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

Date of decision: 12th January, 2021.

\+ **W.P.(C) 5315/2020 & CM APPL.19189/2020**

MASTER ARNESH SHAW ..... Petitioner

Through: Mr. Vivek Chib, Mr. Rahul Malhotra, Mr. Asif Ahmed, Mr. Vikhyat Oberoi and Mr. Manas Tripathi, Advocates. (M:9899218215)

versus

UNION OF INDIA & ANR. ..... Respondents

Through: Mr. Ripudaman Bhardwaj, CGSC with Mr. Kushagra Kumar, Advocate for R-1.
Mr. Satvik Varma and Mr. Tanveer Oberoi, Advocates for R-2/AIIMS.

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\+ **W.P.(C) 322/2021 & CM APPL.812/2021**

KESHAV SHARMA AGE 12 YEARS THROUGH:
HIS NEXT FRIEND AND NATURAL FATHER
SANJEEV KUMAR ..... Petitioner

Through: Mr. Ashok Agarwal, Advocate.

versus

UNION OF INDIA & ANR. ..... Respondents

Through: Mr. Ajay Digpaul, CGSC and Mr. Kamal R. Digpaul, Advocate for R-1.
Mr. V.S.R. Krishna, Advocate for R-2/AIIMS.

CORAM:
JUSTICE PRATHIBA M. SINGH

Prathiba M. Singh, J.(Oral)

1. This hearing has been done by video conferencing.

2. Both these matters concern children, who are suffering from a rare

disease known as Duchenne Muscular Dystrophy (*hereinafter referred as "DMD"*). The drug for this particular condition is stated to be at an experimental stage and is currently being manufactured by a company called Sarepta Therapeutics, USA. The relief sought in these petitions is that the government should be directed to ensure that the Petitioners are provided free treatment for this disorder, as the drug is exorbitantly expensive and is not affordable by the Petitioners.

3. In ***W.P.(C) 5315/2020***, the Union of India through Ministry of Health and Family Welfare has placed on record an affidavit giving details of the various health policies, which are under consideration in respect of such rare diseases. As per the said affidavit, a Draft Health Policy for Rare Diseases has been released by the government in 2020, which is still in the stage of consultation. The earlier policy of 2017 was kept in abeyance by the government vide notification dated 18th December, 2018. This Court, vide order dated 7th August, 2020, had directed the case of the Petitioners to All India Institute of Medical Sciences (*hereinafter, "AIIMS"*), which has placed on record a report along with an affidavit reiterating the report. The first report filed by AIIMS is to the effect that the child is unlikely to show improvement with Exondys 51 therapy, however, a final recommendation in this regard, is to be taken by the Central Technical Committee for Rare Diseases, Ministry of Health and Family Welfare, Govt. of India. The said report has been followed with another affidavit filed on behalf of AIIMS supporting the said earlier report.

4. This Court is of the opinion that just because of the exorbitant price of the drug or treatment, patients, especially children, suffering from a rare disease ought not to be deprived of treatment for their condition. The draft

policy of the government, which was introduced in 2020 for consultation has still not seen the light of the day. Considering the fact that `Right to Health and Healthcare' is a Fundamental Right which has been recognised by the Supreme Court to be a part of the `Right to life' under Article 21 of the Constitution, it is incumbent on society in general and authorities in particular to ensure that the life of such children is not compromised, even if there is a small window of improving their chances of survival or even providing a better quality of life.

5. In the Draft Health Policy for Rare Diseases 2020, DMD is recognised as being one of the rare diseases, the cost of treatment of which is very high. The said disease has been categorised in group 3 of the Policy, which is extracted hereinbelow:

> ***"Group 3: Diseases for which definitive treatment is available but challenges are to make optimal patient selection for benefit, very high cost and lifelong therapy***
>
> *3a) Based on the literature sufficient evidence for good long-term outcomes exists for the following disorders*
>
> 1. *Gaucher Disease (Type I & III (without significant neurological impairment)*
> 2. *Hurler Syndrome [Mucopolysaccharidosis (MPS) Type I] (attenuated forms)*
> 3. *Hunter Syndrome [MPS II] (attenuated form)*
> 4. *Pompe Disease diagnosed early (Both infantile & late on set)*
> 5. *Fabry Disease diagnosed before significant end organ damage*
> 6. *Spinal Muscular Atrophy*
> 7. *MPS IVA*
> 8. *MPS VI*
>
> ***3b) For the following disorders for which the cost of***

treatment is very high and either long term follow up literature is awaited or has been done on small number of patients

