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* **IN THE HIGH COURT OF DELHI AT NEW DELHI**

\+ W.P.(C) 7279/2013

MOHD. AHMED (MINOR) ..... Petitioner
Through Mr. Ashok Aggarwal, Advocate with Ms. Kusum Sharma, Advocate.

versus

UNION OF INDIA & ORS. ..... Respondents
Through Ms.Shyel Trehan, Amicus Curiae with Ms. Tejaswi Shetty, Mr. Nishant Gokhale and Ms. Himanie Katoch, Advocates.

Ms. H.Hnunpuii, Advocate for UOI.
Ms. Zubeda Begum, Standing Counsel with Ms. Sana Ansari, Advocate for GNCT of Delhi.

Mr. Mehmood Pracha, Advocate with Sumit Babbar, Advocate for AIIMS.

Ms. Maneesha Dhir, Advocate for Ministry of Corporate Affairs.

Reserved on : 3rd April, 2014
% Date of Decision : 17th April, 2014

CORAM:
HON'BLE MR. JUSTICE MANMOHAN

J U D G M E N T

MANMOHAN, J:

Martin Luther King Junior said, *"of all forms of inequality, injustice in health care is the most shocking and inhumane"*. The present case many years later illustrates what he had said.

ISSUE

1. The issue that arises for consideration in the present petition is whether a minor child born to parents belonging to economically weaker section of the society suffering from a chronic and rare disease, gaucher, is entitled to free medical treatment costing about rupees six lakhs per month especially when the treatment is known, prognosis is good and there is every likelihood of petitioner leading a normal life.

FACTS

2. The facts of the present case are that the petitioner is a young boy aged about seven years and is represented through his next friend, his father, Mr.Mohd. Sirajuddin. The petitioner suffers from a rare genetic disease called Gaucher Disease, which is Lysosomal Storage Disorder, wherein the body cannot process fat resulting in accumulation of fat around vital organs of the body. If this disease is left untreated, the petitioner is unlikely to survive. Petitioner is the fourth and only surviving child of his parents; his other three siblings have already succumbed to the same disease.

3. A treatment by the name of Enzyme Replacement Therapy is available for this disease. It is expected that patients receiving this treatment have a high degree of normalcy. The treatment, however, is monthly, lifelong and exorbitant. Petitioner's father, who is a rickshaw puller by profession cannot afford the same.

4. Currently the drugs required to treat this condition are manufactured by three pharmaceutical companies globally, Sanofi, Shire and Pfizer. Of these, only one company, Sanofi sells its gaucher's drugs in India. The cost of the treatment is estimated at approximately rupees six-seven lakhs every

month. The reason for the exorbitant cost of the treatment is that gaucher falls in the category of rare diseases. As small number of people suffer from rare diseases, pharmaceutical companies are unable to recover their research and development costs over a large base of patients. It is for this reason that these drugs are exorbitantly priced at a global level. No Indian drug company has developed a competing drug for this disease till date.

WITH DELHI GOVERNMENT'S FINANCIAL ASSISTANCE, ONE MONTH'S TREATMENT GIVEN

5. The petitioner underwent his first treatment in August 2013 availing of financial assistance from the Delhi Arogya Kosh, which provides financial assistance to the extent of rupees five lakhs to needy eligible patients. Under the Scheme, the petitioner received a cheque of Rs.4,80,000/- in favour of the Director, All India Institute of Medical Sciences (AIIMS) and was able to receive the first treatment. However, respondent No.2 has stated in its counter affidavit that the petitioner having exhausted Rs.4,80,000/- can now be extended further financial assistance for medical treatment only to the extent of Rs.20,000/-.

DURING THE PENDENCY OF PETITION, A HOSPITAL, A DRUG COMPANY AND LAWYERS OF DELHI HIGH COURT VOLUNTARILY CAME FORWARD TO ORGANISE SIX MONTH'S TREATMENT

6. Since during the pendency of the present petition, petitioner required urgent medical treatment, on 29th January, 2014 Medanta - The Medicity Hospital, Gurgaon, Haryana offered one month's free treatment of enzyme replacement to the petitioner. Subsequently, on the oral request of this

Court, lawyers of Delhi High Court voluntarily contributed Rupees Seven Lakhs Seventy Five Thousand for petitioner's treatment. The aforesaid amount was electronically transferred to the account of Director, AIIMS wherein the petitioner is now undergoing another month's treatment of enzyme replacement.

7. Just when the judgment was about to be reserved, the Amicus Curiae, Ms. Shyel Trehan handed over an E-mail dated 1st April, 2014 written to Medanta - The Medicity Hospital, Gurgaon, Haryana by Mr. Anil Raina, Director - Commercial (India & South Asia), Genzyme - A Sanofi Company offering to provide therapy free of cost limited to a period of three months. The said mail is taken on record and the petitioner is permitted to undergo enzyme replacement at Medanta - The Medicity Hospital with the therapy provided by Sanofi Company for the next three months.

8. On 3rd April, 2014, Mr. A.S. Chandiok, Senior Advocate mentioned that Delhi High Court lawyers have raised a further amount of rupees four lakhs approx. Whatever further amount is raised by the Delhi High Court lawyers shall be electronically transferred by the Manager UCO Bank, Delhi High Court, New Delhi to the account of Director, AIIMS [Current Bank Account No. 10874584010, State Bank of India]. The aforesaid amount shall be used by AIIMS only for treatment of enzyme replacement therapy of the petitioner, Mohd. Ahmed as and when he requires it after receipt of the aforesaid three month's therapy. This Court places on record its appreciation for the contribution raised by the members of the Delhi High Court Bar Association.

DESPITE MEETING OF HEALTH SECRETARIES OF CENTRAL AND STATE GOVERNMENTS, NO SOLUTION COULD BE FOUND

9. Prior to commencement of arguments, this Court gave an opportunity to the Central and State Governments to see if the matter could be amicably resolved. Consequently, vide order dated 12th February, 2014, the Secretary (Health), Ministry of Health & Family Welfare and Secretary (Health), Government of NCT of Delhi along with other Government officials were directed to hold a meeting on 25th February, 2014. However, the meeting was not very successful. In the meeting, it was decided that:

> *"(i) Following the directions of the Hon'ble Court and while understanding the plights of the patients suffering from the Lysosomal Storage Disorders [LSDs] and also examining the matter from public health point of view, existing guidelines of the available Schemes and the possibly of other further repercussions, it has not been found possible to devise a viable policy for financial assistance on recurring mode on a long term basis for the entire life-time for the patients suffering from LSDs.*
>
> *(ii) It was further decided in this meeting that "The cases may be examined by the States on Case to Case basis.*
>
> *(iii) States would also be advised to examine viable means of supporting these patients through funds being pooled for available sources in the society*
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> *(iv) The serious reasoning arising out of the discussions may thus be submitted to the Hon'ble Court."*
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> (emphasis supplied)

10. Accordingly, on 25th March, 2014, this Court commenced hearing final arguments.

PETITIONER'S ARGUMENTS

11. Mr. Ashok Aggarwal, learned counsel for petitioner stated that since treatment of petitioner's ailment was available in India, the AIIMS, Central Government and Government of NCT of Delhi, were obligated under Article 21 of the Constitution of India to provide totally free treatment to the petitioner and like patients. He submitted that right to health was implicit in Article 21 of the Constitution. In support of his submissions, he relied upon a Division Bench's judgment of this Court in the case of ***All India Lawyers Union (Delhi Unit) vs. Govt. of NCT of Delhi & Ors., 163 (2009) DLT 319 (DB)***.

