (GVHD) is present -if there is sharing of a partial haplotype between the recipient and the donor as may happen between first degree blood relatives or if the recipient is immune-compromised. This is a rare occurrence and can be looked after by having a non-blood related voluntary donor. The best treatment however is prevention by irradiation of blood, a facility that is not available even in majority of blood banks.

117. That the facility of UDBT reduces the need for unnecessary Blood Transfusions: In a study in a peripheral hospital where UDBT was carried out over period of 5 years total 4715 Surgical operations were done, In 942 major operations where blood must be kept ready before surgery, only blood Donor was kept ready but only 309 transfusions were required thus avoiding, almost 633 unnecessary transfusions. If UDBT facilities were not available in all these 942 operations blood would have been brought from a distant blood bank and then would have to be transfused to the patient even though not needed, or the blood would have been wasted.

118. In emergency cases UDBT was declared the only feasible and safe option in India's National Health Policy 2015 draft and should be legally supported in that context. Notably the Ministry of Health Made the following statement on UDBT:

“One major area of concern in district health care services is access to blood and blood safety. Currently the network of approved blood banks is not large enough or dispersed enough to ensure safe blood supply across all districts and sub-district hospitals. There are reports that a considerable part of rural blood transfusion requirements are met through unbanked blood

transfusions and in some contexts this is the only feasible and safe option. Though blood supply was to be free, in some States commercial transactions around blood have developed. Expanding the network of blood banks and ensuring that there is improved access to safe blood shall be one of the important components of improving service delivery.”

119. By this statement the government acknowledges the vital need for UDBT in emergency contexts in rural areas and further recognizes that this is the most safe and feasible option in those circumstances. The time has come for respondents to act on this open acknowledgement and legalize this critical lifesaving process which should never have been made unlawful.

How UDBT should be Regulated in India

120. It is the humble submission of petitioners that UDBT should be legalized and strictly regulated to cater to emergency situations after proper testing by licensed Healthcare facilities whose physician and Lab Technician have undergone appropriate short training. To prevent misuse, it should be mandatory to send blood samples of the patient and donor to the mother blood bank within 24 hours and information online. Each blood bag should be accounted for and could be pre-packed with testing kits/cards.

121. The exemption given to the armed forces personnel under schedule K contains certain conditions. This is exactly how Unbanked Directed Blood Transfusion is done, and even Civilian Peripheral Hospitals should be allowed to do it. Before taking the Blood from the donors all the mandatory

tests required by the Law like grouping, Cross matching, Tests for HIV, Hepatitis B, HCV, VDRL & Malaria – are done, by using rapid Test kits which are as reliable as any tests available. Moreover, as directed by Supreme Court all donors are voluntary donors. So, the blood is as safe as any bank blood. There are no complications caused due to improper storage or transportation or expiry of blood as the blood is given immediately without storing or transporting.

122. The petitioners have not filed any similar petition seeking similar reliefs before any other authority.

GROUND

123. In view of the facts and circumstances stated above, the present petition is being filed on the following grounds:

- a. That the fundamental right to life enshrined in Article 21 of the Constitution of India includes the right to health and, consequently, the right to blood in times of need or emergency situations. That the Respondents have violated citizen's right to life enshrined in article 21 of the Constitution of India, by not providing blood in emergency situations, leading to early avoidable deaths.
- b. That the right to equal protection before the law enshrined in Article 14 requires includes the right to equality without discrimination on any grounds and that physicians serving rural populations should be protected in the same manner as physicians

serving in armed forces. That Article 14 has been violated by respondents given the Drugs and Cosmetics Act, 1940 refuses doctors in any circumstance to perform UDBT but those working in armed services. Furthermore, that this violation extends to rural people given the armed forces exemption places a higher value on the lives of military persons than it does the men, women and children dying from lack of blood in rural areas.

- c. That the Respondents have an obligation to effectively implement and provide health care facilities under the NHM, which seeks, *inter alia*, to improve marginalized women's access to effective, affordable, and accessible primary healthcare including contraceptive information and services.
- d. That the Number of registered and licensed blood banks in India is extremely low with only 2760 licensed blood banks across the country according to recent data from 2015.
- e. That the 1985 judgment of the Hon'ble Supreme Court of India in *Common Cause v. Union of India* regulated the means of Blood transfusion. Blood could only be collected, stored, tested, Components made, and issued for transfusion, after Cross match from a Licensed Blood Bank. This brought unregulated business of blood, rampant profiteering, poor or no testing and encouraging professional donors to a halt. However, 'Access' was never an issue that was considered or mentioned then, because the voluntary sector continued to use blood bags available in the market, (in the absence of any Blood Banks in

small towns and rural areas). Donors (voluntary or family) were bled when the need arose for transfusion.

