Access to medicines and treatment for rare diseases in India

(Based on the Delhi High Court judgment in Baby Devananda D. (through her mother Deepa S.) and Anr. v Employees State Insurance Corporation and Ors.)

2017 SCC OnLine Del 12779

A RARE PREDICAMENT

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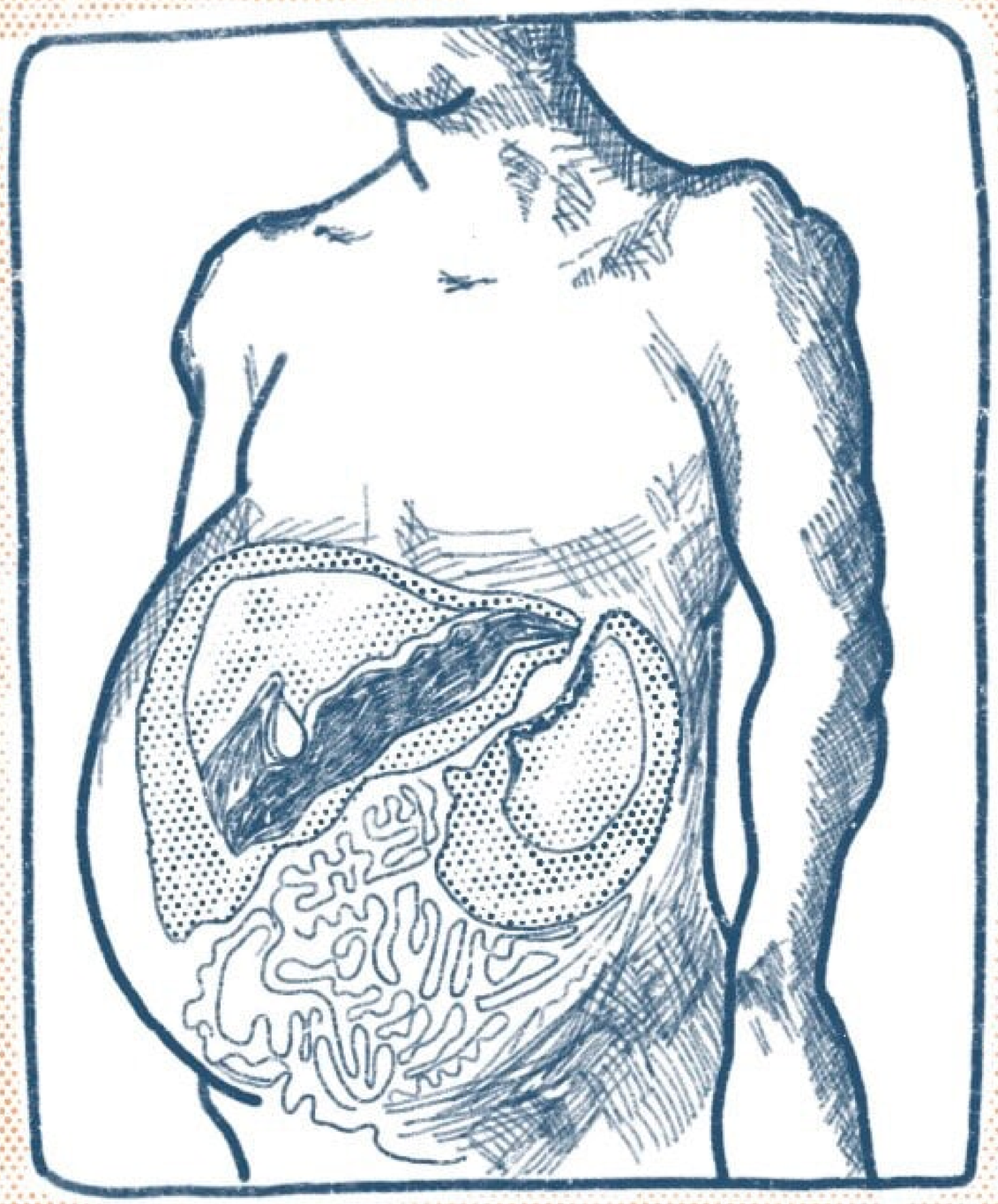

What did they want?

In May 2017, two minors suffering from Gaucher Type I and Hurler Syndrome Type I filed two writ petitions through their parents before the Delhi High Court challenging the validity of certain clauses of the guidelines issued by the Employee State Insurance Corporation ("ESIC") which limited their access to life-saving medicines and treatment.