12. According to Mr. Aggarwal, rules had been bent or revised whenever influential or powerful people had to be accommodated in the matter of providing medical treatment at State expense.

13. Mr. Aggarwal stated that Government of NCT of Delhi which was taking the stand of financial constraint in providing treatment to the petitioner, had reimbursed Rs.1.32 crore as medical expense to a MLA from Rohtas Nagar.

14. Mr. Aggarwal submitted that while providing free treatment to Government employees at State expense and at the same time denying free treatment to the non-Government employees (common man) on the alleged ground of financial constraints was arbitrary, discriminatory and hit by Articles 14 and 21 of the Constitution of India. According to him, ordinary people who are not Government servants also need to be treated equally in the matter of medical treatment at Government expense. He stated that the plea of financial constraint was not available to the Government after sixty-five years of the Independence.

15. Mr. Aggarwal contended that the Central Government needed to bring "Public Health" in Concurrent list of Constitution and make "Right to Public Health" a Fundamental Right as well as enact a Central Legislation on Right to Public Health.

16. Mr. Aggarwal pointed out that the Cuban Constitution adopted in 1976, obligated the State to assure that there shall be "no sick person who does not receive medical attention." The Cuban Constitution also articulated specific obligation of the State to provide a full range of universally accessible health services free of charge, as well as to guarantee the promotion and protection of health of individuals.

17. Mr. Aggarwal stated that the Central Government should forthwith frame a National Policy on Right to Public Health and till such Policy was framed, the petitioner and the like patients should be provided free treatment at State expense.

ARGUMENTS ON BEHALF OF DELHI GOVERNMENT

18. Ms. Zubeda Begum, learned counsel for Govt. of NCT of Delhi stated that in comparison to other States of the country, the Govt. of NCT of Delhi had allocated ten per cent of its budget towards health which was highest in the country. She further stated that despite Delhi having only one per cent of the population of the country, it was spending four times on health, calculated on a pro rata basis, compared to other states.

19. Ms. Zubeda Begum pointed out that Delhi had a comprehensive drug policy. She stated that in 2013 Essential Medicine List had been revised for the eighth time by an expert Committee comprising eminent Doctors.

20. Ms. Zubeda Begum further pointed out that the following four Schemes were being funded by the Government of NCT of Delhi:-

(i) Delhi Arogya Kosh: Under this Scheme, the Govt. of NCT of Delhi, w.e.f FY 2011-12, provided financial assistance upto Rs.5 lakh to eligible patients, who were bonafide residents of Delhi for more than three years and their family income was less than Rs.3 lakh per annum. This Scheme postulated a maximum payment of Rs. 5 lakh. During the current FY 2013-2014, an amount of approximately Rs.4.9 crores had been disbursed.

(ii) Delhi Arogya Nidhi: This Scheme provided financial assistance upto Rs.1.5 lakh to eligible patients, who were bonafide residents of Delhi for more than three years and were living below poverty line. During the current Financial Year 2013-2014, approximately Rs.10.5 lakh had been disbursed as financial assistance.

(iii) Delhi Kalyan Samiti: This Scheme started in 1995 provided non-recurring Grant-in-Aid to NGOs working for the welfare of social/medical, society for upliftment of education, sports and cultural needs and for financial assistance to individuals in case of hardship after objective assessment.

(iv) L.G./Chief Minister's Relief Fund: This fund was utilized for providing relief to people affected by natural calamities or to indigent persons or deserving artists/writers in need of such assistance.

21. Ms. Zubeda Begum stated that for patient suffering from genetic disorders like Lysosomal Storage Disorders (Gaucher's disease etc.) the drugs for bypass Enzyme Replacement Therapy (ERT) was not covered even under the public health care system in the USA. She stated that similar patients in the United States were supported by health insurance and other philanthropic organization like donations from Corporates, Institutions, Charities, etc.

22. Ms. Zubeda Begum submitted that the right to health in a developing country like India could not be so stretched so as to mean to provide free health facilities to a terminally ill patient while other citizens were not even provided basic health care. She stated that the State had an equal obligation towards all citizens and it had to use its limited resources so as to provide the maximum benefit to the maximum number of people. She further submitted that the obligation of the State to provide health care to all people was not an absolute Fundamental Right and was subject to just exceptions. She submitted that the Supreme Court in subsequent judgments in ***State of Punjab & Ors. vs. Ram Lubhaya Bagga, (1998) 4 SCC 117*** and ***Confederation of Ex servicemen Associations and Ors. vs. Union of India & Ors., AIR 2006 SC 2945***, had diluted the right to health. The relevant portions of the aforesaid judgments relied upon by her are reproduced hereinbelow:-

(a) ***State of Punjab & Ors. vs. Ram Lubhaya Bagga*** (supra)

> *"25. .....Question is whether the new policy which is restricted by the financial constraints of the State to the rates in AIIMS would be in violation of Article 21 of the Constitution of India. So far as questioning the validity of governmental*

policy is concerned in our view it is not normally within the domain of any court, to weigh the pros and cons of the policy or to scrutinize it and test the degree of its beneficial or equitable disposition for the purpose of varying, modifying or annulling it, based on howsoever sound and good reasoning, except where it is arbitrary or violative of any constitutional, statutory or any other provision of law. When Government forms its policy, it is based on a number of circumstances on facts, law including constraints based on its resources. It is also based on expert opinion. It would be dangerous if court is asked to test the utility, beneficial effect of the policy or its appraisal based on facts set out on affidavits. The court would dissuade itself from entering into this realm which belongs to the executive. It is within this matrix that it is to be seen whether the new policy violates Article 21 when it restricts reimbursement on account of its financial constraints.

26. When we speak about a right, it correlates to a duty upon another, individual, employer, government or authority. In other words, the right of one is an obligation of another. Hence the right of a citizen to live under Article 21 casts obligation on the State. This obligation is further reinforced under Article 47, it is for the State to secure health to its citizen as its primary duty. No doubt the Government is rendering this obligation by opening government hospitals and health centres, but in order to make it meaningful, it has to be within the reach of its people, as far as possible, to reduce the queue of waiting lists, and it has to provide all facilities for which an employee looks for at another hospital. Its upkeep, maintenance and cleanliness has to be beyond aspersion. To employ the best of talents and tone up its administration to give effective contribution. Also bring in awareness in welfare of hospital staff for their dedicated service, give them periodical, medico-ethical and service-oriented training, not only at the entry point but also during the whole tenure of their service. Since it is one of the most sacrosanct and valuable rights of a citizen and equally sacrosanct sacred obligation of the State, every citizen of this welfare State looks towards the

State for it to perform its this obligation with top priority including by way of allocation of sufficient funds. This in turn will not only secure the right of its citizen to the best of their satisfaction but in turn will benefit the State in achieving its social, political and economical goal. For every return there has to be investment. Investment needs resources and finances. So even to protect this sacrosanct right finances are an inherent requirement. Harnessing such resources needs top priority.