1. *Wolman Disease*
2. *Hypophosphatasia*
3. *Neuronal ceroid lipofuscinosis*
4. *Cystic Fibrosis*
5. *Duchenne Muscular Dystrophy* "

6. Insofar as group 3 diseases are concerned, the relevant proposal in the Draft Health Policy is contained in paragraph 9, which reads as under:

"***9. Voluntary crowd-funding for treatment***

9.1 Keeping in view the resource constraint and competing health priorities, it will be difficult for the Government to fully finance treatment of high cost rate diseases. The gap can however be filled by creating a digital platform for bringing together notified hospitals where such patients are receiving treatment or come for treatment, on the one hand, and prospective individual or corporate donors willing to support treatment of such patients. The notified hospitals will share information relating to the patients, diseases from which they are suffering, prognosis, estimated cost of treatment and details of bank accounts for donation/ contribution through online system. Donors will be able to view the details of patients and donate funds to a particular hospital. This will enable donors from various sections of the society to donate funds, which will be utilized for treatment of patients suffering from rare diseases, especially those under category III.

9.2 The Government will notify selected Centres of Excellence, which will be premier Government tertiary hospitals with facilities for treatment of rare diseases. To begin with the following

institutes would be notified as Centers of Excellence for Rare Diseases:
1. All India Institute of Medical Sciences, New Delhi.
2. Maulana Azad Medical College, New Delhi.
3. Sanjay Gandhi Post Graduate Institute of Medical Sciences, Lucknow.
4. Post Graduate Institute of Medical Education and Research, Chandigarh.
5. Centre for DNA Fingerprinting & Diagnostics, Hyderabad
6. King Edward Medical Hospital, Mumbai
7. Institute of Post-Graduate Medical Education and Research, Kolkata
8. Center for Human Genetics (CHG) with Indira Gandhi Hospital, Bengaluru
The cost of treatment of patient in these centres of excellence will be met out of donations received through the online digital platform, mentioned in Para 8.1 above"

7. As per the above draft policy, in view of the constraint of governmental resources, and competing health priorities, the government proposes that it cannot fully finance the treatment of all high cost rare diseases, but the gap can be filled by seeking donations from prospective individuals or corporate donors, who are willing to support the cost of such diseases. Thus, the government has recognised that DMD is a rare disease and has also recognized the fact that patients in general may not be able to afford its treatment. The Government thus proposes that it shall explore crowd funding as an option to address affordability concerns.

8. This court is of the opinion that the finalisation of the Draft Health Policy for Rare Diseases cannot be kept pending indefinitely, especially when common human lives are at stake. The earlier Policy having been kept

in abeyance, it is incumbent for the Government to finalise and notify the Policy at the earliest. Accordingly, it is directed as under:

(1) A specific timeline shall be provided by the Secretary, Ministry of Health and Family Welfare, in respect of the finalisation and notification of the Draft Health Policy for Rare Diseases, 2020.

(2) Insofar as the Petitioners, who are suffering from DMD, are concerned, the Secretary - Ministry of Health and Family Welfare would proceed in terms of the draft policy and explore crowd funding, including through prospective individuals, corporate donors and independent foundations, which exist to fund such treatments. The Ministry shall in addition also contact the company M/s Sarepta Therapeutics, USA, which publicly advertises that it provides financial support/ medication in deserving cases, as is evident from their website. The Ministry shall come up with a proposal, with respect to the same, within the next 10 days.

9. Let a report in respect of the above two directions be placed on record at least 2 days before the next date.

10. List on 28th January, 2021.

PRATHIBA M. SINGH
JUDGE

JANUARY 12, 2021/*dk/Ak*