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With this thought, we hereby present to you

LEX BONA FIDE: LAW JOURNAL

MOHD AHMED(MINOR) VS. UNION OF INDIA

[Case Analysis]

(Rahul Saini, LL.M, University Of Delhi)

ABSTRACT

Despite the steady increasing government contribution to healthcare, the issue of Rare Diseases was seriously neglected for an extended time. Subsidized drugs for the cure of individuals affected by rare conditions were also rare. These subsidies are essential for citizens experiencing rare disorders, a majority of these patients are from economically backward strata. For a considerably long time, a kind of struggle was ongoing ahead of the Indian courtroom searching the government's attention and fiscal involvement towards these 'Rare Diseases'. India is amongst the countries using the lowest public health financing on the planet, with the public health care system in the country only getting 1.26 per cent of the whole GDP. The missing support in political figures, for example, a complete lacuna of any sort of law on rare diseases was expressed for the first time in 2016 when the Delhi High Court dictated Health Ministry to launch a 'National Rare Disease Policy'. The present case in question marks the initiation of the battle before the court of law and the way the judges have responded to the government's plea of having 'minimal Resources as well as the equitable distribution of the same.

INTRODUCTION

The medical industry plays a major role in the economy of any country, developing and developed nations alike. However, several nations have ignored or neglected this issue of growing genetic diseases and hence, extensive research is still required to counter them. In certain countries such as the United States of America, almost 17% of the GDP is being spent on healthcare.² These figures seem to be compliant with larger-than-life American economies, allowing countries with similarly sized economies to spend identical amounts on medical development. As a developing country, India had a budget of Rs.1900 Crores in 2019-20 for medical research, which seems grossly disproportionate to the healthcare needs of more than 135 crore population.³ In 2017, the Indian government implemented a Policy directed towards addressing the dire need for research in genetic diseases and aid to patients suffering from such rare diseases.

Despite the steady increasing government support to medical research, this sector i.e. Rare Disease Research, has been neglected for an extended period. Subsidized medicines for the treatment of patients suffering from rare diseases were unheard of. These subsidies are necessary for citizens suffering from a rare disease, a majority of such patients are from

economically backward strata. The concentration of wealth in the hands of a few in India has resulted in several citizens falling under a bracket of economic deprivation. This pattern further extends itself into the rarity of these diseases and the sporadic nature of their impact. As with all genetic diseases, it is scientifically impossible to ground genetic anomalies to a particular lifestyle, thereby affecting a larger diaspora of the population.

A major reoccurring problem, several nations tend to overlook is the problem of rare diseases. While most countries aim at eliminating or combating mainstream diseases such as cancer, polio, AIDS etc., rare diseases such as Duchenne Muscular Dystrophy, Gaucher etc., have hardly been researched upon. Over the past century, some countries such as the USA, Japan and Russia have diverted their laws and resources towards combating rare diseases. India has only recently started paying heed to this problem. The lacking support from governmental bodies, including a complete lacuna of any kind of regulation on rare diseases, was expressed for the first time in 2016 when the Delhi High Court ordered the Health Ministry to establish a 'National Rare Disease Policy'.

However, this battle started with a 2013 case of Mohd Ahmed (Minor) vs. Union of India, which is the subject matter of discussion.

FACTS OF THE CASE

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.

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.

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.

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 Gaucher's drugs in India. The cost of the treatment is estimated at approximate 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. A 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 to date.

However, '*every cloud has a silver lining*'.

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. So, with so the Delhi Government's financial assistant one month's treatment was given to the plaintiff.

Since during the pendency of the present petition, the 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 the 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.

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.

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.

Before the commencement of arguments, this Court allowed the Central and State Governments to see if the matter could be amicably resolved. However, the meeting was not very successful. Accordingly, on 25th March 2014, this Court commenced hearing final arguments.

ISSUES BEFORE THE COURT

1. Whether a minor child born to parents belonging to the 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, the prognosis is good and there is every likelihood of petitioner leading a normal life.
2. Whether the availability of finances is a relevant factor for a State to take a plea that it does not have enough resources?
3. Whether the Supreme Court has diluted the 'Right to Health' in its earlier cases?

PETITIONER'S ARGUMENTS

Mr Ashok Aggarwal learned counsel for the 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 free treatment to the petitioner and like patients. He submitted that the 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).

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.

Mr Aggarwal stated that the 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 a medical expense to an MLA from Rohtas Nagar.

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.

Mr Aggarwal contended that the Central Government needed to bring "Public Health" in the 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.

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." He 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.

RESPONDENT'S ARGUMENTS

ARGUMENTS ON BEHALF OF THE DELHI GOVERNMENT

Ms Zubeda Begum learned counsel for Govt. of the NCT of Delhi stated that in comparison to other States of the country, the Govt. of the NCT of Delhi had allocated ten per cent of its budget towards health which was the 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.