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29. No State of any country can have unlimited resources to spend on any of its projects. That is why it only approves its projects to the extent it is feasible. The same holds good for providing medical facilities to its citizens including its employees. Provision of facilities cannot be unlimited. It has to be to the extent finances permit. If no scale or rate is fixed then in case private clinics or hospitals increase their rate to exorbitant scales, the State would be bound to reimburse the same. Hence we come to the conclusion that principle of fixation of rate and scale under this new policy is justified and cannot be held to be violative of Article 21 or Article 47 of the Constitution of India.

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32. Any State endeavour for giving best possible health facility has direct co-relation with finances. Every State for discharging its obligation to provide some projects to its subject requires finances. Article 41 of the Constitution gives recognition to this aspect.

> *"41. Right to work, to education and to public assistance in certain cases.—The State shall, within the limits of its economic capacity and development, make effective provision for securing the right to work, to education and to public assistance in cases of unemployment, old age, sickness and disablement, and in other cases of undeserved want."*

(b) ***Confederation of Ex servicemen Associations and Ors. vs. Union of India & Ors.*** (supra)

"63. ..... The question, therefore, is whether the State can ask the retired defence personnel to pay an amount of contribution for getting medical facilities by becoming a member of such Scheme.

64. In our opinion, such a contributory scheme cannot be held illegal, unlawful or unconstitutional. Ultimately, the State has to cater to the needs of its employees—past and present. It has also to undertake several other activities as a "welfare" State. In the light of financial constraints and limited means available, if a policy decision is taken to extend medical facilities to ex-defence personnel by allowing them to become members of contributory scheme and by requiring them to make "one-time payment" which is a "reasonable amount", it cannot be said that such action would violate the fundamental rights guaranteed by Part III of the Constitution.

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66. We are in agreement with the above view. In our considered opinion, though the right to medical aid is a fundamental right of all citizens including ex-servicemen guaranteed by Article 21 of the Constitution, framing of scheme for ex-servicemen and asking them to pay "one-time contribution" neither violates Part III nor is it inconsistent with Part IV of the Constitution. Ex-servicemen who are getting pension have been asked to become members of ECHS by making "one-time contribution" of reasonable amount (ranging from Rs 1800 to Rs 18,000). To us, this cannot be held illegal, unlawful, arbitrary or otherwise unreasonable.

67. Observations made by this Court in the cases relied upon by the petitioner and interveners including Consumer Education & Research Centre [(1995) 3 SCC 42 : 1995 SCC (L&S) 604] referred to earlier, must be read as limited to the facts before the court and should not be understood to have laid down a proposition of law having universal or general application irrespective of the factual situation before the

court. To us, the policy decision in formulating contributory scheme for ex-servicemen is in accordance with the provisions of the Constitution and also in consonance with the law laid down by this Court. We see no infirmity therein. We, therefore, hold that getting free and full medical facilities is not a part of the fundamental right of ex-servicemen."

(emphasis supplied)

23. In this regard, she also referred to the General Comment 14 issued by the UN Committee on Economic, Social and Cultural Rights in 2000. The relevant portion of the aforesaid Comment relied upon by her reads as under:-

"The notion of the "highest attainable standard of health" in Article 12(1) of ICESCR takes into account both the individual's biological and socio-economic preconditions and a State's available resources. There is a number of aspects which cannot be addressed solely within the relationship between States and individuals; in particular, good health cannot be ensured by a State, nor can States provide protection against every possible cause of human ill health. Thus genetic factors, individual susceptibility to ill health and the adoption of unhealthy or risky lifestyles may play an important role with respect to an individual's health. Consequently, the right to health must be understood as a right to the enjoyment of a variety of facilities, goods, services and conditions necessary for the realization of the highest attainable standard of health."

Thus, it has recognized the obligation and the duty of the state in this regard but also recognized the limitations which a state might face while trying to achieve this ideal.

It also provides that all the patients have to be treated equally.

"At least six other constitutions set out duties in relation to health, such as the duty on the State to develop health services or to allocate a specific budget to them. Part IV of our Constitution deals with the Directive Principles of State Policy.

Among several provisions that touch on the subject of health, reference can be made to Articles 39(e), (f), 42 and 47 of the Constitution. These Articles read as follows:

"39(e) that the health and strength of works, men and women, and the tender age of children are not abused and that citizens are not forced by economic necessity to enter avocations unsuited to their age or strength;

(f) that children are given opportunities and facilities to develop in a healthy manner and in conditions of freedom and dignity and that childhood and youth are protected against exploitation and against moral and material abandonment.

42. Provision for just and humane conditions of work and maternity relief:- The State shall make provision for securing just and humane conditions of work and for maternity relief.

47. Duty of the State to raise the level of nutrition and the standard of living and to improve public health - The State shall regard the raising of the level of nutrition and the standard of living of its people and the improvement of public health as among its primary duties and, in particular, the State shall endeavour to bring about prohibition of the consuming, except for medicinal purposes of intoxicating drinks and of drugs which are injurious to health."

24. Thus, according to Ms. Zubeda Begum, the State cannot concentrate all its resources on one person, while denying basic facilities to others.

UNION OF INDIA'S SUBMISSIONS

25. Similarly, respondent No.1-UOI stated that it granted financial assistance to poor patients under the Rashtriya Arogya Nidhi Scheme, the Health Minister's Discretionary Grant and the Prime Minister's Relief Fund.

SUBMISSIONS ON BEHALF OF AIIMS

26. Respondent No.3-AIIMS confirmed that the petitioner is suffering from Gaucher disease and that it was conducting a humanitarian program wherein sixteen patients were under treatment for Gaucher's disease. Of these, treatment of five patients is being funded by the guardian's employers and the remaining patients are part of a Gaucher's treatment program conducted by two pharmaceutical companies Shire and Genzyme. AIIMS stated that it had no fund for treatment of any of these patients. In fact, it stated that it did not have adequate budget to manage its day-to-day functioning, leave alone fund the petitioner's treatment.

SUMMARY OF RESPONDENTS' SUBMISSIONS

27. In a nutshell the State Government, the Union of India and AIIMS stated that in view of their restricted resources they were not able to fund the treatment of the petitioner as it was lifelong and his condition was chronic.

SUBMISSIONS OF AMICUS CURIAE

28. Ms. Shyel Trehan, learned Amicus Curiae submitted that Courts have taken different views with regard to the issue of limitation of resources in providing health care at the expense of the State. She pointed out that in the case of ***Paschim Bangal Khet Mazdoor Samity and Others Vs. State of W.B. and Another, (1996) 4 SCC 37***,while addressing the argument with regard to lack of resources put forth by the State, the Supreme Court had held that it was the constitutional obligation of the State to provide adequate medical services to the people.

