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

Reserved on : 03rd October, 2024

Pronounced on: 04th October, 2024

(2)

\+ **W.P.(C) 5315/2020 & CM APPL. 19189/2020, 4237/2023**

MASTER ARNESH SHAW ..... Petitioner

Through: Mr. Rahul Malhotra & Mr. Kaustubh Punj, Advocates.
Mr. Asif Ahmed, Adv. (M: 9560995495)
Ms. Shyel Trehan, Mr. Rohan Poddar & Ms. Shivalika Rudrabatla, Advs. (M: 6370344354) **(IN ALL MATTERS)**

versus

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

Through: Mr. Saurabh Kirpal, Sr. Adv. with Mr Anish Chawla, Mr. Dhruv Chatrath & Ms. Adya Luthra, Advs. for SAREPTA. **(IN ALL MATTERS)**
Mr. Kirtiman Singh, CGSC, Mr. Waize Ali Noor & Ms. Vidhi Jain, Advs.
Mr. Swarnendu Singha, (Under Secretary, MoHFW) **(IN ALL MATTERS)**
Mr. Ripudaman Bhardwaj CGSC with Mr. Kushagra Kumar and Mr. Abhinav Bhardwaj, Advs. for UOI
Mr. Sudarshan Rajan, Mr. Hitain Bajaj and Mr. Mahesh Kumar, Advs. for R-3.
Mr. Neeraj, SPC along with Mr. Vedansh Anand (GP) and Mr. Soumyadip Chakraborty, Advs. UOI.
Mr. Tanveer Oberoi & Mr. Jaswinder Singh, Advs. for (AIIMS). (M:9958935556) & (M:9811232066) (**IN ALL MATTERS**)
Dr. Madhulika Kabra, AIIMS (appearing virtually) **(IN ALL MATTERS)**

(1) WITH

\+ **CONT.CAS(C) 415/2022 & CM APPL. 18280/2022**

MASTER MEDHANSH JHAWAR @ MADHAV THROUGH HIS NATURAL GUARDIAN ..... Petitioner

Through: Mr. Rahul Malhotra & Mr. Kaustubh Punj, Advocates.

versus

RAJESH BHUSHAN & ORS. ..... Respondent

Through: Mr. Kirtiman Singh, CGSC, Mr. Waize Ali Noor & Ms. Vidhi Jain, Advs.
Mr. Divyam Nandrajog, Adv. GNCTD with Mr. Mayank Kamra, Adv. for R-2.
Mr. Ripudaman Bhardwaj CGSC with Mr. Kushagra Kumar and Mr. Abhinav Bhardwaj, Advs. for UOI.

(3) WITH

\+ **W.P.(C) 11610/2017 & CM APPL.27637/2018**

FSMA INDIA CHARITABLE TRUST ..... Petitioner

Through: Mr. Ashok Agarwal, Mr. Kumar Utkarsh & Mr. Manoj Kumar, Advs. (M: 9811101923)

versus

UNION OF INDIA AND ANR. ..... Respondents

Through: Mr. Sameer Vashisht, ASC, GNCTD and Mr. Vanshay Kaul, Adv. for R-2.
Mr. Vijay Joshi & Ms. Kayayini Joshi, Advs. for UOI.
Mr. Anand Grover, Sr. Adv. with Mr. Varun Jain, Mr. Rohin Bhatt, Ms. Reny Chauhan, Mr. Sadeeq Ur Rahman, Advs. (M:9971540730)
Mr. Darpan Wadhwa, Sr. Adv. with Mr. Pravin Anand, Mr. Shrawan Chopra, Ms. Prachi Agrawal, Mr. Achyut Tewari, Advs. for Roche India.
Mr. Anuj Aggarwal, ASC, GNCTD with Mr. Yash Upadhyay, Mr. Siddhant Dutt, Advs. for R-2 & 4.

(4) WITH

\+ **W.P.(C) 2943/2020 & CM APPLs.10227/2020, 6633/2022, 7534/2023**

ALISHBA KHAN ..... Petitioner

Through: Mr. Rahul Malhotra & Mr. Kaustubh Punj, Advocates.

versus

UNION OF INDIA AND ORS. ..... Respondents

Through: Mr. Anuj Aggarwal, ASC with Mr. Siddhant Dutt, Adv. (M:9891363718). Mr. Kirtiman Singh, CGSC, Mr. Waize Ali Noor & Ms. Vidhi Jain, Advs.

(5) WITH

\+ **W.P.(C) 7756/2023 & CM APPL.29934/2023**

MASTER PUSPENDER THROUGH HIS NEXT FRIEND AND NATURAL FATHER SH. PAWAN KUMAR..... Petitioner

Through: Mr. Ashok Agarwal, Mr. Kumar Utkarsh & Mr. Manoj Kumar, Advs.

versus

UNION OF INDIA & ANR. ..... Respondent

Through: Mr. Kirtiman Singh, CGSC, Mr. Waize Ali Noor & Ms. Vidhi Jain, Advs.

(6) WITH

\+ **W.P.(C) 8200/2023 & CM APPL. 31454/2023**

MASTER DRASHTANT JHALA THROUGH HIS NEXT FRIEND AND NATURAL FATHER SH. JAYDEEP SINGH JHALA.. Petitioner

Through: Mr. Ashok Agarwal, Mr. Kumar Utkarsh & Mr. Manoj Kumar, Advs.

versus

UNION OF INDIA & ANR. ..... Respondent

Through: Mr. Kirtiman Singh, CGSC, Mr. Waize Ali Noor & Ms. Vidhi Jain, Advs.

(7) WITH

\+ **W.P.(C) 8947/2023 & CM APPL. 33930/2023**

DIVYANSH KARNANI THROUGH HIS NEXT FRIEND AND NATURAL FATHER SH. RAJESH KUMAR KARNANI.. Petitioner

Through: Mr. Ashok Agarwal, Mr. Kumar Utkarsh & Mr. Manoj Kumar, Advs.

versus

UNION OF INDIA & ORS. ..... Respondent

Through: Mr. Kirtiman Singh, CGSC, Mr. Waize Ali Noor & Ms. Vidhi Jain, Advs.

(8) WITH

\+ **W.P.(C) 8948/2023 & CM APPL. 33931/2023**

ARJUN SHARMA THROUGH HIS NEXT FRIEND AND NATURAL FATHER SH. SANJEEV SHARMA ..... Petitioner

Through: Mr. Ashok Agarwal, Mr. Kumar Utkarsh & Mr. Manoj Kumar, Advs.

versus

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

Through: Mr. Kirtiman Singh, CGSC, Mr. Waize Ali Noor & Ms. Vidhi Jain, Advs.

(9) WITH

\+ **W.P.(C) 8973/2023 & CM APPL. 34025/2023**

ADVIK RAYAKAWAR THROUGH HIS NEXT FRIEND AND NATURAL FATHER SH. PIYUSH RAYAKAWAR ..... Petitioner

Through: Mr. Ashok Agarwal, Mr. Kumar Utkarsh & Mr. Manoj Kumar, Advs.

versus

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

Through: Mr. Ripudaman Bhardwaj CGSC with Mr. Kushagra Kumar Adv. for UOI
Mr. Neeraj, SPC along with Mr. Vedansh Anand (GP) and Mr. Soumyadip Chakraborty, Advs. UOI.
Mr. Kirtiman Singh, CGSC, Mr. Waize Ali Noor & Ms. Vidhi Jain, Advs.

(10) WITH

\+ **W.P.(C) 8986/2023 & CM APPL. 34083/2023**

LAKSHAY AGARWAL ..... Petitioner

Through: Mr. Ashok Agarwal, Mr. Kumar Utkarsh & Mr. Manoj Kumar, Advs.

versus

UNION OF INDIA & ANR. ..... Respondent

Through: Mr Anurag Ahluwalia, CGSC with Mr Tarveen Singh Nanda & Ms. Hridyanshi Sharma, Adv. for R-1
Mr. Kirtiman Singh, CGSC, Mr. Waize Ali Noor & Ms. Vidhi Jain, Advs.

(11) WITH

\+ **W.P.(C) 8996/2023 & CM APPL. 34122/2023**

ADARSH SONI THROUGH HIS NEXT FRIEND AND NATURAL FATHER SH. VIJAY KUMAR SONI ..... Petitioner

Through: Mr. Ashok Agarwal, Mr. Kumar Utkarsh & Mr. Manoj Kumar, Advs.

versus

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

Through: Mr. Ripudaman Bhardwaj CGSC with Mr. Kushagra Kumar Adv. for UOI
Mr. Neeraj, SPC along with Mr. Vedansh Anand (GP) and Mr. Soumyadip Chakraborty, Advs. UOI.
Mr Abhishek Sharma, Miss Kritya Sinha, Mr. Pranshul Kulshreshtha, Advs. for R-5. (M: 8294621791)
Mr. Kirtiman Singh, CGSC, Mr. Waize Ali Noor & Ms. Vidhi Jain, Advs.

(12) WITH

\+ **W.P.(C) 10782/2020 & CM APPL.33828/2020**

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

Through: Mr. Ashok Agarwal, Mr. Kumar Utkarsh & Mr. Manoj Kumar, Advs.

versus

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

Through: Ms. Amrita Prakash, CGSC & Mr. Siddharth Khatana, Adv. (M: 9811132326)
Mr. Kirtiman Singh, CGSC, Mr. Waize Ali Noor & Ms. Vidhi Jain, Advs.

(13) WITH

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

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

Through: Mr. Ashok Agarwal, Mr. Kumar Utkarsh & Mr. Manoj Kumar, Advs.

versus

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

Through: Mr. Ajay Digpaul and Ms. Ishita Pathak, Mr. Kamal Digpaul with Ms. Swati Kwatra, Advocates for UOI.
Mr. Kirtiman Singh, CGSC, Mr. Waize Ali Noor & Ms. Vidhi Jain, Advs.

Ms. Arti Bansal & Ms. Akansha Kumari, Advs. for UOI.

(14) WITH

\+ **W.P.(C) 1491/2021 & CM APPLs. 4291/2021, 8671/2022**

MASTER MEDHANSH JHAWAR @ MADHAV ..... Petitioner

Through: Mr. Rahul Malhotra & Mr. Kaustubh Punj, Advocates.

versus

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

Through: Mr. Kirtiman Singh, CGSC, Mr. Waize Ali Noor & Ms. Vidhi Jain, Advs.

(15) WITH

\+ **W.P.(C) 1511/2021 & CM APPLs. 4331/2021, 8616/2022**

MASTER KENIT JHAWAR @ KESHAV ..... Petitioner

Through: Mr. Rahul Malhotra & Mr. Kaustubh Punj, Advocates.

versus

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

Through: Mr. Rishabh Sahu, CGSC with Mr Sameer Sharma, Adv. for UOI.
Mr. Kirtiman Singh, CGSC, Mr. Waize Ali Noor & Ms. Vidhi Jain, Advs.
Mr. Ghanshyam Mishra, Adv. for R-1.

(16) WITH

\+ **W.P.(C) 1611/2021 & CM APPL. 4600/2021**

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

Through: Mr. Ashok Agarwal, Mr. Kumar Utkarsh & Mr. Manoj Kumar, Advs.
Mr. Rahul Malhotra & Mr. Kaustubh Punj, Advocates

versus

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

Through: Ms. Bharathi Raju, Sr. Panel Counsel, for UOI. (M:9868895906)
Mr. Kirtiman Singh, CGSC, Mr. Waize Ali Noor & Ms. Vidhi Jain, Advs.
Mr. Anuj Aggarwal, ASC, GNCTD with Mr. Yash Upadhyay, Mr. Siddhant Dutt, Advs. for R-2.

(17) WITH

\+ **W.P.(C) 3662/2021 & CM APPLs.11103/2021, 25590/2021, 32504/2021**

PAYEL BHATTACHARYA ..... Petitioner

Through: Mr. Aditya Chatterjee and Mr. Ishaan Karki, Advocates.

versus

UNION OF INDIA & ORS. ..... Respondents

Through: Mr. Anuj Aggarwal, ASC, GNCTD, with Mr. Siddhant Dutt Advs for R-2.
Mr. Ripudaman Bhardwaj CGSC with Mr. Kushagra Kumar and Mr. Abhinav Bhardwaj, Advs. for UOI
Mr. Kirtiman Singh, CGSC, Mr. Waize Ali Noor & Ms. Vidhi Jain, Advs.

(18) WITH

\+ **W.P.(C) 3682/2021 & CM APPL.11153/2021**

HARSHIT SONI, 16 YEARS OLD, THROUGH HIS NEXT FRIEND AND NATURAL FATHER SH. TIKAM CHAND SONI ..... Petitioner

Through: Mr. Ashok Agarwal, Mr. Kumar Utkarsh & Mr. Manoj Kumar, Advs.

versus

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

Through: Mr. T.P. Singh, Sr. Central Govt. Counsel for R-1 (M:9971579687).
Mr. Kirtiman Singh, CGSC, Mr. Waize Ali Noor & Ms. Vidhi Jain, Advs.

(19) WITH

\+ **W.P.(C) 3689/2021 & CM APPL.11179/2021**

DHANANJAY BHARDWAJ, 11 YEARS OLD, THROUGH HIS NEXT FRIEND & NATURAL FATHER SH. AMIT KR. ..... Petitioner

Through: Mr. Ashok Agarwal, Mr. Kumar Utkarsh & Mr. Manoj Kumar, Advs.

versus

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

Through: Mr. Sanjeev Uniyal, Mr. Dhawal Uniyal & Mr. Rahul Kumar, Advs for R-1. (M:9560806614)
Mr. Kirtiman Singh, CGSC, Mr. Waize Ali Noor & Ms. Vidhi Jain, Advs.

(20) WITH

\+ **W.P.(C) 3706/2021 & CM APPL. 11229/2021**

KHUSHWANT BHARDWAJ, 7 YEARS OLD, THROUGH HIS NEXT FRIEND AND NATURAL FATHER SH. NIKHIL BHARDWAJ ..... Petitioner

Through: Mr. Ashok Agarwal, Mr. Kumar Utkarsh & Mr. Manoj Kumar, Advs.

versus

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

Through: Mr. Sanjib Kumar Mohanty, Sr. Panel Counsel with Ms. Anushka Jakhodia & Mr. Subesh K. Sahood, Advs. for R-1.
Mr. Kirtiman Singh, CGSC, Mr. Waize Ali Noor & Ms. Vidhi Jain, Advs.

(21) WITH

\+ **W.P. (C) 3707/2021 & CM APPL. 11230/2021**

AARAV GARG, 5 YEARS OLD, THROUGH HIS NEXT FRIEND AND NATURAL FATHER SH. VIVEK ..... Petitioner

Through: Mr. Ashok Agarwal, Mr. Kumar Utkarsh & Mr. Manoj Kumar, Advs.

versus

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

Through: Mr. Siddharth Khatana, Adv. for UOI. (M:9811132326)
Mr. Kirtiman Singh, CGSC, Mr. Waize Ali Noor & Ms. Vidhi Jain, Advs.

(22) WITH

\+ **W.P.(C) 3729/2021 & CM APPL.11269/2021**

MANISH, 8 YEARS OLD, THROUGH HIS NEXT FRIEND AND NATURAL FATHER SH. PHOOL CHAND JAT & ANR.... Petitioners

Through: Mr. Ashok Agarwal Mr. Kumar Utkarsh & Mr. Manoj Kumar, Advs.

versus

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

Through: Mr. Kirtiman Singh, CGSC, Mr. Waize Ali Noor & Ms. Vidhi Jain, Advs.
Mr. Rajkumar Yadav, Adv. for UOI.

(23) WITH

\+ **W.P.(C) 3737/2021 & CM APPL. 11277/2021**

SHOURYA MARU, 7 YEARS OLD, THROUGH HIS NEXT FRIEND & NATURAL FATHER SH. KAMAL KUMAR MARU ..... Petitioner

Through: Mr. Ashok Agarwal, Mr. Kumar Utkarsh & Mr. Manoj Kumar, Advs.

versus

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

Through: Mr. Ranvir Singh (CGSC) for R-1. (M:9818071061)
Mr. Kirtiman Singh, CGSC, Mr. Waize Ali Noor & Ms. Vidhi Jain, Advs.

(24) WITH

\+ **W.P.(C) 3859/2021 & CM APPL.11647/2021**

SIDDHARTH SWARNKAR, 9 YEARS OLD, THROUGH HIS NEXT FRIEND AND NATURAL FATHER SH. DINESH KUMAR SWARNKAR ..... Petitioner

Through: Mr. Ashok Agarwal, Mr. Kumar Utkarsh & Mr. Manoj Kumar, Advs.

versus

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

Through: Mr. Anuj Aggarwal, ASC with Mr. Yash Upadhyay, Mr. Siddhant Dutt, Advs. for GNCTD. (M:9891363718).
Mr. Kirtiman Singh, CGSC, Mr. Waize Ali Noor & Ms. Vidhi Jain, Advs.

(25) WITH

\+ **W.P.(C) 4045/2021 & CM APPL. 12213/2021**

UTKARSH INDRAJIT PAWAR, 10 YEARS OLD, THROUGH HIS NEXT FRIEND AND NATURAL FATHER SH. INDRAJIT DAMAR PAWAR ..... Petitioner

Through: Mr. Ashok Agarwal, Mr. Kumar Utkarsh & Mr. Manoj Kumar, Advs.

versus

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

Through: Mr. Sanjeev Sabharwal, Sr. Panel Counsel with Ms. Shweta, Adv.
Mr. Harish Kumar Garg and Ms. Palak Gupta, Ms. Khushboo Sharma, Advocates for UOI (M:9810150029).
Mr. Kirtiman Singh, CGSC, Mr. Waize Ali Noor & Ms. Vidhi Jain, Advs.

(26) WITH

\+ **W.P.(C) 4067/2021 & CM APPL. 12306/2021**

ANSHU, 10 YEARS OLD, THROUGH HIS NEXT FRIEND AND NATURAL FATHER SH. NARENDRA KUMAR YADAV... Petitioner

Through: Mr. Ashok Agarwal, Mr. Kumar Utkarsh & Mr. Manoj Kumar, Advs.

versus

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

Through: Mr. Kirtiman Singh, CGSC, Mr. Waize Ali Noor & Ms. Vidhi Jain, Advs.

(27) WITH

\+ **W.P.(C) 4259/2021 & CM APPL. 12948/2021**

ISHAAN, 10 YEARS OLD, THROUGH HIS NEXT FRIEND AND NATURAL FATHER SH. RAJVIR SINGH ..... Petitioner

Through: Mr. Ashok Agarwal, Mr. Kumar Utkarsh & Mr. Manoj Kumar, Advs.

versus

UNION OF INDIA & ANR. ..... Respondent

Through: Mr. Ripudam Bhardwaj, CGSC with Mr. Vinod Tiwari, Adv. for R-1 & 3.
Mr. Kirtiman Singh, CGSC, Mr. Waize Ali Noor & Ms. Vidhi Jain, Advs.

(28) WITH

\+ **W.P.(C) 4304/2021 & CM APPL. 13108/2021**

TANAV HANDOO, 6 YEARS OLD, THROUGH HIS NEXT FRIEND AND NATURAL FATHER SH. AMIT HANDOO ..... Petitioner

Through: Mr. Ashok Agarwal, Mr. Kumar Utkarsh & Mr. Manoj Kumar, Advs.

versus

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

Through: Mr. Satya Ranjan, (Sr. Panal Counsel) with Mr. Kautilya Birat, Advs for UOI.
Mr. Kirtiman Singh, CGSC, Mr. Waize Ali Noor & Ms. Vidhi Jain, Advs.

(29) WITH

\+ **W.P.(C) 4551/2021 & CM APPL. 13949/2021**

SHAURYA DAHIYA, 7 YEARS OLD, THROUGH HIS NEXT FRIEND & NATURAL FATHER SH. SATBIR DAHIYA..... Petitioner

Through: Mr. Ashok Agarwal, Mr. Kumar Utkarsh & Mr. Manoj Kumar, Advs.

versus

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

Through: Mr. Avnish Singh, SPC with Mr. Mahendra Vikram Singh & Ms. Kanchan Kumari, Advs (M:8826437138)
Mr. Kirtiman Singh, CGSC, Mr. Waize Ali Noor & Ms. Vidhi Jain, Advs.
Mr. Anurag Ahluwalia, CGSC.

(30) WITH

\+ **W.P.(C) 4812/2021 & CM APPL. 14844/2021**

NIKHIL YOGENDERSINGH CHOUDARY, 17 YEARS OLD, THROUGH HIS NEXT FRIEND AND NATURAL FATHER SH. YOGENDERSINGH P CHOUDARY ..... Petitioner

Through: Mr. Ashok Agarwal, Mr. Kumar Utkarsh & Mr. Manoj Kumar, Advs.

versus

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

Through: Mr. Ranvir Singh (CGSC) for R-1.
Mr. Kirtiman Singh, CGSC, Mr. Waize Ali Noor & Ms. Vidhi Jain, Advs.

(31) WITH

\+ **W.P.(C) 5394/2021 & CM APPL. 16683/2021**

UDAYVEER SINGH GULERIA, 7 YEARS OLD, THROUGH HIS NEXT FRIEND AND NATURAL FATHER SH. RAMESH GULERIA ..... Petitioner

Through: Mr. Ashok Agarwal, Mr. Kumar Utkarsh & Mr. Manoj Kumar, Advs.

versus

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

Through: Mr. Kirtiman Singh, CGSC, Mr. Waize Ali Noor & Ms. Vidhi Jain, Advs.

(32) WITH

\+ **W.P.(C) 5395/2021 & CM APPL. 16686/2021, 63399/2023**

MASTER AYUSHMAN CHATURVEDI ..... Petitioner

Through: Mr. Anurag Ojha, Mr. Vipul Kumar, Mr. Subham Kumar & Mr. Deepak Somani, Advs.

versus

UNION OF INDIA & ORS. ..... Respondents

Through: Mr. Niraj Kumar, Sr. CGSC with Mr. Chaityana Kumar, Adv. for UOI.
Mr. Parth Goyal, Adv. for Mr. Jawahar Raja, ASC(C) GNCTD.
Mr. Kirtiman Singh, CGSC, Mr. Waize Ali Noor & Ms. Vidhi Jain, Advs.

(33) WITH

\+ **W.P.(C) 9684/2021**

AADHYAN JAISWAL 11 YEARS OLD THROUGH HIS NEXT FRIEND AND NATURAL FATHER SH ANIL KUMAR JAISWAL ..... Petitioner

Through: Mr. Ashok Agarwal, Mr. Kumar Utkarsh & Mr. Manoj Kumar, Advs.

versus

UNION OF INDIA & ORS. ..... Respondents

Through: Mr. Divyam Nandrajog, Panel Counsel, GNCTD with Mr. Mayank Kamra, Adv. for R-2.
Mr. Kirtiman Singh, CGSC, Mr. Waize Ali Noor & Ms. Vidhi Jain, Advs.

(34) WITH

\+ **W.P.(C) 14317/2021 & CM APPLs. 45148/2021, 14521/2023**

SHREYANSH AARAV, 11 YEARS OLD, THROUGH HIS NEXT FRIEND AND NATURAL MOTHER SMT. KANCHAN KAMINI ..... Petitioner

Through: Mr. Ashok Agarwal, Mr. Kumar Utkarsh & Mr. Manoj Kumar, Advs.

versus

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

Through: Mr. Ripudaman Bhardwaj CGSC with Mr. Kushagra Kumar and Mr. Abhinav Bhardwaj, Advs. for UOI
Mr. Rajkumar Yadav, Adv. for UOI.
Mr. Kirtiman Singh, CGSC, Mr. Waize Ali Noor & Ms. Vidhi Jain, Advs.

(35) WITH

\+ **W.P.(C) 1182/2022 & CM APPL. 3442/2022**

INSHA MINOR THROUGH HER NEXT FRIEND AND NATURAL FATHER SH IRSHAD AHMAD SOFI..... Petitioner

Through: Mr. Ashok Agarwal, Mr. Kumar Utkarsh & Mr. Manoj Kumar, Advs.

versus

UNION OF INDIA & ORS. ..... Respondents

Through: Mr. Sanjeev Uniyal, Mr. Dhawal Uniyal & Mr. Rahul Kumar, Advs for R-1. (M:9560806614)

Mr. Rishikesh Kumar ASC with Mr Aditya Raj, Mr. Muhammad Zaid, Mr. Sheenu Priya, Mr. Sudhir Kumar Shukla & Mr Sumit Choudhary, Advs.

Mr. Kirtiman Singh, CGSC, Mr. Waize Ali Noor & Ms. Vidhi Jain, Advs.

(36) WITH

\+ **W.P.(C) 1054/2023 and CM APPL. 4164/2023**

MASTER TUSHAR THROUGH HIS NEXT FRIEND AND NATURAL FATHER SH. JAI PRAKASH ..... Petitioner

Through: Mr. Ashok Agarwal, Mr. Kumar Utkarsh & Mr. Manoj Kumar, Advs.

versus

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

Through: Mr. Kirtiman Singh, CGSC, Mr. Waize Ali Noor & Ms. Vidhi Jain, Advs.

Mr. Ripudaman Bhardwaj CGSC and Mr. Hardik Bedi, GP for UOI.

(37) WITH

\+ **W.P.(C) 1079/2023 and CM APPL. 4248/2023**

MASTER RUDRA PAWAR THROUGH HIS NEXT FRIEND AND NATURAL MOTHER SMT. ANU VISHNOI..... Petitioner

Through: Mr. Ashok Agarwal, Mr. Kumar Utkarsh & Mr. Manoj Kumar, Advs.

versus

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

Through: Mr. Kirtiman Singh, CGSC, Mr. Waize Ali Noor & Ms. Vidhi Jain, Advs.

Mr. Ripudaman Bhardwaj CGSC and Mr. Kushagra Kumar, Adv.

Mr. Nitinjya Chaudhry, Sr. Panel Counsel with Mr. Rahul Mourya, Adv.

for UOI.

(38) WITH

\+ **W.P.(C) 2614/2023**

KARAN, 14 YEARS OLD THROUGH HIS NEXT FRIEND AND NATURAL FATHER SH. VIJAY KUMAR ..... Petitioner

Through: Ms. Sonia Sharma, Ms. Purva Chugh & Ms. Neha Chugh, Advs. (M-9582228856)

versus

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

Through: Mr. Nitinjya Chaudhry, Sr Panel Counsel with Mr. Abhishek, GP, Mr. Rahul Mourya, Adv. (M-9810103680).
Mr. Abhishek Khanna, Adv. for R-1.
Mr. Kirtiman Singh, CGSC, Mr. Waize Ali Noor & Ms. Vidhi Jain, Advs.

(39) WITH

\+ **W.P.(C) 4495/2023 & CM APPL.17190/2023**

PARAS JAIN THROUGH HIS NEXT FRIEND AND NATURAL FATHER SH. SANDEEP JAIN ..... Petitioner

Through: Mr. Ashok Agarwal, Mr. Kumar Utkarsh & Mr. Manoj Kumar, Advs.

versus

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

Through: Mr. Raj Kumar, Advocate, SPC, UOI.
Mr. Kirtiman Singh, CGSC, Mr. Waize Ali Noor & Ms. Vidhi Jain, Advs.

(40) WITH

\+ **W.P.(C) 4502/2023 & CM APPL.17238/2023**

SHREYANSH VERMA THROUGH HIS NEXT FRIEND AND NATURAL FATHER SH. DHEERAJ KANT VERMA ..... Petitioner

Through: Mr. Ashok Agarwal, Mr. Kumar Utkarsh & Mr. Manoj Kumar, Advs.

versus

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

Through: Mr. Raj Kumar Yadav, Ms. Nitya Sharma, Ms. Jasmine Sheikh, Adv. for UOI. (M:9818836222)
Mr. Kirtiman Singh, CGSC, Mr. Waize Ali Noor & Ms. Vidhi Jain, Advs.

(41) WITH

\+ **W.P.(C) 4526/2023 & CM APPL.17321/2023**

MASTER LAKSHYAVED KALISHARAN THROUGH HIS NEXT FRIEND AND NATURAL MOTHER SHILPA RAMESH..Petitioner

Through: Mr. Ashok Agarwal, Mr. Kumar Utkarsh & Mr. Manoj Kumar, Advs.

versus

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

Through: Mr. Kirtiman Singh, CGSC, Mr. Waize Ali Noor & Ms. Vidhi Jain, Advs.
Mr. Virender Pratap Singh Charak and Ms. Shubhra Parashar Adv.s for UOI.
Ms. Shubhra Parashar, Mr. Yash Hari Dixit, Mr. Akshay Kumar, Mr. Pushpender Singh Charak, Ms. Pinky Yadav, Advs. (M: 9958458448)

(42) WITH

\+ **W.P.(C) 4535/2023 & CM APPL.17331/2023**

MASTER CHINMAY BARUPAL THROUGH
HIS NEXT FRIEND AND NATURAL
FATHER SH. ASHOK KUMAR BARUPAL ..... Petitioner

Through: Mr. Ashok Agarwal, Mr. Kumar Utkarsh & Mr. Manoj Kumar, Advs.

versus

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

Through: Mr. Kirtiman Singh, CGSC, Mr. Waize Ali Noor & Ms. Vidhi Jain, Advs.
Ms Monika Arora (CGSC) & Ms. Jyoti Tiwari, Adv. for UOI.

(43) WITH

\+ **W.P.(C) 4536/2023 & CM APPL.17333/2023**

MADHAV SHARMA THROUGH HIS NEXT FRIEND AND NATURAL FATHER SH. NEERAJ SHARMA ..... Petitioner

Through: Mr. Ashok Agarwal, Mr. Kumar Utkarsh & Mr. Manoj Kumar, Advs.

versus

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

Through: Mr. Sushil Raaja, SPC, UOI.
Mr. Kirtiman Singh, CGSC, Mr. Waize Ali Noor & Ms. Vidhi Jain, Advs.

Mr. Mukul Singh CGSC with Ms. Ira Singh, Adv. for R-1.

(44) WITH

\+ **W.P.(C) 4538/2023 & CM APPL.17337/2023**

SANDEEP KALIA ..... Petitioner

Through: Mr. Ashok Agarwal, Mr. Kumar Utkarsh & Mr. Manoj Kumar, Advs.

versus

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

Through: Mr. Kirtiman Singh, CGSC, Mr. Waize Ali Noor & Ms. Vidhi Jain, Advs.
Mr. Mukul Singh CGSC with Ms. Ira Singh, Adv. for R-1. (M: 9971359513)

(45) WITH

\+ **W.P.(C) 4539/2023 & CM APPL.17340/2023**

RAJVEER SRIVASTAVA THROUGH HIS NEXT FRIEND AND NATURAL FATHER SH. RAJESH KUMAR SRIVASTAVA ..... Petitioner

Through: Mr. Ashok Agarwal, Mr. Kumar Utkarsh & Mr. Manoj Kumar, Advs.

versus

UNION OF INDIA & ORS. ..... Respondents

Through: Mr. Kirtiman Singh, CGSC, Mr. Waize Ali Noor & Ms. Vidhi Jain, Advs.
Mr. Mukul Singh CGSC, Ms. Ira Singh, Advocate for R-1.

(46) WITH

\+ **W.P.(C) 4591/2023 & CM APPL. 17548/2023**

VANSH THROUGH HIS NEXT FRIEND AND NATURAL FATHER SH. VIPIN KUMAR ..... Petitioner

Through: Mr. Ashok Agarwal, Mr. Kumar Utkarsh & Mr. Manoj Kumar, Advs.

versus

UNION OF INDIA & ORS. ..... Respondents

Through: Mr. Kirtiman Singh, CGSC, Mr. Waize Ali Noor & Ms. Vidhi Jain, Advs.
Ms Monika Arora (CGSC), Mr. Kushal Mr. Subhrodeep Saha Mr Yash Tyagi & Mr Subhrodeep, Adv.
Mr. Mukul Singh CGSC, Ms. Ira

Singh, Advocate for R-1.

(47) WITH

+ **W.P.(C) 5102/2023 & CM APPL.19968/2023**

PRANSHU NAMDAR THROUGH HIS NEXT FRIEND AND NATURAL FATHER SH. PARIXIT NAMDHAR ..... Petitioner

Through: Mr. Ashok Agarwal, Mr. Kumar Utkarsh & Mr. Manoj Kumar, Advs.

versus

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

Through: Ms. Ritu Reniwal (SPC UOI).
Ms Prerna Dhall & Mr Ripu Dhiman, Advocates (M- 8920466138)
Mr. Kirtiman Singh, CGSC, Mr. Waize Ali Noor & Ms. Vidhi Jain, Advs.

(48) WITH

+ **W.P.(C) 5726/2023 & CM APPL. 22436/2023**

MASTER HARENDER THROUGH HIS NEXT FRIEND AND NATURAL FATHER SH. SUNDER SINGH & ANR. ..... Petitioners

Through: Mr. Ashok Agarwal, Mr. Kumar Utkarsh & Mr. Manoj Kumar, Advs.

versus

UNION OF INDIA & ORS. ..... Respondents

Through: Mr. Neeraj, SPC along with Mr. Vedansh Anand (GP) and Mr. Soumyadip Chakraborty, Advs. UOI.
Mr. Sudarshan Rajan, Mr. Hitain Bajaj and Mr. Mahesh Kumar, Advs. for R-4.
Mr. Kirtiman Singh, CGSC, Mr. Waize Ali Noor & Ms. Vidhi Jain, Advs.

(49) WITH

+ **W.P.(C) 5753/2023 & CM APPL. 22528/2023**

VINAY THROUGH HIS NEXT FRIEND AND NATURAL FATHER SH. MEHAR SINGH ..... Petitioner

Through: Mr. Ashok Agarwal, Mr. Kumar Utkarsh & Mr. Manoj Kumar, Advs.

versus

UNION OF INDIA & ORS. ..... Respondents

Through: Mr Atul Sai Krishna Sr. Panel Counsel, Mr Hardik Bedi GP. (M: 8010414123)
Mr. Kirtiman Singh, CGSC, Mr. Waize

Ali Noor & Ms. Vidhi Jain, Advs.
Mr. Sudarshan Rajan, Mr. Hitain Bajaj and Mr. Mahesh Kumar, Advs. for R-2.
Mr Atul Krishna, SPC with Mr Hardik Bedi, GP for R1

(50) WITH

\+ **W.P.(C) 6089/2023 & CM APPL. 23902/2023**

MASTER SAIANSH THROUGH HIS NEXT FRIEND AND NATURAL FATHER SH. AVTAR SINGH MALHOTRA. Petitioner

Through: Mr. Ashok Agarwal, Mr. Kumar Utkarsh & Mr. Manoj Kumar, Advs.

versus

UNION OF INDIA & ORS. ..... Respondents

Through: Mr. Kirtiman Singh, CGSC, Mr. Waize Ali Noor & Ms. Vidhi Jain, Advs.
Mr Atul Sai Krishna Senior Panel Counsel, Mr Hardik Bedi GP.

(51) WITH

\+ **W.P.(C) 7549/2023 and CM APPL. 29273/2023**

MASTER CHUNNU YADAV THROUGH HIS NEXT FRIEND AND NATURAL FATHER SH. SANJEEV KUMAR ..... Petitioner

Through: Mr. Ashok Agarwal, Mr. Kumar Utkarsh & Mr. Manoj Kumar, Advs.

versus

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

Through: Mr. Kirtiman Singh, CGSC, Mr. Waize Ali Noor & Ms. Vidhi Jain, Advs.
Mr. Ripudaman Bhardwaj CGSC with Mr. Kushagra Kumar, Mr. Abhinav Bhardwaj, Mr. Gokul Sharma (GP), Adv. (M- 9045885304)

(52) WITH

\+ **W.P.(C) 7553/2023 and CM APPL. 29299/2023**

MASTER HARSHIT PAWAR THROUGH HIS NEXT FRIEND AND NATURAL FATHER SH. PRAVEEN KUMAR ..... Petitioner

Through: Mr. Ashok Agarwal, Mr. Kumar Utkarsh & Mr. Manoj Kumar, Advs.

versus

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

Through: Mr. Ripudaman Bhardwaj CGSC with

Mr. Kushagra Kumar Adv. for UOI.
Mr. Kirtiman Singh, CGSC, Mr. Waize Ali Noor & Ms. Vidhi Jain, Advs.

(53) WITH

\+ **W.P.(C) 7644/2023 and CM APPLS. 29628-29/2023**

MASTER SATYAKI ADAK THROUGH HIS NATURAL GUARDIAN ..... Petitioner

Through: Mr. Rahul Malhotra & Mr. Kaustubh Punj, Advocate.

versus

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

Through: Mr. Ripudaman Bhardwaj, CGSC with Mr. Kushagra Kumar & Mr. Abhinav Bhardwaj, Advs. for UOI. Mr. Ankit Verma, Advocate.
Mr. Kirtiman Singh, CGSC, Mr. Waize Ali Noor & Ms. Vidhi Jain, Advs.

(54) WITH

\+ **W.P.(C) 10031/2023 and CM APPL. 38666/2023**

ADITYA KUMAR YADAV THROUGH HIS NEXT FRIEND AND NATURAL FATHER SH. PREM SHANKAR ..... Petitioner

Through: Mr. Ashok Agarwal, Mr. Kumar Utkarsh & Mr. Manoj Kumar, Advs.
Mr. Rahul Malhotra, Advocate.

versus

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

Through: Mr. Ripudaman Bhardwaj, CGSC with Mr. Kushagra Kumar, and Mr. Abhinav Bhardwaj, Advs. for UOI.

(55) WITH

\+ **W.P.(C) 10063/2023 and CM APPL. 38727/2023**

SUMIT KUMAR SINGH THROUGH HIS NEXT FRIEND AND NATURAL FATHER SH. AMARJIT SINGH..... Petitioner

Through: Mr. Ashok Agarwal & Mr. Manoj Kumar, Advs.

versus

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

Through: Mr. Kirtiman Singh, CGSC, Mr. Waize Ali Noor & Ms. Vidhi Jain, Advs.
Mr. Ripudaman Bhardwaj CGSC with

Mr. Kushagra Kumar, Mr Vedansh Anand, Advs. for UOI.
Mr. Neeraj, SPC along with Mr. Vedansh Anand (GP) and Mr. Soumyadip Chakraborty, Advs. UOI.

(56) WITH

\+ **W.P.(C) 10064/2023 and CM APPL. 38728/2023**

ADITYA SONI THROUGH HIS NEXT FRIEND AND NATURAL FATHER SH. MUKESH KUMAR SONI ..... Petitioner

Through: Mr. Ashok Agarwal, Mr. Kumar Utkarsh & Mr. Manoj Kumar, Advs.

versus

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

Through: Mr. Kirtiman Singh, CGSC, Mr. Waize Ali Noor & Ms. Vidhi Jain, Advs.
Mr. Ripudaman Bhardwaj, CGSC with Mr. Kushagra Kumar, and Mr. Abhinav Bhardwaj, Advs. for UOI.

(57) WITH

\+ **W.P.(C) 10606/2023 & CM APPL. 41165/2023**

UMANAND KUMAR SONI THROUGH HIS NEXT FRIEND AND NATURAL GRANDFATHER SH. NANDU PRASAD SONI ..... Petitioner

Through: Mr. Ashok Agarwal, Mr. Kumar Utkarsh & Mr. Manoj Kumar, Advs.

versus

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

Through: Mr. Vineet Dhanda, CGSC
Mr. Kirtiman Singh, CGSC, Mr. Waize Ali Noor & Ms. Vidhi Jain, Advs.

(58) WITH

\+ **W.P.(C) 10867/2023 & CM APPL. 42110/2023**

PARTH KAMBOJ THROUGH HIS NEXT FRIEND AND NATURAL FATHER SH. PARDEEP KUMAR ..... Petitioner

Through: Mr. Ashok Agarwal, Mr. Kumar Utkarsh & Mr. Manoj Kumar, Advs.

versus

UNION OF INDIA & ANR. ..... Respondent

Through: Mr. Kirtiman Singh, CGSC, Mr. Waize Ali Noor & Ms. Vidhi Jain, Advs.

(59) WITH

\+ **W.P.(C) 10870/2023 & CM APPL. 42114/2023**

PARV INSAN THROUGH HIS NEXT FRIEND AND NATURAL FATHER SH. WAZIR SINGH ..... Petitioner

Through: Mr. Ashok Agarwal, Mr. Kumar Utkarsh & Mr. Manoj Kumar, Advs.

versus

UNION OF INDIA & ANR. ..... Respondent

Through: Mr. Kirtiman Singh, CGSC, Mr. Waize Ali Noor & Ms. Vidhi Jain, Advs.

(60) WITH

\+ **W.P.(C) 12222/2023 & CM APPL. 48011/2023**

SAKSHAM JANGLA THROUGH HIS NEXT FRIEND AND NATURAL FATHER SH. PARVEEN KUMAR ..... Petitioner

Through: Mr. Ashok Agarwal, Mr. Kumar Utkarsh & Mr. Manoj Kumar, Advs.

versus

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

Through: Mr. Kirtiman Singh, CGSC, Mr. Waize Ali Noor & Ms. Vidhi Jain, Advs.

