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

Date of decision: 2nd March, 2021

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W.P.(C) 10782/2020

AVIRAJ GARG, AGE 4 YEARS, THROUGH HIS NEXT FRIEND
AND NATURAL FATHER SH. ABHINAV GARG Petitioner

Through: Mr. Ashok Aggarwal and Mr. Kumar
Utkarsh, Advocates. (M:9811101923)

versus

UNION OF INDIA & ANR. Respondents

Through: Ms. Amrita Prakash, CGSC for
Respondent/IOI
Mr. Tanveer Oberoi & Mr. Satvik
Verma, Advocates for Respondent
No.2/AIIMS
Mr. Rajdeep Bhattacharya, Advocate
for Respondent No.5/Institute of
Child Health (M: 9163329688)
Dr. Arun Shastry, Chief Scientific
Officer, DART, Bangalore
(M: +91 8023412725/9840219833)

18

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WITH

W.P.(C) 5315/2020

MASTER ARNESH SHAW Petitioner

Through: Mr. Vivek Chib, Mr. Rahul Malhotra,
Mr. Asif Ahmed & Mr. Manas
Tripathi, Advocates.

versus

UNION OF INDIA & ANR. Respondents

Through: Mr. Chetan Sharma, ASG with Mr.
Ripudaman Bhardwaj, CGSC with
Mr. Kushagra Kumar, Advocates for
Respondent No.1/IOI
(M: 9818030700)
Mr. Tanveer Oberoi & Mr. Satvik
Verma, Advocates for Respondent
No.2/AIIMS

Dr. Pulkesh Kumar, Deputy
Secretary, MoHFW.

20
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WITH
W.P.(C) 322/2021

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

..... Petitioner

Through: Mr. Ashok Agarwal & Mr. Kumar
Utkarsh, Advocates

versus

UNION OF INDIA & ANR.

..... Respondents

Through: Mr. Ajay Digpaul, CGSC with Mr.
Kamal R. Digpaul, Advocate for UOI.
Mr. Tanveer Oberoi & Mr. Satvik
Verma, Advocates for R-2/AIIMS.
Dr. Arun Shastry, DART, Bangalore
Mr. Rajdeep Bhattacharya, Advocate
for Respondent No.5/Institute of
Child Health (M: 9163329688)

21
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WITH
W.P.(C) 1491/2021

MASTER MEDHANSH JHAWAR @ MADHAV Petitioner

Through: Mr. Vivek Chib, Mr. Rahul Malhotra
and Mr. Manas Tripathi, Advocates

versus

UNION OF INDIA & ANR.

..... Respondents

Through: Mr. Tanveer Oberoi & Mr. Satvik
Verma, Advocates for Respondent
No.2/AIIMS.

22
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WITH
W.P.(C) 1511/2021

MASTER KENIT JHAWAR @ KESHAV Petitioner

Through: Mr. Vivek Chib, Mr. Rahul Malhotra
and Mr. Manas Tripathi, Advocates

versus

UNION OF INDIA & ANR.

..... Respondents

Through: Mr. Tanveer Oberoi & Mr. Satvik

Verma, Advocates for Respondent
No.2/AIIMS

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AND
W.P.(C) 1611/2021

LAKSHYA KUMAR GOYAL, 8 YRS OLD, THROUGH HIS NEXT
FRIEND AND NATURAL FATHER SH. VIPIN
KUMAR Petitioner

Through: Mr. Ashok Aggarwal and Kumar
Utkarsh, Advocates.

versus

UNION OF INDIA & ANR. Respondents

Through: Mr. Shankar Kumar Jha, Senior Panel
Counsels (M-9811706171)
Mr. Tanveer Oberoi & Mr. Satvik
Verma, Advocates for R-2/AIIMS.

CORAM:
JUSTICE PRATHIBA M. SINGH

Prathiba M. Singh (Oral)

1. This hearing has been done through video conferencing.

CM APPL. 4332/2021 (for exemption) in WP(C) 1511/2021

2. Allowed, subject to all just exceptions. Application is disposed of.

WP(C) 10782/2020 & CM APPL. 33828/2020 (for interim direction)

WP(C) 5315/2020 & CM APPL. 19189/2020 (for interim direction)

WP(C) 322/2021 & CM APPL. 812/2021 (for interim direction)

WP(C) 1491/2021 & CM APPL. 4291/2021 (for interim direction)

WP(C) 1511/2021 & CM APPL. 4331/2021 (for interim direction)

WP(C) 1611/2021 & CM APPL. 4600/2021 (for interim direction)

3. The Court has perused the two affidavits filed by Central Drugs Standard Control Organisation (*hereinafter*, "CDSCO") and the Union of India. The Court has also heard the submissions of Dr. Shastry from Dystrophy Annihilation Research Trust, Bangalore (*hereinafter*, "DART") and on behalf of the Institute of Child Health, Kolkata.