29. Ms. Trehan stated that thereafter, however, a Constitution Bench of the Supreme Court of India when deciding a challenge to the constitutionality of a contributory medical scheme for ex-servicemen in the case of ***Confederation of Ex-servicemen Assns.*** (supra) had held, *"....No State has unlimited resources to spend on any of its projects. Provisions relating to supply of medical facilities to its citizens is not an exception to the said rule. Therefore, such facilities must necessarily be made limited to the extent finances permit. No right can be absolute in a welfare State. An individual right has to be subservient to the right of public at large.* She pointed out that Supreme Court had concluded by observing, *"We, therefore, hold that getting free and full medical facilities is not a part of the fundamental right of ex-servicemen".*

30. Ms. Trehan further stated that the Courts in the United Kingdom had also had the opportunity to examine this issue. In the case of ***R.V. Cambridge Health Authority Ex pare B (A Minor) [1995] EWCA Civ 49***, where the treatment for a child suffering from non-Hodgkins Lymphoma had failed and treatment that was considered experimental was sought under the National Health Service of the UK, the Court refused to intervene while acknowledging the strain on resources and that the question of allocation of resources was a policy decision observed that, *"Difficult and agonising judgments have to be made as to how a limited budget is best allocated to the maximum advantage of the maximum number of patients. That is not a judgment which the Court can make".* The Court concluded that, *"I have no doubt that in a perfect world any treatment which a patient, or a patient's family, sought would be provided if Doctors were willing to give it, no matter how much it cost, particularly when a life was potentially at stake. It*

would however, in my view, be shutting one's eyes to the real world if the Court were to proceed on the basis that we do live in such a world. It is common knowledge that health authorities of all kinds are constantly pressed to make ends meet."

31. Ms. Trehan further stated that in the case of ***T. Soobramoney vs. Minister of Health (Kwazulu-Natal) (Case CCT 32/97)*** the Constitutional Court of South Africa dealt with the issue whether a person who suffered from chronic kidney disease could be provided State funds for dialysis as a matter of right. The Indian case of ***Paschim Bengal Khet Mazdoor Samity*** (supra) was cited in this case. The South African Court distinguished the South African law by stating, *"In India the Supreme Court has developed a jurisprudence around the right to life so as to impose positive obligations on the State in respect of the basic needs of its inhabitants..... Unlike the Indian Constitution ours deals specifically in the bill of rights with certain positive obligations imposed on the State and where it does so, it is our duty to apply the obligations as formulated in the Constitution and not to draw inferences that would be inconsistent therewith."* Eventually dismissing the claim of the petitioner, the Court held that the position in South Africa was that, *"The appellant's demand to receive dialysis treatment at a State hospital must be determined in accordance with the provisions of Section 27(1) and (2) and not Section 27(3). These sections entitle everyone to have access to health care services provided by the State "within its available resources".* The South African Court further observed that, *"The State has to manage its limited resources in order to address all these claims. There will be times when this requires it to adopt a holistic approach to the larger needs of society rather than to focus on the specific needs of particular*

individuals within society".

32. Ms. Trehan also stated that in the case of ***Niteki vs. Poland (Application No.65653/2001)***, The European Court of Human Rights dismissed an application filed by a man suffering from Lou Gehrig's Disease wherein the patient had challenged the requirement to pay for 30% of the treatment cost, while the State funded 70% of the treatment. The Court found that there was nothing wrong in the policy requiring a 30% co-pay and observed that often difficult choices had to be made by States when determining the allocation of scarce resources.

33. Ms. Trehan further stated that the healthcare sector was grossly under-served and the supply and accessibility of various drugs, implants and devices was well short of the desired level. It was therefore a priority to attract CSR donations to the healthcare sector, both in cash and kind.

SUGGESTIONS ON BEHALF OF MR. ANAND GROVER, SENIOR ADVOCATE

34. Mr. Anand Grover, learned senior counsel who takes active interest in pharmaceutical matters stated that as India had signed and ratified the International Covenant of Economical, Social and Cultural Rights (ICESCR), it was duty bound to fulfil its international legal obligations under the said treaty.

35. Mr. Grover submitted that States are required to adopt and implement a public health strategy and plan of action that reflects the epidemiological burden of disease that not only addresses major disease burdens but also the health concerns of the whole population. Therefore, according to him, even if a small percentage of the population had a life-threatening condition there

should be public health strategy and plan to address their treatment needs. In other words, the Government can be directed to have a plan in place to make medicines available for rare diseases, like Gaucher disease etc.

36. Mr. Grover pointed out that the courts in Argentina have ordered the State to ensure an uninterrupted supply of antiretroviral drugs to persons with HIV/AIDS [See *Supreme Court of Justice, Asociacion Benghalensis y otros vs. Ministerio de Salud y Accion Social, case 323:1339, 1 June 2000]***,** to ensure the manufacturing of a vaccine against an endemic disease [See *Federal Administrative Court, Chamber IV, Viceconte, Mariela v. Estado nacional - Ministerio de Salud y Accion Social slamparo ley 16.986, 2 June 1998]*, and to ensure the continued provision free of charge of a drug against bone disease. [See *Supreme Court of Justice, Campodonico de Beviacqua, Ana Carina v. Ministerio de Salud y Accion Social - Secretaria de Programas de Salud y Banco de Drogas Neoplasicas, 24 October 2000*].

COURT'S REASONING

ORPHAN DRUGS

37. This Court finds that the petitioner suffers from a disease/condition which affects such small numbers of individuals that drugs for these diseases/conditions are commonly referred to as *"orphan drugs"*.

APPROACH OF DIFFERENT COUNTRIES TO ORPHAN DRUGS

38. Various countries have adopted different policies to provide affordable treatment to patients suffering from rare and chronic diseases/conditions.

39. In the United States, Orphan Drug Act, 1983 defines the term 'rare disease or condition' to mean any disease or condition which occurs so infrequently that there is no reasonable expectation that the cost of developing and making available a drug for such disease or condition will be recovered from sales of such a drug. The Orphan Drug Act, 1983 not only extends tax credit as well as patent term of such drugs but the government also gives grants and enters into contracts with entities to assist in defraying the costs of expenses incurred in connection with the development of drugs.

40. The European Union Regulation 1999 provides incentive of market exclusivity to the sponsors of orphan drugs. Further, through the EUROPLAN, the European Union has mandated that each member country develop a National Strategy Plan for rare diseases comprising a seven step intervention, viz. policy making, definition and codification of rare diseases, research on rare disease, creation of centres of expertise for rare diseases, gathering expertise at EU level, empowering patient organizations and sustainability of the strategies.

41. Several other countries such as Japan, Australia and Israel have developed policies/strategies to combat the problems of rare diseases and orphan drugs.

NO POLICY/STRATEGY IN PLACE IN INDIA WITH REGARD TO ORPHAN DRUGS

42. Unfortunately, the Government of India does not have any policy measure in place to address rare diseases, particularly those of a chronic nature. All the Central and State schemes at the highest provide for a one-time grant for life-saving procedures and do not contemplate continuous

financial assistance for a chronic disease such as gaucher, which involves lifelong expenditure. There are even no incentives in place for Indian manufacturers to develop local alternatives to orphan drugs.