(61) WITH

\+ **W.P.(C) 13172/2023 & CM APPL. 52098/2023**

TANUJ THROUGH HIS NEXT FRIEND AND NATURAL FATHER MR. SUDHIR KUMAR & ANR. ..... Petitioners

Through: Mr. Ashok Agarwal, Mr. Kumar Utkarsh & Mr. Manoj Kumar, Advs.

versus

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

Through: Mr. Kirtiman Singh, CGSC, Mr. Waize Ali Noor & Ms. Vidhi Jain, Advs.

(62) WITH

\+ **W.P.(C) 13173/2023 & CM APPL. 52099/2023**

AMAN MEENA THROUGH HIS NEXT FRIEND AND NATURAL FATHER SH. SAMAY SINGH MEENA ..... Petitioner

Through: Mr. Ashok Agarwal, Mr. Kumar Utkarsh & Mr. Manoj Kumar, Advs.

versus

UNION OF INDIA & ANR. ..... Respondent

Through: Mr. Ripudaman Bhardwaj CGSC and Mr. Kushagra Kumar, Ms. Manaswini

Kondepudi, Advs. for UOI.
Mr. Kirtiman Singh, CGSC, Mr. Waize Ali Noor & Ms. Vidhi Jain, Advs.

(63) WITH

\+ **W.P.(C) 13174/2023 & CM APPL. 52100/2023**

HARSHIT RAJPUT THROUGH HIS NEXT FRIEND AND NATURAL MOTHER SMT. MEENA RAJPUT ..... Petitioner
Through: Mr. Ashok Agarwal, Mr. Kumar Utkarsh & Mr. Manoj Kumar, Advs.

versus

UNION OF INDIA & ANR. ..... Respondents
Through: Mr. Kirtiman Singh, CGSC, Mr. Waize Ali Noor & Ms. Vidhi Jain, Advs.

(64) WITH

\+ **W.P.(C) 13175/2023 & CM APPL. 52102/2023**

PARMARTH KAPOOR THROUGH HIS NEXT FRIEND AND NATURAL MOTHER MS. SURABHI BHARDWAJ..... Petitioner
Through: Mr. Ashok Agarwal, Mr. Kumar Utkarsh & Mr. Manoj Kumar, Advs.

versus

UNION OF INDIA & ANR. ..... Respondents
Through: Mr. Kirtiman Singh, CGSC, Mr. Waize Ali Noor & Ms. Vidhi Jain, Advs.

(65) WITH

\+ **W.P.(C) 13179/2023 & CM APPL. 52133/2023**

MANVIK KHANGWAL THROUGH HIS NEXT FRIEND AND NATURAL FATHER SH. PARVEEN KUMAR ..... Petitioner
Through: Mr. Ashok Agarwal, Mr. Kumar Utkarsh & Mr. Manoj Kumar, Advs.

versus

UNION OF INDIA & ANR. ..... Respondents
Through: Mr. Kirtiman Singh, CGSC, Mr. Waize Ali Noor & Ms. Vidhi Jain, Advs.

(66) WITH

\+ **W.P.(C) 13180/2023 & CM APPL. 52134/2023**

GAURAV KAPOOR ..... Petitioner
Through: Mr. Ashok Agarwal, Mr. Kumar Utkarsh & Mr. Manoj Kumar, Advs.

versus

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

Through: Mr. Ripudaman Bhardwaj CGSC with Mr. Kushagra Kumar Adv. for UOI

(67) WITH

\+ **W.P.(C) 13186/2023 & CM APPL. 52141/2023**

SOUMYA MISHRA THROUGH HIS NEXT FRIEND & NATURAL FATHER SH. VINOD KUMAR MISHRA ..... Petitioner

Through: Mr. Ashok Agarwal, Mr. Kumar Utkarsh & Mr. Manoj Kumar, Advs.

versus

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

Through: Mr. Kirtiman Singh, CGSC, Mr. Waize Ali Noor & Ms. Vidhi Jain, Advs.

(68) WITH

\+ **W.P.(C) 13187/2023 & CM APPL. 52142/2023**

SUMIT VERMA THROUGH HIS NEXT FRIEND AND NATURAL MOTHER SMT. KRISHNA DEVI ..... Petitioner

Through: Mr. Ashok Agarwal, Mr. Kumar Utkarsh & Mr. Manoj Kumar, Advs.

versus

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

Through: Mr. Kirtiman Singh, CGSC, Mr. Waize Ali Noor & Ms. Vidhi Jain, Advs.

(69) WITH

\+ **W.P.(C) 13188/2023 & CM APPL. 52145/2023**

VIKASH MEENA ..... Petitioner

Through: Mr. Ashok Agarwal, Mr. Kumar Utkarsh & Mr. Manoj Kumar, Advs.

versus

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

Through: Mr. Kirtiman Singh, CGSC, Mr. Waize Ali Noor & Ms. Vidhi Jain, Advs.

(70) WITH

\+ **W.P.(C) 13190/2023 & CM APPL. 52148/2023**

REHAN THROUGH HIS NEXT FRIEND AND NATURAL FATHER SH. VINAY KAMAL ..... Petitioner

Through: Mr. Ashok Agarwal, Mr. Kumar Utkarsh & Mr. Manoj Kumar, Advs.

versus

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

Through: Mr. Ripudaman Bhardwaj CGSC with

Mr. Kushagra Kumar Adv. for UOI.
Mr. Kirtiman Singh, CGSC, Mr. Waize Ali Noor & Ms. Vidhi Jain, Advs.

(71) WITH

\+ **W.P.(C) 13191/2023 & CM APPL. 52149/2023**

YASH THROUGH HIS NEXT FRIEND AND NATURAL FATHER SH. MONU ..... Petitioner

Through: Mr. Ashok Agarwal, Mr. Kumar Utkarsh & Mr. Manoj Kumar, Advs.

versus

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

Through: Mr. Ripudaman Bhardwaj CGSC with Mr. Kushagra Kumar Adv. for UOI
Mr. Kirtiman Singh, CGSC, Mr. Waize Ali Noor & Ms. Vidhi Jain, Advs.

(72) WITH

\+ **W.P.(C) 13192/2023 & CM APPL. 52152/2023**

AARUSH PRITHWANI THROUGH HIS NEXT FRIEND AND NATURAL FATHER SH. BHISHAM PRITHWANI ..... Petitioner

Through: Mr. Ashok Agarwal, Mr. Kumar Utkarsh & Mr. Manoj Kumar, Advs.

versus

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

Through: Mr. Ripudaman Bhardwaj CGSC with Mr. Kushagra Kumar Adv. for UOI.
Mr. Kirtiman Singh, CGSC, Mr. Waize Ali Noor & Ms. Vidhi Jain, Advs.

(73) WITH

\+ **W.P.(C) 13193/2023 & CM APPL. 52153/2023**

MANAV PALSANIA THROUGH HIS NEXT FRIEND AND NATURAL FATHER SH. AJAY KUMAR PALSANIA..... Petitioner

Through: Mr. Ashok Agarwal, Mr. Kumar Utkarsh & Mr. Manoj Kumar, Advs.

versus

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

Through: Mr. Ripudaman Bhardwaj CGSC with Mr. Kushagra Kumar Adv. for UOI
Mr. Kirtiman Singh, CGSC, Mr. Waize Ali Noor & Ms. Vidhi Jain, Advs.
Mr. N. Ganpathy, Sr. Advocate & Mr.

Manpreet Lamba, Adv. for R-2.

(74) WITH

\+ **W.P.(C) 13196/2023 & CM APPL. 52158/2023**

HIMANSHU SHARAMA THROUGH HIS NEXT FRIEND AND NATURAL FATHER SH. VISHAL SHARAMA ..... Petitioner

Through: Mr. Ashok Agarwal, Mr. Kumar Utkarsh & Mr. Manoj Kumar, Advs.

versus

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

Through: Mr. Ripudaman Bhardwaj CGSC with Mr. Kushagra Kumar Adv. for UOI
Mr. Kirtiman Singh, CGSC, Mr. Waize Ali Noor & Ms. Vidhi Jain, Advs.

(75) WITH

\+ **W.P.(C) 13197/2023 & CM APPL. 52159/2023**

MRADUL MISHRA ..... Petitioner

Through: Mr. Ashok Agarwal, Mr. Kumar Utkarsh & Mr. Manoj Kumar, Advs.

versus

UNION OF INDIA & ANR. ..... Respondent

Through: Mr. Kirtiman Singh, CGSC, Mr. Waize Ali Noor & Ms. Vidhi Jain, Advs.

(76) WITH

\+ **W.P.(C) 13236/2023 & CM APPL. 52311/2023**

YASH RAJ SINGH THROUGH HIS NEXT FRIEND AND NATURAL FATHER SH. DHARMENDER SINGH ..... Petitioner

Through: Mr. Ashok Agarwal, Mr. Kumar Utkarsh & Mr. Manoj Kumar, Advs.

versus

UNION OF INDIA & ANR. ..... Respondent

Through: Mr. Ripudaman Bhardwaj CGSC with Mr. Kushagra Kumar Adv. for UOI
Mr. Kirtiman Singh, CGSC, Mr. Waize Ali Noor & Ms. Vidhi Jain, Advs.

(77) WITH

\+ **W.P.(C) 13237/2023 & CM APPL. 52314/2023**

PARMEET SINGH THROUGH HIS NEXT FRIEND AND NATURAL FATHER SH. KULDEEP SINGH ..... Petitioner

Through: Mr. Ashok Agarwal, Mr. Kumar Utkarsh & Mr. Manoj Kumar, Advs.

versus

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

Through: Mr. Kirtiman Singh, CGSC, Mr. Waize Ali Noor & Ms. Vidhi Jain, Advs.

(78) WITH

\+ **W.P.(C) 13239/2023 & CM APPL. 52319/2023**

MOHIT THROUGH HIS NEXT FRIEND AND NATURAL FATHER SH. SURENDER SINGH ..... Petitioner

Through: Mr. Ashok Agarwal, Mr. Kumar Utkarsh & Mr. Manoj Kumar, Advs.

versus

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

Through: Mr. Kirtiman Singh, CGSC, Mr. Waize Ali Noor & Ms. Vidhi Jain, Advs.

(79) WITH

\+ **W.P.(C) 13240/2023 & CM APPL. 52321/2023**

MOHAMMAD ARSHAD THROUGH HIS NEXT FRIEND AND NATURAL FATHER SH. MOHAMMAD HANIF ..... Petitioner

Through: Mr. Ashok Agarwal, Mr. Kumar Utkarsh & Mr. Manoj Kumar, Advs.

versus

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

Through: Mr. Kirtiman Singh, CGSC, Mr. Waize Ali Noor & Ms. Vidhi Jain, Advs.

(80) WITH

\+ **W.P.(C) 13259/2023 & CM APPL. 52378/2023**

SAHIL THROUGH HIS NEXT FRIEND AND NATURAL FATHER SH. MAHESH YADAV ..... Petitioner

Through: Mr. Ashok Agarwal, Mr. Kumar Utkarsh & Mr. Manoj Kumar, Advs.

versus

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

Through: Mr. Kirtiman Singh, CGSC, Mr. Waize Ali Noor & Ms. Vidhi Jain, Advs.

(81) WITH

\+ **W.P.(C) 13260/2023 & CM APPL. 52379/2023**

VISHWAS GOYAL THROUGH HIS NEXT FRIEND AND NATURAL FATHER SH. MANGLESH GOYAL ..... Petitioner

Through: Mr. Ashok Agarwal, Mr. Kumar Utkarsh & Mr. Manoj Kumar, Advs.

versus

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

Through: Mr. Ripudaman Bhardwaj CGSC with Mr. Kushagra Kumar Adv. for UOI.

(82) WITH

\+ **W.P.(C) 13304/2023 & CM APPL. 52496/2023**

VIHAAN GUPTA THROUGH HIS NEXT FRIEND AND NATURAL FATHER SH. GAURAV KUMAR ..... Petitioner

Through: Mr. Ashok Agarwal, Mr. Kumar Utkarsh & Mr. Manoj Kumar, Advs.

versus

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

Through: Mr. Kirtiman Singh, CGSC, Mr. Waize Ali Noor & Ms. Vidhi Jain, Advs.

(83) WITH

\+ **W.P.(C) 13379/2023 & CM APPL. 52805/2023**

SAMEER LAMBA THROUGH HIS NEXT FRIEND AND NATURAL FATHER SH. HANSRAJ ..... Petitioner

Through: Mr. Ashok Agarwal, Mr. Kumar Utkarsh & Mr. Manoj Kumar, Advs.

versus

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

Through: Mr. Kirtiman Singh, CGSC, Mr. Waize Ali Noor & Ms. Vidhi Jain, Advs.

(84) WITH

\+ **W.P.(C) 13389/2023 & CM APPL. 52855/2023**

SALMAN KHAN THROUGH HIS NEXT FRIEND AND NATURAL FATHER SH. HUSAIN ALI ..... Petitioner

Through: Mr. Ashok Agarwal, Mr. Kumar Utkarsh & Mr. Manoj Kumar, Advs.

versus

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

Through: Mr. Shubham Prasad, G.P. for UOI.
Mr. Kirtiman Singh, CGSC, Mr. Waize Ali Noor & Ms. Vidhi Jain, Advs.

(85) WITH

\+ **W.P.(C) 13417/2023 & CM APPL. 53006/2023**

HENIL PATEL THROUGH HIS NEXT FRIEND AND NATURAL FATHER SH. PANKAJ KUMAR PATEL ..... Petitioner

Through: Mr. Ashok Agarwal, Mr. Kumar

Utkarsh & Mr. Manoj Kumar, Advs.

versus

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

Through: Mr. Ripudaman Bhardwaj CGSC with Mr. Kushagra Kumar, Adv. & Mr. Shubham Prasad, G.P. for UOI.

(86) WITH

\+ **W.P.(C) 13449/2023 & CM APPL. 53114/2023**

HENILKUMAR PRAJAPATI THROUGH HIS NEXT FRIEND & NATURAL FATHER SH. KANAIYALAL PRAJAPATI ... Petitioner

Through: Mr. Ashok Agarwal, Mr. Kumar Utkarsh & Mr. Manoj Kumar, Advs.

versus

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

Through: Mr. Shashank Garg, CGSC with Mr. Vanshul Pali, Adv. (M: 9711552649)

(87) WITH

\+ **W.P.(C) 13453/2023 & CM APPL. 53123/2023**

TIRTH RAVI KHAIRNAR THROUGH HIS NEXT FRIEND AND NATURALFATHER SH. KHAINAR RAVI BHAI..... Petitioners

Through: Mr. Ashok Agarwal, Mr. Kumar Utkarsh & Mr. Manoj Kumar, Advs.

versus

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

Through: Mr. Kirtiman Singh, CGSC, Mr. Waize Ali Noor & Ms. Vidhi Jain, Advs.

(88) WITH

\+ **W.P.(C) 13456/2023 & CM APPL. 53134/2023**

RUDRA KIRTI KUMAR PATEL THROUGH HIS NEXT FRIEND AND NATURALFATHER SH. KIRTI KUMAR HIRABHAI PATEL ..... Petitioners

Through: Mr. Ashok Agarwal, Mr. Kumar Utkarsh & Mr. Manoj Kumar, Advs.

versus

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

Through: Mr. Kirtiman Singh, CGSC, Mr. Waize Ali Noor & Ms. Vidhi Jain, Advs.

(89) WITH

\+ **W.P.(C) 13469/2023 & CM APPL. 53236/2023**

JEET GOSAI THROUGH HIS NEXT FRIEND AND NATURAL

FATHER SH. PRAGNESHGIRI PRAVINGIRI GOSAI.... Petitioners

Through: Mr. Ashok Agarwal, Mr. Kumar Utkarsh & Mr. Manoj Kumar, Advs.

versus

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

Through: Mr. Kirtiman Singh, CGSC, Mr. Waize Ali Noor & Ms. Vidhi Jain, Advs.

(90) WITH

\+ **W.P.(C) 13475/2023**

ANUJ KUMAR ..... Petitioners

Through: Mr. Ashok Agarwal, Mr. Kumar Utkarsh & Mr. Manoj Kumar, Advs.

versus

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

Through: Mr. Kirtiman Singh, CGSC, Mr. Waize Ali Noor & Ms. Vidhi Jain, Advs.
Mr. Shashank Garg, CGSC with Mr. Vanshul Pali & Ms Seema Singh, Advs. for UOI. (M: 8588871365)

(91) WITH

\+ **W.P.(C) 14141/2023 & CM APPL. 55947/2023**

TAKSH KAUSHIK THROUGH HIS NEXT FRIEND AND NATURAL FATHER SH VED PRAKASH ..... Petitioner

Through: Mr. Ashok Agarwal, Mr. Kumar Utkarsh & Mr. Manoj Kumar, Advs.

versus

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

Through: Mr. Neeraj, SPC along with Mr. Vedansh Anand and Mr. Mahesh Kumar Rathore, Advs. UOI.

(92) WITH

\+ **W.P.(C) 15263/2023 & CM APPL. 61134/2023**

MOHAMMAD AYAAN SHEIKH THROUGH HIS NEXT FRIEND AND NATURAL MOTHER MRS. AYESHA SHEIKH..... Petitioner

Through: Mr. Ashok Agarwal, Mr. Kumar Utkarsh & Mr. Manoj Kumar, Advs.

versus

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

Through: Mr. Kirtiman Singh, CGSC, Mr. Waize Ali Noor & Ms. Vidhi Jain, Advs.

(93) WITH

+ **W.P.(C) 15301/2023 & CM APPL. 61316/2023**

SHRESHTH SHARMA THROUGH HIS NEXT FRIEND AND NATURAL FATHER SH. DHEERAJ SHARMA ..... Petitioner

Through: Mr. Ashok Agarwal, Mr. Kumar Utkarsh & Mr. Manoj Kumar, Advs.

versus

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

Through: Mr. Ripudaman Bhardwaj CGSC with Mr. Kushagra Kumar Adv. for UOI.

(94) WITH

+ **W.P.(C) 15302/2023 & CM APPL. 61317/2023**

SHIVAM THROUGH HIS NEXT FRIEND AND NATURAL MOTHER SMT. SWATI LOHIA ..... Petitioner

Through: Mr. Ashok Agarwal, Mr. Kumar Utkarsh & Mr. Manoj Kumar, Advs.

versus

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

Through: Mr. Ripudaman Bhardwaj CGSC with Mr. Kushagra Kumar Adv. for UOI.

(95) WITH

+ **W.P.(C) 15315/2023 & CM APPL. 61386/2023**

NIKUNJ GUPTA THROUGH HIS NEXT FRIEND AND NATURAL FATHER SH. ASHWANI GUPTA ..... Petitioner

Through: Mr. Ashok Agarwal, Mr. Kumar Utkarsh & Mr. Manoj Kumar, Advs.

versus

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

Through: Mr. Ripudaman Bhardwaj CGSC with Mr. Kushagra Kumar Adv. for UOI.

(96) WITH

+ **W.P.(C) 15334/2023 & CM APPL. 61502/2023**

DEVANSH AGARWAL THROUGH HIS NEXT FRIEND AND NATURAL FATHER SH. CHANDRAPRAKASH AGARWAL ..... Petitioner

Through: Mr. Ashok Agarwal, Mr. Kumar Utkarsh & Mr. Manoj Kumar, Advs.

versus

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

Through: Mr. Ripudaman Bhardwaj & Mr.

Anurag Ahluwalia, CGSCs with Mr. Kushagra Kumar Adv. for UOI.

(97) WITH

+ **W.P.(C) 15336/2023 & CM APPL. 61505/2023**

RAHUL ..... Petitioner

Through: Mr. Ashok Agarwal, Mr. Kumar Utkarsh & Mr. Manoj Kumar, Advs.

versus

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

Through: Mr Anurag Ahluwalia, CGSC with Mr Tarveen Singh Nanda & Ms. Hridyanshi Sharma, Adv. for R-1
Mr. Ripudaman Bhardwaj CGSC, Mr. Kushagra Kumar, Adv. Ms. Purva Chugh & Ms. Pooja Arora, Advs.

(98) WITH

+ **W.P.(C) 15618/2023 & CM APPL. 62576/2023**

KULDEEP SINGH NARUKA & ANR. ..... Petitioners

Through: Mr. Ashok Agarwal, Mr. Kumar Utkarsh & Mr. Manoj Kumar, Advs.

versus

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

Through: Ms. Pratima N Lakra CGSC with Vanya Bajaj, Advs. (M. 9968324260)

(99) WITH

+ **W.P.(C) 15639/2023 & CM APPL. 62620/2023**

KARAN SONI THROUGH HIS NEXT FRIEND AND NATURAL FATHER SH. JUGAL KISHOR SONI AND ANR ..... Petitioners

Through: Mr. Ashok Agarwal, Mr. Kumar Utkarsh & Mr. Manoj Kumar, Advs.

versus

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

Through: Mr. Ripudaman Bhardwaj CGSC with Mr. Kushagra Kumar Adv. for UOI.
Ms. Pratima N Lakra CGSC with Ms Kashish G Baweja, Advocate.

(100) WITH

+ **W.P.(C) 14150/2023 & CM APPL. 55962/2023**

TANVEER SHARMA THROUGH HIS NEXT FRIEND AND NATURAL FATHER SH. DEEPAK SHARMA ..... Petitioners

Through: Mr. Ashok Agarwal, Mr. Kumar Utkarsh & Mr. Manoj Kumar, Advs.

versus

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

Through: Mr Vedansh Anand, Adv. for UOI.
Mr. Ripudaman Bhardwaj CGSC with Mr. Kushagra Kumar Adv. for UOI.
Mr. Neeraj, SPC along with Mr. Vedansh Anand (GP) and Mr. Soumyadip Chakraborty, Advs. UOI.

(101) WITH

\+ **W.P.(C) 16267/2023 & CM APPL. 65509/2023**

PRINCE PAREEK THROUGH HIS NEXT FRIEND AND NATURAL FATHER SH. PANKAJ PAREEK ..... Petitioners

Through: Mr. Ashok Agarwal, Mr. Kumar Utkarsh & Mr. Manoj Kumar, Advs.

versus

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

Through: Mr. Kirtiman Singh, CGSC, Mr. Waize Ali Noor & Ms. Vidhi Jain, Advs.

(102) WITH

\+ **W.P.(C) 16361/2023 & CM APPL. 65805/2023**

SARANSH KUMAR THROUGH HIS NEXT FRIEND & NATURAL FATHER SH. SATISH KUMAR MANDAL ..... Petitioners

Through: Mr. Ashok Agarwal, Mr. Kumar Utkarsh & Mr. Manoj Kumar, Advs.

versus

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

Through: Mr. Kirtiman Singh, CGSC, Mr. Waize Ali Noor & Ms. Vidhi Jain, Advs.

(103) WITH

\+ **W.P.(C) 55/2024 & CM APPL. 187/2024**

BUSHRA KHAN THROUGH HER NEXT FRIEND AND NATURAL FATHER SH. ASHRAT ALI KHAN ..... Petitioner

Through: Mr. Ashok Agarwal, Mr. Kumar Utkarsh & Mr. Manoj Kumar, Advs.

versus

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

Through: Mr. Kirtiman Singh, CGSC, Mr. Waize Ali Noor & Ms. Vidhi Jain, Advs.

(104) WITH

\+ **W.P.(C) 436/2024 & CM APPL. 2013/2024**

VIKASH KUMAR THROUGH HIS NEXT FRIEND AND NATURAL FATHER SH. SANDEEP ..... Petitioner

Through: Mr. Ashok Agarwal, Mr. Kumar Utkarsh & Mr. Manoj Kumar, Advs.

versus

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

Through: Mr. Ripudaman Bhardwaj CGSC with Mr. Kushagra Kumar Adv. for UOI

(105) AND

\+ **W.P.(C) 479/2024 & CM APPL. 2128/2024**

PARTH SAH THROUGH HIS NEXT FRIEND AND NATURAL FATHER SH. RAMANAND ..... Petitioner

Through: Mr. Ashok Agarwal, Mr. Kumar Utkarsh & Mr. Manoj Kumar, Advs.

versus

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

Through: Mr. Kirtiman Singh, CGSC, Mr. Waize Ali Noor & Ms. Vidhi Jain, Advs.

CORAM:
JUSTICE PRATHIBA M. SINGH

JUDGMENT

Prathiba M. Singh, J.

1. This hearing has been done through hybrid mode.

Table of Contents

INTRODUCTION TO RARE DISEASES

2. The present batch of petitions have been filed by the Petitioners who are mostly children suffering from rare diseases. These matters have been heard by the Court from time to time since 2020 and various directions have been issued for enabling treatment and making medicines available to the Petitioners.

3. It is the case of the Petitioners that the medicines and therapies for all these Rare Diseases are exorbitantly expensive, and directions ought to be issued to the Respondents i.e., the Union of India and its Ministry of Health and Family Welfare, All India Institute of Medical Science (*hereinafter, 'AIIMS'*), as well as the GNCTD, to provide continuous and uninterrupted treatment to the Petitioners, free of cost.

Summary of the Petitioners' and their ailments

S.No.	***Writ Petition No.***	***Patient Name***	***Age***	***Disease***
1.	***Master Arnesh Shaw v. Union of India & Ors. WP(C) No. 5315/2020***	Arnesh Shaw	7	DMD
2.	***Aviraj Garg v. Union of India & Anr. WP(C) No. 10782/2020***	Aviraj Garg	4	DMD
3.	***Keshav Sharma v. Union of India & Anr., WP(C) No. 322/2021***	Keshav Sharma	12	DMD
4.	***Lakshya Kumar Goyal v. Union of India & Anr., WP(C) No. 1611/2021***	Lakshya Kumar Goyal	8	DMD
5.	***Harshit Soni v. Union of India & Anr., WP(C) No. 3682/2021***	Harshit Soni	16	DMD
6.	***Dhananjay Bhardwaj v. Union of India & Anr., WP(C) No. 3689/2021***	Dhananjay Bhardwaj	11	DMD

7.	***Khushwant Bhardwaj v. Union of India & Anr., WP(C) No. 3706/2021***	Khushwant Bhardwaj	7	DMD
8.	***Aarav Garg v. Union of India & Anr.,WP(C) No. 3707/2021***	Aarav Garg	5	DMD
9.	***Manish v. Union of India & Anr., WP(C) No. 3729/2021***	Manish, Chirag	6	DMD
10.	***Shourya Maru v. Union of India & Anr., WP(C) No. 3737/2021***	Shourya Maru	7	DMD
11.	***Siddharth Swarnkar v. Union of India & Anr., WP(C) No. 3859/2021***	Siddharth Swarnkar	9	DMD
12.	***Utkarsh Indrajit Pawar v. Union of India & Anr., WP(C) No. 4045/2021***	Utkarsh Indrajit Pawar	10	DMD
13.	***Anshu v. Union of India & Anr., WP(C) No.4067/2021***	Anshu	10	DMD
14.	***Ishaan v. Union of India & Anr., WP(C) No. 4259/2021***	Ishaan	10	DMD
15.	***Tanav Handoo v. Union of India & Anr., WP(C) No. 4304/2021***	Tanav Handoo	6	DMD
16.	***Shaurya Dahiya v. Union of India & Anr., WP(C) No.4551/2021***	Shaurya Dahiya	7	DMD
17.	***Nikhil Yogendersingh Choudary v. Union of India & Anr., WP(C) No.4812/2021***	Nikhil Yogendersingh Choudary	17	DMD
18.	***Udayveer Singh Guleria DMD v. Union of India & Anr., WP(C) No. 5394/2021***	Udayveer Singh Guleria	7	DMD
19.	***Ayushman Chaturvedi v. Union of India & Anr., WP(C) No. 5395/2021***	Ayushman Chaturvedi	6	DMD
20.	***Shreyansh Aarav v. WP(C) No. 14317/2021***	Shreyansh Aarav	11	DMD
21.	***Master Tushar v. Union of***	Master Tushar	9	DMD

	India & Anr., WP(C) No. 1054/2023			
22.	***Madhav Sharma v. Union of India & Anr., WP(C) No. 4536/2023***	Madhav Sharma	3	DMD
23.	***Paras Jain v. Union of India & Anr., WP(C) No. 4495/2023***	Paras Jain	17	DMD
24.	***Rajveer Srivastava v. Union of India & Anr., WP(C) No. 4539/2023***	Rajveer Srivastava	15	DMD
25.	***Vansh v. Union of India & Anr., WP(C) No. 4591/2023***	Vansh	12	DMD
26.	***Master Chinmay Barupal v. Union of India & Anr., WP(C) No. 4535/2023***	Master Chinmay	13	DMD
27.	***Lakshyaved Kalisharan v. Union of India & Anr., WP(C) No. 4526/2023***	Lakshyaved Kalisharan	8	DMD
28.	***Sandeep Kalia v. Union of India & Anr., WP(C) No. 4538/2023***	Sankalp Kalia	27	DMD
29.	***Shreyansh Verma v. Union of India & Anr., WP(C) No. 4502/2023***	Shreyansh Verma	19	DMD
30.	***Rudra Pawar v. Union of India & Anr., WP(C) No. 1079/2023***	Rudra Pawar	14	DMD
31.	***Vinay v. Union of India & Anr., WP(C) No. 5753/2023***	Vinay	12	DMD
32.	***Harender v. Union of India & Anr., WP(C) No. 5726/2023***	Harender Virender	12	DMD
33.	***Pranshu Namdar v. Union of India & Anr., WP(C) No. 5102/2023***	Pranshu Namdar	14	DMD
34.	***Master Karan v. Union of India & Anr., WP(C) No.***	Master Karan	14	DMD

	2614/2023			
35.	***Master Chunnu Yadav v. Union of India & Anr., WP(C) No. 7549/2023***	Master Chunnu Yadav	7	DMD
36.	***Master Harshit Pawar v. Union of India & Anr., WP(C) No. 7553/2023***	Master Harshit Pawar	10	DMD
37.	***Master Satyaki Adak v. Union of India & Anr., WP(C) No. 7644/2023***	Master Satyaki Adak	13	DMD
38.	***Puspender v. Union of India & Anr., WP(C) No. 7756/2023***	Puspender	4	DMD
39.	***Drashtant Jhala v. Union of India & Anr., WP(C) No. 8200/2023***	Drashtant Jhala	15	DMD
40.	***Divyansh Karnani v. Union of India & Anr., WP(C) No. 8947/2023***	Divyansh Karnani	18	DMD
41.	***Arjun Sharma v. Union of India & Anr., WP(C) No. 8948/2023***	Arjun Sharma	13	DMD
42.	***Advik Rayakawar v. Union of India & Anr., WP(C) No. 8973/2023***	Advik Rayakawar	10	DMD
43.	***Adarsh Soni v. Union of India & Anr., WP(C) No. 8996/2023***	Adarsh Soni	20	DMD
44.	***Aditya Kumar Yadav v. Union of India & Anr., WP(C) No. 10031/2023***	Aditya Kumar Yadav	14	DMD
45.	***Sumit Kumar v. Union of India & Anr., WP(C) No. 10063/2023***	Sumit Kumar	14	DMD
46.	***Aditya Soni v. Union of India & Anr., WP(C) No. 10064/2023***	Aditya Soni	15	DMD
47.	***Saiansh v. Union of India &***	Saiansh	14	DMD

	Anr., WP(C) No. 6089/2023			
48.	***Umanand Kumar Soni v. Union of India & Anr., WP(C) No. 10606/2023***	Umanand Kumar Soni	17	DMD
49.	***Parth Kamboj v. Union of India & Anr., WP(C) No. 10867/2023***	Parth Kamboj	14	DMD
50.	***Parv Insan v. Union of India & Anr., WP(C) No. 10870/2023***	Parv Insan	6	DMD
51.	***Saksham Jangla v. Union of India & Anr., WP(C) No. 12222/2023***	Saksham Jangla	12	DMD
52.	***Tanuj v. Union of India & Anr., WP(C) No. 13172/2023***	Tanuj & Anshul	15 & 13	DMD
53.	***Aman Meena v. Union of India & Anr., WP(C) No. 13173/2023***	Aman Meena	16	DMD
54.	***Harshit Rajput v. Union of India & Anr., WP(C) No. 13174/2023***	Harshit Rajput	17	DMD
55.	***Parmarth Kapoor v. Union of India & Anr., WP(C) No. 13175/2023***	Parmarth Kapoor	8	DMD
56.	***Manvik Khangwal v. Union of India & Anr., WP(C) No. 13179/2023***	Manvik Khangwal	10	DMD
57.	***Soumya Mishra v. Union of India & Anr., WP(C) No. 13186/2023***	Soumya Mishra	12	DMD
58.	***Sumit Verma v. Union of India & Anr., WP(C) No. 13187/2023***	Sumit Verma	15	DMD
59.	***Vikash Meena v. Union of India & Anr., WP(C) No. 13188/2023***	Vikash Meena	19	DMD
60.	***Rehan v. Union of India & Anr., WP(C) No. 13190/2023***	Rehan	9	Under evaluation

61.	***Yash v. Union of India & Anr., WP(C) No. 13191/2023***	Yash	9	DMD
62.	***Aarush Prithwan v. Union of India & Anr., WP(C) No. 13192/2023***	Aarush Prithwan	14	DMD
63.	***Manav Palsania v. Union of India & Anr., WP(C) No. 13193/2023***	Manav Palsania	11	DMD
64.	***Himanshu Sharama v. Union of India & Anr., WP(C) No. 13196/2023***	Himanshu Sharama	14	DMD
65.	***Mradul Mishra v. Union of India & Anr., WP(C) No. 13197/2023***	Mradul Mishra	20	DMD
66.	***Yash Raj v. Union of India & Anr., WP(C) No. 13236/2023***	Yash Raj	11	DMD
67.	***Parmeet Singh v. Union of India & Anr., WP(C) No. 13237/2023***	Parmeet Singh	10	DMD
68.	***Mohit v. Union of India & Anr., WP(C) No. 13239/2023***	Mohit	15	DMD
69.	***Mohammad Arshad v. Union of India & Anr., WP(C) No. 13240/2023***	Mohd Arshad	11	DMD
70.	***Sahil v. Union of India & Anr., WP(C) No. 13259/2023***	Sahil	12	DMD
71.	***Vishwas Goyal v. Union of India & Anr., WP(C) No. 13260/2023***	Vishwas Goyal	10	DMD
72.	***Vihaan Gupta v. Union of India & Anr., WP(C) No. 13304/2023***	Vihaan Gupta	16	DMD
73.	***Sameer Lamba v. Union of India & Anr., WP(C) No. 13379/2023***	Sameer Lamba	13	DMD
74.	***Salman Khan v. Union of India & Anr., WP(C) No. 13389/2023***	Salman Khan	13	DMD

75.	***Henil Patel v. Union of India & Anr., WP(C) No. 13417/2023***	Henil Patel	6	DMD
76.	***Henilkumar Prajapati v. Union of India & Anr., WP(C) No. 13449/2023***	Henilkumar Prajapati	6	DMD
77.	***Tirth Ravi Khairnar v. Union of India & Anr., WP(C) No. 13453/2023***	Tirth Ravi Khairnar	14	DMD
78.	***Rudra Kirti Kumar Patel v. Union of India & Anr., WP(C) No. 13456/2023***	Rudra Kirti Kumar Patel	7	DMD
79.	***Jeet Gosai v. Union of India & Anr., WP(C) No. 13469/2023***	Jeet Gosai	11	DMD
80.	***Anuj Kumar v. Union of India & Anr., WP(C) No. 13475/2023***	Anuj Kumar	14	DMD
81.	***Mohammad Ayaan Sheikh v. Union of India & Anr., WP(C) No. 15263/2023***	Mohammad Ayaan Sheikh	18	DMD
82.	***Shreshth Sharma v. Union of India & Anr., WP(C) No. 15301/2023***	Shreshth Sharma	14	DMD
83.	***Shivam v. Union of India & Anr., WP(C) No. 15302/2023***	Shivam	7	DMD
84.	***Nikunj Gupta v. Union of India & Anr., WP(C) No. 15315/2023***	Nikunj Gupta	9	DMD
85.	***Devansh Agarwal v. Union of India & Anr., WP(C) No. 15334/2023***	Devansh Agarwal	6	DMD
86.	***Rahul v. Union of India & Anr., WP(C) No. 15336/2023***	Rahul	21	DMD
87.	***Kuldeep Singh Naruka v. Union of India & Anr., WP(C) No. 15618/2023***	Kuldeep Singh Naruka & Lokendra Singh Naruka	26 and 24	DMD

88.	***Karan Soni v. Union of India & Anr., WP(C) No. 15639/2023***	Karan Soni Neel Soni	8 and 19	DMD
89.	***Prince Pareek v. Union of India & Anr., WP(C) No. 16267/2023***	Prince Pareek	10	DMD
90.	***Saransh Kumar v. Union of India & Anr., WP(C) No. 16361/2023***	Saransh Kumar	20	DMD
91.	***Taksh Kaushik v. Union of India & Anr., WP(C) No. 14141/2023***	Taksh Kaushik	10	DMD
92.	***Tanveer Sharma v. Union of India & Anr., WP(C) No. 14150/2023***	Tanveer Sharma	6	DMD
93.	***Bushra Khan v. Union of India & Anr., WP(C) No. 55/2024***	Bushra Khan	16	LGMD 2E
94.	***Aadhyan Jaiswal v. Union of India & Anr., WP(C) No. 9684/2021***	Aadhyan Jaiswal	11	Atypical Hemolytic Uremic Syndrome
95.	***Insha v. Union of India & Anr., WP(C) No. 1182/2022***	Insha	4.5	Gaucher
96.	***Alishba Khan v. Union of India & Anr., WP(C) No. 2943/2020***	Alishba Khan	18	Gaucher
97.	***Master Medhansh Jhawar @Madhav v. Union of India & Anr., WP(C) No. 1491/2021***	Medhansh Jhawar	3	MPS II
98.	***Master Kenit Jhawar @Keshav v. Union of India & Anr., WP(C) No. 1511/2021***	Kenit Jhawar	3	MPS II
99.	***Payel Bhattacharya v. Union of India & Anr., WP(C) No. 3662/2021***	Payel Bhattacharya	41	Von-Hippel Linau Syndrome (VHL)

100.	***FSMA India Charitable Trust v. Union of India & Anr., WP(C) No. 11610/2017***	Rohit Dilawari Sunil Kumar Dhruv Malhotra Shahi Alam Khan Parvinder Bedi	-	Spinal Muscular Atrophy (SMA)
101.	***Lakshay Agarwal v. Union of India & Anr., WP(C) No. 8986/2023***	Lakshay Agarwal	21	SMA
102.	***Gaurav Kapoor v. Union of India & Anr., WP(C) No. 13180/2023***	Gaurav Kapoor	23	Suspected LGMD
103.	***Vikash Kumar v. Union of India & Anr., WP(C) No. 436/2024***	Vikash Kumar	19	To be examined
104. T	***Parth Sah v. Union of India & Anr., WP(C) No. 479/2024***	Parth Sah	7	To be examined

History of proceedings

4. Notice was issued on 17th August, 2020 in the lead petition being ***W.P.(C) 5315/2020.*** Two weeks' time was granted to the Union of India to file their counter to the said petition. On the said date, the Court also directed the Petitioner in ***W.P.(C) 5315/2020*** to provide all relevant medical documents to the ld. Counsel appearing for AIIMS. Ld. Counsel for AIIMS was directed to seek an opinion from a doctor at AIIMS regarding the Petitioner's medical condition and treatment. If the doctor determined that physical examination of the Petitioner was necessary, AIIMS was directed to inform the Petitioner of the date and time for the examination. Additional time was granted on 9th October, 2020 to the Petitioner to place on record additional medical documents. Vide order dated 3rd June, 2021 the matter being ***W.P.(C) 5315/2020*** was notified as a lead matter in these batch of

petitions.

5. On 12th January, 2021, in response to the petitions, the Union of India stated that the earlier policy on Rare Diseases i.e., the National Policy for the Treatment of Rare Diseases, 2017 *(hereinafter, '2017 Policy')* was kept in abeyance vide notification dated 18th December, 2018. The Union of India's affidavit dated 28th September, 2020 further averred that a Draft Health Policy for Rare Diseases, 2020 *(hereinafter, 'Draft Policy, 2020')* had been released and the same was pending finalisation. The said affidavit further stated that a national policy was likely to be finalised by 31st March, 2021, and a digital platform was also being created, and the same was also in the process of being operationalised by 31st March, 2021. In relation to the Petitioner in ***W.P.(C) 5315/2020,*** AIIMS' report stated that the Petitioner's condition was unlikely to show improvement with Exondys 51 therapy.

6. Considering the above submissions made by the Union of India and the AIIMS, this Court was of the view that the finalisation of the Draft Policy, 2020 could not be kept pending finalisation, and that it was incumbent on society in general and authorities in particular to ensure that the life of children suffering from Rare Diseases' is not compromised, even if there is a small window of improving their chances of survival or even providing a better quality of life. This view was premised on the fact that 'Right to Health and Healthcare' was 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. Thus, exorbitant price of drug or treatment should not come in the way of treatment of children suffering from Rare Diseases.