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.

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

1. 'Delhi Arogya Kosh' provided financial assistance up to Rs.5 lakh to eligible patients. During the current FY 2013- 2014, an amount of approximately Rs.4.9 crores had been disbursed.
2. 'Delhi Arogya Nidhi': This Scheme provided financial assistance up to Rs.1.5 lakh to eligible patients.
3. 'Delhi Kalyan Samiti', and

L.G./Chief Minister's Relief Fund. She stated that for a 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. She further submitted that the right to health in a developing country like India could not be so stretched 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 to provide the maximum benefit to the maximum number of people.

She submitted that the Supreme Court in subsequent judgments in *State of Punjab & Ors. vs. Ram Lubhaya Bagga*[1], and *Confederation of Ex-servicemen Associations and Ors. vs. Union of India & Ors.* [2], had diluted the right to health.

In-*State of Punjab & Ors. vs. Ram Lubhaya Bagga*[3], the court has stated that “*When we speak about a right, it correlates to 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 an obligation on the State. This obligation is further reinforced under Article 47, which is for the State to secure health to its citizen as its primary duty.*

However, “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.”[4]

Confederation of Ex-servicemen Associations and Ors. vs. Union of India & Ors. [5], the court stated that “*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 a 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 a reasonable amount (ranging from Rs 1800 to Rs 18,000). To us, this cannot be held illegal, unlawful, arbitrary or otherwise unreasonable.”^[6]

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. Several aspects cannot be addressed solely within the relationship between States and individuals; in particular, good health cannot be ensured by a State, nor can States protect 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 concerning 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.

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

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

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, the 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 the Shire and Genzyme. AIIMS stated that it had no funds for

the treatment of any of these patients. It stated that it did not have an adequate budget to manage its day-to-day functioning, leave alone fund the petitioner's treatment.

SUMMARY OF RESPONDENTS' SUBMISSIONS

In a nutshell, the State Government, the Union of India and AIIMS stated that given 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

Ms Shyel Trehan learned Amicus Curiae submitted that Courts have taken different views about 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 Banga Khet Mazdoor Samity and Others Vs. The state of W.B. and Another*[7], while addressing the argument about 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.

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 do not 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 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.*”

Ms Trehan further stated that the healthcare sector was grossly under-served and the supply and accessibility of various drugs, implants and devices were 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

Mr Anand Grover learned senior counsel who takes an 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.

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.

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[8], to ensure the manufacturing of a vaccine against an endemic disease[9], and to ensure the continued provision free of charge of a drug against bone disease. [10]

COURT'S OBSERVATIONS AND REASONING

The 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".

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

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 the 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.

The European Union Regulation 1999 provides an incentive of market exclusivity to the sponsors of orphan drugs. Further, through the EUROPEAN, 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.

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

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.

This Court believes 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.

However, keeping in view the concept of separation of powers as incorporated in the Constitution, this Court cannot direct Parliament to enact Central legislation on the Right to Public Health or concerning rare diseases or orphan drugs, even though the same may be eminently desirable. Similarly, as formulation of a policy is within the exclusive domain of the Executive, this Court refrains from issuing directions.

Consequently, the issue raised in the present proceedings is to be decided in the context of whether the Indian Government owes a constitutional duty to provide free medical treatment to the petitioner suffering from a rare and chronic disease, even though the treatment is expensive and recurring.

This Court is of the view that whilst the jurisprudence of different countries discussed above 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.

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 *T. Soobramoney vs. Minister of Health (Kwazulu-Natal)*^[11] the Indian Supreme Court has developed a jurisprudence around the right to life 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

The Indian Supreme Court in a catena of cases has held that the 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.

In fact, in the 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.

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. Under 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, several steps to be taken by the States parties to achieve the full realization of this right.

The General Comment No. 14 and the General Comment No. 3, issued by the United Nations Committee on Economic, Social and Cultural Rights in 2000 states were also discussed in the case which talks about the essential elements and the obligations, the precise application of which is required to implement and the realization of the right to health in all its forms.

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. [\[12\]](#)

This Court was 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.

The Indian Supreme Court in the case of ***Pt. Parmanand Katara Vs. Union of India and Others***[\[13\]](#), 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.*"

In the case of ***Paschim Bangal Khet Mazdoor Samity and Others***[\[14\]](#), 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 for 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. 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. A time-bound plan for providing these services must 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).

Consequently, the right to health and health care access is 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 THE SUPREME COURT HAS DILUTED THE RIGHT TO HEALTH?

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*[15] and *Confederation of Ex-servicemen Associations and Ors. vs. Union of India & Ors.* [16] is not correct.