43. This Court is of the opinion that neither any promising orphan drug will be developed nor the prohibitive cost of 'orphan drugs' will see a reduction unless changes are made in the applicable laws to reduce the costs of developing such drugs and to provide financial incentives to develop such drugs like in the abovementioned countries.

COURT CANNOT DIRECT EITHER PARLIAMENT TO PASS A LEGISLATION OR THE EXECUTIVE TO FRAME A POLICY.

44. Keeping in view the concept of separation of powers as incorporated in the Constitution, this Court cannot direct Parliament to enact a Central legislation on Right to Public Health or with regard to rare diseases or orphan drugs, even though the same may be eminently desirable.

45. Similarly, as formulation of a policy is within the exclusive domain of the Executive, this Court refrains from issuing directions. A Division Bench of this Court in ***J.K. Sawhney Vs. Punjab National Bank, 2010 VII AD (DELHI) 756*** has held , *"Moreover, it is imperative to emphasise that the formulation of a policy is within the exclusive domain of executive and the Courts should shy away from issuing directions for formulation of a policy which has financial, economic and other implications, which at the best should be left to the wisdom of the executive."*

ISSUE HAS TO BE DECIDED IN THE CONTEXT OF INDIAN CONSTITUTION

46. Consequently, the issue raised in the present proceedings is to be decided in the context whether the Indian Government owes a constitutional

duty to provide free medical treatment to the petitioner suffering from a rare and a chronic disease, even though the treatment is expensive and recurring.

47. This Court is of the view that whilst the Cuban, South African and English jurisprudence on the subject of healthcare access contains valuable insights, it is important to bear in mind that our Constitution is structured differently from the aforesaid Constitutions.

48. In fact, though the issue raised in the present proceedings is common to all developing countries, yet India is fortunate to have a developed, liberal and progressive Constitution. As held by Justice Chaskalson P. of South African Constitutional Court in ***Thiagraj Soobramoney*** (supra) the Indian Supreme Court has developed a jurisprudence around the right to life so as to impose positive obligations on the government in respect of the basic needs of its inhabitants.

RIGHT TO HEALTH IS A FACET OF ARTICLE 21

49. Article 21 of the Constitution of India casts an obligation on the State to preserve life. Article 21 reads as under:-

> ***"21. Protection of life and personal liberty***.- *No personal shall be deprived of his life or personal liberty except according to procedure established by law."*

50. The Indian Supreme Court in a catena of cases has held that right to health and medical care is a fundamental right under Article 21 read with Articles 39(e), 41 and 43. It has further held that self-preservation of one's life is the necessary concomitant of the right to life enshrined in Article 21, fundamental in nature, sacred, precious and inviolable.

51. In fact, in ***State of Maharashtra Vs. Chandrabhan, AIR 1983 SC 803*** the Supreme Court held that right to life, enshrined in Article 21 means something more than survival or animal existence. It includes all those aspects of life which go to make a man's life meaningful, complete and worth living. That which alone can make it possible to live must be declared to be an integral component of the right to life.

52. The human right to health is also recognized in numerous international instruments. Article 25.1 of the Universal Declaration of Human Rights affirms: "Everyone has the right to a standard of living adequate for the health of himself and of his family, including food, clothing, housing and medical care and necessary social services". The International Covenant on Economic, Social and Cultural Rights provides the most comprehensive article on the right to health in international human rights law. In accordance with article 12.1 of the Covenant, States parties recognize "the right of everyone to the enjoyment of the highest attainable standard of physical and mental health", while article 12.2 enumerates, by way of illustration, a number of steps to be taken by the States parties to achieve the full realization of this right. Article 12.2 reads as under:-

> *"2. The steps to be taken by the States Parties to the present Covenant to achieve the full realization of this right shall include those necessary for :*
>
> *(a) The provision for the reduction of the stillbirth-rate and of infant mortality and for the healthy development of the child;*
>
> *(b) The improvement of all aspects of environmental and industrial hygiene;*
>
> *(c) The prevention, treatment and control of epidemic, endemic, occupational and other diseases;*

(d) The creation of conditions which would assure to all medical service and medical attention in the event of sickness."

53. General Comment No. 14 issued by the United Nations Committee on Economic, Social and Cultural Rights in 2000 states as under:-

"12. The right to health in all its forms and at all levels contains the following interrelated and essential elements, the precise application of which will depend on the conditions prevailing in a particular State party:

(a) Availability. Functioning public health and health-care facilities, goods and services, as well as programmes, have to be available in sufficient quantity within the State party. The precise nature of the facilities, goods and services will vary depending on numerous factors, including the State party's developmental level. They will include, however, the underlying determinants of health, such as safe and potable drinking water and adequate sanitation facilities, hospitals, clinics and other health-related buildings, trained medical and professional personnel receiving domestically competitive salaries, and essential drugs, as defined by the WHO Action Programme on Essential Drugs.

(b) Accessibility. Health facilities, goods and services have to be accessible to everyone without discrimination, within the jurisdiction of the State party. Accessibility has four overlapping dimensions:

Non-discrimination: health facilities, goods and services must be accessible to all, especially the most vulnerable or marginalized sections of the population, in law and in fact, without discrimination on any of the prohibited grounds.

Physical accessibility: health facilities, goods and services must be within safe physical reach for all sections of the population, especially vulnerable or marginalized groups, such as ethnic minorities and indigenous populations, women, children, adolescents, older persons, persons with disabilities and persons

with HIV/AIDS. Accessibility also implies that medical services and underlying determinants of health, such as safe and potable water and adequate sanitation facilities, are within safe physical reach, including in rural areas. Accessibility further includes adequate access to buildings for persons with disabilities.

Economic accessibility (affordability): health facilities, goods and services must be affordable for all. Payment for health-care services, as well as services related to the underlying determinants of health, has to be based on the principle of equity, ensuring that these services, whether privately or publicly provided, are affordable for all, including socially disadvantaged groups. Equity demands that poorer households should not be disproportionately burdened with health expenses as compared to richer households.

Information accessibility: accessibility includes the right to seek, receive and impart information and ideas concerning health issues. However, accessibility of information should not impair the right to have personal health data treated with confidentiality.