7. On the said date, the Court also considered the submission of the Union of India that due to the constraint of governmental resources, and competing health priorities, it is not possible to fully finance the treatment of all high-cost Rare Diseases, but the gap could be bridged by seeking donations from prospective individuals or corporate donors, who are willing to support the cost of such diseases. Union of India recognised that Duchenne Muscular Dystrophy *(hereinafter, 'DMD')* was a 'Rare Disease' and the fact that patients, in general, may not be able to afford its treatment. It thus proposed that it shall explore 'crowd-funding' as an option to address affordability concerns.

8. Thus, on 12th January, 2021, this Court directed the Secretary, Ministry of Health and Family Welfare to provide a specific timeline for the finalisation and notification of the Draft Policy, 2020. Insofar as the Petitioners, who are suffering from DMD, are concerned, this Court directed the Secretary, Ministry of Health and Family Welfare to proceed in terms of the Draft Policy, 2020 and explore crowd funding options.

9. This Court also directed the Ministry to contact M/s Sarepta Therapeutics, USA, *(hereinafter, 'Sarepta')*, which publicly advertises on its website that it provides financial support/medication in deserving cases. The Ministry was directed to come up with a proposal, with respect to the same.

10. On 28th January, 2021, this Court again considered the affidavit dated 28th September, 2020 filed by the Union of India. On the said date, considering that for over more than three years, there had been no policy to deal with patients suffering from Rare Diseases, the Ministry of Health and Family Welfare *(hereinafter, 'MoHFW')* was directed to finalise the National Policy on or before 31st July, 2021. Additionally, since the said

National Policy contemplated voluntary crowd funding for treatment, this Court was of the opinion that the creation of a digital platform was essential to enable patients like the Petitioners to avail of funding for medicines and treatment. Thus, the Court directed that such a digital platform to facilitate voluntary crowd-funding, be made operational on or before 31st March, 2021.

11. Insofar as the communication with Sarepta is concerned, on 28th January, 2021, the Court was informed that an email communication dated 19th January, 2021 was sent, and the MoHFW undertook to telephonically contact the said company. On 4th February, 2021, Dr. Pulkesh Kumar, Deputy Secretary, MoHFW joined the proceedings, and submitted that he had attempted to contact Sarepta, however, there was no response. On 22nd February, 2021, this Court was informed that Sarepta had contacted the Petitioners on 19th February, 2021. The company stated that it had attempted to reach Mr. K. Balasubramanian but received no response from him. In response, Dr. Kumar explained that Mr. K. Balasubramanian was on leave at that time. On the same date, the Court observed that there was no reason for not continuing the discussions with Sarepta. Thus, the Court directed the Union of India to engage with Sarepta & place on record a comprehensive affidavit explaining the developments.

12. Regarding the notification of the National Policy for Rare Diseases, it was stated that the Policy would be published by 31st March, 2021, and would include a provision for crowdfunding. Dr. Kumar reiterated the position of the Union of India, explaining that due to the current high cost of gene therapy, which was approximately Rs. 6 crores per child annually, it was financially not feasible for the Union of India to provide this treatment

to all patients suffering from DMD. He further submitted that the government lacks the necessary budget to extend this treatment to all DMD patients.

13. In response to the above submission made, the Petitioner placed on record a communication dated 19th August, 2019, issued by the Office of the Commissioner, Commercial Tax, Uttar Pradesh. In this communication, permission was sought to treat one child for muscular dystrophy at AIIMS, New Delhi, and for the said purpose, sanction for proposed expenses as medical advance for six months was sought by the parent of the child. In terms of the above permission, and the policy of the UP government, sanction for around Rs.2 crores for medical advance was granted for six months. The same was subject to certain conditions as contained in the communication dated 19th August, 2019.

14. On 4th February, 2021, in the context of the above communication, this Court directed AIIMS to place on record the following details:

i) The details of the therapy provided to the patient, mentioned in the order of the Office of the Commissioner, Commercial Tax, Uttar Pradesh dated 19th August 2019;

ii) The manner in which the drug was ordered for the said patient from M/s Sarepta Therapeutics;

iii) Whether there was any Indian supplier who had supplied the drug at that stage for the said patient;

iv) The details of the condition of the child after six months of the therapy and whether the therapy was still continuing or not.

15. Thereafter, the focus of the present petitions shifted to exploring alternative remedies and therapies for the treatment of the Petitioners

suffering from DMD. On 22nd February, 2021, certain documents were placed on record by Mr. Ashok Aggarwal, ld. Counsel for the Petitioners in ***W.P.(C) 322/2021 & W.P.(C) 1611/2021*** to show that some of the treatments and medicines for DMD were available in India, and even generic versions of treatments have been developed. The documents placed on record showed that one 'Indian Association for the Cultivation of Science', 2A & 2B, Raja S C Mullick Road, Jadavpur, Kolkata 700032 claimed to have developed the generic version of the drug for treatment of DMD and the cost for the same would be much less.

16. The Court took into consideration that the Petitioners had placed on record documents demonstrating the development of generic and alternative drugs for treatments and therapies. As a result, the Court directed the Union of India to file a comprehensive affidavit detailing the availability of generic and alternative drugs in India, either approved or under trial, for the treatment of DMD, along with the associated costs. Vide order dated 22nd February, 2021, the Court also directed the Union of India to hold discussions with organizations in India providing treatment for DMD, in order to ascertain the time by which the medicines/therapy can be obtained.

17. Impleadment of the following governmental and other authorities was then directed:

i) Department of Biotechnology *(hereinafter, 'DBT')*: The Department of Biotechnology was directed inform the Court as to whether there were any therapies being developed in respect of DMD and if so, which were the organizations who are developing the same,

ii) Indian Association for the Cultivation of Science,

iii) Institute of Child Health *(hereinafter, 'ICH')*,

iv) Dystrophy Annihilation Research Trust *(hereinafter, 'DART')*, and

v) Drugs Controller General of India *(hereinafter, 'DCGI')*.

18. On the same date, i.e., 22nd February, 2021, considering the fact that the National Rare Diseases Policy had not been notified yet, this Court directed the Union of India to explore crowd funding options, and place a concrete proposal in respect of the same.

19. In compliance of the directions contained in the order dated 22nd February, 2021, following organisations/authorities made their respective submissions on 2nd March, 2021:

i) Central Drugs Standard Control Organisation *('CDSCO')*

ii) Union of India

iii) Dr. Shastry from DART

iv) Institute of Child Health, Kolkata

20. On the said date, i.e., 2nd March, 2021, this Court considered two issues:

i) feasibility of accelerated approval processes

ii) exploration of the confidential proposal put forth by Sarepta for the purpose of making therapies available to children suffering from DMD

21. In respect of the communication with Sarepta, the Court observed that the MoHFW ought to have made greater efforts by engaging with Sarepta, which was willing to provide a confidential proposal at the relevant point in time.

22. With regard to crowdfunding, on 2nd March, 2021, the Union of India

stated that until the Policy was notified and the e-platform for crowdfunding was operationalised, no crowdfunding efforts could be explored. However, on the said date, Dr. Pulkesh Singh from the Ministry of Health, Union of India, orally submitted that he had written to four organizations to arrange funding for the treatment of the patients in question. Again on 14th July, 2021, Mr. Rahul Malhotra, ld. counsel for the Petitioner in **W.P.(C) 1491/2021** submitted that the digital crowd-funding platform, which was to be made operational on or before 31st March, 2021 had not been made operational.

23. In relation to alternative therapies and generic drugs, this Court observed that, as per the affidavit placed on record by CDSCO dated 27th February, 2021, clinical trials were already underway in India for drugs/therapies for treatment of DMD. The said affidavit showed that various organisations and companies are conducting clinical trials in respect of DMD therapies. The said companies are as follows:

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)

24. As a result of the position taken by the CDSCO and the Union of India regarding alternative drug therapies, on 2nd March, 2021, this Court directed the Union of India to file a specific affidavit concerning budget allocations. The said affidavit was to provide details of the health budget

over the past five years and indicate whether any unused portion could be allocated towards the treatment of the Petitioners or the indigenous development of therapies for Rare Diseases. In addition to the affidavit on health budget allocations, vide order 15th March, 2021, the Court further directed MoHFW to file an additional affidavit providing details of any funds allocated for Rare Diseases since 2017, including the amounts expended to date and the name of the scheme under which these funds were allocated. In compliance with these directions, the Union of India filed its respective affidavits on 12th March, 2021 and 18th March, 2021 respectively. The relevant portions of the said affidavits in respect of the budgets allocated for Health and specifically directed for Rare Diseases is extracted below:

Affidavit dated 12th March, 2021

4. That in compliance of the direction at para 9 of order dated 02.03.2021, the budget for health in the last five years is given below:

(Rs. in crore)

Year	Total		
	BE	**RE**	**Actuals**
2015-16	31050.00	32819.00	33121.41
2016-17	37061.55	38343.33	37671.30
2017-18	47352.51	51550.85	51381.89
2018-19	52800.00	54302.50	52953.94
2019-20	62659.12	62659.12	62397.08

5. It is evident that in the last five years Department is almost fully utilising its entire budget and no fund is left unused or surrendered.

Affidavit dated 18th March, 2021

> "*3. That the name of the scheme under which assistance is being provided is by the name* ***"Assistance for Hospitalization of Poor Patients Suffering from Rare-Diseases"*** *which is a component of the scheme namely Rashtriya Arogya Nidhi (RAN) which was specifically introduced in RE 2018-19.*
>
> *4. That further, the details of BE, RE and expenditure in respect of rare diseases component under the Umbrella Scheme of Rashtriya Arogya Nidhi (RAN) are as under:*
>
> *(in Rs. crore)*

Sr. No.	***Year***	***Budget Estimate (BE)***	***Revised Estimates (RE)***	***Expenditure***
1	*2018-19*	*Nil*	*7.50*	*Nil*
2	*2019-20*	*100.00*	*25.00*	*1.30*
3	*2020-21*	*77.32*	*10.00*	*5.90*
4	*2021-22*	*25.00*	*Nil*	*Nil*

> *5. It may be seen from the above table that:*
>
> *i. In the year 2018-19, allocation for the component for rare diseases was 7.50 crore at* ***RE*** *stage. However, no expenditure was made;*
>
> *ii. In the year 2019-20, allocation for the rare diseases was 100.00 crore at* ***BE****, 25.00 crore at* ***RE*** *stage and the expenditure was 1.30 crore;*
>
> *iii. In the year 2020-21, allocation for the rare diseases was 77.32 crore at* ***BE****, 10.00 crore at* ***RE*** *stage and the expenditure till date is 5.90 crore;*
>
> *iv. In the year 2021-22, allocation for the rare disease is 25.00 crore under* ***BE****."'*

The above figures clearly showed that the budgeted amounts for Rare diseases was grossly under-utilised.

Constitution of the Dr. Renu Swarup Committee

25. Considering the fact that the above issues needed a comprehensive

solution, this Court vide order dated 2nd March 2021, constituted a Committee to undertake a comprehensive assessment of the issues underlying these petitions, and to recommend a time-line based solution. The said Committee was constituted under the Chairpersonship of Dr. Renu Swarup, the then Secretary of DBT, and was mandated to submit a report on the following 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.

26. The Report of the Committee constituted vide order dated 2nd March, 2021 *(hereinafter, 'Dr. Renu Swarup Committee')* submitted its report on 12th March, 2021. The same were considered by this Court on 23rd March, 2021. The observations/recommendations of the Dr. Renu Swarup Committee are as follows:

- The cost of drugs and therapies involved in treating these Rare Diseases are extremely exorbitant. Therefore, there is an urgent need to explore sustainable options, and essentially, to invest in research and development, in order to indigenously produce these drugs and

therapies in India.

- Clinical trial/trials for therapies for the treatment of DMD are already in the pipeline and some trials have already been approved by the DCGI.
- At least one state-of-the-art facility ought to be established in India with a stringent requirement for manufacturing enzymes to try and develop treatments for Lysosomal Storage Disorders.
- Efforts for use of biosimilars in the treatment of some Lysosomal Storage Disorders (such as Gaucher disease and Fabry disease) (*hereinafter, "LSD"*) is already ongoing.
- The Committee recommends the establishment of a ***National Consortium for Research and Development on therapeutics for Rare Diseases***, by bringing together all stakeholders- clinicians, basic scientists, pharmacologists, policymakers, motivated industry partners etc. The said consortium should be supported from all major funding agencies such as the DBT, Indian Council for Medical Research *(hereinafter, 'ICMR'),* Department of Science and Technology *(hereinafter, "DST"),* Council for Scientific and Industrial Research *(hereinafter, "CSIR")* and other related Ministries/Departments, with DBT and ICMR jointly taking the lead.
- The Consortium would constitute a National Expert Committee on Rare Diseases for providing scientific advice and continuously evaluating the progress of research and development of therapies.
- There exists an urgent need to target indigenous manufacturing of these drugs and industry ought to get involved in a major way in a

production of these drugs to reduce the cost of the treatments. Public-private partnership also ought to be explored for funding research and development as well as treatment.

- Similar efforts as have been done for DMD and LSD, should also be initiated for other Rare Diseases.
- Crowd funding and alternative funding mechanism ought to be explored for treatment of Rare Diseases.
- Some of the important research areas that ought to be explored include repurposing of drugs, exosomal proteomics and upregulating them and CRISPR CAS 9 based technologies. Establishing more basic laboratory facilities like Mdx mice/ drosophila shall go a long way in further strengthening research in the country.
- Pharma companies ought to be incentivized for production of drugs and therapies for Rare Diseases, by providing production linked incentives.
- Accelerated approval process can be considered *qua* clinical trials and approvals of these orphan drugs and therapies, under the new Drugs and Clinical Trial Rules, 2019, in order to promote and encourage the development and production of therapies and drugs for Rare Diseases.

27. Pursuant to the Report of the Dr. Renu Swarup Committee, vide order dated 23rd March, 2021 this Court was of the view that the following two issues needed to be addressed in the present petitions:

i) Indigenisation of medicines/ therapies for Rare Diseases.

ii) Creation of a permanent fund for the purposes of providing treatment and therapies for patients suffering from Rare Diseases.

28. Insofar as the first aspect is concerned, as per the Report of the Dr. Renu Swarup Committee, various organisations are already working on therapies for dealing with Rare Diseases. On 23rd March, 2021, this Court observed that research and development in this area was required to be made completely robust to ensure that the indigenisation and local development of medicines and therapies takes place in a time bound manner.

29. Secondly, on the said date, after perusing the affidavits dated 12th March, 2021, and 18th March, 2021, submitted by the MoHFW, **this Court observed that approximately Rs. 200 crores had been budgeted for expenditures related to Rare Diseases. However, the affidavit(s) revealed that only around Rs. 7 crores had been spent over the last three years. Thus, on the said date, this Court directed that such budgets ought to be now utilized efficiently for the purposes of both funding of treatments, as well as Research and Development activities.**

30. In respect of the second aspect on creation of a permanent fund, this Court was of the view that such a fund for Rare Diseases ought to not be limited to patients who approach the Court. Instead, a streamlined and sustainable mechanism ought to be in place to ensure that cases of all patients suffering from Rare Diseases are examined in a timely manner. For those patients for whom treatment is recommended, the same ought to be provided promptly, without requiring them to repeatedly seek judicial intervention.

National Policy for Rare Diseases

31. On 23rd March, 2021, in view of the Report of the Dr. Renu Swarup Committee, and the above two aspects, this Court directed the finalisation and notification of the ***'National Policy for Rare Diseases'*** *(hereinafter,*

'NPRD, 2021') in the following terms: "

*i) The **'National Policy for Rare Diseases'** shall be finalized and notified by the Government of India, on or before 31st March, 2021.*

*ii) As a part of the said policy, the **'National Consortium for Research and Development on therapeutics for Rare Diseases'** shall also be set up.*

*iii) A **Rare Diseases Committee** shall be set up at AIIMS consisting of Prof. (Dr.) Madhulika Kabra and Prof. (Dr.) P. Ramesh Menon, who shall examine the applications for treatment and funding, received from any patient suffering from Rare Diseases. The said Committee can, depending upon the condition of the patient, also co-opt any one member from any specialized field into the said Committee. The Committee would, upon examination, recommend the kind of treatment which would be made available to the patients. Upon the approval of the Committee, the expenses for the treatment involved shall be drawn from the Rare Diseases Fund after approval by the Director, AIIMS.*

*iv) The entire unspent budget allocated for Rare Diseases, for the years 2018-19, 2019-20 and 2020-21, as per the amounts extracted above, shall be immediately moved into a fund called the '**Rare Diseases Fund'**, which shall be managed and utilized by AIIMS, which shall serve as a nodal agency for this fund. A separate bank account for the Rare Diseases Fund shall be opened by the Director, AIIMS for this purpose.*

v) The digital platform that is created in the Policy, for the purposes of receiving crowdfunding and other kinds of funding, shall be linked to the Rare Diseases Fund. All individuals, organizations, companies etc., who wish to contribute to the said fund, shall make direct contributions. The Rare Diseases Fund shall be under the direct control and supervision of the Director, AIIMS. Periodic reports may be called for,

by the Ministry of Health and Family Welfare, UOI, from AIIMS, in respect of the contributions that are received, as well as qua the utilization of the said fund.

vi) The other Institutes which shall be notified under the policy, as centres for excellence, for Rare Diseases shall also be entitled to receive applications from patients who need treatment, and shall forward the same to the Rare Diseases Committee based in AIIMS.

vii) In the case of direct applications being made to AIIMS, a decision shall be taken by the Rare Diseases Committee within a period of two weeks, in respect of the treatment and funding etc. In case, the application is routed through other institutes/ centres of excellence which are notified in the Health Policy for Rare Diseases, a decision upon the treatment and funding shall be taken by the Committee within a period of four weeks.

viii) In the context of Rare Diseases, the Government may consider increasing the budget for the year 2021-22 for the Rare Diseases Fund.

ix) The National Consortium for Research and Development on therapeutics for Rare Diseases shall be the nodal agency for supervising and monitoring the indigenization of treatments and therapies, manufacture of drugs, technology transfer, approvals, etc. for Rare Diseases. The said Consortium, as recommended in the report, shall consist of representatives from DBT, ICMR, DST, CSIR, DCGI, and other related Ministries and Departments. DBT and ICMR shall jointly take the lead.

x) The Consortium shall also make recommendations, if any, as to whether the patients suffering from Rare Diseases ought to be included in any of the clinical trials currently taking place.

xi) The Consortium, while monitoring Research and Development, shall also approve applications for funding of research projects in respect of treatment and therapies for Rare Diseases. The Amounts from the

'Rare Diseases Fund' may be utilised for the purpose of Research. All projects approved shall have specific deliverables and timelines. The amounts shall be released for this purpose only after the project is approved by the Chairperson of the Consortium or an official, not below the level of Joint Secretary, Ministry of Health and Family Welfare, until the consortium is fully operational. Upon a project being approved by the Chairperson of the Consortium/Joint Secretary, the amount from the Rare Diseases Fund shall be released for the said project.

xii) The National Policy for Rare Diseases shall also deal with any limits/ caps that are to be imposed for various categories of Rare Diseases, only if required.

xiii) Any financial incentives to be given for manufacturing/ Research and Development of therapies for Rare Diseases shall also be explored in the Policy

xiv) The Policy shall also explore as to whether any financial incentives are to be given to the companies, who could contribute for the treatment/ Research and Development relating to Rare Diseases.

22. The National Policy for Rare Diseases shall incorporate the above directions, prior to it being notified by the Union of India.

23. The Petitioners in all these cases shall make their representations to the Rare Diseases Committee for further processing their treatments in terms of the above directions.

24. Let a copy of the notified National Policy for Rare Diseases be placed on record, by the Union of India, by 10th April, 2021."

Compliance of directions contained in order dated 23rd March, 2021

32. A detailed compliance affidavit dated 16th April, 2021 was placed on record, setting out different compliances taken in terms of the order dated

23rd March, 2021. As per the said affidavit, NPRD 2021 was notified on 30th March, 2021. All the compliances in terms of the affidavit dated 16th April, 2021 were recorded in the order dated 19th April, 2021. Some of the compliances are as follows:

i) **Centres of Excellence:** Setting up of Centres of Excellence *(hereinafter, 'CoEs')* for the prevention and treatment of Rare Diseases, under the leadership of AIIMS.

ii) **Budget for Rare Diseases:** For the year 2021-2022, funds for Rare Diseases amounting to Rs. 4.10 crores under the Rashtriya Arogya Nidhi *('RAN')* scheme have been transferred *via* RTGS to the AIIMS in the RAN account. The budget estimate for 2021-22 is Rs. 25 crores. MoHFW stated that these funds can be increased based on utilization.

iii) **Crowd-funding:** Crowd-funding accepted to provide supplementary funding – each of the eight COEs would manage the digital platform for crowd funding.

iv) **National Consortium:** In terms of para 12(b) of the NPRD 2021, a 'National Consortium for Research and Development on therapeutics for Rare Disease' *(hereinafter, 'National Consortium')* has been set up with an expanded mandate to include research, development, technology transfer and indigenisation of therapeutics for Rare Diseases. The National Consortium will be convened by the Department of Health Research, with ICMR as a member. Includes the DBT, Department of Pharmaceuticals, DST, and the Council of Scientific and Industrial Research *(hereinafter, 'CSIR')*. CSIR will

supplement research efforts.

v) **New Drugs:** Drug manufacturing to be conducted by both public and private pharmaceutical companies. Approvals for new drugs to be granted by the DCGI under the New Drugs and Clinical Trial Rules, 2019 *(hereinafter, '2019 Clinical Trial Rules')*. Inclusion of rare disease patients in clinical trials to be decided by the DCGI as per the 2019 Clinical Trial Rules.

vi) ***'Rare Diseases Committee'*** constituted within AIIMS. All the cases of the Petitioners would be transferred to the said Committee.

33. On 19th April, 2021, this Court queried whether the National Fund for Persons with Disabilities *(hereinafter, 'NFPD')*, established under Section 86 of the Right of Persons with Disabilities Act, 2016 *(hereinafter, 'RPWD Act')*, had been set up. Considering the fact that the said NFPD is part of the RPWD Act, the MoHFW was directed to file an affidavit confirming whether the NFPD has been established, the amount allocated for it, and whether any specific funds have been allocated for the treatment of DMD. This Court directed the Union of India to file an affidavit as to whether the NFPD had been set up and if so what was the amount allocated for the said purpose. Further, the said affidavit ought to also address whether any amount is specifically allocated for DMD. On the next date of hearing i.e., 20th May, 2021, an affidavit was filed by the Union of India, however, the said affidavit did not provide the details sought for in order dated 19th April, 2021. Thus, additional time was granted to the Union of India to again file the said affidavit setting out the details regarding the NFPD and whether any amounts were allocated specifically for DMD. Additionally, vide order

dated 20th May, 2021 the Union of India was directed to deal with the issue regarding the prescribed limit of Rs. 20 lakhs per patient and also in respect of crowd-funding option.

34. Vide order dated 4th August, 2021 this Court was apprised that an online crowd-funding platform for collecting funds for treatment of children suffering from rare diseases had been made operational.[1] In respect of the said online crowd-funding platforms certain issues were pointed out on the said date. Firstly, the names of the Petitioners had not been uploaded/updated on the said online platform and secondly, sufficient publicity had not been carried out which made the reach of the platform limited. Again on 20th September, 2021, this Court was informed that the names of the Petitioners were not uploaded or updated on the online crowd-funding platform. On this aspect, the ld. ASG submitted that the Petitioners' names could not be updated as the same are first required to be examined by the doctors at COEs.

35. In the meantime, since the Rare Diseases' Committee has been set up in AIIMS vide order dated 23rd March, 2021 ld. counsel for AIIMS was directed to place on record fresh status reports in respect of treatment of the Petitioners in terms of the order dated 14th July, 2024.

Compliance of directions contained in the order dated 23rd March, 2021

36. On 20th September, 2021 this Court passed a detailed order stating that even after period of six months had been passed, the directions contained in order dated 23rd March, 2021 had not been complied by the Union of India.

37. On the said date in terms of the directions contained in order dated

23rd March, 2021, this Court observed that the unspent amount allocated for rare diseases for the years 2018-19, 2019-2020 and 2020-21, was about Rs. 193 crores. The Court was informed that even though a bank account was opened for transfer of the unspent amount only a fraction of the same was finally transferred to the said account. Further, no explanation was provided to the Court for not transferring the balance amount.

38. In respect of the crowd-funding platform this Court directed finally that the Nodal Officers of the said COEs would examine the Petitioners' reports and further facilitate the updation of their names on the said online portal within 10 days.

Proceedings before the Kerala High Court

39. On 20th September, 2021 another angle was introduced to the present batch of petitions. It transpired that before the Kerala High Court in **W.P.(C) 7894/2021** funds to the tune of Rs. 63 crores were collected from the general public for the treatment of a person suffering from rare diseases who unfortunately passed away. The Kerala High Court in the said litigation directed the Union of India to utilise the funds which were left unutilised for treatment of the present Petitioners and other similarly placed patients under the National Policy for Rare Diseases. In response to this ld. counsel for the Union of India that it had not taken any steps to transfer the said amount to the rare diseases fund.

40. This Court found the stand of the Union of India completely unacceptable. On the said date, this Court was of the opinion that even though Union of India was not a party before the Kerala High Court ought to

[1] http://rarediseases.nhp.gov.in/

have taken expeditious steps to ensure that the said amount did not lie unutilised and it was incumbent upon the Union of India to transfer the said amount to the rare diseases fund. Finally on 14th December, 2021, the ld. ASG assured that the Union of India would pursue its application before the Kerala High Court for the transfer of approximately ₹53 crores lying with the said Court

41. Again, on 20th September, 2021, this Court directed the Union of India to place on record a comprehensive compliance affidavit setting out the manner in which the directions contained in the order dated 23rd March, 2021 had been complied with the Union of India. The affidavit dated 19th October, 2021, in terms of the directions contained in order dated 20th September, 2021 did not provide any satisfactory details. On 7th December, 2021, this Court noted that the said affidavit filed by the Union of India did not explain the following aspects:

- The justification for not utilising the unspent budget allocated for rare diseases in the last three years.
- The reasons as to why the Petitioners' name had not been included on the online portal for crowd-funding.

42. Thus, on 23rd March, 2021, 14th July, 2021, 4th August, 2021, 20th September, 2021 and 7th December, 2021 the UOI was constantly reminded of its obligation to ensure that the Petitioners' names were uploaded on an online crowd-funding platform and repeatedly explanation was sought as to why the unutilised budgeted amounts for rare diseases were allowed to lapsed. Thus, on 7th September, 2021 the Court directed the ld. ASG to obtain instructions as to whether it was possible for the Union of India to ensure that immediate treatment was provided to the Petitioners. In respect

of the same, the Union of India was also to provide the modalities as to whether the amounts spent on the treatment may be subsequently adjusted from the amounts received on the portal or from any other fund for treatment for rare diseases.

Interim Directions for treatment of the Petitioners

43. On 14th December 2021, this Court considered an affidavit dated 13th December, 2021 filed by the Union of India. In the said affidavit, the UOI had acknowledged that the children in question should receive the necessary treatment at the earliest. The delay in commencing their treatment had been attributed to the non-availability of requisite funds dedicated to the treatment of rare diseases. Due to the stand taken by the Union of India, which had demonstrated their intent to ensure that children covered under the NPRD 2021, would receive all required medical assistance, the Court was of the clear view that the Petitioners could not be made to suffer endlessly. The Union of India admitted that the Petitioners were covered under the NPRD 2021. Clearly, any delay in the commencement of their treatment could have proved to be fatal, and would have defeated the very purpose for which the policy had been created.

44. Therefore, this Court was of the opinion that interim directions for the commencement of treatment for at least the Petitioners before the Court were warranted. On the said date, it was directed that the treatment be started forthwith by AIIMS or any of the other CoEs, as appropriate. The direction to AIIMS and the other CoEs to commence treatment also included a mandate to provide the necessary medicines, the cost of which was to be borne by the Union of India. This Court was of the opinion that it was the responsibility of the Union of India to ensure that necessary funds were

provided to all the CoEs, including AIIMS, as and when demanded.

Use of CSR funding for Rare Diseases

45. On the said date, the Court directed the Union of India to resolve the remaining issues in the implementation of the NPRD 2021, so that all the other persons covered by the policy would receive the necessary treatment at the earliest. The Court further expressed its view that, in light of the facts emerging from the compilation of extracts of the Annual Returns of Public Sector Undertakings *(hereinafter, 'PSUs')* submitted by the ld. Sr. Counsel for the Petitioner, efforts ought to be made to impress upon the PSUs, the importance of directing at least a part of their Corporate Social Responsibility *(hereinafter, 'CSR')* contributions towards the fund set up on the online crowdfunding website http://rarediseases.nhp.gov.in/ for the treatment of children suffering from rare diseases. It was clarified that the amount spent by the Union of India for the treatment of these children, including the procurement of medicines for the petitioners herein, would be adjustable from the funds received in the account set up on the specially dedicated portal, or from any other appropriate fund available with the Union of India for the said purpose.

Issues in Commencement of treatment at AIIMS

46. On 20th September, 2021, AIIMS was directed to file a status report in respect of the directions issued by this Court on 23rd March, 2021 and on subsequent dates. In compliance with the said order, AIIMS filed a status report on 26th October, 2021, wherein evaluation details of the Petitioners were provided. At the relevant point in time, 18 patients were found to be inflicted with DMD. The said report stated that the Petitioner in ***W.P.(C) 3706/2021*** was found to not be amenable to any presently available

treatment. However, the said Petitioner was evaluated and advised standard care applicable to all DMD patients. The conclusions of the said status report were as follows:

i) DMD

- 18 out of 20 petitioners have been evaluated.
- 15 petitioners were found to be amenable to treatment, and their details will be uploaded to a crowdfunding portal.
- 3 petitioners are not amenable to treatment and will receive standard care applicable to all DMD patients.
- 3 petitioners are still to be evaluated.

ii) Mucopolysaccharidosis II ('MPS II'):

- Two Petitioners were evaluated, and their applications for Enzyme Replacement Therapy would be uploaded to the crowdfunding portal.

iii) Atypical Hemolytic Uremic Syndrome ('AHUS'):

- AHUS is not currently covered under the crowdfunding portal.
- A new option for "other disorders" was to be added to the portal for conditions not currently listed.
- The application of the AHUS petitioner will be uploaded once this option is available.

iv) Von-Hipple Linau Syndrome ('VHL')

- Payel Bhattacharya in ***W.P.(C) 3662/2021*** was given repeated opportunities to appear before the Committee at AIIMS. However, upon being contacted by the Petitioner's

lawyer later, the meeting could not be organised.

47. Issues arose in relation to the compliance of the order dated 14th December, 2021, which had directed commencement of treatment of the Petitioners. On 1st February, 2022, this Court was informed that despite all efforts to reach out to the authorities for the commencement of treatment of the Petitioners, no response was received from AIIMS. On the said date, ld. Counsel Mr. Tanveer Oberoi, appearing for AIIMS, submitted that the diseases affecting the Petitioners, primarily DMD and non-DMD conditions, had led to the constitution of an expert committee within AIIMS. This committee was tasked with determining the appropriate treatment and assessing the efficacy of medicines, which were to be procured. It was further submitted that the said committee's report had to be placed before the Government of India for approval before the treatment could commence. He further informed the Court that some of the Petitioners with non-DMD conditions had already been evaluated, and their details were uploaded on the online portal. He stated that treatment for these Petitioners could begin once the necessary funds were allocated.

48. Mr. Oberoi's submissions were vehemently refuted by the Petitioners. As per the Petitioners, the directions in the said order were clear, and the treatment for the Petitioners was supposed to commence immediately.

49. Mr. Oberoi, ld. Counsel in response, submitted that AIIMS was unable to utilize its annual budget for the treatment of the Petitioners and that the Petitioners suffering from non-DMD diseases could report to the Chairman of Rare Diseases Committee, Dr. Madhulika Kabra, for further evaluation and commencement of treatment. This Court did not countenance the submissions made by ld. Counsel Mr. Oberoi. It was noted that the order

dated on 14th December 2021 had clearly directed the immediate commencement of treatment for the Petitioners, and that the Union of India was responsible for providing the necessary funds.

50. In light of the submissions, Mr. Ripudaman Bhardwaj, ld. CGSC assured the Court that directions would be issued to the CoEs to start the treatment of the Petitioners. Thus, on 1st February, 2022, the directions contained in order dated 14th December, 2021, relating to commencement of treatment of the Petitioners was reiterated, and the Union of India was directed to issue communication to the AIIMS as well as COEs to commence treatment of the Petitioners, without any delay.

Report of the ld. Amicus Curiae and status of treatment by AIIMS

51. Vide order dated 5th April, 2022, this Court directed the ld. Amicus to place a short note of the status of proceedings. The said note was required to indicate the various medical afflictions requiring the extension of aid, the stand of respective State and Union bodies submitted till date and the proposed issues as per order of priority. In terms of the said order, the ld. Amicus placed on record a chart on 11th April, 2022. The said chart is reproduced as follows:

Name of the Patient	***Years***	***Disease***	***Recommended Treatment/Drug***	***Cost of Drug (per month)***
Master Arnesh Shaw	11	DMD	Exondys-51 manufactured by Sarepta Therapeutics USA	INR 30 lakhs per month
Aviraj Garg	5	DMD	Exondys-51 manufactured by Sarepta Therapeutics USA	INR 30 lakhs per month
Keshav Sharma	13	DMD	Exondys-45 manufactured by Sarepta Therapeutics USA	INR 30 lakhs per month
Lakshya Kumar Goyal	9	DMD	Exondys-51 manufactured by Sarepta Therapeutics USA	INR 30 lakhs per month
Harshit Soni	17	DMD	Exondys-45 manufactured by Sarepta Therapeutics USA	INR 30 lakhs per month
Dhananjay	12	DMD	Exondys-51 manufactured by	INR 30 lakhs

Bhardwaj			Sarepta Therapeutics USA	per month
Khushwant Bhardwaj	8	DMD	Not amenable to treatment as per AIIMS Compliance Affidavit	------
Aarav Garg	6	DMD	Vyondys-53 manufactured by Sarepta Therapeutics USA	INR 30 lakhs per month
Manish and Chirag	9 and 5	DMD	Exondys-45 manufactured by Sarepta Therapeutics USA	INR 30 lakhs per month per person
Shourya Manu	8	DMD	Exondys-51 manufactured by Sarepta Therapeutics USA	INR 30 lakhs per month
Siddharth Swamkar	9	DMD	Exondys-51 manufactured by Sarepta Therapeutics USA	INR 30 lakhs per month
Utkarsh Indrajit Pawar	11	DMD	Not available	------
Anshu	11	DMD	Exondys-51 manufactured by Sarepta Therapeutics USA	INR 30 lakhs per month
Ishaan	11	DMD	Exondys-45 manufactured by Sarepta Therapeutics USA	INR 30 lakhs per month
Tanav Handoo	7	DMD	Not amenable to treatment as per AIIMS Compliance Affidavit	------
Shaurya Dahiya	8	DMD	Not amenable to treatment as per AIIMS Compliance Affidavit	------
Udayveer Singh Guleria	8	DMD	Exondys-45 manufactured by Sarepta Therapeutics USA	INR 30 lakhs per month
Nikhil Yogendersingh Choudary	18	DMD	Not available	------
Ayushman Chaturvedi	N/A	DMD	Yet to be determined by Doctors at AIIMS	To be determined by AIIMS, Delhi
Shreyansh Aarav	12	DMD	Exondys-51 manufactured by Sarepta Therapeutics USA	INR 30 lakhs per month
Aadhyan Jaiswal	12.0	Atypical Hemolytic Uremic Syndrome (AHUS)	Eculizumab	INR 30 lakhs per month
Insha	4.5	Gaucher	Enzyme Cerezyme Imiglucerase every fortnight	Rs 57,55,776 per year

Alishba Khan	3.5	Gaucher	Enzyme Replacement Therapy	Cerezyme costs Rs 1.1 lakhs per vial
Medhansh Jhawar	3.0	Mucopolysaccharidosis Type II	Enzyme Replacement - Elaprase	Rs 1.1 lakhs per vial
Kenit Jhawar	4	Mucopolysaccharidosis Type II (MPS II)	Enzyme Replacement Therapy - Elaprase	1.25 - 1.5 lakhs per vial, 5 vials/month
Payel Bhattacharya	N/A	Von-Hippel Lindau Syndrome (VHL)	Proton Therapy - Continuing chemo therapy	1.5 lacs (approx.) Varies month to month
Rohit Dilawai	8	Spinal Muscular Atrophy (SMA)	Spinraza, Risdiplam, Zolgensma	Spinraza INR 7.5 crores 1st year, 5.5 crores/year after
Sunil Kumar	N/A	Spinal Muscular Atrophy (SMA)	None (Deceased)	Deceased
Dhruv Malhotra	9	Spinal Muscular Atrophy (SMA)	None (Deceased)	Deceased
Shahi Alam Khan	5	Spinal Muscular Atrophy (SMA)	Spinraza, Risdiplam, Zolgensma	Spinraza INR 7.5 crores 1st year, 5.5 crores/year after
Parvinder Bedi	14	Spinal Muscular Atrophy (SMA)	Spinraza, Risdiplam, Zolgensma	Spinraza INR 7.5 crores 1st year, 5.5 crores/year after

52. On 12th April, 2022, the Court considered the above chart which set out the rare diseases affecting each of the Petitioners, the recommendations

made in respect of each individual child by the Committee for Rare Diseases as constituted by AIIMS and the status of treatment. On the said date, this Court noted that the Petitioners in various writ petitions before this Court[2], all suffering from DMD, had already been assessed by the Rare Diseases Committee and were recommended for treatment. This fact was confirmed vide affidavit dated 26th October, 2021 filed by AIIMS.

53. In relation to the question as to why if the treatment was recommended, the funds had not been released, ld. Counsel for AIIMS, however, pointed out that no demands had been made for the release of requisite funds to the Union of India for this category of patients, following the decision of the Central Technical Committee functioning under the Ministry of Health. Reference was made to the Minutes of the Meeting held on 11th March 2022, where AIIMS was informed that the line of treatment recommended by the Committee for Rare Diseases was accepted by the Central Technical Committee.

54. However, upon examining the Minutes of the Meeting, it was evident that the drugs recommended for the treatment were duly approved by regulatory authorities such as the European Union (EU) and the Food and Drug Administration *(hereinafter, 'FDA')* in the United States. The Central Technical Committee had primarily raised concerns regarding the cost-effectiveness of the treatment, noting that the high cost of Rs. 6-8 crores per annum made the affordability questionable. However, the Committee had also acknowledged that patients in India ought not to be deprived of these therapies, given their approval in other countries. In the opinion of this

[2] W.P.(C) 5315/2020, 10782/2020, 322/2021, 1611/2021, 3682/2021, 3689/2021, 3706/2021, 3707/2021, 3729/2021, 3737/2021, 3859/2021, 4045/2021, 4067/2021, 4259/2021, 4304/2021, 4551/2021, 5394/2021,

Court, AIIMS had not appreciated the Committee's resolution correctly. Therefore, on 12th April, 2022, this Court directed AIIMS to place its demand for the release of requisite funds for the treatment of DMD patients. The Union of India was additionally directed to consider these demands and submit its position by way of an affidavit. Thus, in substance, the directions contained in orders dated 14th December, 2021, and 1st February, 2022, were again reiterated by this Court.

55. On 29th April, 2022, this Court was informed by Dr. Madhulika Kabra, Chairman of the Rare Diseases' Committee at AIIMS, referring to the comprehensive chart placed on record by the ld. Amicus, that while AIIMS had earlier, in its affidavit dated 26th October, 2021, stated that patients with DMD would be "amenable to treatment", the then available drugs and treatment protocols represented *'experimental therapy'*. As per Dr. Kabra, in the absence of sufficient data, the responses and efficacy of the treatment for individual cases remained uncertain. Thus, it was suggested on the said date that it would be prudent for AIIMS to further review the medical records of these patients to recommend whether the commencement of treatment is likely to be effective. Thus, this Court directed that such a review be conducted by the Competent Committee at AIIMS, and a recommendation for the DMD patients be submitted.

56. In respect of the non-DMD patients, on 29th April, 2022, the Court took note of patients diagnosed with Gaucher and MPS Type II. Ld. Counsel for AIIMS submitted that a request for the release of funds to the Union was sent on 16th February, 2022, which was reiterated in a communication dated 27th April, 2022. In respect of non-DMD patients whose funds had not been

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4812/2021, 5395/2021, and 14317/2021

released, the Court directed the ld. ASG to take instructions regarding the status of the fund release for these patients.

Report of the Expert Committee constituted by AIIMS in respect of specific therapies for DMD patients

57. In terms of the order dated 29th April, 2022, AIIMS submitted its report in respect of therapies for DMD patients on 30th May, 2022. On 1st June 2022, the Court noted from the chart appended to the Report of the Expert Committee that the Expert Committee had opined that the administration of the recommended drugs might help in slowing the decline in cardiac, respiratory, and ambulatory functions of the Petitioners in ***W.P.(C) Nos. 3689/2021, 1611/2021, 4067/2021, 3737/2021, and 14317/2021***. Although the Committee further noted that there was no evidence suggesting that the said drugs would stop the progression of the disease and that long-term outcomes were unknown, the Court was of the opinion that the treatment of these patients should not be deferred on these grounds. The Court acknowledged that in the case of rare diseases, there is a scarcity of authoritative research and long-term outcome data, but this ought not to prevent patients from accessing available treatment options, especially those being administered to similar patients globally, even if considered experimental therapies.