4. Firstly, this Court is of the opinion that there ought to have been

greater effort by the Ministry of Health by engaging with M/s Sarepta Therapeutics, which was willing to provide a confidential proposal; by exploring more concrete options for crowdfunding etc. The clear stand of the Union of India appears to be that until the policy gets notified and the e-platform for crowdfunding is created, there can be no crowdfunding which can be explored. However, orally Dr. Pulkesh Singh for the Ministry of Health, Union of India, has mentioned that he has written to four organisations to arrange for funding for treatment of the said patients.

5. From the submissions made by Dr. Shastry from DART as also from the affidavit filed on behalf of CDSCO, it appears that clinical trials are already underway in India for drugs/therapies for the treatment of DMD. The details of the same are set out in the affidavit filed by CDSCO. The said affidavit and the submissions made today shows that there are various organisations and companies which are conducting clinical trials in respect of DMD therapies. The same include :-

- (i) M/s Medspace Clinical Research India Private Limited
- (ii) M/s Muscular Dystrophy Patients Welfare Society
- (iii) M/s Dystrophy Annihilation Research Trust
- (iv) Institute of Child Health, Kolkata
- (v) Nizam's Institute of Medical Sciences (non sense mutation DMD)
- (vi) Child Trust Hospital, Chennai (non sense mutation DMD)

6. In view of the fact that there are various therapies for DMD which are already being researched upon in India and there are several children suffering from these diseases, the feasibility of accelerated approval processes ought to be examined. Further, the Union of India ought to explore the confidential proposal which is being put forward by M/s Sarepta

Therapeutics for the purpose of making the therapy available for children who are suffering from DMD. In order to undertake a comprehensive assessment of the issues that have arisen and for recommending a time-line based solution, this Court constitutes the following Committee:

- (i) Chairperson - Dr. Renu Swarup, Secretary of Department of Biotechnology, Govt. of India. (secy@dbt.nic.in)
- (ii) Dr. (Prof.) Madhulika Kabra, Division of Genetics, Department of Paediatrics, AIIMS (madhulikakabra@hotmail.com)
- (iii) Dr. IC Verma Director, Centre of Medical Genetics, Sir Ganga Ram Hospital (dr_icverma@yahoo.com)
- (iv) Dr. P. Ramesh Menon, Associate Professor, Department of Paediatrics, AIIMS (M: 8800997737) (rpmiims@gmail.com)
- (v) Dr. Arun Shastry, Chief Scientific Officer, Dystrophy Annihilation Research Trust (DART) (M:9840219833) (arunshastry@dartindia.in)
- (vi) Dr. Apurba Ghosh, Director, Institute of Child Health (apurbaghosh@yahoo.com)
- (vii) Dr. Angamuthu Meena Kanikannan, Nizam's Institute of Medical Sciences (M:+914065863509) (meenaak@hotmail.com)
- (viii) Dr. V, Viswanathan, Kanchi Karnakoti, CHILDS Trust Hospital (M: 9840100072) (vishneuro@gmail.com)
- (ix) Dr. Pulkesh Kumar, Deputy Secretary, Ministry of Health and Family Welfare.

The Chairperson is free to consult or co-opt any other member or organisation, if deemed expedient, into the Committee.

7. The committee shall submit a report on the following major aspects:
 - (i) How to immediately provide treatment and therapy options to the Petitioners and similarly situated patients suffering from DMD, Hunter's syndromes and other rare diseases.
 - (ii) Steps to be taken to indigenize the development of the therapies in India, and reasonable timelines required to be followed thereof.
 - (iii) Whether accelerated approval processes can be considered especially in view of the research currently being undertaken in India for DMD?
 - (iv) Immediate concrete proposals for crowdfunding of the costs of treatment for children with rare diseases.
8. The first meeting of the Committee shall be held on 5th March, 2021 at 3.00 p.m. A report be submitted to this Court on or before 12th March, 2021.
9. Further, a specific affidavit shall be filed by the Union of India specifying the budget for health in the last five years, as also whether any part of the budget has been unused and can be used for the purpose of treatment of the Petitioners or the indigenous development of therapies for the treatment of rare diseases.
10. List this matter on 15th March, 2021.

PRATHIBA M. SINGH
JUDGE

MARCH 2, 2021/mw/Ak