(c) Acceptability. All health facilities, goods and services must be respectful of medical ethics and culturally appropriate, i.e. respectful of the culture of individuals, minorities, peoples and communities, sensitive to gender and life-cycle requirements, as well as being designed to respect confidentiality and improve the health status of those concerned.
(d) Quality. As well as being culturally acceptable, health facilities, goods and services must also be scientifically and medically appropriate and of good quality. This requires, inter alia, skilled medical personnel, scientifically approved and unexpired drugs and hospital equipment, safe and potable water, and adequate sanitation.

xxxx xxxx xxxx xxxx

36. The obligation to fulfil requires States parties, inter alia, to give sufficient recognition to the right to health in the national

political and legal systems, preferably by way of legislative implementation, and to adopt a national health policy with a detailed plan for realizing the right to health. States must ensure provision of health care, including immunization programmes against the major infectious diseases, and ensure equal access for all to the underlying determinants of health, such as nutritiously safe food and potable drinking water, basic sanitation and adequate housing and living conditions. Public health infrastructures should provide for sexual and reproductive health services, including safe motherhood, particularly in rural areas. States have to ensure the appropriate training of doctors and other medical personnel, the provision of a sufficient number of hospitals, clinics and other health-related facilities, and the promotion and support of the establishment of institutions providing counselling and mental health services, with due regard to equitable distribution throughout the country. Further obligations include the provision of a public, private or mixed health insurance system which is affordable for all, the promotion of medical research and health education, as well as information campaigns, in particular with respect to HIV/AIDS, sexual and reproductive health, traditional practices, domestic violence, the abuse of alcohol and the use of cigarettes, drugs and other harmful substances. States are also required to adopt measures against environmental and occupational health hazards and against any other threat as demonstrated by epidemiological data. For this purpose they should formulate and implement national policies aimed at reducing and eliminating pollution of air, water and soil, including pollution by heavy metals such as lead from gasoline. Furthermore, States parties are required to formulate, implement and periodically review a coherent national policy to minimize the risk of occupational accidents and diseases, as well as to provide a coherent national policy on occupational safety and health services.

xxxx xxxx xxxx xxxx

<u>Core obligations</u>

43. In General Comment No. 3, the Committee confirms that States parties have a core obligation to ensure the satisfaction of,

at the very least, minimum essential levels of each of the rights enunciated in the Covenant, including essential primary health care. Read in conjunction with more contemporary instruments, such as the Programme of Action of the International Conference on Population and Development, the Alma-Ata Declaration provides compelling guidance on the core obligations arising from article 12. Accordingly, in the Committee's view, these core obligations include at least the following obligations:

(a) To ensure the right of access to health facilities, goods and services on a non-discriminatory basis, especially for vulnerable or marginalized groups;

(b) To ensure access to the minimum essential food which is nutritionally adequate and safe, to ensure freedom from hunger to everyone;

(c) To ensure access to basic shelter, housing and sanitation, and an adequate supply of safe and potable water;

(d) To provide essential drugs, as from time to time defined under the WHO Action Programme on Essential Drugs;

(e) To ensure equitable distribution of all health facilities, goods and services;

(f) To adopt and implement a national public health strategy and plan of action, on the basis of epidemiological evidence, addressing the health concerns of the whole population; the strategy and plan of action shall be devised, and periodically reviewed, on the basis of a participatory and transparent process; they shall include methods, such as right to health indicators and benchmarks, by which progress can be closely monitored; the process by which the strategy and plan of action are devised, as well as their content, shall give particular attention to all vulnerable or marginalized groups.

xxxx xxxx xxxx xxxx

Violations of the obligation to fulfil

52. Violations of the obligation to fulfil occur through the failure of States parties to take all necessary steps to ensure the

realization of the right to health. Examples include the failure to adopt or implement a national health policy designed to ensure the right to health for everyone; insufficient expenditure or misallocation of public resources which results in the non-enjoyment of the right to health by individuals or groups, particularly the vulnerable or marginalized; the failure to monitor the realization of the right to health at the national level, for example by identifying right to health indicators and benchmarks; the failure to take measures to reduce the inequitable distribution of health facilities, goods and services; the failure to adopt a gender-sensitive approach to health; and the failure to reduce infant and maternal mortality rates."

54. Additionally, the right to health is recognized, inter alia, in article 5 (e) (iv) of the International Convention on the Elimination of All Forms of Racial Discrimination of 1965, in articles 11.1 (f) and 12 of the Convention on the Elimination of All Forms of Discrimination against Women of 1979 and in article 24 of the Convention on the Rights of the Child of 1989. Several regional human rights instruments also recognize the right to health, such as the European Social Charter of 1961 as revised (art. 11), the African Charter on Human and Peoples' Rights of 1981 (art. 16) and the Additional Protocol to the American Convention on Human Rights in the Area of Economic, Social and Cultural Rights of 1988 (art. 10). Similarly, the right to health has been proclaimed by the Commission on Human Rights, as well as in the Vienna Declaration and Programme of Action of 1993 and other international instruments. [See **: *United Nations. Economic and Social Council. The Right to the highest attainable standard of health : 08/11/2000. E/C 12/2000/4]***

55. This Court is of the view that Article 21 has to be interpreted in conformity with International Covenant on Civil and Political Rights, 1966

as India is a signatory to the same.

56. The Indian Supreme Court in the case of ***Pt. Parmanand Katara Vs. Union of India and Others, (1989) 4 SCC 286*** recognized the obligation of the Government to preserve life. In the said case a victim of a scooter accident was denied treatment as the hospital did not have the requisite arrangements for medico-legal cases. Failure to receive timely treatment eventually led to the victim's death. While interpreting the ambit of the right to life under Article 21 of the Constitution, the Supreme Court held *"Article 21 of the Constitution casts the obligation on the State to preserve life. .....The obligation being total, absolute and paramount, laws of procedure whether in statutes or otherwise which would interfere with the discharge of this obligation cannot be sustained and must, therefore, give way."* (emphasis supplied).

57. In the case of ***Paschim Bangal Khet Mazdoor Samity and Others*** (supra), a member of the petitioner Mazdoor Samity suffered a brain injury after falling from a train and was denied treatment at several hospitals due to lack of expertise and lack of beds and was forced to seek treatment at a private hospital. The petition was filed for compensation of the expenses incurred. The Supreme Court observed that the obligation to provide medical care was an obligation of the welfare state and held *"The Constitution envisages the establishment of a welfare State at the federal level as well as at the State level. In a welfare State the primary duty of the Government is to secure the welfare of the people. Providing adequate medical facilities for the people is an essential part of the obligations undertaken by the Government in a welfare State. The Government discharges this obligation by running hospitals and health centres which*

provide medical care to the person seeking to avail of those facilities. Article 21 imposes an obligation on the State to safeguard the right to life of every person. Preservation of human life is thus of paramount importance. The government hospitals run by the State and the medical officers employed therein are duty-bound to extend medical assistance for preserving human life. Failure on the part of a government hospital to provide timely medical treatment to a person in need of such treatment results in violation of his right to life guaranteed under Article 21. .....It is no doubt true that financial resources are needed for providing these facilities. But at the same time it cannot be ignored that it is the constitutional obligation of the State to provide adequate medical services to the people. Whatever is necessary for this purpose has to be done.....In the matter of allocation of funds for medical services the said constitutional obligation of the State, has to be kept in view. It is necessary that a time-bound plan for providing these services should be chalked out keeping in view the recommendations of the Committee as well as the requirements for ensuring availability of proper medical services in this regard as indicated by us and steps should be taken to implement the same." (emphasis supplied).

58. Consequently, right to health and health care access are a part of Articles 21, 38 and 46 of the Constitution. Accordingly, every person has a fundamental right to quality health care -- that is affordable, accessible and compassionate.