Amendment to the NPRD 2021 – Increase in financial support upto 50 lakhs

58. The Court was also informed on 1st June, 2022, that the Government of India, through an Office Memorandum dated 19th May, 2022, had increased the financial support for patients suffering from any category of rare diseases from **Rs. 20 lakhs to Rs. 50 lakhs**. This support would be

provided for treatment at any CoE listed under the NPRD 2021. The relevant portion of the Office Memorandum is set out below:

> *"**Financial support upto Rs. 50 lakhs shall be provided to the patients suffering from any category of the Rare Diseases. The financial support will be provided to the patients for the treatment in any of the Centre of Excellence (CoE) mentioned in NPRD-2021, outside the Umbrella Scheme of Rashtriya Arogaya Nidhi**."*
>
> *2. All other provisions of the policy will remain unchanged.*
>
> *3. These amendments come into effect from the date of issue of this Office Memorandum.*
>
> *4. The guidelines/procedure for providing financial assistance to the patients as per amended provisions are being finalized. **However, till the finalization of guidelines and in order to provide uninterrupted and enhanced financial assistance i.e. upto Rs. 50 lakhs to the patients of rare diseases irrespective of category of disease, funds may continued to be granted from the current budget head of Umbrella Scheme of Rashtriya Arogya Nidhi (RAN).***
>
> *5. This Issues with the approval of the competent authority."*

59. In view of the above developments, the Court directed AIIMS to forward its proposal for the commencement of treatment for the aforementioned Petitioners to the competent officer in the MoHFW. The Court further directed the DBT to explore and file a response disclosing any other generic treatment norms that may be under development for children suffering from rare diseases in the present batch of writ petitions.

SLP against order dated 14th December, 2021

60. In the meantime, the Court was apprised on 1st June, 2022 that an SLP being ***Petition for Special Leave to Appeal (C) Nos. 10152-10174/2022*** titled ***'Union of India v. Master Arnesh Shaw & Anr.'*** was preferred against the order dated 14th December, 2021. Vide order dated 11th July, 2022, the Supreme Court did not entertain the said Special Leave Petitions challenging the common order dated 14th December, 2021. The said SLP was disposed of on 11th July, 2022 in the following terms:

> *"The present Special Leave Petitions seek to challenge the order dated 14.12.2021, which was purely interlocutory in nature.*
>
> *It appears that the concerned writ petitions are still engaging the attention of the learned Single Judge of the High Court and orders have been passed on 05.04.2022, 12.04.2322, 29.04.2022 and 01.06.2022. As a matter of fact, the last order dated 01.06.2022 specifically referred to and relied upon the* ***Policy Statement dated 19.05.2022.***
>
> ***Since the matters are still pending before the learned Single Judge of the High Court, we see no reason to entertain these Special Leave Petitions challenging the common orders dated 14.12.2021****.*
>
> ***We however reserve the liberty to the petitioner to advance such submissions before the learned Single Judge as are deemed appropriate.***
>
> ***With these observations, the instant Special Leave Petitions are disposed of.***
>
> ***Pending applications, if any, also stand disposed of****."*

61. The above order of the Supreme Court clearly noticed several earlier orders as also the Policy which was modified in May 2022 wherein the amount was increased to Rs.50 lakhs per patient.

DART, Indigenous Therapies, and the Amended NPRD 2021

62. On 1st June, 2022, this Court had directed the ld. *Amicus* to contact Dr. Apurba Ghosh and Dr. Arun Shastry, two doctors researching rare diseases, to attend the proceedings. On 5th August, 2022, Dr. Shastry appeared before the Court.

63. In respect of development of drugs and medicines for rare diseases, the Court was informed that DART had developed a drug for the treatment of DMD and had received statutory permission from the Director General of Health Services on 25th August, 2020 to conduct clinical trials for the drug. It was stated that the first phase of the clinical trial had been completed and the drug had shown encouraging results in an individual patient who was administered the drug over 26 weeks. The drug has been approved for the second and third phase of clinical trials, with nine trial sites identified and 54 children already enrolled for participation. However, the issue of funding for the expenses related to the clinical trials, which require around Rs. 20 lakhs per child, was raised. In respect of the funding, the Court noted that the Office Memorandum dated 19th May 2022, had enhanced the financial support in respect of rare diseases from **Rs. 20 lakhs to Rs. 50 lakhs** for the treatment of patients suffering from rare diseases listed in the NPRD 2021. The experimental trials were being conducted for DMD, which had been recognized as a rare disease under the NPRD.

64. Thus, on 5th August, 2022, the Court was of the opinion that the financial support envisaged in the Office Memorandum dated 19th May

2022 could potentially cover the expenses related to the clinical trials of the DMD drug. The significant cost difference between DART's trial drug and other experimental therapies currently available, as well as the potential for this indigenously developed drug to be used to treat many more DMD-afflicted children in India and worldwide, warranted consideration by the Union of India. In addition to the cost-saving benefits, the clinical trial could lead to a readily accessible treatment for DMD in India.

65. Further, the Court acknowledged that the said drug was still undergoing rigorous clinical trials to assess its efficacy. The Court was also conscious of the submission made on behalf of AIIMS that existing drugs might help in slowing the decline of cardiac and respiratory functions in patients. However, there was no clear evidence to suggest that such treatments could halt the progression of the disease. Given that even the costliest experimental therapies present used lack long-term clinical studies[3], the Court observed that that these factors ought to be considered by the competent authority in the Union Government while determining whether expenses for the 54 enrolled patients should be covered under the said Office Memorandum. Thus, funding issue was a roadblock to further trials and this Court sought to explore whether the financial assistance provided under the Office Memorandum of 19th May 2022 (which increased financial support from Rs. 20 lakhs to Rs. 50 lakhs) could be used to cover the clinical trial expenses.

66. Additionally, on the said date, the Court noted that the Rare Diseases Cell in the Department of Health and Family Welfare had received indents from AIIMS on 1st August, 2022 for children not enrolled in the clinical

trials, who would require treatment with existing alternatives available at the various CoEs. On this aspect, Mr. Chetan Sharma, ld. ASG, was directed to obtain instructions on whether the Office Memorandum dated 19th May 2022 be applied to cover the expenses for the second and third phases of the clinical trials of the experimental drug, as well as the treatment of the children enrolled in those trials.

67. On 18th October, 2022, the Court was informed that the Union had filed an affidavit of compliance, appending the minutes of the 14th meeting of the Central Technical Committee for Rare Diseases *(hereinafter, 'CTCRD')*, held on 2nd September, 2022. The CTCRD, in light of the Court's previous order, stated that financial assistance up to Rs. 50 lakhs per patient was intended for the ***'treatment'*** of rare diseases. CTCRD expressed the view that conducting clinical trials is the responsibility of the drug developer, and that under-trial drugs might not qualify as "treatment" under the financial support scheme.

68. The Court, however, referred to its order of 5th August 2022, where it had already noted that the Office Memorandum dated 19th May 2022 could potentially cover the expenses of administering the trial drug. The Court emphasized that many of the drugs presently being used for treating children with rare diseases are themselves experimental therapies, lacking definitive research to prove efficacy. Therefore, indigenously developed experimental drugs should be treated in a similar light. In this backdrop, the Court on 5th August, 2022 had asked the Union to consider whether the financial support under the Office Memorandum could also be extended to the 54 children enrolled in the clinical trial for the DMD drug. The Court reiterated the need

[3] Reference is made to affidavit dated 30th May, 2022.

for a pragmatic approach, especially considering the high costs of importing other experimental drugs.

69. As recorded in the order dated 18th October, 2022, the CTCRD also raised the issue that the Rs. 50 lakhs support was tied to treatment being administered at a CoE, and not all nine trial sites are designated as CoEs. The Court observed that three of the nine sites—Indira Gandhi Institute of Child Health (Bangalore), AIIMS (Delhi), and Post Graduate Institute of Medicine and Research (Chandigarh)—are CoEs. Thus, the Court directed the Union to consider releasing the grant for children enrolled in clinical trials at these sites while also considering the geographical constraints that patients might face if strict limitations are applied. The Court also clarified that the CTCRD is not restricted from evaluating the data from completed trial phases and determining whether further exploration is warranted.

70. In relation to the treatment for rare diseases for the Petitioners, Mr. Oberoi, ld. Counsel for AIIMS, informed the Court on 18th October, 2022, that funds for all 14 Petitioners had been received, and the procurement process for the necessary drugs, including imports, had commenced. He assured the Court that the process would be expedited to ensure timely treatment. Additionally, the Court considered the case of the Petitioners in ***W.P.(C) 1491/2021 and W.P.(C) 1511/2021***, both suffering from MPS II (Hunter Syndrome, Attenuated Type). Mr. Oberoi submitted that the treatment for the Petitioner in ***W.P.(C) 1511/2021*** was funded by crowdfunding effort by the child's parents, and confirmed that the ongoing procurement process would also cover the treatment of Petitioners in both cases.

71. In respect of funding of clinical trials, an affidavit dated 28th

November, 2022 was placed on record by the MoHFW which included an agreement between the DBT and DART. The said affidavit stated that MoHFW had convened a meeting with key stakeholders, including representatives from Indira Gandhi Institute of Child Health (Bangalore), AIIMS (Delhi), Post Graduate Institute of Medical Research (Chandigarh), Indian Council for Medical Research (ICMR), and the Central Drugs Standard Control Organisation (CDSCO). The purpose of the said meeting was to discuss issues raised by this Court in its order dated 18th October, 2022. It was submitted that none of the experimental drugs under trial /research are administered to patients with rare discases. Drugs are being used only after approval from regulatory bodies like FDA/EU/DCGI etc. Experimental drugs under research were only given to patients enrolled in the trial after going through the process of Ethics Committee's clearance, consenting from the family etc. as per the guidelines. Hence, the drugs being used which are undergoing trials and the ones being given for treatment cannot be considered similar.

72. The same affidavit also described the CDSCO's stand. As per the CDSCO, drugs approved/licensed under the Drugs and Cosmetics Act, 1945, *(hereinafter, 'Drugs and Cosmetics Act')* may be used for treating rare diseases. Important provisions of the Drugs and Cosmetics Act are as follows:

- For imported drugs, provisions under Rule 36 of the Drugs Rules, 1945 allow the import of small quantities for personal use, provided a prescription is made by a registered medical practitioner and CDSCO grants approval in Form 12-A.
- Rule 86 of the New Drugs and Clinical Trial Rules, 2019 allows a

medical officer from a government hospital or institution to import a drug not approved in India but authorized for marketing in the country of origin for treating life-threatening diseases. Such drugs can be imported with approval in Form CT-25 from CDSCO.

73. With regard to financial assistance for patients, the said affidavit stated that the provision under Para 10 of the NPRD, 2021, allows financial support of up to ₹20 lakh for the treatment of rare diseases listed under Group 1. This includes diseases that require one-time treatment and is available under the Rashtriya Arogya Nidhi scheme. The said financial assistance was originally available to Below Poverty Line (BPL) families but was extended to cover about 40% of the population, eligible under the Pradhan Mantri Jan Arogya Yojana (PMJAY), for treatment at government tertiary hospitals. This provision was amended in May 2022, increasing the financial assistance limit to ₹50 lakh per patient. The procedure for accessing financial assistance was simplified as per the Guidelines and Procedures for Financial Assistance for Rare Diseases, dated 11th August, 2022. Therefore, as per the affidavit, support of a maximum of Rs. 50 lakhs per patient provided through the Guidelines, is only for the *"treatment"* of the patients suffering from Rare Diseases. The affidavit took the stand that the NPRD only mentioned about the financial grant being provided to the patients of rare diseases, and does not mention about the financial grants being provided to the trial subjects.

74. The other important aspects of the said affidavit are as follows:

- As per the affidavit, till 28th November, 2022, representatives from AIIMS, PGIMER, and CHG (Bengaluru) confirmed that, as of the meeting, no patients had been enrolled in the 3 CoEs for clinical trials.

Only one patient was enrolled privately by the DART group, but the results are not available with the DCGI, and therefore, could not be generalized without DCGI's approval.

- DART's Financial Support from BIRAC: Dr. Sanjeeva GN from CHG, Bengaluru, informed that DART group had approached Biotechnology Industry Research Assistance Council *(hereinafter, 'BIRAC')* for funding. BIRAC had approved a project through the Biotechnology Industry Partnership Programme *('BIPP')* for a 24-month duration. The Grant-in-aid Letter Agreement was signed between Hanugen Therapeutics Pvt. Ltd. (Bengaluru) and BIRAC. Hanugen is the laboratory arm of DART and BIRAC.
- CDSCO granted permission to DART on 25th August, 2020 to conduct a clinical study titled *"A Double Blind, Placebo-Controlled, Multicentre Study with an Open-Label Extension to Evaluate the Efficacy and Safety of 2'O Methyl Antisense Oligonucleotide in Patients with Duchenne Muscular Dystrophy"*. DART declared that it was the sponsor of the clinical study and responsible for funding it entirely. Neither the investigators nor the institutions involved in the study will bear any costs.

75. Thus, on 29th November, 2022, this Court, considering the stand of the Union of India, and that DBT & DART had an important role in these matters, impleaded Union of India, through Secretary, DBT and DART as Respondent Nos. 3 and 4 respectively. DART was also permitted to place an affidavit on record explaining the manner in which the clinical trials would proceed further.

<u>Continuous Efforts towards commencement of treatment</u>

76. On 9th December 2022, the Court issued several directions regarding the treatment of rare diseases under the NPRD, 2021. The NPRD was notified on 30th March 2021, and set up a consortium of CoEs led by AIIMS, and established a Rare Diseases Committee within AIIMS.

77. In respect of the crowd-funding platform, the Court noted that the crowdfunding platform, as directed to be set up by the order dated 23rd March 2021, was operational but required publicity to attract contributions from the general public and corporate entities, including PSUs. Thus, the Court directed the Union of India to communicate details of the said platform to all Navratna PSUs and at least ten major business houses/private companies in India to encourage contributions under their CSR initiatives. A follow-up was also directed, and any responses were to be placed on record.

78. In respect of the Rare Diseases Fund, the Court was informed that the same was being managed by the MoHFW. The Court directed the MoHFW and the DBT to file a status report detailing the following:

- Compliance with the directions of the 23rd March, 2021 order.
- Data on the number of patients for whom CoEs have received funding and commenced treatment.
- Timelines followed by the Ministry for approving funding and treatment.

Commencement of Gaucher's Treatment

79. Further, on 9th December, 2022, the Court was informed that treatment for patients suffering from Gaucher Disease had commenced. However, despite repeated orders of this Court, treatment for DMD patients had not yet begun. Mr. Oberoi, ld. Counsel for AIIMS, stated that funds were received for some patients, tenders had been called, and purchase

orders had been placed with manufacturers. In respect of this submission, the Court directed AIIMS to place on record an affidavit outlining the expected timelines for receiving the medicines and starting treatment for DMD patients. AIIMS was also directed to file a detailed status report on the working of the Rare Diseases Committee.

80. In respect of Indigenous Development of Treatment for Rare Diseases, on 29th November, 2022, the Court was informed about the Memorandum of Understanding *('MoU')* between BIRAC and Hanugen dated 8th January 2021, for conducting a multi-centric study on therapeutic evaluation for DMD patients. The approved amount for the study was Rs. 9.24 crores, with 50% funding from the government and 50% from Hanugen. On 9th December, 2022, this Court was informed that while Phase 2-3 trials of the therapy were approved by the DCGI, and 54 patients had been enrolled, the trials were delayed due to a lack of funds.

81. Recognizing the importance of developing indigenous therapies to reduce reliance on expensive imported medication, this Court directed Hanugen Therapeutics to file an affidavit, detailing the funding requirements, patient enrolment, DCGI approval, and the plan for conducting the Phase 2-3 trials.

82. Considering the high cost of the trials, this Court directed the ld. CGSC to seek directions on whether Rs. 5 crores could be released from the Rare Diseases Fund to Hanugen to commence the trials.

Cont. Cas(C) 722/2022

83. In the meantime, the captioned contempt petition was filed alleging that the AIIMS had not commenced the treatment, pursuant to the orders dated 19th January, 2022 and 2nd February, 2022 passed by the Court. As per

the said two orders, the Petitioner had to be provided free of cost Enzyme Replacement Therapy treatment.

84. In respect of this, Mr. Oberoi, ld. Counsel for AIIMS, under instructions, submitted that the first infusion was administered on the Petitioner on 2nd December, 2022. An affidavit dated 8th December, 2022, was also placed on record to this effect. The timeline of events in the case of the Petitioner-Insha, was as follows:

- 2022: AIIMS requested funds from MoHFW for the treatment of patients including Insha, but no funds were released under the NPRD 2021 as her condition (Group-3 disorder) was not covered.
- ***19th May, 2022***: The NPRD, 2021 was amended, increasing financial support to Rs. 50 lakhs per patient, covering all categories of rare diseases (Group-1, 2, and 3).
- ***22nd July 2022***: AIIMS, in light of the amended NPRD-2021, submitted a fresh request for funds to the MoHFW for the treatment of Insha and other patients.
- ***Mid-October 2022***: The funds were received by AIIMS from the MoHFW.
- ***2nd November 2022***: Administrative approval for the procurement of medicines was granted by AIIMS.
- ***10th November 2022***: Financial approval for procurement was issued.
- ***12th November 2022***: Supply orders for the medicines were placed.
- ***15th November 2022***: The medicines were received by AIIMS.
- ***29th November 2022***: The Petitioner was called to AIIMS for the infusion of the medicine, but was unable to attend.

- ***2nd December 2022***: The first dose of the medicine was administered to the said Petitioner.
- ***16th December 2022***: The next dose scheduled to be administered to the Petitioner.

85. Thus, from the affidavit placed on record by AIIMS, the total time taken for the process, from the fresh request for funds from MoHFW to the administration of the first dose of medicine, was approximately **4 months**.

86. In view of the submissions made, and considering the fact that the Petitioner-Insha had received the requisite treatment, the contempt was disposed of.

87. In respect of the directions contained in the order dated 9th December, 2022, the Union of India placed on record a note dated 22nd December, 2022. The said note detailed the steps taken by the MoHFW in respect of the directions contained in the order dated 9th December, 2022. A point-wise of the said note is as follows:

- ***Efforts to publicise Online Crowdfunding Platforms***: A virtual meeting was held on 17th June, 2021 chaired by the Union Minister, involving key ministries, industry associations, and PSUs to raise awareness about rare diseases and the need for voluntary donations. The Ministry of Corporate Affairs *('MoCA')* was requested to include "Donation for Rare Diseases" under Schedule VII of the Companies Act, 2013, to facilitate contributions under CSR provisions.
- ***MoCA's Response:*** On 27th August 2021, MoCA responded, stating that Schedule VII already includes "promoting health care", which covers the treatment of rare diseases, making it eligible for CSR contributions. Request was made to MoCA to again look into

including “Donation for Rare Diseases” more specifically in the CSR provisions.

- ***Action taken Department of Public Enterprises (‘DPE’):*** On 30th September, 2022, the Department of Public Enterprises (DPE) was requested by the MoHFW to encourage PSUs and corporate bodies to contribute under CSR to the treatment of patients with rare diseases or directly to CoEs. On 10th October, 2022 DPE urged MoCA to expedite proposals allowing CPSEs to spend CSR funds on Rare Diseases Research & Development.
- As per guidelines issued on 11th August 2022, CoEs are permitted seek financial assistance from other agencies, drug manufacturers, or corporates through CSR under an MoU, which needs to be finalized and approved by the CoE’s committee.
- ***Budget Allocation for Rare Diseases***: A budget of Rs. 100 crore was initially allocated for rare diseases treatment during the 2019-2020 financial year under the Rashtriya Arogya Nidhi (RAN) scheme. However, only Rs. 1.30 crores were released during that period, and the unutilized funds lapsed at the end of the financial year. In 2022-23 (as of 16th December, 2022), the Budget Estimate was Rs. 25 crores, the Revised Estimate was Rs. 25 crores, and the Expenditure was at Rs. 0.48 crore.
- The MoHFW reiterated its stand that DART was receiving funding from the DBT for their drug trial. Further, an amount of Rs. 141.375 lakhs as Grants-in aid was released to Hanugen vide BIRAC Ietter dated 2nd February, 2021.
- The MoHFW’s position was that the drug currently under trial is yet

to be approved by the DCGI, and there is insufficient data on its safety and efficacy for the broader population. It was further reiterated that since the drug under investigation had not yet proven its efficacy or safety, it could not have been administered to patients suffering from rare diseases. MoHFW emphasized that funds for the trial could not be released from the Rare Diseases Fund since it is allocated only for the treatment of patients with approved therapies. Therefore, MoHFW was unable to release Rs. 5 crores to support the trial.

88. In respect of the note submitted by the MoHFW, on 22nd December, 2022, this Court was of the opinion that, in order to ensure that there was a specific recognition of voluntary donations for rare diseases, the subject *"Donation for Rare Diseases"* ought to be included in Schedule VII of the Companies Act, 2013. This Court had directed the Union to sensitise the PSUs for resource mobilisation for rare diseases under the CSR fund of the companies. Different communications were stated to have been sent to the DPE. Concerning the same, this Court directed the MoCA to file an affidavit in respect of the status of the request dated 3rd August, 2021 and 13th June, 2022 made by the MoHFW, as also, the request dated 10th October, 2022 made by the DPE, which was also directed to file an affidavit on the request dated 10th October, 2022.

89. Considering the submissions, and the steps taken to publicise, this Court was of the clear opinion that the efforts in respect of the digital crowdfunding platform had not yielded desired results in creating awareness in the society. Thus, this Court directed the MoHFW to consider publicizing the crowdfunding platform by alternative means, including through television and radio platforms, as also, social media platforms, in order to

attract voluntary donations for the purpose of rare diseases. Any other steps deemed fit to be taken by the MoHFW, were allowed to be pursued.

90. On the same date, the Court noted that Guidelines and Procedure for providing financial assistance to patients suffering from rare diseases was issued on 11th August, 2022, and was communicated to all the CoEs. The Court was informed that the COEs were given the option to explore the possibility of receiving financial assistance from other agencies/drug manufacturers/corporate sector under CSR by signing an MoU. Thus, it was directed that the content of the said MoU may be finalized by the Committee of the CoE, and approved by the Director of the CoE.

MoU between DART and BIRAC

91. On 22nd December, 2022, this Court was informed that pursuant to the previous order dated 9th December, 2022, an affidavit dated 17th December, 2022, was filed on behalf of Hanugen, highlighting that the total budget for the clinical trials involving 54 patients was estimated to be Rs.13.15 crores. It was further submitted that Hanugen and DART were unable to fund their portion of the amount as per the MoU dated 8th January, 2021, signed with BIRAC. It was submitted that if clinical trial was conducted by administering the medicines in respect of half of the total of 54 patients, the total budgetary requirement for commencing the said trial, would be a sum of approximately Rs.5.35 crores. That amount would be required by Hanugen. Thus, this Court reiterated its earlier directions regarding release of 5 crores from the Rare Diseases Fund.

92. Upon a query from the Court, it was confirmed that BIRAC had already released Rs.1.41 crores and that the remaining Rs.3.2 crores would be required to complete the funding under the MoU. In view of the

submissions made, the Court had directed BIRAC to release Rs.5.35 crores for the commencement of clinical trials, subject to the intellectual property rights in the data and therapies vesting with the Government of India or BIRAC. The MoU dated 8th January, 2021, provided for 'Intellectual Property Governing Framework' for a drug development project. The New Intellectual Property (IP) rights belong to the company, unless the project is classified as a 'Nationally Important Project' by the Government of India. In such cases, specific terms for licensing, pricing, or march-in rights would apply to address public interest. According to the said MoU, the said project was not to treated as a 'Nationally Important Project'.

93. On the said date, this Court was of the opinion that the MoU dated 8th January, 2021, was executed when the full magnitude of the issue concerning rare diseases had yet to be fully recognized by the Court. Accordingly, the enormity of the challenges faced by children with rare diseases left no doubt in the Court's opinion that the development of treatment for such children ought to be considered a '*Nationally Important Project*'.

94. Dr. Shastry, representing Hanugen, confirmed to the Court that the company had no objection to the IP in the data and any therapeutics developed during the project vesting with the Government of India, subject to further terms negotiated with BIRAC. Consequently, the Court directed that a fresh agreement be entered into between BIRAC and Hanugen, outlining the intellectual property framework in accordance with this Court's observations.

95. Regarding the commencement of treatment for DMD patients, Mr. Oberoi, ld. Counsel for AIIMS, submitted that the affidavit pursuant to the

Court's order dated 9th December, 2022, was filed on 21st December, 2022. He further informed the Court that the medicines for DMD patients, which were being imported, were expected to arrive in India by 10th February, 2023, from the United States, and AIIMS was taking all necessary steps to expedite the process. The Court directed that the timelines mentioned be strictly adhered to, and the treatment of the patients commence without further delay. The said affidavit dated 21st December, 2022, placed on record the different therapies/treatments that were available for patients with DMD. The affidavit also provided *'Proposed DMD guidelines discussed in the meeting with modifications incorporated'*. A chart detailing all the available drugs as per AIIMS is reproduced below:

Name of the Medicine (Trade Name)	***Age Group as Applicable***	***Dose, Frequency, and Route (Oral/IV/Intrathecal/Intramuscular)***	***Any Major Side Effects***	***Cost (INR)***	***Approved by (FDA/ EMA/ DCGI)***	***Company (Brand Name)***
Eteplirsen (Exondys 51)	All age groups (exon 51 skipping amenable mutation)	30 mg/kg, weekly infusion (intravenous)	Balance disorder, vomiting	$936,000 (Rs 6,88,95,836) per person per year (for a 30kg patient)	FDA	Sarepta Therapeutics
Golodirsen (Vyondys 53)	All age groups (exon 53 skipping amenable mutation)	30 mg/kg, weekly infusion (intravenous)	Headache, pyrexia, abdominal pain, nasopharyngitis, cough, nausea, vomiting	$936,000 (Rs 6,88,95,836) per person per year (for a 30kg patient)	FDA	Sarepta Therapeutics
Viltolarsen (Viltepso)	All age groups (exon 53 skipping amenable mutation)	80 mg/kg, weekly infusion (intravenous)	Injection site reaction, upper respiratory tract infection, cough, fever	$1,092,000 (Rs 8,04,95,142) per person per year (for a 30kg patient)	FDA	NS Pharma
Casimersen (Amondys 53)	All age groups (exon 45 skipping	30 mg/kg, weekly infusion (intravenous)	Upper respiratory tract infection,	$936,000 (Rs 6,88,95,836) per person	FDA	Sarepta Therapeutics

	amenable mutation)		cough, fever, headache, arthralgia, oropharyngeal pain	per year (for a 30kg patient)		
Ataluren (Translarna)	Ambulatory patients aged five years and older	40 mg/kg/day, three divided doses (total dose divided into 10 mg/kg, 10 mg/kg, and 20 mg/kg 8 hourly doses), oral	Hyperlipidemia (cholesterol, triglycerides), renal function derangement (increase in serum creatinine, BUN, and cystatin C)	€3,60,000 (Rs 3,11,18,025) per person per year (for a 30kg patient)	EMA	PTC Therapeutics

96. The Court also addressed concerns regarding MPS II (Hunter Syndrome) patients in ***W.P.(C) 1491/2021*** and ***W.P.(C) 1511/2021***. It was submitted that, despite the assurances given on 23rd February, 2022, stating that the requisition for medicines would be received by 25th February, 2022, and treatment would commence thereafter, the medicines had still not been received. Thus, the Court directed AIIMS to ensure compliance with the earlier statement and to expedite the receipt of the necessary medicines.

97. Lastly, the Court revisited the issue of the Rare Diseases Fund, which was being managed by the MoHFW. The Court reminded the MoHFW of the previous directions issued on 9th December, 2022, requiring a status report detailing the compliance with previous orders, data on the number of patients who had received funding, and the timelines being followed for the approval of funding and treatment. Despite the lapse of time, such a status report detailing the compliances was still not filed.

DART and BIRAC: Framework for funding the clinical trials

98. On 30th January, 2023, this Court noted that pursuant to its order dated 22nd December, 2022, a direction had been issued for the release of

Rs. 5.35 crores by BIRAC to Hanugen. The said amount was directed to be released to enable the commencement of clinical trials for the indigenous development of therapies for DMD. The Court had also directed that a fresh agreement be entered into between BIRAC and Hanugen for the vesting of intellectual property rights in the data, therapies, and products/processes developed during the trial. A meeting for finalizing this agreement was scheduled for 12th January 2023.

99. On the said date, it was brought to the attention of the Court that no effective meeting had taken place between BIRAC and Hanugen as directed. Instead, Hanugen filed ***CM No. 4237/2023*** seeking clarification that the Rs. 5.35 crores was only the first tranche of payment for the clinical trials. In response, the Court took note of two emails sent by BIRAC on 13th January 2023, which indicated a misinterpretation of the previous order dated 22nd December, 2022. BIRAC sought clarification on the source of the remaining funds for the trial and incorrectly suggested that Rs. 5.35 crores was the total project cost.

100. Thus, the Court observed that the Rs. 5.35 crores were to be disbursed as the first tranche of payment, and it was clear from Hanugen's submissions that the total cost of the clinical trial was approximately Rs. 13.5 crores, with Rs. 10.67 crores still remaining to be funded. The Court had directed that half of the project amount be released to Hanugen to ensure the commencement of the trial, covering 50% of the enrolled patients for the first six months. Further, the Court recalled its earlier observations that the Government had agreed to release Rs. 50 lakhs per patient as financial support. The Court emphasized that the indigenous development of therapies for DMD was a viable and cost-effective alternative to the expensive

imported medicines, which cost approximately Rs. 50 lakhs per patient annually. The need for exploring indigenous research had been stressed in earlier orders as well, including the order dated 5th August 2022, which had underscored the importance of considering financial aid for clinical trials under the Office Memorandum dated 19th May 2022.

101. To ensure that the order dated 22nd December, 2022 is complied with, the Court directed that the order passed on the said date i.e., 30th January, 2023, along with the order dated 22nd December 2022, be brought to the attention of Ms. Alka Sharma, Managing Director, BIRAC, and Mr. Rajesh Gokhale, Secretary, Department of Biotechnology (DBT). Officials, along with representatives of Hanugen, were requested to hold a meeting to explore the **framework for funding the clinical trials in the larger interest of children suffering from DMD**. According to the Court, the Government had an obligation to invest in this research, given that there are multiple petitions filed by patients seeking financial assistance for treatment.

102. The Court further directed that a meeting between BIRAC and Hanugen be scheduled for 2nd February, 2023 to finalize the agreement on intellectual property and funding. The draft agreement was to be placed before the Court, and Mr. Amit Kumar from BIRAC was instructed to brief the concerned officials about the proceedings thus far.

103. On 15th February 2023, this Court reviewed the progress regarding the clinical trials for the indigenous development of treatments for rare diseases, including DMD. It was informed that a meeting had been held on 2nd February 2023, as directed. However, the minutes of the meeting revealed no significant progress. BIRAC, bound by the Biotechnology Industry Partnership Programme (BIPP), maintained that Hanugen

Therapeutics Pvt. Ltd. was obligated to contribute 50% of the total project cost, per their Grant-in-aid Letter Agreement.

104. Given this impasse, the Court directed that the matter ought to be now referred to the Secretary, MoHFW, for a decision regarding clinical trials for rare diseases, including DMD. The Court further directed that its previous orders dated 18th October 2022, 29th November 2022, and 9th December 2022 be communicated to the Secretary, MoHFW, by Mr. Kirtiman Singh, ld. CGSC.

105. The Court again on 6th March, 2023 noted that no consensus had been reached between BIRAC and DART regarding government funding for clinical trials for developing indigenous therapies for rare diseases. As a result, the Court referred the matter to the Secretary, Ministry of Health and Family Welfare. The minutes of the meeting held on 2nd February 2023 revealed that BIRAC was bound by the Biotechnology Industry Partnership Programme (BIPP), stalling further progress. Hence the further funding of clinical trials could not be undertaken and DART/Hanugen obtained funds on their own. They are currently stated to be continuing with their research and development process.

Commencement of Treatment

106. In respect of the commencement of treatment, which had been stuck for DMD patients, the Court noted that, despite funds being released by the MoHFW, as early as September 2022, no purchase orders had been placed with M/s. Sarepta, the sole supplier of DMD therapeutics. This was contrary to the representations made by ld. Counsel for AIIMS in earlier hearings, including on 9th December 2022, when it was submitted that tenders had been called and purchase orders had been placed. The Court expressed

concern over the grossly negligent attitude of the relevant authorities at AIIMS and directed an affidavit to be filed explaining the delay in placing the orders.

Affidavit filed by AIIMS in terms of order dated 30th January, 2023

107. An affidavit dated 11th February, 2023 was filed by AIIMS explaining the position with regard to the placing of orders for procurement of medicines for the Petitioners suffering from DMD. AIIMS had previously procured Eteplirsen medicines for another DMD patient, Ansh Singh, between 2019-2020, through myTomorrows (Sarepta's distributor in India), based on a Proprietary Article Certificate. The affidavit placed on record further demonstrated the manner in which the order was placed:

- ***17th August, 2022*** – MoHFW approved and sanctioned funds for AIIMS. Fresh quotations were obtained from myTomorrows in August 2022.
- Quotations/bids from two additional firms, I.B. Pharma Pvt. Ltd. and Alleviare Life Sciences Ltd., were also obtained on 15th September 2022 and 7th September 2022, respectively. The price bids received from these firms were substantially higher than the estimated cost.
- ***12th October 2022*** –AIIMS sent a request for the procurement of medicines.
- ***26th October 2022*** –Hospital Billing Section confirmed the receipt of funds by AIIMS.
- ***31st October 2022***: AIIMS proposed to retender the procurement due to the high prices received in the initial bids.
- ***1st November 2022*** –Administrative approval for uploading the

tender for procurement.

- ***7th November 2022*** – Tender floated.
- ***28th November 2022*** – Last date for the receipt of bids. Bids were received from Ikris Pharma Netwrok Pvt. Ltd., the distribution agent for myTomorrows.
- ***1st December 2022*** – Technical bid opened.
- ***20th December 2022*** – Price bid was opened.
- ***22nd December 2022*** – AIIMS sought information regarding the number of vials to be ordered for patients.
- ***6th January 2023*** – Treating doctors provided the required information.
- ***16th January 2023*** – Finance Division raised certain remarks and sought clarifications regarding the procurement.
- ***25th January 2023*** – Date when financial concurrence was provided by the Finance Department.
- ***31st January 2023*** – Date when the supply order was placed.

Thus, a total time of more than six months was taken from the time funds were sanctioned to the date when the order was placed. The supplies finally arrived on 17th March, 2023.

108. In relation to the commencement of treatment for children suffering from rare diseases, on 15th February, 2023 the Court reiterated its earlier directions from the order dated 14th December 2021, emphasizing that the treatment for these children ought to start immediately. The Court noted that any delay in treatment could be fatal, and directed AIIMS or the respective CoEs to provide the necessary treatment and medicines, with the costs to be

borne by the Union of India. The Court also reminded the Union of its responsibility to ensure that necessary funds were provided to these Centres.

109. Further, as per the order dated 30th January 2023, AIIMS was directed to file an affidavit regarding the non-placement of purchase orders for DMD medicines with M/s Sarepta. AIIMS has since filed an affidavit dated 30th January 2023, submitting a copy of the invoice issued on 31st January 2023 by M/s MyTomorrows, the distributor for Sarepta. Ld. Counsel for AIIMS, under instructions, informed the Court that although the delivery date was noted as 17th March 2023, it was expected by 28th February 2023 based on correspondence with Sarepta.

110. In the case of Ms. Alishba Khan, a patient suffering from Gaucher disease, the Court was informed that treatment was stopped due to the exhaustion of funds. AIIMS explained that the funds initially received for this patient had run out. The Court, noting that AIIMS was recognized as a CoE under the NPRD, 2021, directed the Union of India on 6th March, 2023 and 15th February, 2023 to immediately release Rs. 5 crores to AIIMS within two weeks to ensure that treatment for children, where it had commenced, would not be interrupted due to lack of funds. Dr. Kabra, head of the Rare Diseases Committee at AIIMS, was tasked with directly supervising the expenditure of these funds, and AIIMS was instructed to recommence treatment as soon as the funds were received.

111. The Court also noted that the Petitioners in ***W.P.(C) 1491/2021*** and ***W.P.(C) 1511/2021***, suffering from Hunter's Syndrome, had not yet begun treatment. Dr. Kanika from AIIMS, who was present in Court, informed that orders had been placed with Takeda Pharmaceuticals, and the treatment would commence upon receipt of the medicines.

112. Finally, on 15th February, 2023, the Court also directed the Union of India to file an affidavit within one week detailing the funds released from the Rare Diseases Fund to the various CoEs and the number of patients for whom treatment had been approved thus far.

DCGI and Sarepta

113. On 15th February, 2023, the Court was also informed that M/s Sarepta had registered for clinical trials in India for the same medicines being procured by AIIMS, with AIIMS Delhi identified as one of the trial centres. Accordingly, the Court directed the DCGI to file an affidavit providing details of M/s Sarepta's trial or any other trials approved for DMD, Gaucher, or Hunter's Syndrome therapies. A competent official from the office of the DCGI was also directed to be present.

114. On 1st March, 2023, this Court noted that affidavits were filed in compliance with its previous order dated 15th February, 2023, by the DCGI and MoHFW. During the hearing, Mr. Rajiv Manjhi, Joint Secretary, MoHFW informed that, under the existing policy of the Ministry, financial assistance of only Rs. 50 lakhs per patient could be released due to the NPRD 2021. The Court then considered the issue of clinical trials for DMD and Gaucher disease. From the submissions made and queries raised, it became clear to the Court that several clinical trials had already been approved by the DCGI in India for these diseases. The Court was informed that some candidates for these trials had already been enrolled, including some at AIIMS, Delhi. Moreover, it was revealed that some of these trials had even been completed. The said affidavit revealed that as of 1st March, 2023, the following clinical trials were on-going:

S.	***Applicant Name***	***Sponsor Name***	***Investigational***	***Disease***	***Status***

No.			***Product***		
1	M/s Medpace Clinical Research (India) Pvt. Ltd.	M/s PTC Therapeutics, USA	Ataluren	DMD	Study is active and ongoing
2	M/s PPD Pharmaceutical Development (India) Pvt. Ltd.	M/s Sarepta Therapeutics, USA	Casimersen & Golodirsen	DMD	Study is active and ongoing
3	M/s PPD Pharmaceutical Development (India) Pvt. Ltd.	M/s Sarepta Therapeutics, USA	Eteplirsen	DMD	Study is active and ongoing
4	M/s Dystrophy Annihilation Research Trust	M/s Dystrophy Annihilation Research Trust	2'O Methyl Antisense Oligonucleotide	DMD	No enrolment in the trial
5	M/s Siro Clinpharm Pvt. Ltd.	M/s Genzyme Europe B.V., Netherlands	Genz-112638	Gaucher Disease Type-1	Study is completed
6	M/s Siro Clinpharm Pvt. Ltd.	M/s Genzyme Europe B.V., Netherlands	Genz-112638	Gaucher Diseases	Study is completed

115. The Court expressed deep concern that despite the fact that this litigation had been ongoing for over two years, neither AIIMS nor the DCGI had brought the existence of these clinical trials to the Court's attention during this period. Such lack of transparency and communication, especially in a matter involving critically ill patients, was noted with some consternation by the Court. The Court emphasized that it should have been made aware of these trials earlier, especially since it had been actively involved in overseeing the treatment and care of the Petitioners.

116. Given the number of clinical trials and the large group of Petitioners—almost 30 in number—who were suffering from rare diseases, the Court found it necessary to gather a complete picture of the status of clinical trials and to ascertain how the Petitioners might benefit from them. To ensure that further proceedings would be effective and addressed all the

necessary facts, the Court issued the following directions:

- AIIMS was directed to submit a complete and detailed chart of all clinical trials being conducted for DMD and Gaucher disease in which AIIMS is involved. The chart should also assess the feasibility of enrolling the petitioners in these trials. The Court emphasized that this information was crucial to determine whether the Petitioners could be integrated into ongoing or upcoming clinical trials, which could potentially expedite their access to treatment.
- The Court ordered the DCGI to place on record a comprehensive chart of all clinical trials that have either been approved or are pending approval for DMD and Gaucher disease. This would include trials that were conducted in India and those currently enrolling patients. The Court expected this information to be detailed and up to date, ensuring that all relevant facts were made available.
- The Court also directed the MoHFW to specifically address the case of Petitioner-Alishba Khan. It was noted that the said Petitioner had begun receiving treatment for DMD, but this treatment was stopped due to the non-release of additional funds. The Ministry was directed to provide its position, explaining why the funds had not been released and what steps could be taken to ensure that the treatment could continue.