- f. That poor access/ unavailability of blood in rural areas was raised later and the government in response to this announced an amendment to the rules, whereby blood storage units were to be established in areas where Blood Banks were not present and requirement for blood was likely to be less than 2000 units per year. All First Referral Units were mandated to have Blood Storage Centers and all District Hospitals as per IPHS norms were to have Blood Banks. Guidelines for BSCs were published in 2007, yet to date only a fraction of CHCs have the infrastructure for BSCs and a miniscule percentage actually function to any significant extent, approximately transacting and using >100 units blood / yr).Also many district hospitals do not have functional Blood Banks.
- g. That over 5 lakh women die annually globally, during childbirth and one third of these deaths happen in India. Obstetric Hemorrhage (PPH and APH) is by far, the largest cause of these maternal deaths, the situation being compounded by rampant anemia, especially among the rural poor.
- h. That nearly 50,000 Deaths could have been averted, if there was a well-resourced (read with functional blood bank or BSC) functioning facility within 50 km
- i. That most Blood Banks, especially those in the public sector (government) rely heavily on 'replacement' donations and often

refuse issuing blood even in emergency situations where no replacement donor is available.

- j. That the focus on replacement donation and not on VNRD (voluntary, non-remunerated donation) also means that the ‘mother’ Blood Banks, that are supposed to ‘feed’ the BSCs under them (usually 4-5) will never be able to ‘Spare’ blood for the BSUs, as they themselves have a ‘hand to mouth’ existence. Thus most BSCs are starved and have hardly transacted any blood units. NBTC has called for completely phasing out replacement donation by 2020. Even though this is still a pipe dream as evidenced by NACO’s own data.
- k. That at least 81 districts across India do not have a single functioning Blood Bank or Blood Storage Unit. District Hospital is suggested to cater to a population, often as large as 25 lakh, spread over hundreds of kilometers and is often the only hope for this population. Such District Hospitals, even when they have a full quorum of Human Resources (Anesthetist, Gynecologist, and Surgeon) will rightfully refuse to perform Cesarean Sections or deal with other obstetric or surgical emergencies in the absence of blood. Many patients in urgent need would die in the process of referral.
- l. That the price of Blood and blood products being part of Essential Drugs List must be regulated through the Drug price control order.

- m. That UDBT has been used by doctors to save lives for decades and is still used to save lives across the globe and in the United States.
- n. That UDBT offers significant benefits including blood that is available immediately in life saving situations, anywhere, anytime, even in remote places which is particularly important in rural areas during the golden hour; there is no risk of spoiling of blood during transportation, storage or due to expiry; Relatives are saved the trouble of traveling, the travelling expenses, loss of a day's wages for fetching blood from the nearby city; and the pool of voluntary donors in the villages is utilized

PRAYERS

That by this writ petition the petitioner prays for issuance of an appropriate writ(s)/ order(s)/ direction(s) particularly:

1. To issue orders and directions for setting up of Blood banks in all District Hospitals in compliance with National Blood Policy and the NBTC Guidelines.
2. To issue orders and directions to Union of India and all State Governments to make Blood Banks fully fed through non- remunerative blood donation with monthly calendar with effective propagation of Blood Donation Camps in compliance with NBTC Guidelines, 2007.
3. To issue orders and directions for setting up of Regional Blood Banks in all Divisional Headquarters of the State, mostly Government Medical

Colleges, to act as a hub to direct and regular supply of blood to district hospital blood banks and Blood Storage Units.

4. To issue orders, directing rapid upscale of the BSUs in FRUs and even in other CHCs with BSUs being fed from their 'mother' Blood Banks- without need for replacement.
5. To issue orders and directions legalizing Unbanked Directed Blood Transfusion that is well regulated which at present is the only feasible and safe option to meet blood demands in rural areas in our country, because to achieve the target to expand the network of blood banks to improve access to safe blood across the country may take many years.
6. To issue orders and directions to Union of India and all State Governments to make Blood Banks fully fed through non- remunerative blood donation with effective propagation of Blood Donation Camps in compliance with NBTC Guidelines, 2007.
7. To issue orders and directions to Union of India for establishing a separate monitoring body for all purposes relating to blood and blood transfusion services under the Ministry of Health and Family Welfare, Government of India.

8. To issue orders and directions to Union of India for revising and rationalizing the NBTC Guidelines in consultation with the Petitioners.
9. To issue orders and Directions to Union of India for strict enforcement of Notification No. S/12016/01/2012-NACO(NBTC) issued on 12.02.2014 by Ministry of Health and Family Welfare, Government of India by making necessary amendments in the Drugs and Cosmetic Rules, 1945, regulating the price of blood and blood components.
10. To issue orders and directions to Union of India and State Governments to provide free and non- replacement blood in all Government health facilities including district hospitals, CHCs and PHCs.
11. Any other orders that this Hon'ble Court may deem fit in the interest of Justice.
12. AND FOR THIS ACT OF KINDNESS THE PETITIONERS AS IN DUTY BOUND SHALL EVER PRAY.