WHETHER IN RAM LUBHAYA BAGGA AND CONFEDERATION OF EX SERVICEMEN ASSOCIATIONS (SUPRA), SUPREME COURT HAS DILUTED THE RIGHT TO HEALTH

59. The argument that the right to health as envisaged under Article 21 has been diluted in later decisions of the Supreme Court in ***State of Punjab & Ors. vs. Ram Lubhaya Bagga*** (supra) and ***Confederation of Ex servicemen Associations and Ors. vs. Union of India & Ors.*** (supra) is not correct. A Division Bench of this Court in ***All India Lawyers Union (Delhi Unit) vs. Govt. of NCT of Delhi & Ors*** (supra) to which this Court was a party has held as under:-

> *"ROLE OF NON-STATE ACTORS*
> *43. Health care is an essential concomitant to quality of life. Its demand and supply cannot therefore be left to be regulated solely by the invisible hands of the market. The State must strive to move towards a system where every citizen has assured access to basic health care, irrespective of capacity to pay. In an article by Shri R.Srinivasan "Health Care In India – Vision 2020 – Issues and Prospects" the author suggested four criteria for establishing a just health care system - (i) universal access, and access to an adequate level, and access without excessive burden (ii) fair distribution of financial costs for access and fair distribution of burden in rationing care and capacity and a constant search for improvement to a more just system, (iii) training providers for competence empathy and accountability, pursuit of quality care and cost effective use of the results of relevant research and (iv) special attention to vulnerable groups such a children, women, disabled and the aged."*

60. In ***Consumer Education and Research Centre and Others Vs. Union of India and Others, (1995) 3 SCC 42*** the Supreme Court held *"Therefore, we hold that right to health, medical aid to protect the health and vigour to a worker while in service or post retirement is a fundamental right under*

Article 21, read with Articles 39(e), 41, 43, 48A and all related Articles and fundamental human rights to make the life of the workman meaningful and purposeful with dignity of person..... It would thus be clear that in an appropriate case, the Court would give appropriate directions to the employer, be it the State or its undertaking or private employer to make the right to life meaningful; to prevent pollution of work place; protection of the environment; protection of the health of the workman or to preserve free and unpolluted water for the safety and health of the people. The authorities or even private persons or industry are bound by the directions issued by this Court under Article 32 and Article 142 of the Constitution." (emphasis supplied).

61. It is pertinent to mention that judgments of Supreme Court in ***Pt. Parmanand Katara*** (supra) and ***Paschim Bangal Khet Mazdoor Samity and Others*** (supra) have not been overruled till date. In fact, in the subsequent Constitution Bench judgment in the case of ***Confederation of Ex servicemen Associations and Ors.*** (supra) the Supreme Court reiterated that right to medical aid is a fundamental right of all citizens guaranteed by Article 21. The Constitution Bench only held that the contributory scheme framed by the Government qua ex-service men, under which they had to pay one time contribution, was constitutionally valid. In the opinion of this Court, if a class or category of its citizens can afford to pay or partially pay for their medical treatment because of their economic background, Government can certainly frame a contributory scheme for medical treatment.

AVAILABILITY OF FINANCE IS A RELEVANT FACTOR

62. Undoubtedly, availability of finance with the Government is a relevant factor. Courts cannot be unmindful of resources and finances. No court can direct that entire budget of a country should be spent on health and medical aid. After all competing claims like education and defence cannot be ignored.

63. Consequently, courts cannot direct that all inhabitants of this country be given free medical treatment at state expense. Even if such a direction were issued it would not be implementable as there would be neither infrastructure nor finance available for compliance of the said direction.

HOWEVER CORE OBLIGATIONS LIKE ACCESS TO ESSENTIAL MEDICINES ARE NON-DEROGABLE.

64. At the same time, no Government can say that it will not treat patients with chronic and rare diseases due to financial constraint. It would be as absurd as saying that the Government will provide free treatment to poor patients only for stomach upset and not for cancer/HIV/or those who suffer head injuries in an accident!

65. Disease is a natural catastrophe that fells its victims unpredictably. The right to adequate health care flows from the sanctity of human life and the dignity that belongs to all persons. Health is a fundamental human right, which has as its prerequisites social justice and equality. It should be accessible to all.

66. Healthcare access is the ability to obtain healthcare services such as prevention, diagnosis, treatment and management of diseases, illness,

disorders, and other health-impacting conditions. For healthcare to be accessible it must be affordable and convenient.

67. This Court is of the view that core obligations under the right to health are non-derogable. This minimum core is not easy to define, but includes at least the minimum decencies of life consistent with human dignity. No one should be condemned to a life below the basic level of dignified human existence.

68. In the opinion of this Court, Article 21 of the Constitution clearly imposes a duty on the Government to take whatever steps are necessary to ensure that everyone has access to health facilities, goods and services so that they can enjoy, as soon as possible, the highest attainable standard of physical and mental health. By virtue of Article 21 of the Constitution, the State is under a legal obligation to ensure access to life saving drugs to patients. A reasonable and equitable access to life saving medicines is critical to promoting and protecting the right to health. This means that Government must at the bare minimum ensure that individuals have access to essential medicines even for rare diseases like enzyme replacement for Gaucher disease. Availability of a very expensive drug virtually makes it inaccessible.

69. Government cannot cite financial crunch as a reason not to fulfil its obligation to ensure access of medicines or to adopt a plan of action to treat rare diseases. In the opinion of this Court, no government can wriggle out of its core obligation of ensuring the right of access to health facilities for vulnerable and marginalized section of society, like the petitioner by stating that it cannot afford to provide treatment for rare and chronic diseases.

HABIT OF GIVING/DONATION NEEDS TO BE POPULARISED AND FACILITATED

70. The Central and State Governments can certainly tap the resources of the civil society to provide healthcare access to the poor and unprivileged. The Governments can and should attract donations to the healthcare sector, both in cash and kind. Both corporate social responsibility and donations need to be made particularly attractive for pharmaceutical and other companies involved in this sector, as the drugs, implants and devices required are often very expensive and inaccessible to the common man.

71. This Court is also of the view that the habit of 'giving'/donation needs to be encouraged by the Government. Adequate steps have to put in place to emphasise, popularise and facilitate the process of giving. For instance, in the present case itself this Court is pleased to note that just at its oral request not only High Court lawyers but also Medanta - The Medicity Hospital, Gurgaon, Haryana and the drug manufacturer namely, Genzyme - A Sanofi Company have voluntarily raised funds and/or donated drugs to facilitate free treatment for the petitioner for nearly six months.

CORPORATE SOCIAL RESPONSIBILITY.

72. This Court may mention that before the final hearing commenced, the counsel for the petitioner had drawn this Court's attention to the Companies Act, 2013 which for the first time incorporated Corporate Social Responsibility (for short "CSR"). Section 135 of the Companies Act, 2013 stipulates that a company having a net worth of more than Rs. 500 crores or turnover in excess Rs. 1,000 crores or a net profit of Rs. 5 crores during a

financial year must spend at least 2% of its average net profits during the last three financial years on CSR activities covered in Schedule VII of the Companies Act, 2013.