117. Despite the progress made during the hearing, the Court noted that the proceedings had remained inconclusive, primarily due to the large number of issues yet to be fully addressed. The Court also reminded all parties that the treatment of patients suffering from rare diseases like DMD and Gaucher was of utmost priority, and delays caused by bureaucratic hurdles or lack of

coordination between agencies would not be tolerated.

118. On 6th March, 2023, this Court assessed the ongoing efforts regarding the commencement of clinical trials and the release of funds for treatment. A Status Report dated 4th March, 2023 was handed over to the Court by ld. Counsel for AIIMS. The Report indicated the current clinical trials being conducted for rare diseases in India:

- By Sarepta Therapeutics (DMD):
  - Exon 51 skipping – Drug Name: Eteplirsen
  - Exon 45 & Exon 53 skipping - Drug Name: Casimersen (Exon 45) & Golodirsen (Exon 53)
- By PTC Therapeutics (DMD) for drug 'Ataluren'
- By Shaare Zedek Medical Center, Israel (Gaucher disease)

119. The said status report also assessed the eligibility of children before the Court for inclusion in these trials. Dr. Kabra and Dr. Shefali Gulati, who were present in Court, submitted that four children, namely Aviraj Garg, Shourya Maru, Chirag, and Aarav Garg, were found to be eligible on a preliminary assessment.

120. On the same date, Dr. Gulati informed the Court that Aviraj Garg had already been included in Sarepta's clinical trials. The other three children had been examined via video conferencing, and Dr. Gulati assured the Court that they would be physically examined, and necessary tests would be conducted on 9th March 2023. The Court directed that on 9th March 2023, the three Petitioners would be informed that if they agreed to participate in the trials, they would not be eligible to receive medication for the trial's duration. The Court directed that after obtaining consent, the children should be accommodated in the trials accordingly.

Approval for Further Subjects in Clinical Trials

121. On behalf of the DCGI, Mr. B.K. Samantrai, Deputy Drug Controller, informed the Court that approval for 19 additional subjects for the Sarepta DMD clinical trial was granted by DCGI on 2nd March, 2023. Additionally, as per the affidavit submitted by DCGI on 6th March 2023, post-trial access to medication would be provided to the trial subjects by Ms. PPD Pharmaceuticals Development (India) Ltd., as mandated by the New Drugs and Clinical Trial Rules, 2019.

Continued funding constraints and National Consortium

122. Mr. Rajiv Manjhi, Joint Secretary, reiterated that as per the Office Memorandum dated 19th May 2022, there was a cap of Rs. 50 lakhs per patient for treatment under the NPRD. However, it was submitted by Dr. Kabra and Dr. Gulati that the annual treatment costs for rare disease patients ranged between **Rs. 20 lakhs to Rs. 7 crores** per patient, far exceeding the cap.

123. On 6th March, 2023, following the Court's order on 15th February 2023, an OM dated 28th February 2023 stated that under the NPRD, 2021, the National Consortium for Research and Development on Therapeutics for Rare Diseases *(hereinafter, 'National Consortium')* could be provided with an expanded mandate. This mandate would include research, technology transfer, and indigenization of therapeutics for rare diseases, in coordination with ICMR and DHR. In light of the ongoing issues, the Court referred the matter to the National Consortium, instructing it to hold a meeting on clinical trials for DMD and Gaucher. The Consortium was tasked with providing recommendations to the Court on the following:

i. Funding of clinical trials for development of indigenous therapies in

respect of DMD and other rare diseases.

ii. The manner in which the order of this Court, directing releases of funds for treatment, dated 14th December, 2021 was to be implemented.

iii. The manner in which therapies were to be arranged for children with rare diseases, suffering either from DMD or other Lysosomal Storage Disorders.

iv. An affidavit was directed to be filed on the various research and development activities carried out by the National Consortium/DHR in respect of rare diseases and their current status.

124. This Court had directed that the National Consortium was free to call any other entity or person, deemed appropriate and whose participation would be required to make effective recommendations. The recommendations were to be comprehensive in nature and shall consider the following aspects:

i. The age of the children, whose life may be curtailed if the treatment is not commenced on priority.

ii. The expenses, which may be incurred if the medicines are to be provided to all the children which have approached the CoEs seeking treatment.

iii. The possibility and feasibility of exploring indigenous therapies in the already approved trials.

iv. Any negotiations or arrangements to be entered into with the companies, who already have approved therapies for administration to children with rare diseases in India.

<u>Directions qua Alishba Khan</u>

125. Regarding the Petitioner-Alishba Khan in ***W.P.(C) 2943/2020***, the Court was informed that her treatment was stopped in January, 2023 due to lack of funds. The Court had previously directed on 15th February, 2023 that Rs. 5 crores be released by the Union of India to AIIMS to ensure her treatment was not interrupted. To the said directions, Mr. Manjhi reiterated the Ministry's position that under the NPRD, a maximum of Rs. 50 lakhs could be released per patient. The Court noted that earlier orders dated 14th December, 2021 and 1st February, 2022 had directed the Union of India to release funds for the Petitioners' treatment. Attention was drawn to the fact that these orders had been upheld by the Supreme Court in its order dated 11th July 2022.

126. Thus, on 6th March, 2023, the Court directed that Rs. 5 crores be released by the Union of India within one week as an *ad hoc* amount, subject to further orders. AIIMS was instructed to immediately recommence Alishba Khan's treatment after receiving the funds.

127. On 29th May, 2023, this Court was informed that the said Petitioner had already received treatment worth Rs.50 lakhs. The NRDC, which was constituted on 15th May, 2023, was directed to consider her case for continuation of treatment. The Committee was also permitted to contact Sanofi India, if necessary, to facilitate this.

128. This Court again reiterated on 10th July, 2023, its previous directions where it had ordered the Committee to consider her case for continuation of treatment. AIIMS was instructed to procure the next level of treatment for her, especially as Rs.10 crores released by the Union of India had already been received by AIIMS. On 3rd August, Dr. Kabra informed the Court that, in the interim, Sanofi had agreed to provide three months of medication

further on humanitarian considerations.

129. On 1st September, 2023, the Court was informed that her treatment had commenced.

Report of the National Consortium

130. On 13th April, 2023, the Union of India placed on record the Report of the National Consortium dated 12th April, 2023 sent by the Department of Health Research. The salient recommendations of the said Report are as follows:

- Experts agreed that the clinical trial titled "A double-blind, placebo-controlled, multicentric study to evaluate the efficacy and safety of 2'O methyl oligonucleotide in patients with Duchenne Muscular Dystrophy" may aid in developing new treatments for DMD in India.
- CoE has provided the estimates of patients with DMD who may be requiring medicines and therapies across India. There is limited information on prevalence estimate on DMD cases in the country. As the annual birth rate in India is 24 million (the year 2021) at a sex ratio of 1.1 : 1, the approximate number of male births will be 12 million. At an estimated prevalence of 1 :5000 male birth for DMD, the total number of patients in a year will be about 2400 of which about 50% are amenable to therapy (approximately 1200).

131. On 20th April 2023, it was submitted by Ms. Shyel Trehan, ld. *Amicus Curiae*, that the Petitioners- Master Aviraj Garg and Master Shaurya Maru have been successfully enrolled in the Sarepta Therapeutics clinical trials. On the said date, Ms. Trehan informed the Court that although medicine doses had been procured for 14 DMD patients and the administration of these doses had begun, the funds allocated for these

children has been exhausted. Ms. Trehan also raised the issue that a consent form had been given to the parents of the patients by AIIMS, stating that only Rs. 50 lakhs worth of medicines would be provided. The Court directed AIIMS to file an affidavit explaining the reasoning behind this consent form.

132. It was pointed out that in relation to the release of Rs. 5 crores ordered earlier, the Union of India had filed an LPA being ***LPA 364/2023*** titled ***'Union of India v. Alishba Khan'***. Vide order 22nd November, 2023, the ld. Division Bench clarified that no interim order passed and that the ld. Single Judge was free to proceed ahead with the matter.

133. Dr. Nabendu Sekhar Chatterjee, representing the Indian Council of Medical Research *('ICMR')*, informed the Court that ICMR is willing to fund the on-site clinical trials directly. However, it was clarified that the manufacturing of the drug would need to be carried out by the relevant pharmaceutical company, and the associated costs must be borne by the company itself. In light of Dr. Chatterjee's submission, on 20th April, 2023, the Court directed Hanugen Therapeutics to submit an affidavit stating whether they can fund the manufacturing of the required drugs.

Arrangement of funds by Hanugen

134. In respect of directions given on 20th April, 2023, on 3rd May, 2023, ld. Counsel for BIRAC submitted that Hanugen had informed them that it had arranged its share of the funds under the Grant-in-aid Letter, and BIRAC was willing to proceed with the trials in collaboration with ICMR. Additionally, Hanugen was preparing to meet with ICMR to discuss the funding of on-site trials. Email communications to this effect was placed on record as part of annexures to the affidavit by BIRAC dated 8th May, 2023. Thus, on 3rd May, 2023, the Court directed Hanugen, BIRAC, and ICMR to

file affidavits detailing how they intended to proceed with the trials and funding by ICMR.

135. In the affidavit dated 8th May, 2023, BIRAC's stand was that Hanugen Therapeutics vide its e-mail dated 19th April, 2023 contacted BIRAC, and informed of having arranged the funds required for completion of the project from its end. It was reiterated by BIRAC that if the company contributes its share in the project as per the milestones mentioned under the GLA, BIRAC was ready and willing to provide the financial assistance as per the BIPP guidelines, GLA, and BIRAC norms.

136. On 20th April 2023, the Court was informed that the ICMR was willing to fund the on-site trials for therapies being developed by Hanugen-BIRAC. However, the responsibility for manufacturing the drugs and covering the associated costs would rest with the company. On 3rd May 2023, it was submitted by learned counsel for BIRAC that Hanugen had arranged its share of the funds, as per the Grant-in-aid Letter Agreement (GLA), and BIRAC was willing to continue supporting the agreement.

137. On 15th May, 2023, Dr. Shastry from DART and Mr. Amit Kumar representing BIRAC informed the Court that Hanugen had successfully arranged the second tranche of Rs.92 lakhs. Consequently, BIRAC was required to make its contribution as per the terms of the GLA. Additionally, the affidavit filed on 10th May, 2023 confirmed that ICMR had agreed to provide complete technical and financial support for clinical trials at four designated trial sites.

138. The Court directed on 15th May, 2023 that the clinical trials by M/s Hanugen should proceed without further delay. Since Hanugen had arranged its share of funds, BIRAC was directed to promptly contribute the second

tranche of funds. To ensure smooth coordination, the Court directed that a meeting be held during the week commencing 22nd May, 2023 between Hanugen, BIRAC, and representatives of ICMR. The purpose of the meeting was to develop a timetable for the clinical trials based on the approved protocols. The Court further directed that an updated status report be filed, based on instructions received from BIRAC and ICMR. This report would provide details on the progress of the clinical trials and any further developments.

139. An affidavit dated 26th May, 2023 was placed on record by the Union of India in respect of the meeting between ICMR, BIRAC and Hanugen which took placed on 23rd May, 2023. The same was considered by this Court on 29th May, 2023. The following action points emerged from the said meeting:

- ICMR would fund four clinical trial sites for the study titled "A Double Blind, Placebo-Controlled, Multicentre Study to Evaluate the Efficacy and Safety of 2'O Methyl Antisense Oligonucleotide in Patients with Duchenne Muscular Dystrophy" once Hanugen Therapeutics meets the conditions mentioned in the Minutes of the Meeting.
- ICMR would provide additional support to Hanugen Therapeutics in the form of Data Monitoring, Data Management, Quality Assurance, and Regulatory Support.
- BIRAC would inform ICMR if they wished to sign an MoU for the funding of the trial. BIRAC would nominate an official to be part of ICMR's secretariat to oversee the trial.
- **Tentative Timelines:** ICMR to complete the project review and hold

a meeting with site Principal Investigators (PIs) by 30th June, 2023. Hanugen Therapeutics would manufacture the required amount of investigational drug at a GMP-approved facility by the 3rd week of July 2023. ICMR to release the first-year funds to the trial sites by 30th September 2023.

140. On 10th July, 2023, Dr. Arun Shastry on behalf of Hanugen Therapeutics/DART, submitted that the arrangement with ICMR did not materialize. Hence, DART decided to proceed on their own by obtaining third party investment in accordance with the contract with BIRAC.

141. Accordingly, vide order dated 10th July, 2023, this Court allowed Hanugen Therapeutics/DART to proceed for clinical trials, however, DART/Hanugen was required to update the Court periodically on the progress of the trials.

AIIMS' application - constitution of the Rare Diseases' Committee

142. On 3rd May 2023, the Court considered an application filed by AIIMS, New Delhi, seeking permission to reconstitute the Rare Diseases Committee. The said application sought to replace the "two-member Rare Disease Committee", originally constituted by Court vide order dated 23rd March 2021, with a new Committee formed within AIIMS under the NPRD, 2021. Mr. Oberoi, ld. Counsel for AIIMS, along with Dr. Madhulika Kabra, who appeared virtually, submitted that the new COE Committee was formed at AIIMS to ensure efficient handling of rare disease cases. They listed the new members of the proposed Committee as follows:

Core Committee Members:

i. Dr. Madhulika Kabra, Chairperson (Professor, Dept. of Pediatrics & Head, Genetics Division)

ii. Dr. Arvind Bagga, Member (Prof. & Head, Dept. of Pediatrics)

iii. Dr. Sidhartha Satpathy, Member (Prof. & Head, Dept. of Hospital Administration)

iv. Dr. Vineet Ahuja, Member (Professor, Dept. of Gastroenterology)

v. Dr. Rakesh Lodha, Member (Professor, Dept. of Pediatrics)

vi. Dr. Rajesh Khadgawat, Member (Professor, Dept. of Endocrinology)

vii. Dr. Tulika Seth, Member (Professor, Dept. of Hematology)

viii. Dr. Jitender Sodhi, Member (Assoc. Professor, Dept. of Hosp. Administration)

ix. Dr. Kanika Jain, Member (Asst. Professor, Dept. of Hosp. Administration)

x. Financial Advisor or his representative, Member

xi. F&CAO (Hospital Billing Section), Member

xii. Administrative Officer, Legal Cell, Member

xiii. Dr. Neerja Gupta, Member Secy. (Addl. Professor, Dept. of Pediatrics)

143. The Court inquired whether such a large Committee would be efficient in dealing with urgent cases of children with rare diseases. Dr. Kabra assured the Court that the size of the Committee would not impede the timely and efficient decision-making process. Thus, the Court approved the reconstitution of the Committee, subject to the condition that the number of members should not cause any delays in decisions.

Treatment Progress: Case of specific Petitioners, and issuance of contempt notices.

144. On 3rd May, 2023, the Court perused a chart detailing the treatment provided to the Petitioners, revealing that some children had received the initial sum of Rs.50 lakhs under the NPRD, 2021, but others had not yet received the funds. The Court directed that Rs.50 lakhs be released within a week for the Petitioners listed from serial numbers 25 to 37. AIIMS was instructed to place orders for the necessary medicines to ensure timely commencement of treatment once funds were received.

145. In cases where treatment had been interrupted due to exhaustion of funds, such as the case of Alishba Khan and Master Keshav Sharma, the Court expressed concern over the severe consequences on their health. In respect of Master Ayushman Chaturvedi, the Court was informed that a vial was missing from his treatment, causing the treatment to stop on 11th April 2023. AIIMS explained that there had been a shortage in the supply, and the Court directed them to expedite obtaining the vial from the supplier.

146. Considering the stand of both the Union of India and the MoHFW, the Court emphasized the grave condition of the 40 children Petitioners before it, stating that if additional funds were not released, their medical conditions would deteriorate further. It was noted that previous orders directing the release of funds had not been implemented, which was of particular concern.

147. The Court referred to earlier orders and affidavits confirming that nearly Rs.193 crores allocated for rare diseases had lapsed, with only Rs.7 crores being spent between 2018 and 2021. Despite orders dated 15th February, 2023 and 6th March, 2023, directing the release of Rs.5 crores, the funds had not been released, and the Union of India had filed an LPA challenging these orders, though no stay had been granted.

148. The Court directed the Secretary, Ministry of Health & Family

Welfare, to be physically present at the next hearing, given the urgency of the matter. This Court also stated that it would consider whether to issue contempt notices in light of the Ministry's failure to release the directed funds.

149. The Rare Diseases Committee at AIIMS was directed to act with urgency and ensure that the missing vial for Master Ayushman Chaturvedi was obtained and administered as quickly as possible. The Court also ordered that all the children who had been administered medicines be physically evaluated, with a status report on their medical condition to be filed before the Court. On 15th May, 2023, it was informed to the Court that the one remaining vial was a wrong medicine sent by the supplier. The replacement for this vial would only be available in the next procurement cycle. This fact was also allowed to be brought to the notice of the National Rare Diseases' Committee, constituted on 15th May, 2023.

150. On 10th May, 2023, A supplementary affidavit was placed on record by the MoHFW. Salient points of the said affidavit are as under:

- The Ministry of Health & Family Welfare, under its Rare Diseases Cell, issued a sanction order on 8th May, 2023, approving Rs. 40 crores for rare disease treatment at 11 CoEs. AIIMS, New Delhi, received Rs. 10 crores for treating enrolled rare disease patients.
- The Ministry reiterated that this case does not involve adversarial litigation. The Ministry and the CoEs are utilizing limited resources optimally. If further funds are required beyond the present budget, an application to the Ministry of Finance would be necessary.
- The Court was asked to consider the fact that even with significant expenditure, rare diseases like DMD cannot be cured, only managed.

Therefore, a rational use of limited resources is crucial.

- The Department of Health & Family Welfare, ICMR, and BIRAC are fully committed to expediting the clinical trials, generating data, and submitting it to the DCGI. BIRAC has committed to funding 50% of the research costs. ICMR will fully support the trials at identified sites, covering the analysis of data, which will later be submitted for regulatory approval.
- The promoter companies, since they would be selling the drug (once approved), as a commercial enterprise, would need to invest the balance of financial resources. Thus, according to the Ministry, High Court may direct Hanugen to cover the costs of drug materials, manufacturing, and import for the trial.
- Subsequent to the order on 3rd May, 2023, the Respondent sought clarification from the ld. Division Bench in ***LPA 365/2023*** titled '***Union of India v. Master Arnesh Shaw'***, and the ld. Division Bench modified the order dated 3rd May, 2023 passed by this Court on 8th May, 2023, clarifying that the Joint Secretary, instead of the Secretary, should remain present before the Court as directed. The relevant portion of the said order reads as follows:

> *"Mr. Rajiv Manjhi, IAS, Joint Secretary, Ministry of Health and Family Welfare is present in person and has informed this Court that the Government of India has sanctioned about Rs. 40 crores vide order dated 08.05.2023 under the National Policy for Rare Diseases, 2021.*
>
> *Out of the Rs. 40 crores, Rs. 10 crores have been sanctioned only for All India Institute of Medical Science, and the matter is under active*

consideration for releasing the further amount which is required for treatment of such children.

By order dated 03.05.2023, the Secretary, Department of Health and Family Welfare was directed to remain present before the learned Single Judge. The learned ASG has stated that the Secretary, Department of Health and Family Welfare is already having a meeting of Committee of Secretaries on 10.05.2023 at 3:00 P.M., and in his place Mr. Rakesh Manjhi, Joint Secretary will remain present before the Learned Single Judge to assist the Court. The prayer made by the Learned ASG is allowed. The Order dated 03.05.2023 is modified to that extent. The Joint Secretary shall remain present to assist the Court*."*

151. In terms of the order dated 8th May, 2023 passed by the ld. Division Bench, on 10th May, 2023, Mr. Rajiv Manjhi, Joint Secretary, Ministry of Health and Family Welfare, was present in Court.

152. Mr. Oberoi, learned counsel for AIIMS, submitted that although the funds had been received, they were grossly inadequate. He highlighted that there were over 600-700 patients suffering from rare diseases who were still awaiting medicines and therapies. Thus, the Court directed that a chart be prepared and placed on record, detailing the nature of the rare diseases and the number of patients awaiting treatment for each disease. An affidavit dated 15th May, 2023 was filed which showed number of patients as follows:

S. No.	Disorder/Rare Disease	No. of Patients Enrolled	No. of Patients Amenable to treatment
1	DMD	517	312
2	SMA	189	189
3	Other Rare Diseases (e.g. Lysosomal Storage Disorders. Gaucher, MPS, etc.)	166	116

Sarepta's subscription model

153. During the course of hearing, one of the Petitioners informed the Court about an email from Sarepta, a pharmaceutical company, expressing their willingness to discuss a subscription model with the Government of India. In this model, the government would pay an annual fee for blocks of patients. It was further mentioned that, by the end of the year, approximately 80 patients with DMD would receive free medication as part of Sarepta's clinical trials. On 10th May, 2023, this email was handed over to Mr. Kirtiman Singh, CGSC, for obtaining further instructions from the Government of India regarding Sarepta's proposal. In the meantime, a second email from Sarepta dated 15th May 2023, confirmed that treatment for DMD patients could be facilitated if the Government initiated contact with the company.

Constitution of the National Rare Diseases' Committee (NRDC)

154. On 15th May 2023, the Court considered the creation and functioning of the National Rare Diseases' Committee *(hereinafter, 'NRDC')* to implement the NPRD, 2021 effectively.

155. The Court, having been considering petitions related to children with rare diseases since early 2021, noted the need for an effective and coordinated framework to treat these diseases. While the NPRD, 2021 had been notified, issues such as lack of data, awareness, high drug costs, and unavailability of treatment continued to hinder efforts. Thus, to address the ongoing challenges and ensure the proper implementation of the NPRD, 2021, the Court deemed it appropriate to constitute a **National Rare Diseases' Committee**, consisting of the following members:

- Director General - Indian Council for Medical Research (ICMR) (Member)
- Dr. Nikhil Tandon, Professor - AIIMS (Member)
- Secretary - Ministry of Health & Family Welfare or a nominee (Member)
- Drug Controller General of India (DCGI) (Member)
- Dr. Madhulika Kabra, Professor - AIIMS (Member)

156. The mandate of the Committee was to take all steps needed for implementation of the NPRD, 2021 including -

(i) Procurement of therapies & drugs and creation of associated logistical framework for administration of treatment for patients with rare diseases;

(ii) Recommending necessary steps for the indigenisation of therapies, medicines for rare diseases and identify the manner in which the same can be made accessible to the lakhs of patients who, as per the Policy, are suffering from rare diseases;

(iii) The Committee, while working broadly under the umbrella of the Policy, would undertake a periodic review of the Policy and recommend to the Ministry of Health and Family Welfare, the changes needed in the Policy if the same is deemed necessary.

157. In addition to the above mandate, this Court directed that the immediate requirement of the patients whose treatment has been stopped due to lack of funding, and whose details have been captured in **paragraph 16** of the order dated 3rd May, 2023 should also be taken up by the Committee on an urgent basis, so that the treatment could be re-commenced. The Committee was free to contact the providers or manufacturers or distributors of the DMD therapies as also other therapies, in a manner to ensure immediate commencement of providing adequate doses for the said patients.

158. The Committee was also free to consult any other persons or organisations as Invitees to the Committee meetings to work for the overall objective of the Policy. The Committee was also permitted to contact any subject expert or persons with domain knowledge for the sake of expediting the procurement of medicines or therapies.

159. In relation to the chart handed over by the ld. Counsel for AIIMS in respect of the patients suffering from rare diseases enrolled at AIIMS, this Court directed the NRDC to examine the cases of these patients enrolled at AIIMS and determine the manner in which their treatment can be commenced.

Working of the NRDC

160. On 29th May, 2023, this Court was informed that the NRDC, in the meeting dated 25th May 2023, discussed rare diseases extensively, identifying short-term, mid-term, and long-term goals. A short report was submitted by the NRDC setting out various aspects that were discussed and considered by them. On the issue of tackling of rare diseases in the Indian context , the NRDC categorised the goals as follows:

"10. ***Short-Term Goal***

Procurement of drugs *– for which following data is required-*

(i) Need of the drug dosages in the country i.e the number of patients suffering from the

rare diseases in the country.

(ii) How much resources are available for implementation of policy?

(iii)Need to enlist –

o Various rare diseases identified in the country.

o effective drugs for their management.

o who are the manufacturers of these drugs.

o Whether they are approved in the country.

(iv) How to make these drugs available in the country

o Through negotiations with the companies for prices.

o Promoting Manufacturing in the country through Technology Transfer.

11. ***Mid-Term Goal***

Indigenization of drugs *in the country-*

(i) Encourage generics.

(ii)Through Research and development of newer therapeutics.

12. ***Long-Term Goal***

Periodic review of the Implementation of "National

Policy of Rare diseases" through-

(i) To check change in demand of the drugs.

(ii) How much more number of patients with rare diseases are reported?

(iii) To check how many drugs are now available in the country?

(iv) How much more drugs needs to bring in the country.

(v) How much manufacturing has increased or generics came.

(vi) Research and Development of new drugs."

161. Role for each of the limbs was considered as follows:

- Role and Responsibility of AIIMS:
  - (i) To provide the list patients of rare diseases treated under CoE.
  - (ii) To provide list of various rare diseases, effective drugs, Drug cost and manufacturer.
- Role and Responsibility of DCGI:
  - (i) To check the regulatory status of the drugs effective in rare diseases.
  - (ii) To promote fast track approval of clinical trials for rare diseases in the country.
- Role and Responsibility of ICMR:
  - (i) To provide the epidemiological data/prevalence data of rare diseases in the country.
  - (ii) To promote and fund clinical trials for indegeniously developed drugs in rare diseases.

- Role and Responsibility of MoHFW:
  (i) To provide the available resources.
  (ii) To implement the rational use of resources through CoEs.

162. The key action points discussed were as follows:

- Dr. Madhulika Kabra was tasked with compiling a list of all rare disease patients treated under CoEs, along with a comprehensive list of diseases, drugs, costs, and manufacturers by 5th June 2023.
- Sarepta was to be called for discussions on how the drugs can be made available in India. In relation to this, Ms. Vidhi Jain, ld. Counsel for the Union of India had submitted that the Government had contacted Sarepta on 27th May 2023, inviting them to discuss the possibility of making medications for DMD available in India. Sarepta replied on 29th May 2023, agreeing to a virtual meeting with the Committee.

163. The Court on 29th May, 2023 reiterated the urgency for addressing the treatment of patients whose treatment had stopped due to a lack of funding. The Committee was directed to urgently take up these cases, as highlighted in paragraph 22 of the order dated 15th May 2023, to ensure the immediate recommencement of treatment. The Committee was also tasked with discussing treatment options with Sarepta and finalizing timelines for drug supply.

164. This Court was presented with the Minutes of the Meeting dated 13th June, 2023 of the NRDC on 10th July, 2023. One of the key issues raised was related to the DCGI clearance for market authorisation for M/s Sarepta Therapeutics. The Court noted that while Sarepta Therapeutics did not have marketing approvals in India, AIIMS and other CoE had been importing

medications from Sarepta through distributors and administering them to patients across the country. Thus, the Committee was directed to proceed with negotiations with Sarepta Therapeutics, especially considering the urgency for those patients who have already received doses and need further medication. The Committee was also tasked with expediting the national procurement of medications to ensure there are no delays in administering them to patients.

165. Vide order dated 3rd August, 2023, this Court considered the non-continuation of medication to DMD patients, who are 14 in number due to exhaustion of funds provided under the NPRD, 2021. These patients already received treatment till about March-April 2023. The concern of these patients and their parents was that if further doses were not administered, it would have an adverse impact on their health.

166. Thus, the Court directed the NRDC to take a specific position on how to proceed with these 14 DMD patients who had already received medical doses.

Spinal Muscular Atrophy (SMA)

167. On 3rd August 2023, this Court considered the issues arising out of another rare disease, Spinal Muscular Atrophy *(hereinafter, 'SMA')*. In ***W.P.(C) 11610/2017***, titled '***FSMA India Charitable Trust v. Union of India'***, notice was issued to Mr. Pravin Anand, ld. Counsel representing some pharmaceutical companies involved in making therapies for SMA. On 21st July 2023, this Court directed the NRDC to review a note submitted by Mr. Anand Grover, ld. Senior Counsel, and to engage with companies manufacturing and marketing medicines for SMA to explore reasonable

pricing. The Court emphasized the importance of effective negotiations between the companies and the NRDC, noting that any positive response would significantly impact the lives of children suffering from rare diseases. Companies were also asked to consider providing medications as part of their CSR.

168. On the said date, Mr. Pravin Anand, ld. Counsel for Roche, informed the Court that Roche manufactures ***'Evrysdi-Risdiplam'***, which is the only approved treatment for SMA in India. Roche has made significant efforts to make the drug available for patients, both through compassionate programs and commercially. Of the 168 patients receiving Roche's treatment for SMA, 56 are treated for free under the company's Compassionate User Program (CUP). Another 53 patients are covered under various government policies. The remaining 59 patients are purchasing the drug under Roche's Patient Access Program, where for every two bottles purchased, three are provided free of cost.

169. The Court was informed on 3rd August, 2023, that Roche, Sanofi, and Sarepta had been actively negotiating with the NRDC regarding pricing. A meeting was held on 17th July 2023. Ms. Vidhi Jain and Mr. Swarnendu Singha informed the Court that discussions with pharmaceutical companies regarding pricing and supplies were continuing, with solutions to be expected soon. Dr. Madhulika Kabra from AIIMS, participating virtually, assured the Court that ongoing clinical trials at AIIMS would attempt to enroll the Petitioners in trials for well-accepted treatments globally.

170. On 1st September, 2023, Mr. Pravin Anand, ld. Counsel, informed the Court that the Managing Director of Roche India had met with the NRDC on 30th August, 2023. Roche agreed to submit a proposal to the NRDC within a

week from the meeting.

Customs Duty and GST

171. In respect of medicines for SMA, on 3rd August, 2023, Mr. Pravin Anand raised the issue of taxes and customs charges. While there are no taxes or customs duties when patients import rare disease medicines, companies importing such medicines face 11% customs duty and 12% GST. He argued that an exemption from these taxes would significantly reduce the cost of the medicines.

172. Regarding customs and GST issues, Mr. Singha submitted that the matter was raised with the Ministry of Finance.

Cure SMA Foundation of India

173. Mr. Anand Grover, ld. Senior Counsel representing Cure SMA Foundation of India, on 3rd August, 2023, offered to nominate two representatives to participate in the Committee's discussions. The Cure SMA Foundation consists of parents of over a thousand SMA patients. The NRDC was directed to consider meeting with two representatives of the Foundation to understand the practical issues faced by SMA patients. Mr. Grover was directed to submit a complete list of all the Foundation's members, including their age groups and current weights, to communicate the data to the CoEs.

Further directions qua NRDC

174. On behalf of the NRDC, a status report dated 1st September 2023 was presented to the Court on 1st September, 2023. The NRDC had engaged in deliberations with various companies that manufacture and sell drugs for rare diseases, including Sanofi Therapeutics, Sarepta, Roche Pharma, and Takeda Pharmaceuticals. Additionally, the NRDC was negotiating with

BioMarin Pharmaceutical, Novartis, and Pfizer. Further, the NRDC was in active deliberations with all these companies who agreed to give their proposals to the Committee by 15th September, 2023. The NRDC decided to put in place a mechanism to provide treatment to patients suffering from rare diseases for at least five years and on the said basis, called for proposals from the companies. NRDC also appealed to pharmaceutical companies to continue supporting treatment for 14 DMD patients who have exhausted the maximum funding limit of Rs. 50 lakhs. NRDC also planned to approach the Secretary, Department of Public Enterprises, to encourage PSUs to support rare disease treatments under CSR programs. Relevant portion of the report is set out below:

> *"6. The third meeting of National Rare Diseases' Committee was held under the Chairmanship of Secretary DHR & DG ICMR on 17.07.2023. In the 3rd meeting of NRDC, representatives from M/s Sarepta Therapeutics, M/s. Sanofi, M/s. Roche Pharma were invited for discussions.*
>
> *7. As per the mandate of the Committee, positive discussions were held with those pharma entities towards negotiation for reduction of prices of the drugs used for treatment of rare disease patients and options would be explored for central procurement.* ***It is also informed that a physical meeting with representatives of M/s Sanofi India was again held on 01.08.2023 so as to understand the requisite data they require for preparation of a proposal for price negotiation from their side.***
>
> *8. Fourth and Fifth meetings of NRDC were held on 24.08.2023 and 30.08.2023 under the Chairmanship of Secretary, DHR & DG, ICMR. In the 4th meeting, the Committee met with the representatives of M/s Sanofi India and M/s Takeda Bio- pharmaceuticals Pvt. Ltd. In the 5th meeting, the Committee met with M/s*

Sarepta and M/s Roche Pharma for further discussions relating to pricing and supplies of medicines. The Committee had decided to meet more companies like Pfizer, Novartis etc.

9. As regards continuance of the treatment of the 14 DMD patients who have already exhausted max. limit of Rs. 50 lakhs, it is stated that the Chairman of the Committee made an appeal to the companies to support treatment of the patients ensuring continuity till the time a final decision is arrived at.

10. The Committee has decided to approach Secretary, Department of Public Enterprises for requesting them to sensitize the PSUs to support the treatment of rare diseases patients from Corporate Social Responsibility (CSR).

11. All the Pharma companies to whom the Committee has met, have agreed to submit their proposal in respect of the offered price of drugs in a sealed envelope by 15.09.2023 to the Committee. ***The Committee has decided to put in place a mechanism to provide treatment to the rare diseases patients for atleast 5 years or so****."*

175. On 13th October, 2023, the Court was informed that a petition titled ***'Ratnesh Kumar Jigyasu v. Union of India' (W.P.(C) 1012/2023)*** had been filed before the Supreme Court on behalf of 251 persons, a majority of whom are minors suffering from muscular dystrophy, seeking the formulation of a national plan for their treatment. The Supreme Court, in its hearing on 6th October 2023, issued notice to the Union of India.

176. The NRDC, in its previous status report, indicated that the Chairman had appealed to pharmaceutical companies to continue the treatment for these 14 patients. However, the Court was informed on 13th October, 2023, that the treatment had still not started. The NRDC was directed on 13th October, 2023, to obtain a specific assurance from the companies and to

direct Dr. Madhulika Kabra and her team to proceed with the treatment of these patients. The Court was also informed that the final meeting of the NRDC to negotiate prices for procuring medicines for rare diseases was scheduled for 17th October, 2023. To this, Mr. Pravin Anand, ld. counsel for Roche, submitted that Roche had already submitted its proposal in a sealed envelope to the NRDC.

Treatment of Medhansh Jhawar and Kenith Jhawar

177. Regarding the cases of Medhansh Jhawar and Kenith Jhawar ***(W.P.(C) 1491/2021 and W.P.(C) 1511/2021),*** the Court was informed on 1st September, 2023, that both children had received treatment through the Rs. 50 lakhs funding limit under the NPRD, 2021, as well as through crowdfunding. If their funds were exhausted, AIIMS was directed to continue providing treatment until the matter was heard. Thus, the Court directed the continuation of treatment for children in the interim period, till the matter was finally heard.

178. Despite specific orders from the Court on 1st September, 2023 directing that their treatment be continued until the next hearing, the Court was informed on 13th October, 2023, that the treatment for Medhansh Jhawar and Kenith Jhawar had stopped. Their father had approached Dr. Madhulika Kabra, who had refused to continue the treatment. The Court reiterated that the order of 1st September 2023 was clear, requiring the continuation of treatment for Medhansh and Kenith. The medicines they had already received would be rendered ineffective if further doses were not administered. The Court directed Dr. Madhulika Kabra to immediately recommence their treatment until further orders.

179. On 2nd November, 2023, this Court was informed that despite

repeated orders, the treatment of these two children has not been continued by AIIMS. Considering the submissions, this Court was of the opinion that the nature of the present batch of petitions was intrinsically non-adversarial, and it was not the intention of the Court to seek deficiencies in actions taken by AIIMS. It was made clear that compliance with the orders of this Court was expected as a part of a collective effort to address the challenges faced by children with rare diseases.

180. Dr. Kabra and Mr. Oberoi, ld. Counsel on the said date submitted that there was a communication received from the Government of India stating that a budget of Rs.10 crores had been allocated for children with rare diseases. The Court pointed out that the sum of Rs.10 crores was released pursuant to the orders passed by this Court on various instances, i.e. 15th February 2023, 6th March 2023 and 10th July 2023. In respect of the two children i.e. Medhansh Jhawar and Kenith Jhawar in ***W.P.(C) 1491/2021 & W.P.(C) 1511/2021*** who need the MPS II ('Hunter Syndrome, Attenuated Type') treatment, the Court directed AIIMS to continue their treatment till further orders of this Court, from the funds received from the Government of India. The Court emphasised that the health of these children cannot be compromised in this manner.

181. In respect of the treatment of both the patients, AIIMS' status report dated 6th December, 2023 revealed the following aspects:

- AIIMS had written to MoHFW seeking funds for the continuation of treatment. The estimated cost for their treatment was Rs. 19,45,000/- per month, and AIIMS requested MoHFW to sanction this amount.
- Since no response was received, AIIMS sought internal permission to provide one month's treatment for the two patients using available

AIIMS funds, with the expectation of reimbursement once funds were sanctioned. **The treatment was provided on 6th December, 2023**.

- AIIMS had already allocated the Rs. 10 crore fund received from MoHFW for the treatment of 106 other patients (excluding these two Petitioners) and treatment for many of those patients had already begun. The procurement of medicines for the remaining patients was stated to be underway.

Communication from M/s Sarepta Therapeutics

182. On 2nd November, 2023, the Union of India placed on record a positive development from the NRDC. Sarepta agreed to provide their therapy free of charge for the 14 children who have already been administered treatment for DMD. This commitment covers three months of therapy. Sarepta communicated that they would continue to treat these 14 children, ensuring the free supply of medication for the next three months, subject to various conditions. However, since the matters were under consideration, Sarepta agreed to provide free treatment, without any conditions, for the 14 patients.

183. In light of this development, Dr. Madhulika Kabra from AIIMS, who attended the proceedings virtually, was requested to place the order with M/s Sarepta Therapeutics to procure the medicines for these 14 patients. The aim was to resume the treatment without delay. Dr. Kabra was directed to place the order for the required therapies with M/s Sarepta Therapeutics within one week to ensure continued treatment for these patients.

184. This Court was of the view that while the above arrangement was a temporary measure, the NRDC was still working on formulating a permanent solution for the treatment of these children. The Court had

directed the NRDC to continue deliberations with the companies and put up a final proposal, to which Mr. Singha gave an assurance that the final report from the NRDC would be submitted.

185. In terms of the order dated 2nd November, 2023, AIIMS had filed a status report on 6th December, 2023. The status report showed that at different points in time, communications were being exchanged between AIIMS and Sarepta. The important points emerging from the said Status Report is as follows:

- Communication dated 9th February, 2023: AIIMS wrote to the MoHFW regarding placing orders with M/s Sarepta Therapeutics for 14 DMD patients. The letter highlighted that Sarepta had committed to providing free treatment to these patients but had addressed the communication to MoH&FW, with a condition that free treatment would be given **if the Ministry assured the number of patients for whom orders would be placed annually**.
- Follow-up communication was sent on 21st November, 2023.
- On 1st December, 2023, the Rare Disease Cell of MoHFW responded by requesting AIIMS to place the order directly with M/s Sarepta Therapeutics.
- On 2nd December, 2023, Dr. Kabra wrote to Sarepta for the submission of supply orders for the 14 DMD patients. A follow-up email was sent on 3rd December, 2023, as an urgent response was awaited.
- On 4th December, 2023, Sarepta replied, offering to provide 3 months of free treatment to the 14 DMD patients, **provided a clear path forward could be agreed upon for all identified patients**. It was

further stated that they had made a written offer to the Rare Disease Committee back in September and were still waiting for a response from the Government.

186. On 7th December, 2023, this Court noted that vide email dated 5th December 2023, Sarepta communicated to Dr. Madhulika Kabra, AIIMS that it would be willing to provide 3 months' free treatment to the 14 DMD patients, if a path forward could be agreed upon for all the patients that were identified. Thus, on the said date, Mr. Charles Gerrits from Sarepta appeared online. It was clarified that if Sarepta wished to be heard by the Court in these matters, it shall have to engage a counsel and be represented before this Court. Additionally, on the said date, the Court took note of a communication from Sarepta Therapeutics, dated 10th May 2023, indicating that at least two clinical trials for DMD are ongoing in India without a placebo control group.

187. On 5th January, 2024, Sarepta was represented before this Court. Mr. Saurabh Kirpal, ld. Sr. Counsel, appearing for Sarepta, handed over to the Court a communication/submission on behalf of Sarepta, as sent by Mr. Charles Gerrits, through its counsel- Mr. Anish Chawla. The Court perused the terms contained in the said email. In terms thereof, the following directions were issued on 5th January, 2024:

i. The said communication/submission, including two emails dated 4th January, 2024 were directed to be placed before the NRDC on 8th January, 2024.

ii. Representatives of M/s. Sarepta Therapeutics, along with ld. Counsel Mr. Anish Chawla, may attend the meeting either

online or physically or through hybrid mode.