FILED BY:

Place:

Date:

SATYA MITRA
ADVOCATE FOR PETITIONERS

INDEX

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10.	Appendix: Relevant Portions of Drugs and Cosmetics Act, 1940.			
11.	Annexure P-1 A true typed copy of Letter to the editor of the Times of India by the former president of the ARSI, Dr. R. R. Tongaonkar, dated 8th February, 2015.			
12.	Annexure P-2 A true typed copy of Article published by LiveMint entitled “Direct Donor-Patient Blood Transfusion to Be Legalized” dated 16 January 2014.			
13.	Annexure P-3 A true typed copy of article published in Indian Journal of Medical Ethics entitled “Walking blood banks: an immediate solution to rural India’s blood drought”, dated – 2 nd April- June, 2018.			
14.	Annexure P-4 As a result, the deficit in the			

	<p>number of blood bags is always high. A true typed copy of the relevant portion of “Towards 100% Voluntary Blood Donation: A global Framework for Action” published by WHO, 2010 dated- nil.</p>			
15.	<p>Annexure P-5</p> <p>A typed copy of the Objections and Suggestions to Proposed Rules prepared by the Association of Rural Surgeons of India dated 26 May 1998.</p>			
16.	<p>Annexure P-6</p> <p>A true typed copy of letter rejecting objections and suggestions to proposed rules dated 11.12.1998.</p>			
17.	<p>Annexure P-7</p> <p>A true copy of the Letter of Dr. R. R. Tongaonkar entitled, “<u>Denying Right to Life: Can a Rural Surgeons or Gyneocologists deny ‘Right to Life’ to the Rural Civilian</u></p>			

	<p>population by with-holding lifesaving ‘Blood Transfusions’ because of Recent Amendment of Drugs & Cosmetics Act?” dated 12 February 2004.</p>			
18.	<p>Annexure P- 8</p> <p>A true copy of report entitled “Functioning of Community Health Centres (CHCs),” issued by the Programme Evaluation Organization for the Government of India, dated September 1999.</p>			
19.	<p>Annexure P-9</p> <p>A true typed copy of article published in Journal of Perinatology entitled “Indian Health Systems” dated 7th December 2016.</p>			
20.	<p>Annexure P-10</p> <p>A true typed copy of “No Staff to run Blood Storage centres” published by The Hindu, dated- 23.06.2013.</p>			
21.	<p>Annexure P-11</p>			

	<p>A true typed copy of statement entitled Present Position of Blood Storage Centers in State of Maharashtra prepared and submitted by Dr. R. R. Tongaonkar dated nil.</p>			
22.	<p>Annexure P-12</p> <p>A true typed copy of article published in Scroll entitled “Should hospitals give patients unbanked blood to save their lives” dated 06 August 2016.</p>			
23.	<p>Annexure P-13</p> <p>A true typed copy of article published in BJM Global Health titled “Access to safe blood in low-income and middle-income countries: lessons from India” dated 16 February 2017.</p>			
24.	<p>Annexure P-14</p> <p>A true copy of the Correspondence between Dr. R. R. Tongaonkar and the M.O. Sub-district Hospital, dated 8th</p>			

	January 2019.			
25.	<p>Annexure P-15</p> <p>A true typed copy of ‘No blood bank or blood storage centre can save these patients’! Statistics of a rural hospital – One year study” dated nil.</p>			
26.	<p>Annexure P-16</p> <p>A true typed copy of “Blood banks running without licenses, facing staff shortage” published by The Hindu, dated-04.04.2018.</p>			
27.	<p>Annexure P-17</p> <p>A true typed copy of the press release from the Ministry of Health and Family Welfare dated 26 February, 2016.</p>			
28.	<p>Annexure P-18</p> <p>A true copy of article published in the International Journal of Research in Medical Sciences titled “Patterns of voluntary and replacement blood donors in a tertiary care center: a</p>			

	retrospective study” dated 14 July 2017.			
29.	Annexure P-19 A true copy of the “Bloodless Ban” published with the Down To Earth, dated- 17 August 2015.			
30.	Annexure P-20 A true copy of article published in the Indian Express entitled “Blood banks sell plasma, make a killing” dated 2 April 2013.			
31.	Annexure P-21 A true typed copy of the article “Dead Women Talking: A civil society report on maternal deaths in India” published by Common health and Jan Swasthya Abhiyaan, dated- July, 2014.			
32.	Annexure P-22 A true typed copy of “A lifeline that Rural India cannot do without” published by The Hindu, dated- 02.06.2016.			

33.	<p>Annexure P-23</p> <p>A true typed copy of Article published in Scroll entitled “Should hospitals give patients unbanked blood to save their lives” dated 06 August 2016.</p>			
34.	<p>Annexure P-1</p> <p>A true typed copy of Letter to the editor of the Times of India by the former president of the ARSI, Dr. R. R. Tongaonkar, dated 8th February, 2015.</p>			
35.	<p>I.A. No. _____ of 2019- Application seeking permission to file lengthy synopsis and list of dates.</p>			
36.	F/M			
37.	Vakalatnama			