73. Section 135, Schedule VII and the Companies (Corporate Social Responsibility Policy) Rules, 2014 were notified on 27th February, 2014 and have come into effect from 1st April, 2014. Prior to the enactment of the new Companies Act, there existed only a set of Voluntary Guidelines issued by the Ministry of Corporate Affairs in 2009.

74. Prior to its notification on 27th February, 2014 Schedule VII of the Companies Act, 2013 permitted companies to carry out CSR activities under ten heads which included "reducing child mortality"(at Sr. no. 4 of the un-notified Schedule VII) and "combating HIV, AIDS, malaria and other diseases" (at Sr. no. 5 of the un-notified Schedule VII).

75. However, when Schedule VII was notified on 27th February, 2014 these two entries were inexplicably dropped from the list of permitted CSR activities. The only area under the then notified Schedule VII was "preventive healthcare". Since the notified Schedule VII would have closed the CSR funding route as an option to sponsor treatments for rare diseases, this Court vide its order dated 28th February, 2014 directed the Ministry of Corporate Affairs to re-examine the matter.

76. The Ministry of Corporate Affairs filed a letter dated 24th March, 2014 before this Court stating *"Ministry of Corporate Affairs has decided to amend the Schedule VII of the Companies Act, 2013 to bring in clarity regarding the ambit of 'promoting preventive health care' as included in the said Schedule. It has been decided to amend the said item in Schedule VII as follows: 'promoting health care including preventive health care'. This*

would encompass the entire health care area, including the treatment of diseases etc."

77. On 28th March, 2014, the Ministry of Corporate Affairs filed an affidavit clarifying the scope of the term "normal course of business" used in Rules 4 and 6 of the Companies (Corporate Social Responsibility Policy) Rules, 2014, by giving the following example:-

"....a pharmaceutical company donating medicines/drugs within section 135 read with Schedule VII to the Act is a CSR Activity, as the same is not an activity undertaken in pursuance of its normal course of business which is relatable to health care or any other entry in Schedule VII."

78. This Affidavit clarifies that an activity carried out by a Company covered under Schedule VII which is a part of its core business, if not done with a profit motive, amounts to a CSR Activity. The aforesaid letter and affidavit of Ministry of Corporate Affairs are taken on record and accepted by this Court. Government of India is held bound by the same.

GOVERNMENTS WOULD BE WELL ADVISED TO CONSIDER EXPANDING THEIR HEALTH BUDGET

79. It is unfortunate that even after sixty-six years of independence, universal medical healthcare is still a distinct dream. Even today, economically weaker sections of the society do not have access to free medical treatment. But one need not be despondent. Only on 26th August, 2009, the Parliament passed The Right of Children to Free and Compulsory Education Act, 2009 which provides for free and compulsory education to all children of the age of six to fourteen years.

80. This Court is of the view that Government needs to seriously consider expanding its health budget if their right to life and right to equality as enumerated in Articles 14 and 21, are not to be rendered illusionary. If poor patients are to enjoy benefit of recent innovations in the medical field, like robotic surgery, genome engineering the Government must immediately think of increasing its investment in the health sector.

SUGGESTIONS BY THE COURT

81. This Court suggests that both the Central and State Governments should consider the following suggestions:

i. All government hospitals could have a separate CSR/ Charitable entity/account wherein donations can be received. The donations could be subject to an audit.

ii. Each hospital could have a designated officer, to whom applications for assistance can be made by patients in need. The decision to whom financial assistance could be provided, be left to the Medical Superintendent/CEO of the Hospital along with Head of the Departments. Delhi could be adopted as the first model state.

iii. The Ministries of Corporate Affairs and Finance could consider providing extra credit (for instance increased credit) for donations in certain sectors, such as health.

iv. The Government could adopt a holistic approach to facilitate donations, so that the tax regime supports the said efforts.

v. All donations in cash and kind must be accounted for, with complete transparency to ensure no misuse or misappropriation of donations.

vi. Government hospitals could put up list on the State Department of Health website of the drugs, implants and devices they require for EWS/BPL patients. This way people would donate as per the need of each hospital. This could be revised on a monthly basis.

vii. The State Government may put up a list of drugs, implants and devices which are excluded from its budget for which donations would be welcome.

viii. Both the Central and State Governments could create a revolving fund to take care of recurring expenditure of patients suffering from chronic and rare diseases.

ix. The Government could constitute a High Powered Inter-disciplinary Committee to:

- Develop and update a list of guiding principles/best practices in the area of donations in healthcare.
- Develop a policy for tackling rare diseases and promoting the development of orphan drugs.
- Evolve new and innovative methods for attracting spending in the area of healthcare.
- This Committee could have representatives from various State and Central Government departments, private and government hospitals, non-governmental organizations working in the area of healthcare, representatives of patients rights groups, representatives of pharmaceutical and other companies in the healthcare sector.

82. However, as the concept of CSR is still at a nascent stage and there is no mechanism in place which popularizes and facilitates donation, this Court is of the view that State must bear the burden of the treatment.

83. Before parting with the judgment, this Court would like to place on record its appreciation for the high level of debate and the assistance rendered to it by all the counsel appearing in the present case.

84. While Mr. Ashok Aggarwal deserves credit for filing the present petition and for bringing the plight of the petitioner to the notice of this Court, Ms. Zubeda Begum put forth her submissions in a concise manner. Ms. Manisha Dhir was very helpful in getting the Ministry of Corporate Affairs to promptly accept and implement the suggestions given by this Court with regard to CSR. Mr. Anand Grover, learned senior counsel not only provided valuable insight, but also gave a contextual meaning to the right to health. This Court may mention that without the assistance and the hard work put in by the Amicus Curiae, Ms. Shyel Trehan, it would not have been possible for this Court to conclude the hearing and pronounce judgment in a short time period.

CONCLUSION

85. To conclude, today, on account of lack of Government planning, there is ***'pricing out'*** of orphan drugs for rare and chronic diseases, like Gaucher. The enzyme replacement therapy is so expensive that there is a breach of constitutional obligation of the Government to provide medical aid on fair, reasonable, equitable and affordable basis. By their inaction, the Central and the State Governments have violated Articles 14 and 21 of the

Constitution.

86. Just because someone is poor, the State cannot allow him to die. In fact, Government is bound to ensure that poor and vulnerable sections of society have access to treatment for rare and chronic diseases, like Gaucher especially when the prognosis is good and there is a likelihood of the patient leading a normal life. After all, health is not a luxury and should not be the sole possession of a privileged few.

87. Although obligations under Article 21 are generally understood to be progressively realizable depending on maximum available resources, yet certain obligations are considered core and non-derogable irrespective of resource constraints. Providing access to essential medicines at affordable prices is one such core obligation.

88. Since a breach of a Constitutional right has taken place, the Court is under a duty to ensure that effective relief is granted. The nature of the right infringed and the nature of the infringement provides guidance as to the appropriate relief in a particular case.

89. As health is a State subject, the present petition is disposed of with a direction to the Government of NCT of Delhi, to discharge its constitutional obligation and provide the petitioner with enzyme replacement therapy at AIIMS free of charge as and when he requires it.

MANMOHAN, J

APRIL 17, 2014
js/rn