188. On 5th January, 2024, Sarepta agreed to provide free treatment for 14 patients for three months. Accordingly, directions were issued to place the required order on Sarepta. Mr. Anish Chawla was directed to provide all necessary assistance to Dr. Kabra and the Petitioners, so as to enable them to receive the required treatment. In terms of the orders dated 7th December, 2023 and 2nd November, 2023, the supplies of the drugs were directed to be made within a period of two weeks by Sarepta.

189. The Court was informed on 19th January, 2024 that pursuant to the order dated 5th January, 2024, AIIMS had placed an order for therapies for 14 children which M/s. Sarepta assured, would be supplied.

190. In compliance with previous orders dated 5th January 2024 and 19th January 2024 concerning the treatment of 14 patients, ld. Senior Counsel Mr. Kirpal confirmed that medications were being procured from Sarepta, and delivered to AIIMS. However, he expressed concerns over the potential imposition of customs duties by the Union of India.

191. The Court referred to a press release dated 30th March, 2023 from the Ministry of Finance, which announced a full exemption from basic customs duty for all drugs and Food for Special Medical Purposes imported for the treatment of rare diseases listed under the NPRD, 2021. This exemption requires certification from the Central or State Director Health Services or District Medical Officer/Civil Surgeon. The Court further noted that the Ministry of Finance, in a gazette notification dated 29th March, 2023 under the Customs Act, 1962, listed several rare diseases, including DMD, as being exempted from customs duties.

192. Thus, on 26th February, 2024, the Court clarified that no customs

duties or charges would be levied on medicines, drugs, or therapies for rare diseases. Customs authorities were directed to ensure the prompt clearance of such medicines without unnecessary delays. On 22nd March, 2024, the Court was informed that the customs duty exemption certificate had been submitted, and the medicines were expected to be released soon. Directions issued on 26th February 2024 were reiterated, specifically emphasizing that no customs duties or charges would be levied on medicines for rare diseases. Customs authorities were directed on 22nd March, 2024, to release the medicines expeditiously without any unnecessary delay, ensuring that they reached the concerned hospitals promptly.

193. The Court was informed on 10th May, 2024 that, in compliance with the orders dated 26th February 2024 and 22nd March 2024, Sarepta had supplied medicines for the 14 patients through AIIMS, New Delhi. However, ld. *Amicus* noted that the supply is expected to run out by mid-July.

194. The Court recalled its direction from the order dated 22nd March 2024, which had instructed that a meeting be scheduled between the National Rare Diseases' Committee (NRDC) and M/s. Sarepta Therapeutics, with the communication of the same to the representatives of M/s. Sarepta Therapeutics.

195. Regarding the ongoing negotiations with M/s. Sarepta Therapeutics, it was brought to the Court's attention that a proposal had been made by the NRDC on 9th May 2024. Ld. Counsel for M/s. Sarepta Therapeutics, Mr. Anish Chawla, informed the Court that he would seek instructions on providing a written response to the NRDC. However, he indicated that the current offer made by the NRDC may not be acceptable to his client at this

stage.

Directions qua all 91 Petitioners

196. On 2nd November 2023[4], AIIMS provided the names of the patients, their specific DMD diagnoses, detailing which Exon (part of the gene) was affected, and their ambulation status, indicating whether an individual was ambulatory (able to walk) or not. Additionally, it was specified whether the Petitioners could be treated with specific therapies, such as exon skipping, a type of therapy for DMD.

197. Accordingly, for all the 91 writ petitioners, this Court passed the following directions:

(i) For all those patients/Petitioners for whom evaluations have been completed by AIIMS, and are amenable to treatment, AIIMS was directed to commence the procurement of medicines for the said patients/Petitioners as per the fund allocated of Rs. 50 lakhs per patient, in terms of the Rare Diseases Policy. Upon receipt of these medicines, the administration of the medicines to the patients/Petitioners shall commence in an expedited manner.

(ii) In respect of those patients/Petitioners who are not amenable to treatment, as submitted by Dr. Kabra, the standard protocol of steroid administration and provision of care was directed to be commenced.

(iii) In addition, both Dr. Kabra and Dr. Sheffali Gulati were directed to shall ensure that any patient/Petitioner who could be enrolled in approved clinical trials was given an opportunity to get enrolled. They shall make an effort to enroll them, so that continuous

treatment can be provided to the patients/Petitioners, if they satisfy the criteria.

(iv) In respect of the above, AIIMS was directed to initiate and provide the necessary treatment for the patients/Petitioners within a specific timeline. Let a timeline in respect of the above directions be placed on record.

198. In respect of the above directions, AIIMS placed on record an affidavit dated 6th December, 2023. The said affidavit provided as follows:

- AIIMS wrote to the MoHFW on 9th November, 2023, stating that 38 of the 64 petitioners evaluated were found to be eligible for exon skipping therapy.
- AIIMS requested Rs. 19 crores to procure medicines for these 38 patients, with an allocation of Rs. 50 lakhs per patient as per the NPRD, 2021.
- AIIMS informed that the treatment duration for these patients would vary between 2-3 months, depending on individual needs.
- The requested amount of Rs. 19 crores were not received, which delayed the procurement of medicines for the 38 petitioners found eligible for treatment.

199. Thus, on 7th December, 2023, insofar as the patients suffering from rare diseases were concerned, except DMD, those patients for whom treatment had commenced, it was directed that the treatment shall be continued by AIIMS. For the said purpose, this Court directed that the required funds be released by the MoHFW to AIIMS, to ensure that there

[4] 2023:DHC:8007

was no stoppage of treatment.

200. An affidavit dated 4th January 2024 was placed before the Court on 5th January, 2024, providing an update on funds received by AIIMS, New Delhi for the financial year 2023-24. According to the said affidavit, subsequent to the last hearing, AIIMS received Rs. 25 Crores for treating patients with rare diseases. This amount is in addition to Rs. 10 Crores already released earlier for the same financial year.

Quotations from Various Manufacturers received by NRDC

201. On behalf of the NRDC, a note containing quotations from various manufacturers was submitted to the Court in a sealed cover on 7th December, 2023. These quotations detailed the best prices offered to the Union of India for the treatment of various medical conditions, including:

- Gaucher's Disease
- Pompe's Disease
- Fabry's Disease
- Spinal Muscular Atrophy (Drug)
- Spinal Muscular Atrophy (Gene Therapy)

202. Regarding DMD, Sarepta provided a quotation to the NRDC, but under the condition that it could not be shared, even with the Court. Therefore, no figures related to DMD were available for the Court's consideration on 7th December, 2023. The note also discussed the impact of these treatments on the listed medical conditions. The Court was informed on 7th December, 2023, that the final report of the NRDC had been prepared and was awaiting the approval of competent authorities. The Court directed the MoHFW and relevant authorities to ensure the expedited processing of the final report.

203. On 5th January, 2024, the final report of the NRDC was handed over to the Court in a sealed cover. It was noted that on 7th December, 2023, quotations had been received for all diseases, except for DMD. On 5th January, 2024, since communication was received in respect of DMD, NRDC was directed to conduct negotiations with M/s. Sarepta Therapeutics, and thereafter, place its report in respect of DMD as well. Thus, the Court deferred orders on the final report of the NRDC. It was directed that orders would be passed after perusing the same and after the NRDC held negotiations with M/s. Sarepta Therapeutics. In the meantime, it was directed that the NRDC to place before the Court, the final negotiated price for each of the rare diseases negotiated by them, with the respective companies, in a sealed cover.

204. The final report of the NRDC was received by the Court on 19th January, 2024. The quotation given by M/s. Sarepta Therapeutics to the NRDC was placed on record in a sealed cover.

205. On 26th February, 2024, ld. Senior Counsel Mr. Saurabh Kirpal, appearing on behalf of Sarepta, submitted that despite an offer made by Sarepta to the NRDC, no negotiations had taken place due to the absence of a counter-offer from the Union of India. He further stated that Sarepta Therapeutics remained open to exploring the possibility of supplying therapies for DMD patients. On the said date, the Court acknowledged that one of the primary issues in these petitions was the treatment of DMD, given the significant number of affected patients and the physical and emotional toll on their families. It was therefore directed on 26th February, 2024, that the NRDC meet with Sarepta within two weeks. Ld. CGSC Mr. Kirtiman Singh was directed to facilitate the meeting.

206. During the hearing on 26th February, 2024, it was also clarified that the NRDC report submitted on 5th January 2024 had already addressed concerns related to SMA, including specific allocations for its treatment.

207. Again, on 22nd March, 2024, regarding ongoing negotiations between Sarepta and the NRDC, ld. Counsel for the Union of India confirmed that discussions were progressing.

Clinical Trials

208. In respect of the DART trials, the ld. *Amicus* was advised on 7th December, 2023, to contact Hanugen and DART to inquire about the progress of these indigenous therapies. Both Hanugen and DART were free to appear before the Court to provide a status update on the trials.

209. The Court expressed concern that despite specific orders dated 2nd November, 2023, the DCGI had failed to provide the necessary information regarding trials for DMD. Repeated requests for an affidavit with details of all ongoing clinical trials had not been fulfilled. During the hearing on 7th December, 2023, Dr. Rajeev Raghuvanshi, representing the DCGI, joined online and assured the Court that data regarding pending trials for rare diseases would be submitted within a week.

210. The DCGI was directed by this Court on 7th December, 2023, to include in its report all details of clinical trials for DMD conducted by Sarepta Therapeutics or any other entity. The report should clarify whether these trials were open to recruitment and, if so, the number of Indian participants that can be enrolled. The DCGI was also asked to explain how recruitment for these trials could be maximized. In compliance with the order dated 7th December, 2023, the DCGI filed its affidavit dated 21st December, 2023 which was considered by this Court on 5th January, 2024.

In the said affidavit, the DCGI clarified that after approval from DCGI, the maximization of recruitment rests with the applicant/sponsor. In case proposal to increase number of trial subjects in a trial, is submitted to DCGI, the same is evaluated and approved in consultation with Subject Expert Committee. In the specific clinical trials, if any such proposal is received, the same would be considered on priority basis to maximise the recruitment in the trial.

211. In respect of the directions given to the ld. *Amicus* on 7th December, 2023, the Court was informed on 26th February, 2024, that Hanugen approached AIIMS for clinical trials in respect of three Exon Skipping Therapies, namely, Exon 51, Exon 53, and Exon 45. AIIMS confirmed that Hanugen had reached out, but the exact nature of the trial and the number of persons who can be enrolled was not clear. Thus, this Court directed AIIMS to file an affidavit within a week detailing the nature of the trials, enrolment numbers, and other relevant information.

212. On 22nd March, 2024, this Court took note of the status report filed by AIIMS on 13th March 2024, in compliance with the previous order dated 26th February 2024. The report detailed the clinical trials for Duchenne Muscular Dystrophy (DMD), including the following key points:

(i) The scientific title of the study is "A Double Blind, Placebo-Controlled, Multicentre Study with an Open-Label Extension to Evaluate the Efficacy and Safety of 2'0 Methyl Antisense Oligonucleotide in Patients with Duchenne Muscular Dystrophy."

(ii) Sponsor is DART, supported by Vibrance Clinical Research, Bangalore, Karnataka.

(iii) A Clinical Trial Agreement was signed between DART and AIIMS in October 2021.

(iv) The Central Drugs Standard Control Organization (CDSCO) granted an extension of validity for conducting the clinical trial and manufacturing the investigational drug, with effect from 25th August 2023, for a period of one year.

213. The status report also stated that a meeting took place between AIIMS, New Delhi, and DART/Vibrance Clinical Research on 19th February 2024, to initiate the DMD study at AIIMS. It was revealed that the study had been delayed for over two years due to funding issues, but DART has now committed to financing the study independently and is prepared to start the clinical trial. AIIMS also raised concerns about the need for a coordinator and physiotherapist for the study, to which DART agreed to provide through a third party. A total of 54 randomized DMD patients are expected to be included in the study across various sites in India, with AIIMS targeting 12-15 patients at its site.

214. On 1st August, 2024, ld. *Amicus Curiae* informed the Court that DART and Hanugen were about to commence clinical trials for DMD at AIIMS. Preparations for the trials were finalised, with the final meeting held on 25th July 2024. Dr. Arun Shastry from DART, who joined the Court proceedings virtually, submitted that patients aged 5 to 10, ambulatory, and requiring EXON 45, EXON 51, or EXON 53 therapies, would be eligible to enrol in the trials. AIIMS had already finalised the inclusion and exclusion criteria for the clinical trials.

215. The Court noted on 1st August, 2024, that the list of writ petitioners and their medical conditions was already with AIIMS, and patients meeting

the criteria—up to 15 as agreed between AIIMS and DART—may be enrolled in the trial. Thus, a status report on the trials conducted by DART and AIIMS was directed to be placed on record.

Rare Diseases Fund (RDF)

216. The Court on 7th December, 2023, reiterated its concern about the unspent funds exceeding Rs. 200 crores from the budget allocated for rare diseases, which had not yet been released by the MoHFW. The issue was to be addressed in the final report of the NRDC.

Commencement of Final Hearing

217. Considering that the final report of the NRDC was submitted to the Court on 19th January, 2024, and to facilitate the conclusion of submissions in these writ petitions, the Court directed that the final report of the NRDC, submitted on 5th January 2024, along with the addendum handed over to the Court on 19th January, 2024, be provided to the ld. *Amicus*, Ms. Trehan, and Mr. Anand Grover, ld. Sr. Counsel. In addition, AIIMS was directed to file a chart regarding the status of treatment of each of the Petitioners before this Court. On 26th February, 2024, the ld. *Amicus* commenced her final arguments. In addition, the final offers received from various companies were also placed by the NRDC in a sealed cover before the Court.

Status of treatment for all writ petitioners

218. Vide AIIMS' status report dated 23rd February, 2024, the status of all the Petitioners was provided, and the same was considered by this Court on 22nd March, 2024. The said status report provided as follows:

- 14 petitioners have already received treatment upto 50 lakhs under the NPRD, 2021, and for whom orders have been placed with M/s. Sarepta Therapeutics for further medicines.

- 2 Petitioners were selected and included in the clinical trials which are currently underway.
- The said status report also mentions names of the DMD Petitioners who were found amenable to the treatment, and whose treatment is yet to commence. The details are as follows:
  - 19 Petitioners were found amenable to the Exon-51 Skipping Therapy
  - 16 Petitioners were found amenable to the Exon-53 Skipping Therapy
  - 15 Petitioners were found amenable to the Exon-45 Skipping Therapy
- 31 Petitioners were found to non-amenable to treatment.
- 6 non-DMD Petitioners, are non-amenable to treatment or have refused evaluation.
- 2 Petitioners are still under evaluation at AIIMS, New Delhi.
- 1 Petitioner has decided to not avail the treatment of Rs. 50 lakhs under the NPRD.
- 4 Petitioners are afflicted with disorders other than DMD. These 4 Petitioners have already received treatment of Rs. 50 lakhs under the NPRD, and are continuing to receive treatment under the orders of this Court.
- 1 Petitioner is afflicted with disorder other than DMD. This Petitioner has already received treatment of Rs. 50 lakhs under the NPRD.

219. The following table encapsulates the position in relation to treatment of children as on date:

S. No.	***Category***	***Number of Petitioners***
1	DMD Petitioners who have received treatment of Rs. 50 lakhs and for whom further medicines are to be provided by M/s Sarepta	14
2	DMD Petitioners who have been enrolled in clinical trials	2
3	DMD Petitioners found amenable to treatment	19+16+15=50
4	DMD Petitioners evaluated as non-amenable to treatment	31
5	Non-DMD Petitioners who have received treatment of Rs. 50 lakhs and are continuing to receive treatment under orders of this Hon'ble Court	4
6	Non-DMD Petitioners who have received treatment of Rs. 50 lakhs	1
7	Non-DMD Petitioners evaluated as nonamenable to treatment	4
8	Petitioners still under evaluation	2
9	Patients refused treatment/evaluation	3
	Total	111

Exploring solutions for the Petitioners' treatment

220. On 10th May 2024, the final arguments commenced in these matters, with ld. Amicus Curiae Ms. Shyel Trehan initiating her submissions. At the outset, she highlighted the various difficulties faced by the Petitioners and their guardians in accessing the necessary medicines for treatment. These challenges include financial support for the Petitioners and addressing logistical difficulties for patients suffering from rare diseases. It was submitted by ld. *Amicus* on behalf of the Petitioner, Master Ayushman Chaturvedi, in ***W.P.(C) No. 5395/2021***, that the State Government of Uttar Pradesh had released Rs. 5 lakhs to AIIMS for persons with disabilities. AIIMS is reported to have received this amount. Accordingly, on the said

date, the Court directed Dr. Madhulika Kabra to examine the Petitioner and procure any necessary aids or equipment, including a motorized wheelchair, which must be provided within ten days.

221. For patients residing outside Delhi, who required weekly infusions, the inconvenience of frequent travel was raised by their family members. Dr. Kabra coordinated with the Medical Superintendent, AIIMS, and other departmental officials to explore the possibility of dispatching medications to local hospitals, clinics, or CoEs for infusion. Dr. Kabra was authorized by this Court to take the necessary steps to facilitate this arrangement, and a status report on this issue was directed.

222. On 27th May 2024, ld. Counsel for AIIMS, Mr. Oberoi, presented the decision taken by AIIMS, Delhi, regarding the handing over of medicines/drug vials to the parents of patients suffering from DMD residing outside Delhi. The decision outlines the following conditions under which patients can receive these vials:

a. The first and last doses must be administered at AIIMS, New Delhi.
b. After the first week's dose, the remaining supply may be given in temperature-controlled boxes for administration at a nearby facility.
c. Parents are responsible for arranging temperature-controlled boxes, which will be verified by the AIIMS team, to ensure compliance with temperature requirements (2 to 8 degrees Celsius) during travel.
d. The temperature between 2 to 8 degrees Celsius must be maintained throughout the transport period

e. Parents must deposit the empty vials of all doses administered at the local facility when returning for the last dose at AIIMS.

f. A nodal person, the treating doctor at the local facility, will be in contact with AIIMS. The infusion process will be explained to the local doctor by the AIIMS team before handing over the vials.

g. A written protocol for drug infusion will be provided to each patient individually.

223. Additionally, it was submitted that Sarepta agreed to supply medicines directly in Kolkata, and the costs of transporting the medication would be borne by the parents of the Petitioner. On 27th May, 2024, the Court reviewed the conditions imposed by AIIMS and found them reasonable. Accordingly, parents who wish to have the vials administered in their respective cities would be allowed to do so, subject to compliance with the above conditions.

Fallout of the negotiations between Sarepta and NRDC

224. On 10th May, 2024, the Court was informed that Sarepta has supplied medicines for the 14 patients through AIIMS, New Delhi. The Court recalled its directions from the order dated 22nd March 2024, which had instructed that a meeting be scheduled between the NRDC and Sarepta. Regarding the ongoing negotiations with M/s. Sarepta Therapeutics, it was brought to the Court's attention that a proposal had been made by the NRDC on 9th May 2024. Ld. Counsel for M/s. Sarepta Therapeutics, Mr. Anish Chawla, sought instructions on providing a written response to the NRDC. However, he indicated to the Court that the current offer made by the NRDC may not be acceptable to his client at this stage.

Directions issued

225. On 12th July 2024, the Court issued the following directions:

i. Dr. Kabra at AIIMS was requested to compile and submit a report by the next hearing, covering the following:

(i) The number of children who have received treatment under the NPRD at AIIMS and on a nationwide basis.

(ii) A breakdown of the types of treatments provided for each rare disease.

ii. Ld. Counsel Mr. Tanveer Oberoi, along with officials from AIIMS, was directed to prepare a flow chart illustrating the steps from the initial contact of a child with a rare disease at the CoE in Delhi or other cities, up to the commencement of treatment. This chart should detail the steps under the relevant policies and include an example of one case to demonstrate the process followed.

226. Mr. Anish Chawla, ld. Counsel representing Sarepta, was instructed on 12th July, 2024 to file a note by the next hearing providing details on:

(i) The new gene therapy developed by Sarepta for DMD and whether it constitutes a cure.

(ii) The cost of the therapy and any clinical trials planned in India or abroad.

(iii) The status of FDA approval, among other relevant details.

227. The Union of India was directed to file an affidavit on 12th July, 2024, detailing the amounts spent and the number of patients who received funding under the NPRD, 2021. The affidavit was also to include the types

of disorders treated under the Policy.

228. Ms. Vidhi Jain, ld. Counsel from the office of Mr. Kirtiman Singh, ld. CGSC, referred to an affidavit from the MoHFW dated 19th July 2024 on 1st August, 2024. It was noted that 105 and 430 patients had received treatment in the years 2022-2023 and 2023-2024, respectively. The amounts transferred to the various CoE were also filed by means of a chart, which showed that the amounts transferred were lesser than the budget estimates approved by the MoHFW towards the implementation of the NPRD, 2021, and towards the disbursal for the 50 lakhs amount under the said Policy.

229. Considering the number of patients seeking treatment, and the fact that the budgets for treatment were still available, the Court issued the following directions on 1st August, 2024:

i) Dr. Kabra was directed to immediately request the release of the next dose of treatment for the 14 DMD patients who had already been administered the medicines. The names of these patients were listed in the Court's order dated 5th January 2024, which was reproduced.

ii) A chart was directed to be prepared and placed before the Court, detailing the budget required for a three-month period for the Petitioners in various writ petitions, if medicines were to be ordered.

230. On the said date, Ms. Jain further informed the Court that two trials for DMD therapies were currently approved by the DCGI in India. Although recruitment for the trials was closed, the number of subjects recruited by Sarepta Therapeutics appeared to be less than the approved number. Thus, to get a clear picture on the position of the clinical trials in relation to the drugs

manufactured by Sarepta, this Court directed M/s. Sarepta Therapeutics on 1st August, 2024, to file an affidavit, addressing the recruitment status and providing details on whether the pricing of its DMD medicines varied across different countries. A chart showing retail prices in at least 10 advanced and 10 developing countries, including India's neighbouring countries, was also to be included.

231. On 21st August 2024, further directions were issued. On behalf of M/s Sarepta Therapeutics, it was submitted that the affidavit could not be placed on record. The Court directed that the affidavit be brought on record in a sealed cover. The directions issued to M/s Sarepta Therapeutics in paragraph 12 of the order dated 1st August 2024, were extended to M/s Roche with respect to medicines for Spinal Muscular Atrophy (SMA).

232. On 31st August, 2024, in accordance with the Court's order dated 1st August, 2024, Dr. Kabra was directed to request the release of the next dose of treatment for 14 patients diagnosed with DMD. Ld. Counsel for AIIMS, Mr. Tanveer Oberoi, informed the Court that a letter had been communicated to the Ministry of Health in compliance with the order dated 1st August, 2024. The Respondent-Union of India was directed to inform the Court of the steps taken by the next hearing.

233. On 21st August 2024, the Court had directed both Sarepta Therapeutics and Roche to place on record a chart providing details of the pricing of their respective products. Ld. Senior Counsel Mr. Saurabh Kirpal submitted that the affidavit in compliance with the orders dated 1st August, 2024 and 21st August, 2024 would be handed over to the Court. Thus, on the said date, the Court directed both M/s. Sarepta Therapeutics and M/s. Roche to submit their respective affidavits in a sealed cover.

234. Additionally, Sarepta was directed to place on record a chart detailing the following:

i. The distributor(s) in India, if any, of drugs manufactured and sold by M/s. Sarepta Therapeutics.

ii. A Standard Operating Procedure (SOP) outlining the production, procurement, and distribution of drugs for DMD in India, including timelines for each step in the process.

235. Again, on 9th September, 2024, time was sought by Sarepta to file their written submissions.

236. On 9th September, 2024, ld. *Amicus Curiae* informed the Court that the next doses for the 14 patients had not been procured, despite AIIMS having written to the MoHFW. Ld. Counsel for AIIMS, Mr. Tanveer Oberoi, submitted that a letter dated 28th August 2024 was received from MoHFW, indicating that funding would only be provided in accordance with the NPRD, 2021. The amount required for an additional three months of treatment was substantial. Additionally, AIIMS stated that for four other patients, further funds have not been released by the MoHFW. Considering the logjam between the AIIMS and MoHFW, the Court directed Mr. Swarnendu Singha, Under Secretary, MoHFW, to explain the funding situation by way of an affidavit.

Order dated 13th September, 2024

237. The Court referred to the previous order dated 9th September 2024, where the MoHFW had not released funds for the next doses for 14 patients. On 13th September, 2024, Mr. Swarnendu Singha appeared and informed the Court that the budget allocated for AIIMS Delhi, under the NPRD, 2021 had been exhausted. The Court directed MoHFW to grant approval to AIIMS to

place orders with Sarepta for the necessary medicines, and to release a sum of Rs. 10 crores based on the last price quoted to the NRDC. This approval was to be granted by 19th September 2024, failing which contempt action may be taken.

238. Upon receiving approval, AIIMS was directed to place the order with the designated distributor, whose details were to be communicated by M/s Sarepta through its counsel, Mr. Anish Chawla. The distributor was also ordered to be present in Court at the next hearing.

Doses for Gaucher's and MPS Patients

239. The Court noted that doses for four patients (two suffering from Gaucher's disease and two from MPS) had not been provided. Considering that these patients had already received some doses and the budget for the NPRD, 2021 had been reduced since FY 2022-2023, the Court directed MoHFW to release Rs.10 crores to AIIMS for treatment of non-DMD patients until the final judgment in these matters.

Sarepta's response

240. On 13th September, 2024, a document titled *'Procedure and Distribution System of eteplirsen, goloditsen, and casimersen in India'* was presented on behalf of M/s Sarepta Therapeutics, Inc., India. The document, provided on the letterhead of 'myTomorrows' (a Netherlands-based company called 'Impatients N.V.'), lacked details of any distributor in India and failed to specify timelines for order fulfilment. The Court noted the delay in supplying medicines to DMD patients and highlighted the need for Sarepta to establish adequate measures to ensure availability of medicines.

241. Thus, Sarepta Therapeutics was directed to file an affidavit from a competent person based in India, along with details of a distributor

responsible for timely supply of the medicines. This affidavit was to be submitted within three days of the order's release, along with a cost of Rs.1 lakh to be deposited into the 'AIIMS Rare Disease Fund'.

242. In relation to the directions contained in order dated 9th September, 2024, Mr. Swarnendu Singha, Under Secretary, MoHFW stated that the budget allocated for payments in terms of the NPRD, 2021 had been exhausted. Thus, considering that the treatment of 14 patients had already commenced, on 13th September, 2024, this Court directed the MoHFW to grant approval to AIIMS to place orders on Sarepta for supply of the necessary medicines and release the corresponding funds, based on the price last quoted by Sarepta to NRDC. The said approval was directed to be granted by 19th September, 2024, failing which action for contempt would be liable to be taken. Upon receiving the approval, it was directed AIIMS shall place the order on the designated distributor, whose details shall be communicated by Mr. Anish Chawla, ld. Counsel appearing for M/s. Sarepta to Mr. Tanveer Oberoi, ld. Counsel. The Court further directed that the concerned distributor of M/s. Sarepta, who would be taking responsibility for supplying the medicines, to remain present in Court on the next date of hearing.

243. Further, directions were given by this Court in relation to doses for two patients suffering from Gaucher's disease and two patients suffering from MPS. On 13th September, 2024, this Court directed the MoHFW to release a sum of Rs.10 crores to AIIMS, so that even the non-DMD patients may be provided the requisite treatment(s) till the final judgment of this Court in these batch matters. The relevant portion of the order dated 13th September, 2024 is as follows:

"19. This Court is of the opinion that the medicines for these four patients ought not to be discontinued. The same is being directed after considering the following facts:

- *that, as per affidavit dated 19th July, 2024, filed by the Union of India, the budget for expenditure under the National Rare Diseases' Policy, 2021 since FY 2022-2023, has, in fact, been reduced from previous years, and,*
- *that these four patients have already been administered the medicines.*

***20. Let the MoHFW release a sum of Rs.10 crores to AIIMS by the next date of hearing, so that even the non-DMD patients may be provided the requisite treatment(s) till the final judgment of this Court in these batch matters. It is made clear that the said approval/release of funds shall be subject to the final outcome in these batch matters**.*

21. Let a comprehensive status report in respect of all the directions contained in the present order be filed by the next date of hearing, by the respective parties, in respect of whom the directions have been issued."

244. On 24th September, 2024, in terms of the order dated 13th September, 2024. Mr. Anish Chawla, ld. Counsel appearing for M/s. Sarepta Therapeutics handed over to the Court the affidavit dated 19th September, 2024, and the same was taken on record on the said date.

Application seeking recalled of the order dated 13th September, 2024 filed by the Union of India

245. Vide order dated 27th September, 2024, ***CM APPL.56264/2024*** seeking recall of the order dated 13th September, 2024 was considered by this Court, by which the UOI was directed to release a sum of Rs. 10 crores

to AIIMS, Delhi to continue the treatment of 18 patients suffering from DMD, Gaucher's disease and MPS. This Court dismissed the said application on 27th September, 2024, in the following terms:

> *"4. In this application, the stand of the Union of India is that the budgeted amount for AIIMS has already been exhausted, and there are other Centres of Excellence (hereinafter, 'CoEs'), who have requested for release of funds.*
>
> *5. In the context of rare diseases, this Court has recognised, from time to time, that AIIMS, Delhi is one of the nodal Centres of Excellence, actively administering treatment for patients suffering from rare diseases. Eighteen patients have already commenced treatment, and discontinuation of treatment would have a negative repercussion on their health. Moreover, the negotiated price with M/s. Sarepta, has been significantly reduced, as per the last quotation given to the National Rare Diseases' Committee (hereinafter, 'NRDC').*
>
> *6. Under such circumstances, withholding the treatment of these 18 patients would be completely unjust and contrary to law, as the same would have a debilitating effect on their general living condition and health. Since the treatment of these children has already begun, the amount as directed shall be released within next three working days, failing which Ms. Latha Ganapathy, Joint Secretary, Ministry of Health and Family Welfare, shall remain present in Court on the next date of hearing.*
>
> ***7. It is alleged by Mr. Kirtiman Singh, ld. CGSC that out of the allocated amount of Rs.34 crores, AIIMS has spent only Rs.9 crores as yet. Dr. Madhulika Kabra, appearing virtually, has clarified that the total spent amount on the procurement of medicines for***

patients suffering from rare diseases would be reflected only after the medicines have been procured. There are a number of patients for whom orders have already been placed and the amount has to be utilized for the said patients. Accordingly, she submits that the continuation of the treatment would not be possible without further allocation of money. In support of this submission, the affidavit dated 21st July, 2024 is referred to and relied upon. In the said affidavit, AIIMS stated that approximately 227 children were allocated funds NPRD, 2021, and it further provided a detailed chart indicating the type of disorder, nature of treatment, funds allocated, expenditure incurred, and other relevant/important information pertaining to such cases.

8. Be that as it may, considering that the amount is being directed to be paid to AIIMS, Delhi, which is fully accountable for all the money spent, let the amounts in terms of order dated 13th September, 2024 be released by the UOI.

9. CM APPL.56264/2024 is dismissed in the above terms*."*

246. In terms of the order dated 13th September, 2024, Mr. Anish Chawla, ld. Counsel appearing for M/s. Sarepta Therapeutics handed over to the Court an affidavit dated 19th September, 2024. In terms of the directions contained in order dated 24th September, 2024, Ms. Priyanka appeared virtually before the Court. Thereafter, in respect of Sarepta, vide order dated 27th September, 2024, this Court considered the affidavit dated 19th September, 2024, filed by Sarepta passed the following directions:

> *"12. The above process is extremely cumbersome and long-drawn as an agreement is contemplated for each patient. Customs waivers have to be obtained for each*

patient. The proposed process is completely unrealistic in terms of efficiency of procurement and administration.

13. Thus, M/s. Sarepta shall place on record the general process for procurement of medicines on a bulk basis and not on a patient-to-patient basis so that upon orders being placed the same can be supplied without delay, in India itself. Let the same be done by the next date of hearing. 14. In addition, M/s. Sarepta Therapeutics is also directed to place on record a chart containing the details of all its granted patents and patent applications filed in India, along with the updated Form 3 as required by Section 8 of the Patents Act, 1970, in respect of the medicines currently being used for DMD patients, by the next date of hearing."

247. On 27th September, 2024, the Court noted that the process for procuring medicines, which required separate agreements and customs waivers for each patient, was cumbersome and inefficient. M/s. Sarepta was, thus, directed to submit a general process for bulk procurement of medicines, to avoid delays in India. Additionally, the said company was directed to provide a chart detailing all granted patents and patent applications in India, along with updated Form 3 information as required under Section 8 of the Patents Act, 1970, for the medicines used to treat DMD patients.

248. On 3rd October, 2024, Mr. Kirpal, Senior Counsel for M/s. Sarepta, informed the Court that Ms. Priyanka has been selected as the Indian distributor for Sarepta's medicines for DMD, sourced from *'myTomorrows'*. However, no formal documentation or Board Resolution was submitted to confirm her appointment. Thus, the Court directed that such authorization be

filed. Regarding the order dated 27th September, 2024, to reconsider the distribution agreement and the execution of Confidential Disclosure Agreements (CDAs), Mr. Kirpal, ld. Sr. Counsel proposed that a single CDA between the ordering institution and the patient would suffice to ensure confidentiality of drug prices. He further assured the Court on 3rd October, 2024, that the supply of drugs would be made within 11 days upon receipt of a purchase order and customs duty exemption certificate.

249. In terms of the order dated 27th September, 2024, Sarepta had not filed its details of granted patents and patent applications in India. On 3rd October, 2024, the Court noted the lack of details qua patents granted, and patent applications from Sarepta.

250. Additionally, the Joint Secretary, MoHFW failed to appear in Court on 3rd October, 2024, as was directed on 27th September, 2024. An application was stated to have been moved, seeking exemption from the appearance of the Joint Secretary, MoHFW. The said application was not listed on 3rd October, 2024.

SUBMISSIONS OF PARTIES

Submissions on behalf of the Petitioners and the ld. Amicus

251. Ms. Shyel Trehan, ld. *Amicus* commenced her submissions by referring to the decision of this Court in ***Mohd. Ahmed (Minor) v. Union of India & Ors. [2014 SCC OnLine Del 1508]*** where after recognizing that a person with rare disease cannot be deprived of therapy only due to the costs, directed administration of Enzyme Replacement Therapy *(hereinafter, 'ERT')* to the patient. She points out that this order was upheld in ***LPA 764/2014*** titled ***'Govt. of NCT of Delhi v. Mohd Ahmed & Ors.'*** though it

was clarified that the said decision would not be treated as a precedent. Reliance is also place on similar orders passed by different Courts in the following decisions to argue that Courts have repeatedly directed the administration of ERT free of cost:

- *Manoj v. State of Kerala & Ors. (2016) 4 KLT 491,*
- *State of M.P. v. Prajwal Shrikhande, 2021 SCC OnLine MP 3584,*
- *Koppaddi Hani v. Union of India, 2022 SCC OnLine AP 846*
- *Baby Ananya Sri. Bhargav Thanga v. State of A.P., 2022 SCC OnLine AP 553*
- *Kanatham Sailaja v. Union of India, Ministry of Health and Family Welfare, 2022 SCC OnLine AP 58*

252. On a query as to whether there were any cases relating to DMD, considering the expense of the medicine, ld. *Amicus* submits that there are no decisions as yet which she could place at this stage.

253. Ld. Amicus then dealt with the nature of these diseases and the therapies available for them. Insofar as DMD is concerned, she submits that there is, in fact, a new therapy, *i.e.*, Gene Replacement Therapy *(hereinafter, 'GRT')*, which has been approved by the USFDA; however, the cost of this treatment would be 3.2 million dollars for certain types of diseases. For Gaucher, where lifelong therapy is required, the medicine is now locally produced in India. For SMA, it is a one-time treatment, which is very expensive. Insofar as cystic fibrosis is concerned, she submits that there are two types of therapies. The more expensive therapy, involving modulators, etc., is generally not used, while a lower-cost therapy, which is more affordable, is currently in use, as confirmed by Dr. Kabra.

254. The ld. *Amicus*, submits that, worldwide, the use of the more

expensive therapy is more prevalent and is often made available at reasonable or subsidized costs, or even free, in several countries. The ld. *Amicus* has taken the Court through the first National Rare Diseases Policy, 2017 introduced by the Government after the judgment in ***Mohd. Ahmed (supra)***. As per this policy, a Rs. 100 crore corpus fund was created; however, this policy was not very successful due to lack of clarity. By an office order dated 16th November 2018, a new Expert Committee was constituted to review the policy, and the earlier 2017 policy was kept in abeyance.

255. The lead petition in these matters being ***W.P.(C) 5315/2020*** titled '***Master Arnesh Shaw v. Union of India'*** was then filed, and vide order dated 23rd March, 2021 various directions were issued by the Court. The Court also noted that the Union of India had been called upon to present a specific timeline for finalising the policy. In paragraph 21 of the said order, the Court had directed the Union of India to finalise and notify the National Policy for Rare Diseases on or before 31st March, 2021.

256. The second National Policy for Rare Diseases was then notified by the Government called the 'NPRD, 2021'. This policy did look into rare diseases in a much more detailed manner. Different types of rare diseases were grouped into three Groups in paragraph 6 of the NPRD, 2021, and paragraph 10 of the NPRD, 2021 outlined the manner in which Government would provide the financial support for the treatment. Under paragraph 10 of the NPRD, 2021, financial support up to Rs. 20 lakhs was allocated for rare diseases falling in Group 1, which required a one-time treatment. The policy was also extended to non-BPL families who would be eligible under the Pradhan Mantri Jan Arogya Yojana. Under paragraph 10.3, Group 3 was

not covered and only crowdfunding was contemplated. Insofar as the Group 2 patients are concerned, State Governments were nudged to manage the Group 2 patients who have rare diseases. The said policy also listed 8 institutes as CoEs across the country though there was a need for a larger number of such CoE for example Patna, where the Patna High Court has also seized of the matter regarding setting up of a CoE in Patna, in ***CWJC Case No. 8053 of 2021*** titled ***'Raju Yadav v. Union of India'***.

257. This policy was, thereafter, amended on 19th May, 2022 where clause 10 was amended. The policy now extended financial support of Rs. 50 lakhs to patients from all groups. The condition of BPL families was also removed.

258. According to Ms. Trehan, ld. *Amicus*, there are broadly two types of treatment — one is management of the disease by the use of steroids, and another is the use of new treatments of which the costs are exorbitant. In her submission, even the year marked budgets are not being used by the Government, as is clear from various material which has come on record. Further, she submits that the procedure for treatment is not streamlined. Reliance is placed upon the following judgments, both of which recognised the right to life:

- *Parmanand Katra v. Union of India (1989) 4 SCC 286*
- *Paschim Banga Khet Mazdoor Samiti v. State of West Bengal and Anr. (1996) 4 SCC 37*

259. On the other hand, she also places before the Court two other judgments, which take the view that, in the context of government employees and employees in various services, the Court has observed that resources are not unlimited. The two judgments are:

- *State of Punjab & Ors. v. Ram Lubhaya Bagga (1998) 4 SCC 117* and
- *Confederation of Ex-Servicemen Associations v. Union of India 2006 (8) SCC 399*

260. Currently, she submits that cases relating to DMD have been taken up before the High Courts of Patna, Orissa and Karnataka.

261. Reference has also been made to the following documents:

Case Laws:

- *Order dated 6th October, 2023 passed in Ratnesh Kumar Jigyasu v. Union of India and Ors., in WP(C) No. 1012/2023 by the Supreme Court.*
- *Association of Medical Super Speciality Aspirants and Residents v. Union of India (2019) 8 SCC 607*
- *Navtej Singh Johar & Ors. v. Union of India (2018) 10 SCC 1*
- *Consumer Education & Research Centre & Ors. v. Union of India & Ors. (1995) AIR 922*
- *Arif v. State of Kerala, WP(C) No. 7984 of 2021*
- *State of Punjab v. Ram Lubhaya Bagga (1998) 4 SCC 117*
- *Lysosomal Storage Disorders Society in India v. State of Karnataka, WP No. 19061 of 2015 (GM-RES)*
- *Rogeeth v. State of Karnataka, WP No. 6756 of 2019*

International Materials

- United Nations Resolution on Addressing the Challenges of Persons Living with a Rare Disease and their Families, A/RES/76/132, dated 16th December, 2021 passed by the United Nations General Assembly

- Regulation (EC) No. 141/2000 and the Council Recommendation 2009/C 151/02.
- Details of the LSDP as published by the Australia Government on the website.
- Relevant portions of the laws governing the treatment of rare diseases in Bulgaria, and the website of the National Health Insurance Fund.
- Relevant portions of the laws governing treatment of rare diseases in Czech Republic.
- Information regarding the Rare Disease Fund available on the website of the Ministry of Health, Singapore.
- Information regarding the Rare Disease Fund available on the website of Health Promotion Administration, Taiwan.
- Report of NHS England on High Specialised Services 2020/21 published on 28th November, 2023.
- *R v. Cambridge Health Authority (1995) EWCA Civ 49*
- *Thiagraj Soobramoney v. Minister of Health, Case CCT 32/97*
- *Nitecki v. Poland, Application No. 65653/01*
- *Edward Wiater v. Poland, Application No. 42290/08*

News Articles

- A true copy of the news article reporting the availability of indigenous drugs for 4 rare diseases.
- A copy of the news article regarding Kerala's state policy on rare diseases.
- Question and Answer before the Lok Sabha regarding enrollment of rare disease patients.