What were these guidelines? How would ESIC guidelines impact their health? What are rare diseases? and most importantly, what could the courts do to help them?

THE RARE DISEASES CONUNDRUM

The World Health Organization (WHO) defines rare diseases as debilitating life-long diseases or disorders with a prevalence of 1 or less per 1,000 people. Many countries have different parameters to respond to rare diseases based on local contexts like population disease prevalence, healthcare systems and availability of resources. Around 80% of rare diseases are genetic in nature, thus disproportionately impacting children.

As rare diseases affect a small proportion of the population, pharmaceutical companies do not invest in developing medicines to treat them; there is little expectation that costs would be recovered from the sale of these medicines.

RARE DISEASES CURRENTLY AFFECT 3.5-5.9% OF THE TOTAL WORLD POPULATION.

A low prevalence leads to:

> a scarcity of expertise and knowledge

> limited access to diagnosis and care

> general lack of public awareness

C-HELP

JUSTICE adda

HOW DID THE STATE DECIDE TO PROVIDE FOR THESE DISEASES?

The Employees' State Insurance Corporation falls under the Ministry of Labour and Employment of the Government of India. It was established by the Employees' State Insurance Act, 1948, a leading legislation related to social security for workers.

The two clauses that the petitioners challenged were Clauses 5.1 and 5.3 of the **ESIC Decisions on Medical Services, July 2014** ("The Guidelines").

Clause 5.1 stated that the upper limit on expenses incurred for procedures not covered under the Central Government Health Scheme would be Rs. 10 lakh per beneficiary, per year. Clause 5.3 stated that with respect to children of insured persons, congenital diseases which may require referral to super specialty treatment ("SST"), and genetic conditions, would be eligible for coverage up to Rs. 10 lakh, only in cases where the child is born after the insured person has become eligible for SST.

The guideline prevented the petitioners and others similarly placed - who were not covered by the Central Government's scheme by virtue of suffering from a rare disease - from getting the required treatment.

FIRST THINGS FIRST: THE HIGH COURT'S APPROACH

While the case remained pending, the court passed an interim order directing ESIC to commence the appropriate treatment for the two children or refer them for treatment to an empanelled SST hospital, with the cost for this treatment to be borne by the ESIC.

The court appointed an *amicus curiae,* a "friend of the court" - someone who did not represent either side but assisted the court with relevant facts and law to help it reach its decision.

During pendency, ESIC amended Clause 5.1 to state that for treatments exceeding Rs. 10 lakh, the matter would be considered on a case-by-case basis and modified Clause 5.3 such that it provided different dates of eligibility for SST and provided that the insured person (or their children) will not be entitled for SST if the employer of the insured person fails to pay the monthly contribution.

LOOKING BACK TO LOOK AHEAD: THE DECISION IN MOHD. AHMED (MINOR) V UNION OF INDIA

The court observed that the case stood in the same factual and legal context as an earlier decision in *Mohd. Ahmed (Minor) v Union of India*, (2014) 6 HCC (Del) 118 where it had to pass orders to facilitate treatment of a child also suffering from Gaucher's disease.

In *Mohd. Ahmed's* case, the court held that as it did not have the power to direct the government to frame a policy on rare diseases on the basis of the doctrine of separation of powers, it decided the matter on the touchstone of Article 21 of the Constitution and held that access to life saving medicines is a component of the right to health that cannot be infringed. It observed,

> "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."

DOES THE LAW DEMAND THE TREATMENT OF RARE DISEASES?

By invoking *Mohd. Ahmed's* case the court placed rare diseases within the wide ambit of Article 21 and held that:

"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"

On the social determinants of rare diseases, the court noted,

"Even though rare genetic diseases like Gaucher and Hurler Syndrome are treatable, yet because of the prohibitively expensive treatment majority of the patients do not have access to the same. The burden of the rare genetic diseases like Gaucher and Hurler Syndrome disease is disproportionately borne by low and middle-income countries and the individuals most vulnerable to them in India are the poor and minorities. These groups often do not have access to testing and treatment services and lack awareness about the nature of the diseases and preventive techniques. Consequently, this public health crisis is driven by social and economic factors."

THE COST OF NOT FUNDING DRUGS: A "POLICY VACUUM"

The court further noted that despite its order in *Mohd. Ahmed*, there was a continued lack of any policy framework for rare diseases and again directed the **Ministry of Health** to convene a meeting to consider framing such a policy.