It is pertinent to mention that judgment of the Supreme Court in *Pt. Parmanand Katara*[17] and *Paschim Bangal Khet Mazdoor Samity and Others*[18] have not been overruled to date. In fact, in the subsequent Constitution Bench judgment in the case of *Confederation of Ex-servicemen Associations and Ors.* [19], the Supreme Court reiterated that the 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-servicemen, under which they had to pay a 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.

WHETHER AVAILABILITY OF FINANCE IS A RELEVANT FACTOR

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

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 with the said direction.

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

At the same time, no Government can say that it will not treat patients with chronic and rare diseases due to financial constraints. 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!

The disease is a natural catastrophe that falls 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.

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.

This Court is of the view that core obligations under the right to health are non-derogable. This minimum score 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.

CONCRETE JUDGEMENT

JUDGEMENT IN REM

This Court is of the view that core obligations under the right to health are non-derogable. This minimum score 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.

In the opinion of this Court, Article 21 of the Constitution 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. Under Article 21 of the Constitution, the State is under a legal obligation to ensure access to life-saving drugs to patients. 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. The availability of a very expensive drug virtually makes it inaccessible.

Government cannot cite financial crunch as a reason not to fulfil its obligation to ensure access to medicines or to adopt a plan of action to treat rare diseases.

JUDGEMENT IN PERSONAM

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 the vulnerable and marginalized section of society, like the petitioner by stating that it cannot afford to provide treatment for rare and chronic diseases.

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.

ADDITIONAL TAKEOUTS FROM THE JUDGMENT

This Court is also of the view that the habit of 'giving'/donation needs to be encouraged by the Government. Adequate steps have to be put in place to emphasise, popularise and facilitate the process of giving.

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.

PROMOTE THE 'CORPORATE SOCIAL RESPONSIBILITY

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.

Before the enactment of this new Companies Act of 2013, there existed only a set of Voluntary Guidelines issued by the Ministry of Corporate Affairs in 2009 and 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).

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 gives its order dated 28th February 2014 directed the Ministry of Corporate Affairs to re-examine the matter.

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 as 'promoting health care including preventive health care. This would encompass the entire health care area, including the treatment of diseases etc. '*"

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."

GOVERNMENTS WOULD BE WELL ADVISED TO CONSIDER EXPANDING THEIR HEALTH BUDGET

The court also notes the fact that 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 society do not have access to free medical treatment.

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 illusory. If poor patients are to enjoy the 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.

CONCLUSION

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 the constitutional obligation of the Government to provide medical aid on a fair, reasonable, equitable and affordable basis. By their inaction, the Central and the State Governments have violated Articles 14 and 21 of the Constitution.

Just because someone is poor, the State cannot allow him to die. The 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.

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.

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 guides as to the appropriate relief in a particular case.

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. Also, since 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 the State must bear the burden of the treatment.

LEX BONA FIDE

SUGGESTIONS

The following are a few suggestions that were brought by the Court in this judgement which are notable and the court through this judgement suggests that both the Central and State Governments should consider the following recommendations:

1. All government hospitals could have a separate CSR/ Charitable entity/account wherein donations can be received. The donations could be subject to an audit.
2. 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 the Head of the Departments. Delhi could be adopted as the first model state.
3. The Ministries of Corporate Affairs and Finance could consider providing extra credit (for instance increased credit) for donations in certain sectors, such as health.
4. The Government could adopt a holistic approach to facilitate donations so that the tax regime supports the said efforts.

5. All donations in cash and kind must be accounted for, with complete transparency to ensure no misuse or misappropriation of donations.
6. Government hospitals could put up a 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 every month.
7. 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.
8. Both the Central and State Governments could create a revolving fund to take care of recurring expenditures of patients suffering from chronic and rare diseases.
9. 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.

CITATIONS

[1] (1998) 4 SCC 117

[2] AIR 2006 SC 2945

[3] supra

[4] Para 26 and 29, (1998) 4 SCC 117

[5] supra

[6] Para 66, AIR 2006 SC 2945

[7] (1996) 4 SCC 37

[8] Supreme Court of Justice, Asociacion Benghalensis y otros vs. Ministerio de Salud y Accion Social, case 323:1339, 1 June 2000

[9] Federal Administrative Court, Chamber IV, Viceconte, Mariela v. Estado nacional - Ministerio de Salud y Accion Social slamparo ley 16.986, 2 June 1998

[10] 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

[11] Case CCT 32/97

[12] United Nations. Economic and Social Council. The Right to the highest attainable standard of health : 08/11/2000. E/C 12/2000/4

[13] (1989) 4 SCC 286

[14] Supra

[15] Supra

[16] Supra

[17] Supra

[18] Supra

[19] Supra