Submissions of ld. Sr. Counsel Mr. Anand Grover

262. Mr. Anand Grover, ld. Senior Counsel, appears for the Cure SMA Foundation in ***W.P.(C) 11610/2017***, which is stated to represent over 1800 SMA patients. Mr. Grover's primary submission concerns the pricing of the drugs currently used for the treatment of SMA in India. According to him, the main drug is marketed by M/s. Roche in India and was approved by the US FDA in August 2020 for SMA patients between 2 months and 60 years, covering all types of SMA. The drug was also approved by the DCGI in October 2020 and was commercially launched in July 2021. He submits that under the Patient Support Program, Roche makes the drug available at Rs. 72 lakhs annually for the first two years and Rs. 56 lakhs annually for the third year. However, the same medicine is available at much lower costs in countries such as China and Pakistan. He thus contends that the Union of India has a responsibility to negotiate better prices with the company to ensure that a larger number of patients can access these medicinal products at an affordable price. He further submits that the reason these products are not available at more affordable prices is due to the fact that they are patented products.

263. Thereafter, Mr. Grover lays emphasis on the right to health being a part of right to life and has relied upon various decisions of the Supreme Court including ***Francis Coralie Mullen v. The Administrator, Union Territory of Delhi, (1981) 1 SCC 608***, the following the judgment of the US Supreme Court in ***Munn v. Illinois [1877] 94 US 133***. Thereafter, Article 12 of the International Covenant on Economic, Social, and Cultural Rights *(hereinafter, 'ICESCR')*, which has been ratified by India is highlighted.

264. He submits that the negotiations which the Union of India has

conducted with M/s. Roche are not in public domain and considering that these drugs are required for a large number of patients, failing which, it would almost be fatal. He urges that the State has a responsibility to make these medicines available. The ICESR being a treaty which is ratified by India, there can be no impediment for the Union of India in making drugs more accessible by resorting to proper negotiations with the company concerned.

265. In the case of SMA, there is no data regarding the expenditure on R&D made by the company, and thus the right to life of all these children is being compromised on the grounds that there must be proper remuneration for research. The entire group of children would be exposed to ill health if the medicinal products are not made available, and therefore the Union of India must resort to any available means to ensure these drugs are accessible. Additionally, Mr. Grover has emphasized that crowdfunding should be encouraged by the Government, as there are numerous companies and individuals willing to pool their resources. It is also suggested that for drugs related to rare diseases, the 12% GST should also be exempted. The Government has not utilized most of the budgeted amounts allocated for rare diseases, which should be used effectively. He further submits that the availability of these drugs should not be restricted to CoEs, but extended to hospitals across the country. His client, Cure SMA Group, is also accessing these products through a distributor appointed in India, and thus the restriction to obtain these drugs only from the CoEs should be removed.

266. He highlights the fact that various corporate entities are willing to deposit and donate for rare diseases. It is argued that the Government should not refuse funding when it is available for payment of patients medicines.

There have been few cases where funding by public sector companies has been refused permission for no disclosed reason. Union of India has refused funding, for example, in the case of Mahanadi Coalfields which was donating a sum of Rs.17.70 crores. Ms. Alpana Sharma, office bearer of Cure SMA Group appears and submits that there are 1800 patients whose condition is quite sensitive with each passing day. There is an Indian company based in Hyderabad which has filed an application before the CDSCO for approval which is still pending. According to her, medicines available in India by M/s. Roche ought to be added to the National List of Essential Medicines.

267. Ms. Archana Panda, whose daughter Anushka, a student at IIT Kanpur, is an SMA patient, also submits that access to these medicines should be available through all hospitals, as these are life-long treatments. It is emphasized that while the commencement of treatment is crucial, the continuation of treatment is even more critical. Upon administration of the drug, patients tend to show improvement, but if the medication is stopped, the condition worsens immediately. Therefore, on behalf of SMA patients, it is highlighted that, in addition to accessibility, there must also be continuity in the provision of the medication.

268. Mr. Rohin Bhatt, ld. Counsel appearing for SMA Foundation, on instructions, submits that the registration of SMA patients at CoEs have considerable hurdles. Procurement of medicines by patients from the CoEs is difficult as they are located in distinct parts of the country. Therefore, wherever Roche distributors are available, distribution should be made through them even through nearest Government hospitals and other patients also need to be considered. Finally, he submits that on the basis of decision

in ***Nipun Malhotra v. Sony Pictures Films India Private Limited & Ors (2024 INSC 465)***, the Court ought to consider making the SMA Foundation as a member of the NRDC, so as to ensure that the adequate representation for SMA patients and their concerns are addressed at the Committee level.

269. Ms. Panda further submits that a conclave was held in July, 2024 by MoHFW wherein the PSUs, including Coal India expressed concerns that they were not sure as to who is going to be the implementer of these programmes and, thus, a TriPartite Agreement would be needed for administration of the funds itself. To this submission, Mr. Sidharth Luthra, ld. Senior Counsel then submits that such issues raised by PSUs are to be dealt with efficiently by the MoHFW, and cannot be left to the NGOs themselves or the patients themselves to spend their own costs.

Submissions on behalf of ld. Sr. Counsel Mr. Sidharth Luthra

270. Mr. Sidharth Luthra, ld. Senior Counsel appearing for the Petitioner Master Rajveer Srivastava in ***W.P.(C) 4539/2023*** submitted that the Petitioner, in the present petition, is suffering from DMD. According to the ld. Sr. Counsel, the National Policy for Treatment of Rare Diseases, 2017, had a general clause that liability is to be borne in the ratio of 60:40 by the Centre and State. However, in the NPRD, 2021, Group 3 diseases have been excluded. DMD falls in Group 3 diseases in NPRD, 2021. In the 2022, however, change was again effected for funding DMD patients for a maximum of Rs.50 lakhs, which also has not been spent on the present Petitioner as yet. He also submits that Right to Health is a part of the Right to Life, as has been already submitted by ld. *Amicus*. Reliance is placed upon the judgment titled ***Mohd. Ahmed (supra)***, ***Association of Medical Super Speciality Aspirants (supra)*** and ***Paschim Banga (supra).***

271. The clear ratio in ***Paschim Banga (supra)*** is that, irrespective of financial constraints, the State has an obligation to ensure that proper healthcare is provided to its citizens. It is further emphasized that steps which were ordered to be taken for setting up a crowdfunding platform, as per orders dated 4th August, 2021 and 9th December, 2022, have not been implemented. In fact, the platform itself has remained non-functional. Additionally, the CSR funding of PSUs has not been followed up with due diligence. The inclusion of rare diseases in Schedule VII, which was directed on 22nd December 2022, has also not been implemented. Reference is made to excerpts from a few annual reports of PSUs, which show substantial funds spent on CSR and healthcare, but none of it has been allocated for rare diseases. Considering the high level of expenditure required for rare diseases, Government's steps should have been more effective and diligent, but unfortunately, that has not been the case.

272. Reference is also made to a chart of all patients, which demonstrates that the Petitioner, Master Rajveer Sarivastava, has not received any treatment despite the AIIMS' report dated 23rd July, 2024 (para 4, page 3) clearly stating that he is amenable to treatment with Exon-51 medicines. The State's limitations and financial constraints could be addressed with some effort by the Government, but such effort is lacking.

Submissions on behalf of Mr. Ashok Aggarwal for the Petitioners

273. Mr. Ashok Aggarwal, ld. Counsel appearing in various writ petitions handed over a short note to argue that apart from the Right to Health, which is read as part of the Right of Life, due to the nature of the rare diseases, the Right to Education of children suffering from rare diseases, which is now a fundamental right in view of Article 21A of the Constitution of India, is also

severely impeded. The Right of Children to Free and Compulsory Education Act, 2009 contemplates in Section 3, the fundamental right of a child to free and compulsory education in a neighbourhood school without any fee or charges or expenses including such expenses, which may pervade the child from obtaining the education.

274. The provision of the Rights of Persons with Disabilities Act, 2016 has also been placed before the Court to argue that in the Schedule of the said Act, 'muscular dystrophy' is added as a Specified Disability in terms of Section 2(zc) of the said Act. Thus, children with disabilities are also entitled to free education under Section 31 of the said Act. Apart from that, the persons with disabilities, which include persons suffering from muscular dystrophy, are also entitled to assistant devices, books, learning materials, till the age of 18 in terms of Section 17(g) of the Rights of Persons with Disabilities Act, 2016.

275. It is his submission that a conjoint reading of the Right of Children to Free and Compulsory Education Act, 2009 and the Rights of Persons with Disabilities Act, 2016 would lead to the conclusion that since the non-provision of treatment impedes the Right to Education, a fundamental right, the State has an obligation to provide the same to these children. It is also urged that there ought to be no limit fixed for the expenses on medicines of children with rare diseases. Especially in the case of DMD, the sum of Rs.50 lakhs provided in the NPRD, 2021, has proven to be completely insufficient.

276. Mr. Aditya Chatterjee, ld. Counsel appearing in ***W.P.(C) 3662/2021*** submits that the Petitioner in this case suffers from a medical condition called Von-Hippel-Lindau syndrome, which is a cancer-causing syndrome. He has placed documents on record to show that Von Hippel-Lindau disease

is a genetic disease characterised by growth of mostly benign but also cancerous tumours in many organs of the body, including in the kidneys, pancreas, adrenal glands and inner ear, as well as abnormal growth of blood vessels in the eye, brain and spinal cord. The disease is caused by a defect in the VHL gene which is responsible for the production of a protein that prevents tumour formation. In patients with von Hippel-Lindau disease, the defective gene cannot produce sufficient protein that works properly, leading to the development of tumours. Von Hippel-Lindau disease is a long-term debilitating and life-threatening disease due to the complications caused by the various tumours that can have wide-ranging effects on the body.

277. According to the ld. Counsel for the Petitioner, the Petitioner already has more than dozens cancer tumours, however, this disease which is an open disease in the US, is not included in the list of Rare Diseases though there are 46,000 patients who may be said to have contracted the said disease. He submits that the NPRD, 2021, should be revisited from time to time and such diseases ought to be included in the same for financial support. The said Petitioners, even though the diseases may not be included to also be permitted to avail crowd funding through the crowd funding platform. The reliefs claimed by the Petitioner is as follows:

> *"19. Considering the evolving nature of the NPRD and the admitted scope for inclusion of disorders in the definition of rare diseases based on epidemiological data, the Petitioner prays that:*
>
> *A. the Respondents be directed to consider inclusion of VHL Syndrome within the groups of 'rare diseases' specified under the NPRD.*

B. The Respondent be directed to set up a mechanism by which the diseases comprised in each Group under NPRD is reviewed annually for addition of newer rare diseases that were previously unknown, based on expert and public consultations.

C. Diseases that are otherwise categorised as "rare" but do not have available treatment at one of the identified Centres of Excellence must also be permitted to seek one-time funding assistance and be able to access the crowd-funding platform set up under NPRD, after due verification."

278. In a written note of submissions, ld. Counsel for the Petitioner submits that even though VHL has not been given rare disease status in India, on 21st August, 2020, Orphan designation was granted by the European Union to a drug called MK-6482 for treatment of the VHL. In the USA, VHL was designated as Orphan disease on 24th June, 2020, marketing approval granted for a drug was granted on 13th August, 2021. As per the National Cancer Institute, USA, prevalence of VHL in USA is between 1 in 31,000 to 1 in 91,000, it has been stated that precise screening of VHL is not been possible. The following documents have been relied upon by the Petitioner in ***W.P.(C) 3662/2021:***

- Article by the European Medicines Agency confirming orphan designation for treatment of Von-Hippel Lindau Disease.
- Article on approval granted by the Food and Drug Administration, USA, to an orphan drug for treatment of Von-Hippel Lindau Syndrome.
- National Cancer Institute of USA data on Von-Hippel Lindau

Syndrome.

- Research Paper titled 'Von Hippel–Lindau disease: insights into oxygen sensing, protein degradation, and cancer' published in the Journal of Clinical Investigation.
- Research Paper titled 'Von Hippel–Lindau (VHL) disease and VHL-associated tumors in Indian subjects: VHL gene testing in a resource constraint setting' published in the Egyptian Journal of Medical Human Genetics.
- Article titled as 'Von Hippel-Lindau disease: a genetic study'; published in the Journal of Medical Genetics
- Article about Von-Hippel Lindau Disease on Orphanet.com - a portal for rare diseases and orphan drugs.

279. In ***W.P.(C) 5395/2021,*** on behalf of Mr. Chaturvedi, it is submitted by his grandfather, who is also a practicing lawyer that orders for the remaining vials have been placed. It is expected that the M/s Sarepta Therapeutics would take adequate steps to expeditiously send the medicines for the said vials.

280. Ms. Purva Chugh, ld. Counsel submits that the Petitioner in Item 40 ***W.P.(C) 2614/2023*** is a non-amenable-patient and is not amenable to any treatment. It is her submission that such a patient ought to be given priority in any case of clinical trial.

<u>Submissions on behalf of the Union of India</u>

281. Mr. Kirtiman Singh, learned CGSC for the Union of India, MoHFW, at the outset, submits that the Union of India framed its policy in 2021, and a perusal of the same shows that various considerations were borne in mind while framing the policy, especially in the context of rare diseases. The

Union of India is also conscious of the fact that children with rare diseases need to be taken care of, and the constraints are also outlined in the said policy. The prohibitive cost of treatment for rare diseases, as well as the experiences of other countries, have been highlighted in the policy. Emphasis is laid on the fact that the Government must balance competing public health priorities within the limited resources, including financial resources, available to it. In 2021, the NPRD, 2021 restricted funding support to patients suffering from Group I and Group II medical conditions and not Group III, which includes high-cost rare diseases. Furthermore, under paragraph 10 of the 2021 policy, funding was available not only to BPL families but also to other eligible families under the Pradhan Mantri Jan Arogya Yojana. However, the Office Memorandum dated 19th May 2022 amended the policy and extended financial assistance up to Rs. 50 lakhs to patients suffering from all groups of medical conditions, including Group III. This policy, read with the office memorandum, is not under challenge. The Government has taken proactive steps.

282. Pursuant to order dated 15th May, 2023 passed by the Court, the NRDC has been constituted and the Committee is continuously engaged with CoEs, patients groups, manufacturers and providers of therapies. The NRDC has also made several recommendations which have been positively considered by the Union of India.

283. The submission on the basis of the note of arguments handed over is that if all the registered patients are taken into consideration an annual budget of Rs. 2,500 crores would be required to cater to all the patients, however, despite the financial constraints the MoHFW has increased the budget for the rare diseases for the next two years to Rs. 974 crores. This is

a substantial growth in comparison to the previous budget which was less than Rs.100 crores per year.

284. It is, further, argued that while Right to Health is considered as a fundamental right, there is an imminent need to balance the fundamental rights of competing interests as held in ***Mazdoor Kisan Shakti Sangathan v. Union of India (2018) 17 SCC 324*** and ***Ram Lubhaya Bagga (supra)***.

285. Ld. CGSC also highlights the fact that various countries across the world have faced constraints in dealing with rare diseases and have come out with their own polices which would also show that even the developed world faces immense constraints to fund these patients. Mr. Kirtiman Singh, ld. CGSC submits that the procurement of the medicines would be done centrally as per the recommendations of the NRDC in order to ensure speedy procurement and disbursement to all the CoEs.

Submissions on behalf of AIIMS

286. On behalf of AIIMS, Mr. Oberoi, ld. Counsel has handed over a chart to give the estimates for what would be the expenses that would have to be incurred for treating the 14 patients who already been administered the medications and for the remaining 65 patients who are amenable to treatment. According to him, in terms of this chart by way of an average for each patient an amount running to crores would be required for the treatment. Secondly, the total amount that would be required would be Rs. 350 crores.

287. He also emphasizes that the doctors at AIIMS who have continuously dealt with the patients and examined them and provided for their treatment even during the pandemic time have dedicated their time, effort and

resources for the rare disease patients.

Submissions on behalf of the companies- Sarepta and Roche

288. Mr. Kirpal, ld. Sr. Counsel appearing for M/s Sarepta Therapeutics at the outset submits that M/s Sarepta Therapeutics has made offers to the NRDC as to the best price that it can offer for procurement of medicines in India. He submits that NRDC has made a counter offer. However, the same may not be acceptable to M/s Sarepta Therapeutics as M/s Sarepta Therapeutics has made the lowest offer anywhere in the world to the NRDC for supply in India. Insofar as conditions are concerned, the same can be negotiated with the NRDC.

289. With respect to enrolment of further candidates in the trial of M/s Sarepta Therapeutics are concerned, it is submitted that all required slots have been filled and charges proceeded further. It is further stated that it is not possible to enrol any further candidates into the trial. As far as procurement and supply of the medicines is concerned, M/s Sarepta Therapeutics is agreeable for central procurement of the medicines and is willing to submit an SOP for the manner in which it shall be ensured by M/s Sarepta Therapeutics that no delay would be caused in the supply. Insofar as the GST and Customs duties are concerned, it is prayed that the same ought to be waived which would make the medicines much more reasonable for procurement.

290. Mr. Darpan Wadhwa, ld. Sr. Counsel appearing for Roche India submits that the best offer on behalf of Roche has already been made by Roche India to the Government. As per the negotiations which were conducted with the NRDC in August, 2023, Roche India has offered the best price and Roche India had not heard back from the NRDC.

291. Insofar Roche India's own programme to support the SMA patients are concerned, the directions in these cases would not affect the said programme which is already programmed.

ANALYSIS AND CONCLUSIONS

A. National Rare Diseases Policy and its different versions.

292. The Government of India had firstly introduced the 'National Policy for Treatment of Rare Diseases, 2017' - the salient features of which were as under:

- A rare disease is defined as a health condition of particularly low prevalence. There is no universally accepted definition, but the policy aims to define rare diseases for India based on prevalence, severity, and availability of therapeutic options.
- Immediate Implementation Measures:
  - Establishment of inter-ministerial and technical cum administrative committees to manage the policy's implementation and the funding for rare diseases at both central and state levels.
  - Creation of a corpus fund at both central and state levels to support part-funding of treatments.
  - Creation of a patient registry housed in the ICMR to track and monitor rare disease cases.
  - Development of an online platform to streamline the application process for treatment funding.
- Long-Term Measures:
  - Systems for collecting epidemiological data on rare diseases in India.

- To promote research for drug development, diagnostics, and assistive devices for rare diseases. Collaborations at the regional and international levels.
- Encouraging local manufacturing of drugs for rare diseases, supported by legislative measures to ensure affordability.
- Introduction of mechanisms for price control to make drugs for rare diseases affordable and sustainable for the health system.
- Encouraging the insurance sector to provide coverage for rare genetic disorders.

- Prevention and Early Diagnosis:
  - Exploring a national plan for testing newborns for rare genetic diseases as part of an early diagnosis strategy.
- Affordability and Access to Treatment:
  - Emphasises need for financial assistance, particularly for families below the poverty line, ensuring that they receive supportive services in both public and private hospitals.
  - The policy encourages funding support from PSUs and corporate houses under CSR initiatives.
- Proposals to amend the DCA to facilitate clinical trials for rare diseases and the import of essential drugs, including ERTs.
- Exploration of initiatives to promote open access to drug development and local manufacturing, including the use of compulsory licenses under the Patents Act.

293. The above Policy of 2017, was kept in abeyance vide notification dated 18th December, 2018, and, thereafter, a draft policy was introduced in 2020. After this Court had entertained the initial writ petitions and directions

were issued, vide order dated 23rd March, 2021, the National Policy for Rare Diseases Policy, 2021 was finalised and approved on 30th March, 2021. The salient features of the said policy of 2021 are as under:

- ***Definition of Rare Diseases***: NPRD, 2021, categorizes rare diseases into three groups:
  - Group 1: Disorders that can be cured with one-time treatments, such as certain Lysosomal Storage Disorders and immune deficiency disorders.
  - Group 2: Diseases requiring long-term or lifelong treatment with relatively lower costs, such as phenylketonuria and homocystinuria.
  - Group 3: Disorders for which definitive treatment exists but with high costs and lifelong therapy, such as Gaucher Disease and Duchenne Muscular Dystrophy.
- Treatment options are limited and expensive, with only 5% of rare diseases having available therapies.
- ***Government Support***: Financial assistance up to Rs. 20 lakhs will be provided for one-time treatments (Group 1 diseases) under the Rashtriya Arogya Nidhi scheme. Broadened financial assistance to include up to 40% of the population, including non-BPL families. Voluntary crowd-funding platforms will be created to finance high-cost treatments for Group 3 diseases.
- Rs. 20 lakh support is provided once for treatments that are curative and typically require a single intervention. It is not an annual or recurring payment but is linked to Group 1 diseases that can be cured with a one-time treatment.
- ***CoEs***: The Government will notify specific CoEs for the diagnosis,

prevention, and treatment of rare diseases. One-time financial support up to Rs. 5 crore to be provided for infrastructure development, including screening, diagnostics, and treatment services. These centres would be responsible for quick decision-making (within two weeks) on fund allocation for treatment.

- A National Consortium for Research and Development on rare diseases to be formed to synchronize research efforts. AIIMS Delhi to act as the nodal hospital, coordinating the efforts of CoEs across the country for prevention, research, and treatment of rare diseases.
- NPRD, 2021, emphasizes primary prevention through premarital and prenatal screening, secondary prevention through prenatal diagnosis, newborn screening, and early postnatal diagnosis, and tertiary prevention with rehabilitation and supportive care for advanced cases.
- Implementation Strategy: A hospital-based National Registry for Rare Diseases will be created to gather data on rare diseases in India. Awareness campaigns will be conducted to educate the public and healthcare professionals about rare diseases. Collaboration with the pharmaceutical industry and public-private partnerships will be encouraged to ensure affordable access to treatments.
- Promote indigenous drug manufacturing by encouraging PSUs and private pharmaceutical companies to develop affordable rare disease treatments locally. It also includes initiatives to reduce customs duties on imported drugs.
- The State Governments may undertake treatment of disorders managed with special dietary formulae or food for special medical purposes (FSMP) and Disorders that are amenable to other forms of

therapy (hormone/ specific drugs)- diseases covered under Group 2.

294. NPRD, 2021 was subsequently reconsidered and an Office Memorandum dated 19th May, 2022 was issued by MoHFW by which certain further modifications.

295. The said modification is as under:

"File No: W-11037/40/2022-Grants (RD)
Government of India
Ministry of Health & Family Welfare
(Rare Diseases Cell)
Nirman Bhawan, New Delhi
Dated: 19/5/2022

OFFICE MEMORANDUM

The undersigned is directed to state that the following provision envisaged under Para 10(i) of National Policy for Rare Diseases (NPRD), 2021:

"Financial support upto Rs. 20 lakh under the Umbrella Scheme of Rashtriya Arogaya Nidhl shall be provided by the Central Government for treatment, of those rare diseases that require a one-time treatment (diseases listed under Group 1). Beneficiaries for such financial assistance would not be limited to BPL families, but extended to about 40% of the population, who are eligible as per norms of Pradhan Mantri Jan Arogya Yojana, for their treatment in Government tertiary hospitals only."

may be treated as replaced with the following:

"Financial support upto Rs. 50 lakhs shall be provided to the patients suffering from any category of the Rare Diseases. The financial support will be provided to the patients for the treatment in any of the Centre of Excellence (CoE) mentioned in NPRD-2021, outside the

Umbrella Scheme of Rashtriya Arogaya Nidhi."

2. All other provisions of the policy will remain unchanged.
3. These amendments come into effect from the date of issue of this Office Memorandum.
4. The guidelines/procedure for providing financial assistance to the patients as per amended provisions are being finalized. However, till the finalization of guidelines and in order to provide uninterrupted and enhanced financial assistance i.e. upto Rs. 50 lakhs to the patients of rare diseases irrespective of category of disease, funds may continued to be granted from the current budget head of Umbrella Scheme of Rashtriya Arogya Nidhi (RAN).
5. This Issues with the approval of the competent authority.

(Manish Raj)
Under Secretary to the Govt. of India
Tel. 011-23062068"

296. Thus, as on date, on a conjoint reading of NPRD, 2021 along with the Office Memorandum, dated 19th May, 2022, the position as it stands is as under:

i) Rare diseases are defined as per the prevalent policy i.e., NPRD, 2021 which acknowledges that there is no universal definition of rare diseases, with countries typically defining them based on prevalence in their specific population and healthcare context. India, however, lacks sufficient epidemiological data to define rare diseases in this way. To address this, ICMR initiated a National Registry for Rare Diseases to collect data from hospitals across the country. Until

adequate data is available, the NPRD, 2021, defines rare diseases based on a categorization of disorders identified by clinical experts through their experience:

- ***Group 1:*** Disorders that are amenable to one-time curative treatment, such as certain Lysosomal Storage Disorders and immune deficiency disorders.

- ***Group 2***: Diseases requiring long-term or lifelong treatment, where relatively lower-cost treatments are available and beneficial, such as metabolic and hormonal disorders.

- ***Group 3***: Disorders for which definitive treatment is available but the cost is very high, and lifelong therapy is required, such as Gaucher disease and Duchenne Muscular Dystrophy.

ii) As per the NPRD, as amended on 9th May 2022, the one-time amount that can be expended per patient is Rs. 50 lakhs for all categories of diseases.

E. <u>Legal Position on Right to Health</u>

297. It is now well settled that Right to health is an integral part of Right to Life under Article 21 of the Constitution of India. The said Right cannot distinguish between persons with more prevalent diseases on one hand and rare diseases on the other hand. To discriminate between patients suffering from more prevalent diseases, and those who suffer from rare diseases would also be discriminatory and violative of Article 14 of the Constitution of India. Right to health has to be equally recognised for persons suffering from rare diseases.

298. While there is no doubt that the Constitutional obligation to provide healthcare rests upon the State, the same is to be balanced with the available constraints. However, the recognition of the Right to Health and Healthcare

cannot be completely negated due to these constraints. The country ought to strive to provide adequate healthcare to persons with rare diseases within the available limitations and in the best possible manner.

299. According to one publication[5], there are about 7,000 known rare diseases, affecting around 8% of the world's population, and 75% of rare disease patients are children. These rare diseases are even referred to as '***orphan diseases'***. It is a well-established and documented fact that therapies and medicines for treating orphan diseases are not usually a priority for the pharmaceutical industry. Therefore, the therapies and treatments that are available are limited. The categorization of rare diseases is based on the percentage of the population suffering from them. In a country like India, even a small percentage translates into lakhs of individuals affected by rare diseases. Merely because they represent a small percentage does not mean their concerns and health can be ignored. Within the available resources, the State must continuously make efforts to provide the best possible care for such patients.

300. In India, where health insurance is lacking for most strata of society, the fact that therapies for rare diseases are completely out of reach for the common man deserves attention. Steps must be taken, even on a long-term basis, to make therapies and medications available and also to indigenize them. Regulatory authorities, such as the DCGI and CDSCO, play a very important role in this process. These authorities must be conscious of the need to accelerate local manufacturing of such medicines and therapies. Indigenization must be encouraged. The State should utilize existing

[5] Nandita Jayaraj, 'What Incentives Do Scientists Have to Study Rare Diseases?' The Hindu (Mangaluru, 28 December 2023) https://www.thehindu.com/sci-tech/science/scientists-incentives-study-rare-diseases-

resources and create additional avenues to ensure that even the last patient is duly recognized and cared for.

301. A country like India, where thousands, if not lakhs of patients suffer from rare diseases, cannot adopt a helpless approach. Courts also cannot be mute spectators. There are several of registered patients, but there may be many more unregistered individuals suffering from rare diseases. While priorities may lean towards diseases affecting a larger number of people, patients suffering from rare diseases cannot be fully ignored. Effort has to be made to make the globally available treatments procured at reasonable cost.

302. A society is judged by how it treats its most vulnerable members. Children with rare diseases, being among the most vulnerable, deserve care and attention. The Union of India, and other authorities, have a duty to ensure that these children are not left to suffer simply because they represent a smaller group within the population. Rare disease patients, particularly children, should not be marginalized simply because they are in the minority. Denying treatment to these children because of the rarity of their condition contradicts the fundamental principle that every individual has the right to the same level of care and consideration. Furthermore, rare diseases often come with immense suffering, not only physically but also emotionally and mentally, for both the child and their family. A model society is one that mitigates unnecessary suffering wherever possible, and ensuring access to appropriate treatment is an essential part of this. This is also considering the fact that children cannot represent themselves before this Court. They rely on adults to ensure their voices are heard and their needs are met.

<u>International Law on Right to Health</u>

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breakthrough-prizes-explained/article67671810.ece accessed 4 October 2024.

303. India is a country, which with all its limitations on resources has committed itself for the protection of human rights, the right to live with dignity and the intention of the State to endeavor for all its citizens beyond animal existence. International covenants, namely International Covenant on Economic, Social, and Cultural Rights, which has been ratified by India, specifically recognizes the consent of the signatory States, rights of citizens for enjoyment of the highest attainable standard of physical and mental health.

304. The Universal Declaration of Human Rights *(hereinafter, 'UDHR')* records and recognises the inherent dignity of human life[6] in Article 25 of the said Declaration. Article 12 of the International Covenant on Economic, Social and Cultural Rights *('ICESCR')* recognizes the right of everyone to the enjoyment of the highest attainable standard of physical and mental health., and Article 12(2), lists the steps to be taken by States to achieve the full realization of this right, including the improvement of environmental and industrial hygiene, prevention, treatment, and control of diseases, and access to medical services. In relation to the rights of children, the Convention on the Rights of the Child *('CRC')*, 1989, in Article 24(1) recognises the right of the child to the enjoyment of the highest attainable standard of health and to facilities for the treatment of illness and rehabilitation of health.

305. Considering the number of international instruments that regulate the right to life and health, there is still a significant gap at the global level in ensuring that therapies for rare diseases are made affordable and accessible

[6] See, Article 25(1) of the Universal Declaration of Human Rights (UDHR), 1948: Article 25(1): "Everyone has the right to a standard of living adequate for the health and well-being of himself and of his

on a global scale. The present is a classic case, especially in respect of DMD patients. Gene therapies are available in some countries, which are stated to cure DMD, but the same is not accessible to most of the world. Similar is the situation with exon-skipping therapies, which are being currently being administered for globally for DMD patients. The ICESCR recognises the right of every human being to the enjoyment of the highest attenable standard of physical and mental health, however, the above covenants would merely be paper covenants if children with rare diseases cannot be provided treatment.

306. A review of the manner in which most Governments deal with rare diseases would show that there is no consistent framework or pattern. In some countries, there are legislations which deal with rare diseases or orphan diseases – for e.g., US Orphan Diseases Act, 1983, European Union Regulation (EC) No. 141/2000 of the European Parliament and of the Council of 16th December 1999 on orphan medicinal products.

307. In some countries, the national health care plans deal with rare diseases. The written submissions placed on record by the ld. Amicus are useful in this regard. The same are extracted hereinbelow:

> ***"a) Australia:*** *Patients with rare diseases who fulfil certain eligibility criteria can access the fully subsidized life-saving medicines under the Life Saving Drugs Program (LSDP) in Australia. This assistance is provided for 18 medicines for 11 rare diseases including Fabry's Disease, Gaucher, MPS I, MPS II, Pompe Disease, etc. The Australian Government Department of Health and Aged Care funds and*

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family, including food, clothing, housing, and medical care.

administers the program, and the ordered medicines are delivered to the patient's nominated pharmacy in terms of the LSDP. True copies of the details of the LSDP as published by the Australia Government on the website are annexed herewith as Annexure G (Colly).

(b) Bulgaria: *The cost of several orphan drugs is reimbursed in full in Bulgaria under the National Health Insurance Fund set up under the National Health Insurance Act, 1998, if the drug is included in the Positive Drug List maintained by the National Council on Prices and Reimbursement of Medicinal Products. A 100 percent reimbursement is provided under Article 262 of the Medicinal Products in Human Medicine Act, 2007, read 49 with Article 53 of the Ordinance on Terms, Rules and Procedure for Regulation and Registration of Prices for Medicinal Products, for medicines for diseases with a chronic course, leading to severe disruptions in the quality or life or disablement and requiring prolonged treatment. Several drugs for rare diseases such as Spinraza for SMA, Prednisone for DMD and Cerdelga for Gaucher Disease, are included in the Positive Drug List and, therefore, reimbursable by the Bulgarian government. True copies of the relevant portions of the laws governing treatment of rare diseases in Bulgaria, and the website of the National Health Insurance Fund are annexed herewith as Annexure H.*

(c) Czech Republic: *The Public Health Insurance Act, Act No. 48/1997 in Section 11(f) read with Section 14 provides for healthcare for rare diseases and reimbursement of costs of healthcare provided in*

Czech Republic. The State Institute for Drug Control decides the amount and conditions of the reimbursement. This provision has been made pursuant to Article 3 of Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products. True copy of the relevant portions of the 50 laws governing treatment of rare diseases in Czech Republic is annexed herewith as Annexure I.

(d) Singapore: *In Singapore, a Rare Disease Fund has been created for five medicines for the treatment of rare diseases such as Gaucher, Pompe Disease, MPS VI, etc. The Rare Disease Fund is a charity fund that seeks to provide long-term financial support for patients with rare diseases requiring treatment with high cost medicines. The Fund is supported by the Ministry of Health of Singapore and community donations. A true copy of the information regarding the Rare Disease Fund available on the website of the Ministry of Health, Singapore is annexed herewith as Annexure J.*

(e) Taiwan: *In accordance with the Rare Disease and Orphan Drug Act, 2000 and the National Health Insurance program implemented in Taiwan, medical care for special groups is fully paid for, which includes persons who have been diagnosed with a rare disease. For medicines for rare diseases/ orphan drugs which are not covered by the insurance policy, the National Health Insurance Administration subsidizes the cost of diagnosis and treatment through specially earmarked funds. While the maximum subsidy amount is 80% of*

the expenses, 51 expenses of patients from low-income or middle-low-income households, and expenses of emergency medicine and special nutrient foods essential for the maintenance of life are fully subsidized. A true copy of the information regarding the Rare Disease Fund available on the website of Health Promotion Administration, Taiwan is annexed herewith as Annexure K.

(f) United Kingdom: *The National Health Service ('NHS') England (previously National Health Service Commissioning Board) has been set up under the Health and Care Act, 2022 and covers a wide spectrum of primary, specialized and highly specialized health services which includes treatment and care for rare diseases. Services are commissioned by the Integrated Care Board set up under the scheme of the NHS. Some of the highly specialized services commissioned in the year 2021 include gene therapy (Onasemnogene abeparvovec) for SMA, Type I, enzyme replacement therapy, substrate reduction therapy (SRT) or other disease modifying drugs for Lysosomal Storage Disorders, etc. NHS England also has a Rare Diseases Advisory Group which makes recommendations to NHS England and the devolved administrations of NHS Scotland, NHS Wales and NHS Northern Ireland on developing and implementing the strategy for rare diseases and highly 52 specialized services. NHS England is guided by the UK Strategy for Rare Diseases implemented by the United Kingdom, which aims at empowering rare disease patients, identifying and preventing these diseases (screening and carrier testing), diagnosis and early intervention, coordination*

of care (specialist centers) and research. A true copy of the Report of NHS England on High Specialised Services 2020/21 published on 28.11.2023 is annexed herewith as Annexure L."

308. In countries like Brazil, intervention of Courts has been necessitated for providing treatment. The Supremo Tribunal Federal, in ***Petição 1246 (decision dated 4th October, 1997)***, held that when faced with the dilemma of protecting the inviolability of the right to life—an inalienable subjective right guaranteed by the Constitution of the Republic (Art. 5, caput)—or allowing the financial and secondary interests of the State to prevail against this fundamental prerogative, ethical and legal considerations compel the judge to make only one choice: the unwavering respect for life[7]. Thus, the Supremo Tribunal Federal directed the State to cover the costs of treatment of an experimental therapy for 'Distrofia Muscular de Duchene' or DMD.

309. Thus, each country is prioritising the needs of patients suffering from rare diseases, based on the number of patients, availability of resources, insurance schemes etc.

Supreme Court on Right to Health

310. The Supreme Court has, on several occasions discussed the scope and ambit of the Right to Health. In ***Association of Medical Super Speciality Aspirants and Residents v. Union of India (2019) 8 SCC 607,*** the Supreme Court categorically held that the Government has the constitutional obligation to provide health facilities. The observations of the Court are set

[7] Supreme Federal Court (Brazil), (2023) https://redir.stf.jus.br/paginadorpub/paginador.jsp?docTP=AC&docID=325774 accessed 4 October 2024. Caroline Tauk, 'Expectativa e Realidade: Uma Análise Pragmática dos Litígios de Saúde' (2020) 18 R. bras. de Dir. Público 1. Daniel Wei L. Wang, 'Right to Health Litigation in Brazil: The Problem and the Institutional Responses' (2015) 15 Human Rights Law Review 617 https://doi.org/10.1093/hrlr/ngv025

out below:

> *"**26.** Right to health is integral to the right to life. Government has a constitutional obligation to provide health facilities. The fundamental right to life which is the most precious human right and which forms the ark of all other rights must therefore be interpreted in a broad and expansive spirit so as to invest it with significance and vitality which may endure for years to come and enhance the dignity of the individual and the worth of the human person. The right to life enshrined in Article 21 cannot be restricted to mere animal existence. It means something much more than just physical survival. **The right to life includes the right to live with human dignity and all that goes along with it, namely, the bare necessaries of life such as adequate nutrition, clothing and shelter, and facilities for reading, writing and expressing oneself in diverse forms, freely moving about and mixing and commingling with fellow human beings**. Every act which offends against or impairs human dignity would constitute deprivation pro tanto of this right to live and the restriction would have to be in accordance with reasonable, fair and just procedure established by law which stands the test of other fundamental rights."*

311. Courts have repeatedly made attempts to ensure that patients suffering from rare diseases are protected. In ***Mohd Ahmed (supra)***, the Court noted clearly that there are no incentives to develop local alternatives to orphan drugs. In the said case, the Court directed the patient to be given treatment *i.e.,* providing enzyme replacement therapy, however, in appeal being ***LPA 764/2014*** titled ***'GNCTD v. Mohd Ahmad and Ors.'***, it was held that the said order would not be treated as precedent. Similar orders have been passed by various Courts directing providing of medicines for patients

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accessed 4 October 2024.

suffering from rare diseases. The list of such cases is as follows:

- *Manoj M. v. State of Kerala & Ors., (2016) 4 KLT 491*
- *State of M.P. v. Prajwal Shrikhande, 2021 SCC OnLine MP 3584*
- *Baby Ananya Sri. Bhargav Thanga v. State of Andhra Pradesh, 2022 SCC OnLine AP 553*
- *Koppadi Hani v. Union of India, 2022 SCC OnLine AP 846*
- *Konatham Sailaja v. Union of India, Ministry of Health and Family Welfare, 2022 SCC OnLine AP 58*
- *Arif v. State of Kerala, WP(C) No. 7984 of 2021*
- *Lysosomal Storage Disorders Society in India v. State of Karnataka, WP No. 19061 of 2015*
- *Rogeeth v. State of Karnataka, WP No. 6756 of 2019*

312. In ***Rakesh Malhotra v. GNCTD [W.P.(C) 3031/2020, order dated 1st June, 2021],*** the Court observed that a policy decision has to be taken by the Union of India as the manner in which the available resources can be optimally utilised. The relevant extract from the judgment is set as under:

> *"10. From the status reports placed before us, it appears that the UOI has been making efforts to procure the said drug by getting in touch with the primary manufacturer of the said drug and patentholder Gilead through its associate/ subsdiary i.e. Mylan. The manufacturing capacity of several manufacturers in India has also been augmented, and fresh licenses have also been issued. There are issues with regard to availability of basic rawmaterial used for manufacture of the said drug and efforts are being made to source the same from abroad. However, the requirement of the Liposomal Amphotericin-B is far in excess of the availability of the said drug, and it is*

absolutely clear that the acute shortage of the said medicine shall continue for some time, at least, during which period many more lives would be lost to the said disease.

11. In this situation, in our view, the responsibility has fallen on the shoulders of the UOI to take a policy decision with regard to the manner in which the said drug should be made available to the suffering patients, till such time as the shortage of Liposomal Amphotericin-B continues, or an alternate equally effective and safe medicine is found for treatment of the said disease. If all patients suffering from the said disease cannot be treated on account of non-availability of the said drug in sufficient quantity, the responsibility falls on the UOI to spell out its policy with regard to the priority of patients who should be administered the said drug, to maximize the lives that could be saved, amongst patients suffering from Mucormycosis (Black Fungus). Any such policy decision necessarily has to be taken with sufficient inputs from medical and legal experts. ***Administration of the said drug on patients who have better chances of survival may have to be prioritized. Similarly, within the group of patients who have same or similar chances of survival, patients who are younger and who hold the promise to run the nation in future, may have to be prioritised in comparison with the older generation which has lived its life and on whom others may not be as dependent financially. While so observing, we are, not for a moment, discounting the emotional and psychological support that the older generation provides to families, particularly, the Indian families who are so closely bonded. However, in times like these, practical choices have to be made, and should be made by the State. The learned Amicus has prepared a tabulation of how other countries have approached similar situations and prioritized***

<u>patients falling in different categories for the purpose of treatment. The said tabulation shall be shared with both the GNCTD and the UOI as the same may assist the Central Government in creating the categories and priorities for the purpose of treatment of the disease in question</u>.