Subsequently, the Ministry framed the National Policy for Treatment of Rare Diseases (2017) for patients who were not eligible for financial assistance for treatment under any existing health scheme by central or state governments, and notified the court of the same in August 2017. However, by November 2018, the Ministry informed the court that it was withdrawing the said policy, reasoning that the policy was framed unlawfully since public health was an issue to be legislated by states. Further it justified the withdrawal due to lack of financial resources to allocate for rare disease treatment.

In the later case of *Master Arnesh Shaw and Ors. v Union of India and Anr.* (Writ Petition No. 5315 of 2020) on access to medicines and treatment for rare diseases, the court closely monitored developments by the Ministry up to the finalization of the policy within a stipulated time period.

The court's decision:

ESIC regulations cannot exclude specific diseases and make distinctions on basis of primary, secondary and tertiary care or super specialty treatments, as it is a product of a social welfare law, i.e., the Employees State Insurance Act, 1948 – and in case of any doubt on interpretation, the law has to be construed in favour of the intended beneficiaries – the employees.

ESIC's submission that it can only provide reasonable treatment or that it is not 'State' for provision of super specialty treatment to the insured person or his dependents was rejected, as access to life-saving treatments cannot be termed as 'unreasonable' and the ESIC has the power to regulate cost of treatment by policy interventions and price-control measures.

ESIC's contention that it performed functions similar to a private insurance corporation was rejected, as in case of private insurance the nature of obligation between parties is only contractual and such service providers function on profitability, whereas in a public insurance scheme the nature of obligation is statutory and the ESIC's objective is employee welfare.

The guideline on non-deposit of premium by the employer resulting in non-eligibility of the insured person and dependents for super specialty treatment amounted to penalization of the victim, and was therefore bad in law.

The challenged guidelines were inconsistent with the parent statute and regulations framed under the law, and thus illegal.

A 'SUGGESTION' OF A HUMAN RIGHTS BASED APPROACH

With these orders passed, the court further made a non-binding recommendation to the central government to:

Adopt a human rights based approach to rare diseases and super speciality treatment to realize the right to health

Focus on the social determinants of rare diseases

Create an enabling legal environment for research and development of new, more effective drugs and diagnostics and lower the prices of existing drugs

For the State, civil society and large pharmaceuticals to come forward and operationalise this approach to make treatment available at grassroot levels, in the manner that the global rights campaign on HIV/AIDS galvanized public support, inspired research and improved access to life-saving medicines and treatment.

THE NATIONAL POLICY FOR RARE DISEASES 2021: WHERE ARE WE TODAY?

On 30 March 2021, the Union Health and Family Welfare Minister approved the National Policy for Rare Diseases (NPRD) 2021.

The aims of the NPRD are:

Preventive care including information, education, counselling (IEC) programmes, pre/post marital and pre/post conception screening of rare diseases.

Indian Council of Medical Research (ICMR) and other government bodies to research and develop a pipelines of drugs in partnerships with pharmaceutical companies for improvement of access and affordability of medicines for rare diseases,

Ministry of Finance to be lobbied for reduction of import duties on medicines for rare diseases;

National Pharmaceutical Pricing Authority (NPPA) and others to make medicine prices for rare diseases publicly available and make efforts to augment affordability in consultation with the Ministry of Health.

ICMR to initiate a national hospital-based registry of rare diseases so that sufficient epidemiological data is available to both define and conduct the requisite research on rare diseases.

The nomination of 8 government tertiary hospitals as Centres of Excellence for diagnosis, prevention and treatment of rare diseases.

The creation of "Nidan Kendras" for early screening and prevention, as well as plans to strengthen extant secondary and tertiary health facilities.

Government of India financial support up to Rs. 20 lakh for one-time treatment at a tertiary hospital.

Setting up of digital platforms for crowd-funding to finance treatment by individual and corporate donors.

While the policy promises to provide a lifeline to many, concerns remain, chiefly over the funding provided for in this policy. It is worth exploring if this new 2021 Policy is rooted in the court's recommendation of a human rights approach to rare diseases.

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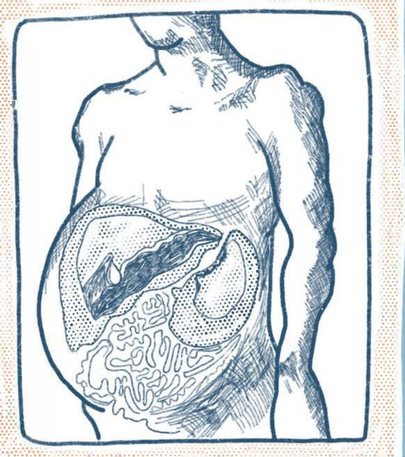

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