12. We, therefore, direct the UOI to frame a policy with regard to administration of Liposomal Amphotericin-B and other drugs as aforesaid, amongst the patients who are suffering from the said disease and once the policy is made, on the basis of the said policy, allocation should be made by the UOI since it is calling for information on its portal from all over the country of all the patients who are suffering from the said disease.

13. We may also observe that there may be a category of persons who are serving the nation in high positions and whose safety and security may be necessary in view of the pivotal role that they play in the administration of the country. While formulating its policy, the UOI should carve out such exceptional cases for good reasons. Looking to the urgency of the situation, we direct the UOI to place their status report in this regard, which shall be considered on Friday, i.e. 04.06.2021."

The above decision recognises the need to prioritise, which can also be done in cases involving persons with rare diseases.

313. The sum and substance of all the decisions and the international position on dealing with rare diseases is that there is insufficient research and development in the area. Countries like the US have introduced legislations such as the Orphan Drugs Act, 1983 to encourage, research and investment in this sector. Similarly, in other countries, orphan diseases or

rare diseases are given greater importance by the State owing to the general lack of alacrity towards these medical conditions.

314. In India, the Government has already taken the right steps by introducing National Policy for the Treatment of Rare Diseases in 2017, and slowly expanding the same till 2023. Currently, all major rare diseases are already covered under the policy, though there may be a few over which further discussions are required.

315. The main impediment is in respect of the upper limit of Rs. 50 lakhs that has been fixed by the Government under the NPRD, 2021, read with the Office Memorandum dated 19th May, 2022. There are several diseases for which Rs.50 lakhs is not required, and there are some diseases for which a higher amount would be required. The ceiling, therefore, needs to be kept flexible, and should be left to the decision of experts in the NRDC. The Committee being the expert committee ought to decide on the appropriate treatment, to what extent it should be provided, and in what form. In some cases, it could involve the administration of medicines, while in others, it might require providing better support, such as wheelchairs, transport, or other necessary equipment/assistive devices. The NRDC should make the final decision for each patient after receiving recommendations from the CoEs.

316. Citizens with rare diseases, predominantly include children and any special provisions made for them would also be permissible under Article 15(3) of the Constitution of India. As pointed out by ld. Counsel Mr. Agarwal, one of the counsels appearing for the Petitioners, disabilities also include physical disabilities including locomotor disabilities in the schedule to Rights of Persons with Disabilities Act, 2016 *(hereinafter, 'RPwD Act')*.

Persons affected with rare diseases also require high support needs and other measures, which may be required to be taken for a dignified existence. While the State's endeavor has been to provide health support to ***all*** its citizens, the countervailing need for persons with ***special needs and disabilities*** and afflicted with rare diseases cannot also be ignored.

317. As our country marches, on its aspiration to become a developed country, baby steps, if not giant steps, have to be taken for allocation of resources for specially blessed individuals and their families. Families of persons suffering from rare diseases, of which majority are children, are undergoing enormous trauma seeing their loved ones dissipating in front of their eyes and the only reason why adequate medical care is not being provided to them is on economic considerations alone. A large number of persons may be afflicted with rare diseases across the country, out of which many might not be diagnosed with it. In the case of those, who are diagnosed and amenable to treatment, steps have to be taken to provide with the treatment to the best extent possible. Lapsing of budgets, non-release of funds in an efficient manner, non-procurement of medicines, not providing adequate procedure for procurement and non-taking of measures provided under the law merely reflects lack of a concerted and coordinated approach towards rare diseases.

318. The root of the problem lies in -

(i) Not identifying rare diseases in a timely manner;

(ii) Not taking measures for indigenous research for such diseases;

(iii) Not invoking measures available under law to ensure manufacturing and existence of therapies and medicines in India.

319. Most of these therapies and medicines can be made available to all persons with rare diseases, if these measures are undertaken. Thus, there is a need for a streamlined and coordinated approach between the Government, doctors and pharmaceutical companies to make available therapies and drugs in India for treating rare diseases in an affordable setting.

Patented Medicines

320. A number of medicines and therapies for rare diseases are also patented. The Patents Act, 1970 recognizes the need for working patented medicines in India. This is adequately enshrined in Section 84 of the Patents Act, 1970, which requires that the products have to be made available at reasonable prices to the public in India. It also mandates that the patentee has to satisfy the reasonable requirement of the public[8].

321. ***`Working'*** of a patented invention, in India, primarily means manufacturing in India, though importation is also permissible if sufficient quantities in affordable prices are made available. In the case of rare diseases, if therapies and medicines are not available, the Government is also empowered under the Patents Act, 1970 to use the invention under Section 100 of the Patents Act, 1970 for Government use, and permit manufacturing by a third party subject to payment of royalty to the patentee. Acquisition of inventions and patents is also permissible by the Central Government under Section 102 of the Patents Act, 1970. These provisions exist so as to ensure that in case, patentees of medicines and drugs, despite

[8] Section 83(g) of the Patents Act,1970 " Without prejudice to the other provisions contained in this Act, in exercising the powers conferred by this Chapter, regard shall be had to the following general considerations, namely: (g) that patents are granted to make the benefit of the patented invention available at reasonably affordable prices to the public."

all efforts taken by the Government, do not make the same available, steps can be taken for ensuring availability in accordance with law.

322. In terms of orders dated 27th September, 2024, Sarepta has not placed the required information in relation to the number of granted patents and patent applications which have been filed by Sarepta in India. On preliminary research, from the website of IP Office, the details of the patents granted to Sarepta (as Patentee/Grantee) in India, and information provided in relation to working of these granted patents is tabulated as follows:

S.No	***Patent Number***	***Date of filing***	***Date of grant***	***Grant title***	***Working information u/S. 146***
1	515440	23/11/2022	26/02/2024	PROCESSES FOR PREPARING PHOSPHORODIAMIDATE MORPHOLINO OLIGOMERS	No information provided
2	505673	04/06/2021	31/01/2024	PROCESSES FOR PREPARING PHOSPHORODIAMIDATE MORPHOLINO OLIGOMERS	No information provided
3	532915	21/05/2021	15/04/2024	PROCESSES FOR PREPARING OLIGOMERS	No information provided
4	447232	28/06/2019	25/08/2023	EXON SKIPPING OLIGOMER CONJUGATES FOR MUSCULAR DYSTROPHY	No information provided
5	414275	24/06/2019	12/12/2022	EXON SKIPPING OLIGOMER CONJUGATES FOR MUSCULAR DYSTROPHY	No information provided
6	460670	21/12/2018	19/10/2023	PROCESSES FOR PREPARING OLIGOMERS	No information provided
7	422221	22/11/2018	17/02/2023	PROCESSES FOR PREPARING PHOSPHORODIAMIDATE MORPHOLINO OLIGOMERS	No information provided
8	390567	20/11/2018	27/02/2022	PROCESSES FOR	Not worked

				PREPARING PHOSPHORODIAMIDATE MORPHOLINO OLIGOMERS	Reason: "The patented technology relates to drug candidates in development that are not yet approved for marketing or sale by the Ministry of Health. Without having a Marketing Authorization approved by the Ministry of Health, it is not possible to work the patent under the local patent laws."
9	444724	19/11/2018	11/08/2023	OLIGONUCLEOTIDE ANALOGUES TARGETING HUMAN LMNA	No information provided
10	375970	09/11/2018	31/08/2021	PROCESSES FOR PREPARING PHOSPHORODIAMIDATE MORPHOLINO OLIGOMERS	Not worked Reason: "The patented technology relates to drug candidates in development that are not yet approved for marketing or sale by the Ministry of Health. Without having a Marketing Authorization approved by the Ministry of Health, it is not possible to work the patent under the local patent laws."
11	543804	06/11/2018	29/06/2024	ANTISENSE OLIGOMERS AND METHODS OF USING THE SAME FOR TREATING DISEASES ASSOCIATED WITH THE ACID ALPHA-GLUCOSIDASE GENE	No information found
12	402621	01/06/2018	05/08/2022	MULTIPLE EXON SKIPPING COMPOSITIONS FOR DMD	No information found
13	380546	12/12/2017	28/10/2021	PEPTIDE OLIGONUCLEOTIDE CONJUGATES	Not worked Reason: "The patented technology relates to drug candidates in development that are not yet approved

					for marketing or sale by the Ministry of Health. Without having a Marketing Authorization approved by the Ministry of Health, it is not possible to work the patent under the local patent laws." "The patentee is looking for an opportunity to work in India."
14	382489	07/03/2016	24/11/2021	ANTISENSE INDUCED EXON2 INCLUSION IN ACID ALPHA GLUCOSIDASE	Not worked Reason: same as above
15	362002	26/12/2012	18/03/2021	OLIGONUCLEOTIDE ANALOGUES HAVING MODIFIED INTERSUBUNIT LINKAGES AND/OR TERMINAL GROUPS	Not worked Reason: "Patents are not yet commercialized, incubation of technology is in process."
16	302489	26/04/2011	26/10/2018	MULTIPLE EXON SKIPPING COMPOSITIONS FOR DMD	Not worked since 2018-2019 Five working statements filed in 2018-19, 2019-20, 2020-21, 2021-22, 2022-23. Reason: "The patented technology relates to drug candidates in development that are not yet approved for marketing or sale by the Ministry of Health. Without having a Marketing Authorization approved by the Ministry of Health, it is not possible to work the patent under the local patent laws."

The above list of Patents includes those relating to medicines for healing DMD. The non-working of these patents ought to be taken into consideration by the concerned authorities.

Price Control

323. The Drug Price (Control) Order, 2013 (issued under the provisions of the Essential Commodities Act, 1955) *(hereinafter, 'DPCO')* controls the prices of all essential medicines by fixing ceiling prices, limiting the highest prices companies can charge. Paragraph 32 of said Order provides the conditions under which the provisions of the DPCO would not apply. In relation to rare diseases, the Department of Pharmaceuticals issued an order dated 3rd January, 2019, wherein the provisions of para 32 of the DPCO were also extended to drugs for treating orphan diseases as decided by the MoHFW. The said order reads as follows:

> *"Drugs for treating orphan diseases as decided by the Ministry of Health and Family Welfare, Government of India"*

In effect therefore, drugs for orphan diseases or rare diseases are excluded from price controls. When companies enjoy this exception and are permitted to price the drugs in the manner they wish, there is a reasonable expectation that the drugs would at least be available and affordable. However, the situation in the present case qua DMD reveals exactly the opposite. The medicines are patented in India, not manufactured in India, not properly distributed in India and they are exorbitantly priced and outside price control. The position cannot continue in this manner especially when so many patients are suffering from DMD.

Under-utilisation of Budgeted amounts for Rare Diseases

324. Mr. Grover, ld. Sr. Counsel has placed the position of the UOI relying upon the answers given in Parliament by the Minister of State, Health and Family Welfare[9]. In fact, in response to the question raised in Parliament, the Union Minister of State, Health and Family Welfare has, in the context of rare diseases, stated as under:

GOVERNMENT OF INDIA
MINISTRY OF HEALTH AND FAMILY WELFARE
DEPARTMENT OF HEALTH AND FAMILY WELFARE

LOK SABHA
UNSTARRED QUESTION No. 1247
TO BE ANSWERED ON 9th FEBRUARY, 2024

ENROLLMENT OF RARE DISEASE PATIENTS

1247. DR. SHASHI THAROOR:

Will the Minister of ***HEALTH AND FAMILY WELFARE*** *be pleased to state:*

(a) the number of Rare Diseases Patients enrolled within the Centres of Excellence across the country;
(b) the details of the allocation and utilisation of funds by the different Centres of Excellence across the country during the last three years and the current year till date, year-wise;
(c) whether regular meetings have been conducted by the National Rare Diseases Commission ever since its constitution by the Delhi High Court in 2023; and
(d) if so, the details thereof and if not, the reasons therefor?

[9] Government of India, Ministry of Health and Family Welfare, Department of Health and Family Welfare, 'Enrolment of Rare Disease Patients' Lok Sabha, Unstarred Question No. 1247, dated 9th February, 2024 https://sansad.in/getFile/loksabhaquestions/annex/1715/AU1247.pdf?source=pqals accessed 4 October 2024

ANSWER
THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE
(DR. BHARATI PRAVIN PAWAR)

(a) Rare Disease patients, who are amenable to treatment, are enrolled with Centres of Excellence (CoEs). As per the data maintained by 12 CoEs, there are 2420 patients enrolled as on date.

(b) The National Policy for Rare Disease, 2021 was launched on 30.03.2021. The details of financial assistance released to the different Centres of Excellence across the country for treatment of patients during the last three years and the current year till date, year-wise, is annexed.

(c) & (d) In compliance with the Order dated 15.05.2023 of the Hon'ble High Court of Delhi in the matter of WP No. 5315/2020 and other connected petitions, a National Rare Diseases' Committee (NRDC) under the Chairmanship of Secretary, Department of Health Research & DG, ICMR was constituted by the Ministry of Health and Family Welfare (MoHFW). As of now, twelve(12) NRDC meetings have been held since constitution of the Committee.

COE-WISE EXPENDITURE DETAILS

Financial Year 2021-22

S.No.	***Name of the CoE***	***Financial Assistance released in FY 2021-22 (In Rs.)***	***Funds Utilized (In Rs.)***
1.	*Center for Human Genetics*	*3,00,00,000*	*3,00,00,000*

	(CHG) with Indira Gandhi Hospital, Bengaluru		
2.	*All India Institute of Medical Sciences, New Delhi*	*15,00,000*	*8,93,993*

Financial Year 2022-23

S. No.	***Name of the CoE***	***Financial Assistance released in FY 2022-23 (In Rs.)***	***Funds Utilized (In Rs.)***
1.	*Centre for DNA Fingerprinting & Diagnostics with Nizam's Institute of Medical Sciences, Hyderabad*	*4,38,47,943*	*6,21,690*
2.	*King Edward Medical Hospital, Mumbai*	*1,99,70,876*	*1,67,45,652*
3.	*Sanjay Gandhi Post Graduate Institute of Medical Sciences, Lucknow*	*3,40,00,000*	*3,40,00,000*
4.	*Post Graduate Institute of Medical Education and Research, Chandigarh*	*3,92,95,360*	*1,04,20,101*
5.	*Institute of Child Health and*	*4,94,63,018*	*3,98,60,000*

	Hospital for Children (ICH & CH), Chennai		
6.	*Center for Human Genetics(CHG) with Indira Gandhi Hospital, Bengaluru*	*5,38,45,000*	*5,38,45,000*
7.	*All India Institute of Medical Sciences, New Delhi*	*7,88,29,854*	*7,55,98,991*
8.	*Institute of Post-Graduate Medical Education and Research, Kolkata*	*1,66,40,000*	*1,63,28,822*
9.	*Maulana Azad Medical College, New Delhi*	*1,40,10,000*	*Nil**

** The financial assistance of Rs.1,40,10,000/- was released to MAMC, Delhi vide Sanction Order dated 20.03.2023, which was reflected in their account on 24.03.2023. As the financial year closes by 31st March, the CoE carried forward the whole amount to the next financial year i.e. 2023-24.*

Note : Unspent balance of Financial Year 2022-23 has been carried forward by the CoEs for continuing treatment of the patients. Only ICH&HC, Chennai had surrendered the unspent balance of Rs. 96,03,018/- in CFI.

Financial Year 2023-24

S. No.	***Name of the CoE***	***Financial Assistance released in***	***Funds Utilized (In Rs.)***	***Available Balance for continuing***

		FY 2022-23 (In Rs.)		***treatment (In Rs.) As on date***
1.	*All India Institute of Medical Sciences, New Delhi*	*35,00,00,000*	*7,25,76,446*	*28,12,60,424*
2.	*Maulana Azad Medical College, New Delhi*	*3,00,00,000*	*77,56,644*	*3,62,53,356*
3.	*Sanjay Gandhi Post Graduate Institute of Medical Sciences, Lucknow*	*3,00,00,000*	*2,51,84,272*	*2,13,23,307*
4.	*Post Graduate Institute of Medical Education and Research, Chandigarh*	*3,00,00,000*	*2,75,51,952*	*24,48,048*
5.	*Institute of Post-Graduate Medical Education and Research, Kolkata*	*3,00,00,000*	*2,73,48,738*	*29,62,440*
6.	*King Edward Medical Hospital, Mumbai*	*3,00,00,000*	*3,00,00,000*	*28,29,968*
7.	*Centre for DNA Fingerprinting & Diagnostics with Nizam's Institute of Medical Sciences, Hyderabad*	*3,00,00,000*	*27,20,726*	*7,05,05,527*
8.	*Center for Human Genetics(CHG) with Indira Gandhi Hospital, Bengaluru*	*9,00,00,000*	*1,61,96,912*	*7,38,03,088*
9.	*All India Institute of Medical Sciences, Jodhpur*	*3,00,00,000*	*91,17,801*	*2,08,82,199*
10.	*Institute of Child*	*3,00,00,000*	*3,00,00,000*	*Nil*

	Health and Hospital for Children (ICH & CH), Chennai			
11.	*Sree Avittam Thirunal Hospital (SAT), Government Medical College, Thiruvananthapuram*	*3,00,00,000*	*53,00,000*	*2,47,00,000*

325. The above position of the UOI, MoHFW, as reflected in the answer given by the Hon'ble Minister in Parliament reveals that the functioning of the NRDC is duly commended. The data attached to the said answer would actually show that in most cases, the financial assistance released for rare diseases have not been utilized by various[10] CoEs. According to the above information placed on record, while nearly 2,420 patients have been enrolled across the 11 CoEs in India, the data presented highlighted significant under-utilization of funds allocated to these Centres over the past three years. Only 48.7% of the approximately ₹109 crore disbursed by the Ministry over the last three years had been utilised. The year-wise details of the fund allocation and utilisation by each CoE, indicated that only around ₹53 crore out of the ₹109 crore allocated by the Health Ministry to all CoE over the last three years had been spent.

326. In addition, repeated affidavits filed by the Union of India and the documents filed before the Court show that the actual budgets for rare

[10] See, The Hindu, 'Gross Under-Utilisation of Funds for Rare Diseases by Centres of Excellence is Revealed in Information Furnished by Health Ministry in Lok Sabha' (2023) https://www.thehindu.com/sci-tech/health/gross-under-utilisation-of-funds-for-rare-diseases-by-centres-of-excellence-is-revealed-in-information-furnished-by-health-ministry-in-lok-sabha/article67842188.ece accessed 4 October 2024.

diseases have not been utilized in most financial years since launch of the NPRD, 2021. The same is evident from the following table:

	2021-22	***2022-23***	***2023-24***	***2024-25***
Patients treated by CoEs	-	105	430	N/A
Budget Estimate (Rs. Crores)	25	25	92.94	82.41
Revised Estimate (Rs. Crores)	Nil	35	74	N/A
Expenditure (Rs. Crores)	3.15[11]	35	74	24.20

327. The above figures also confirm the admitted position that there is underutilization of budgets. The same is obviously not due to lack of patients and lack of medicines, but due to lack of streamlined procedure for ensuring enrollment of patients with rare diseases, evaluation of the said patients, procurement of medicines and administration of the medicines.

Status of available therapies for some Rare Diseases.

328. As per the NPRD, 2021, various rare diseases, have already been identified. The status of some of the rare diseases and available therapies is discussed below:

Duchenne Muscular Dystrophy (DMD)

329. In respect of DMD, the submission on behalf of ld. *Amicus* Ms. Trehan, Dr. Madhulika Kabra and the documents submitted by the NRDC show that this is a condition for which there are very limited therapies/medicines, which are available. Not all patients with DMD are

[11] https://sansad.in/getFile/loksabhaquestions/annex/1714/AU1135.pdf?source=pqals

amenable to treatment as well. Gene replacement therapy, which is available, is extremely expensive and costs 3.2 million dollars. The only therapy that is currently being used in India is Exon-skipping therapy. Within Exon-skipping therapy, different treatments are available depending on the specific nature of the condition. Medications for Exon-skipping therapy are manufactured solely by M/s Sarepta, with no other manufacturer currently producing them. M/s Sarepta does not manufacture drugs in India. From the affidavits filed by M/s Sarepta, it is evident that while distribution in the U.S. is handled by M/s Sarepta, international distribution is managed by an entity called *'myTomorrows'*, which is based in the Netherlands. During the course of the hearing, the Court directed M/s Sarepta to identify the distributor for India, which has now been done. The procedure initially prescribed by M/s Sarepta was overly cumbersome, and a simplified procedure was directed to be submitted. However, the final affidavit submitted by M/s Sarepta states as follows:

> *"2. I say that M/s Sarepta Therapeutics Inc., through its global distributor Impatients N.V. (myTomorrows), has appointed me to be a point of local contact in India to look into receipt, review, submission, approval and fulfilment of orders placed upon Sarepta for supply of medicinal products eteplirsen, golodirsen and casimersen.*
> *3. The designated mobile number for queries with regards to such orders shall be +91 7011611219 and designated email ID shall be priyanka@ikrispharmanetwork.com (with sarepta.eap@mytomorrows.com in copy) However, it is submitted that the orders for supply shall be strictly placed through designated email. In case there is a change of email, phone number or the point of contact, due to any reasons whatsoever in future, the same shall*

be informed to the concerned Indian authorities in advance.

4. It is humbly submitted that currently the medicines are not being produced in India by Sarepta. Sarepta has appointed a global distributor, Impatients ("myTomorrows"), to supply drugs on a named patient/early access basis, and myTomorrows has engaged a service provider in India to assist with the supply of Sarepta's products to named patients.

5. It is humbly submitted that, as of the date of this document, the prices offered in India for the medicinal products eteplirsen, golodirsen, and casimersen are the lowest globally provided to any national healthcare system.

6. It is humbly submitted that for the purchase and supply process to be smooth, the following particulars of the patient should be provided at the time of placing the purchase order by the concerned Ordering Health Institute / Centre for Excellence and/or Rare Disease Committee:

a. Name of patient
b. Name of the medicinal product
c. Weight
d. Height
e. Quantity / vials
f. Gender
g. Year of birth
h. Relevant medical information and condition

A Confidential Disclosure Agreement (CDA) will be executed by myTomorrows and the Ordering Health Institute / Centre for Excellence and/or Rare Disease Committee before sharing the aforementioned patient details.

7. The concerned Ordering Health Institute / Centre for Excellence and/or Rare Disease Committee shall also provide the following documents along with the

email for purchase of the medicines:
a) Signed Confidential Disclosure Agreement (CDA)
b) Custom duty and IGST exemption certificate, preferably simultaneously, in order to expedite the supply
c) Application Form 12A and the corresponding Permit Form 12B
d) Institute/hospital name, address, and contact details
e) Treating physician name
f) Pharmacist name
g) Signed and/or stamped Physician statement/Doctor's declaration on unmet medical need
h) Physician license
i) Pharmacy license
8. Upon receipt of the purchase order and the patient particulars with the above information (mentioned in Points 6 and 7), the patient will be enrolled within 48 hours, and the order will be forwarded to myTomorrows for processing.
9. Within 24 hours of receipt of the purchase order and the above-mentioned documents, the Finance Team of myTomorrows will share the Invoice containing the instructions for Pre-Payment with the Ordering Health Institute. Once the pre-payment is received by myTomorrows, the order will be processed within 24 hours.
10. Once customs clearance is obtained, shipping to the Ordering Institute will take approximately 5 business days.
11. The tentative overall timeline for the delivery of the medicinal products will be about 11 days from the date of receipt of the purchase order and documents via the designated email."

330. From the above, it is clear that impediments *qua* M/s. Sarepta for ensuring not just proper pricing of medicines but also proper distribution and procurement. The negotiations conducted between M/s Sarepta and the

NRDC, would show that the final price, which was submitted by M/s Sarepta, was not fully accepted to NRDC, which had made a counter offer. The said counter offer was not accepted by M/s. Sarepta.

331. However, at this stage since M/s. Sarepta has made a voluntary offer of substantially reduced prices, as compared to the prices at which supplies were earlier made. For the time being this Court is of the view that the price offered by M/s Sarepta to the NRDC ought to be accepted, at this stage, as the price for immediate procurements. The prices are reflected in the email dated 4th January, 2024, from M/s. Sarepta, to which the NRDC made a counteroffer on 9th May, 2024. Since the counteroffer was not accepted, M/s. Sarepta's offer shall be considered for immediate supplies. The said price is approximately 1/4th of the present procurement cost, which will result in substantial savings. M/s. Sarepta has exhibited its *bona fides* by engaging with the NRDC and by providing free medicines to 14 patients.

Spinal Muscular Atrophy (SMA), Gaucher, Pompe and Fabry

332. Insofar as SMA is concerned, negotiations have taken place between NRDC and M/s Roche Pharma, which has given a price and has now been accepted by the NRDC as captured in the document dated 14th June, 2024 signed by Dr. B. S. Charan, ADG, Member Secretary. The procurement/approvals may now be commenced.

333. Similarly in respect of Gaucher, Pompe and Fabry discounted prices have been negotiated and documented in the said communication dated 14th June, 2024.

C. <u>NRDC, its constitution and the work undertaken</u>

334. Initially, as captured in the background facts, a Committee was constituted by this Court vide order dated 2nd March, 2021, under the

Chairmanship of Dr. Renu Swarup, the then Secretary of Department of Biotechnology, Government of India. The said Committee had recommended a *National Expert Committee for Rare Diseases*. Pursuant thereto, vide order dated 15th May, 2023, the National Rare Diseases' Committee has been constituted with the following persons as its members:

S.No.	**Name of the Member**	**Capacity**
1	Director General - Indian Council for Medical Research	Member
2	Dr. Nikhil Tandon, Professor – AIIMS	Member
3	Secretary - Ministry of Health & Family Welfare or one of his nominee.	Member
4	Drug Controller General of India	Member
5	Dr. Madhulika Kabra, Professor - AIIMS	Member

335. The Committee has functioned in an effective manner and has taken various steps towards reviewing issues concerning rare diseases, including the grouping of rare diseases, the impact of rare diseases, and indigenisation. Under the Court's directions, the Committee has also held negotiations with various companies that manufacture therapies for treating rare diseases. Additionally, the Committee has defined certain principles for a national plan to enable access to the treatment of rare diseases in a realistic and pragmatic manner. According to the NRDC, rare diseases can be categorized into the following three groups:

> *"**6. Definition of Rare Diseases:***
>
> *6.1 There is no universal or standard definition of rare disease. A disease that occurs infrequently is generally considered a rare disease, and it has been defined by different countries in terms of prevalence – either in absolute terms or in terms of prevalence per 10,000*

population. A country defines a rare disease most appropriate in the context of its own population, health care system and resources.

6.2 As mentioned above, India faces the limitation of lack of epidemiological data to be able to define rare diseases in terms of prevalence or prevalence rate, which has been used by other countries. To overcome this, a hospital based National Registry for Rare Diseases has been initiated by ICMR by involving centers across the country that are involved in diagnosis and management of Rare Diseases. This will yield much needed epidemiological data for rare diseases. In the absence of epidemiological data on diseases considered as rare in other countries, it is not possible to prescribe threshold prevalence rates to define a disease condition as rare.

Till the time such data is available and the country arrives at a definition of a rare disease based on prevalence data, the term rare diseases, for the purpose of this policy, shall construe the following groups of disorders identified and categorized by experts based on their clinical experience:

Group 1: Disorders amenable to one-time curative treatment:

a) Disorders amenable to treatment with Hematopoietic Stem Cell Transplantation (HSCT) –

i. Such Lysosomal Storage Disorders (LSDs) for which Enzyme Replacement Therapy (ERT) is presently not available and severe form of Mucopolysaccharoidosis (MPS) type I within first 2 years of age.

ii. Adrenoleukodystrophy (early stages), before the onset of hard neurological signs.

iii. Immune deficiency disorders like Severe Combined Immunodeficiency (SCID), Chronic Granulomatous disease, Wiskot Aldrich Syndrome etc.

iv. Osteopetrosis
v. Fanconi Anemia

b) Disorders amenable to organ transplantation

i. Liver Transplantation -Metabolic Liver diseases:

a. Tyrosinemia,

b. Glycogen storage disorders (GSD) I, III and IV due to poor metabolic control, multiple liver adenomas, or high risk for Hepatocellualr carcinoma or evidence of substantial cirrhosis or liver dysfunction or progressive liver failure,

c. MSUD (Maple Syrup Urine Disease),

d. Urea cycle disorders,

e. Organic acidemias.

ii. Renal Transplantation

a. Fabry disease

b. Autosomal recessive Polycystic Kidney Disease (ARPKD),

c. Autosomal dominant Polycystic Kidney Disease (ADPKD) etc.

iii. Patients requiring combined liver and kidney transplants can also be considered if the same ceiling of funds is maintained. (Rarely Methyl Malonicaciduria may require combined liver & Kidney transplant) etc.

Group 2: Diseases requiring long term / lifelong treatment having relatively lower cost of treatment and benefit has been documented in literature and annual or more frequent surveillance is required:

a) Disorders managed with special dietary formulae or Food for special medical purposes (FSMP)

i) Phenylketonuria (PKU)

ii) Non-PKU hyperphenylalaninemia conditions

iii) Maple Syrup Urine Disease (MSUD)

iv) Tyrosinemia type 1 and 2
v) Homocystinuria
vi) Urea Cycle Enzyme defects
vii) Glutaric Aciduria type 1 and 2
viii)Methyl Malonic Acidemia
ix) Propionic Acidemia
x) Isovaleric Acidemia
xi) Leucine sensitive hypoglycemia
xii) Galactosemia
xiii) Glucose galactose malabsorbtion
xiv)Severe Food protein allergy

b) Disorders that are amenable to other forms of therapy (hormone/ specific drugs)

i) NTBC for Tyrosinemia Type 1
ii) Osteogenes isImperfecta – Bisphosphonates therapy
iii)Growth Hormone therapy for proven GH deficiency, Prader Willi Syndrome, Turner syndrome and Noonan syndrome.
iv) Cystic Fibrosis- Pancreatic enzyme supplement
v) Primary Immune deficiency disorders - Intravenous immunoglobulin and sub cutaneous therapy (IVIG) replacement eg. X-linked agammablobulinemia etc.
vi) Sodium Benzoate, arginine, citrulline, phenylacetate (Urea Cycle disorders), carbaglu, Megavitamin therapy (Organic acidemias, mitochondrial disorders)
vii) Others - Hemin (Panhematin) for Acute Intermittent Porphyria, High dose Hydroxocobalamin injections (30mg/ml formulation – not available in India and hence expensive if imported)
viii) Large neutral aminoacids, mitochondrial cocktail therapy, Sapropterin and other such

molecules of proven clinical management in a subset of disorders

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 [Mucopolysaccharisosis (MPS) Type I] (attenuated forms)

3. Hunter syndrome (MPS II) (attenuated form)

4. Pompe Disease (Both infantile & late onsetdiagnosed early before development of complications)

5. Fabry Disease diagnosed before significant end organ damage.

6. MPS IVA before development of disease complications.

7. MPS VI before development of disease complications.

8. DNAase for Cystic Fibrosis.

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.Cystic Fibrosis (Potentiators)

2.Duchenne Muscular Dystrophy (Antesensce oligoneucletides, PTC)

3. Spinal Muscular Atrophy (Antisense oligonucleotides both intravenous & oral & gene therapy)

4. Wolman Disease
5. Hypophosphatasia
6. Neuronal ceroid lipofuschinosis

6.3. The list of diseases under Group 1, Group 2 and Group 3 are not exhaustive and will be reviewed periodically based on updated scientific data by the Technical Committee."

336. Insofar as Group 1 and Group 2 diseases are concerned, as per the Committee, all patients who are registered and suffering from these diseases are fully funded by the Government as the treatments are not exorbitant. The challenge, however, is in respect of rare diseases falling in Group 3 category.

337. The report of the NRDC shows that it has also analysed the impact on patients of the therapies that are available. According to the NRDC, in terms of the existing therapies and treatments, the impact would depend upon:

a) The age of the patient.
b) Amenability of the patient to treatment and the level of progression to determine whether the patient deserves to be administered the medications
c) The nature of treatment i.e., whether completely curative or merely betterment in lifestyle.

338. On the basis of these factors, as per the NRDC, the impact of the existing therapies on patients is as under:

Disease	***Impact of the therapy***
Fabry	6/10
Pompe	6/10
Gaucher	10/10
Spinal Muscular Atrophy	9/10

(SMA)	
Mucopolyssachridosis (MPS)	4/10
Duchenne Muscular Dystrophy (DMD)	4/10

Thus, in the case of some conditions, the promise from treatment is very high i.e., almost curable. However, for some conditions, the expectation is merely one of better lifestyle and there is no possibility of cure. In DMD patients the impact of the therapy is 4/10 i.e., less than 50% as an average. Thus, as per the NRDC, in case of DMD and other similar conditions, each patient would have to be assessed and only based upon the impact of medicines on the patient, expensive medications ought to be recommended.

339. Based on the above impact assessment, NRDC held deliberations with various companies that manufacture medicines and treatments. The NRDC is clearly of the opinion that the present budget is insufficient and needs to be increased. With a budget of approximately Rs. 100 crores, Group 1 and Group 2 patients can be treated. Group 3 patients—those with Gaucher, DMD, and Pompe diseases—can be treated if the annual budget is increased to Rs. 200 crores. As for DMD and SMA, these therapies are extremely expensive, and the required budget would be exorbitant i.e., more than 2500 crores. However, the NRDC made presentations to the MoHFW with a proposal to increase financial assistance for rare disease patients. Accordingly, the Court has been informed that the MoHFW is taking steps to increase the present budget of **Rs. 144.19 crores to Rs. 974 crores for the next two financial years**. The extract from the NRDC's report is set out below:

"x. However, as the cost of rare disease drugs is

prohibitive for rare diseases and in order to comprehend the strengthening of the implementation of NPRD 2021, a presentation was made to the Secretary, Health & Family Welfare on rare diseases with a proposal to increase financial assistance for rare disease patients.

xi. Based on the decision of the NRDC, MoHFW is also taking steps to increase the budget from the present Rs. 144.19 crore in the current financial year, including Rs. 92.84 crore for the treatment of patients, to Rs. 974.00 crore during the next two financial years in consultation with the Ministry of Finance and other stakeholders*."*

340. In addition, the NRDC has conducted highly effective negotiations with the companies and has obtained favourable quotations for Gaucher, Pompe, and SMA. With regard to DMD, the company-M/s Sarepta Therapeutics made a specific offer, which was considered to be on the higher side. However, when the NRDC made a counter-offer, it was not accepted by Sarepta. The Court notes, however, that the offer made by Sarepta is, in any event, at this stage still competitive as compared to the existing pricing being charged. According to the company, it is the lowest offer made by it anywhere in the world. Considering the large number of DMD patients in India, the Court proceeds in these matters based on the final quotation provided by Sarepta, as per its email dated 4th January, 2024.

341. Insofar as all the other companies are concerned, the approval has already been granted by the MoHFW vide its communication dated 14th June 2024 to the Chairman, NRDC. Insofar as the NRDC is concerned, therefore, the constitution of the Committee has been of immense significance, considering the manner in which the NRDC has proceeded to categorise the

rare diseases, assessed the impact of diseases and negotiated with the companies. In the opinion of this Court, therefore, the continuation of the functioning of the said Committee would be required.

D. Handling of Rare Diseases at the National Level

342. Presently, the NRDP 2021 is the applicable policy, along with the amendments made in terms of the Office Memorandum issued on 9th May 2022. The present status of the handling of rare diseases reveals that sufficient penetration of the policy has not yet taken place. The crowd-funding initiative has barely begun. In almost all the years since this policy was introduced, the amounts spent have been less than the budgeted amounts, resulting in a reduction of budget estimates. In most years, even the budgeted amounts have lapsed.

343. To illustrate, from 2017 to 2022, the total budgeted amount was Rs. 402.67 crores[12] and the total amount spent was Rs. 119.35 crores. The Court then called for an affidavit from the Union of India regarding the number of patients who have received treatment under the NPRD, 2021. The affidavit from the Union of India reveals the following facts and figures:

	2018-19	***2019-20***	***2020-21***	***2021-22***	***2022-23***	***2023-24***	***2024-25***
Patients treated by CoEs	-	-	-	-	105	430	N/A
Budget Estimate (Rs. Crores)	Nil	100	77.32 (RAN)	25	25	92.94	82.41
Revised Estimate (Rs.	7.50 crores	25	10	Nil	35	74	N/A

[12] Obtained by adding the Budget Estimates over the years.

Crores)							
Expenditure (Rs. Crores)	Nil	1.30	5.90	3.15[13]	35	74	24.20

344. From the above table, it can clearly be seen that after the introduction of the 2017 policy, in most years, the budgets have either lapsed or the initial estimated budget has been revised to a lower figure. Therefore, there is a need to ensure that the entire budgeted amount is not just on paper but is expended for the benefit of rare disease patients, most of whom are children.

345. This Court is of the opinion that the budget for implementation and functioning of the NPRD, 2021, should be overseen on a monthly basis by the NRDC. For this purpose, and to coordinate between the NRDC and the MoHFW, a specific official or officials shall be designated by the Secretary, MoHFW, whose functions shall be as under:

- To ensure coordination of the meetings of the NRDC.
- To implement all the directions given by the NRDC.
- To maintain and update records of all decisions made by the NRDC and ensure timely communication of these decisions to relevant stakeholders.
- To ensure that the authorities to whom directions may be given by the NRDC duly comply with the same.
- To obtain feedback from CoEs and provide the same to the NRDC.
- To liaise with higher officials in the MoHFW and to obtain requisite approvals from time to time.

[13] https://sansad.in/getFile/loksabhaquestions/annex/1714/AU1135.pdf?source=pqals

- To coordinate the procurement of the medicines and therapies from the various companies and to ensure timely distribution and administration to patients.
- To monitor budget allocations and expenditures for rare disease treatments, ensuring funds are utilized appropriately and reporting any discrepancies or lapses to the NRDC.
- To maintain a communication channel with patients and their families, providing updates on treatment progress, availability of therapies, and any changes in NPRD, 2021.

FINAL CONCLUSIONS AND DIRECTIONS

346. The present batch of petitions, which are 106 in number involving 106 patients of rare diseases, reveal an arduous journey that the Petitioners, and all other stakeholders, including patient groups, patients' families, the government, the medical community, as well as counsels, senior counsels, ld. *Amicus Curiae*, and, above all, the members of the NRDC and pharmaceutical companies, have undergone over the last four years. The conclusions that emerge from the events that have transpired as captured above are as follows:

(i) **Identification of rare diseases:** That there are several rare diseases, which have been identified and number of patients, who suffer from the same. Some rare diseases are yet to be identified and recognized.

(ii) **Amended NPRD**: The Union of India has already taken note of the requirement of a coordinated action plan to deal with rare diseases and thus, the government introduced National Policy for the Treatment of Rare Diseases, 2017 pursuant to the decision of ld.

Single Judge of this Court in ***Mohd. Ahmed (supra)***. Thereafter, in the present batch of writ petitions during hearing, NRDP, 2021 and the Office Memorandum of 19th May, 2022 have been notified by the Union of India.

(iii) **Periodic review:** Going forward, the NPRD, 2021, would require a periodic review and continuous working on various aspects.

(iv) **Arising challenges:** Therapies for rare diseases are available globally. The challenge is threefold: first, procuring them at reasonable and affordable prices; second, indigenizing the manufacturing of these medicines; and third, streamlining the evaluation and administration of these medicines to patients.

(v) **Expansion of CoEs:** The NPRD, 2021 also recognizes various CoEs, and the list would need to be continuously expanded to create more centers equipped to diagnose, evaluate, treat, and provide care for patients with rare diseases.

(vi) **Coordination between DCGI and CDSCO**: The DCGI and the CDSCO are currently not coordinating effectively to address the needs of persons with rare diseases by enrolling maximum patients for clinical trials, expediting approvals for medicines and therapies, and exercising its powers to grant exemptions from clinical trials on a global basis where these medicines are already in use. As per the Order dated 7th August, 2024, issued by the DCGI, Directorate General of Health Services, it is noticed that in terms of Rule 101 of the New Drugs and Clinical Trials Rules, 2019, orphan drugs for rare diseases can be considered for waiver of local clinical trial approvals,

if such drugs originate from countries with well established regulatory processes including USA, UK, Japan, Australia, Canada and EU[14];

(vii) **Price Controls:** In addition, the DCGI ought to consider as to whether the exemption from pricing under the DPCO ought to be considered for all rare diseases or on a case-to-case basis;

(viii) **Crowd Funding:** The attempts towards crowd funding for rare diseases have not been successful, hence, there is a need to create a more vibrant crowdfunding platform. This is considering the fact that according to the crowd-funding website[15], there are around 2268 patients registered, and only a meagre amount of Rs. 349,280/- has been collected so far. The crowd funding platform ought to be given adequate publicity and steps be taken to attract funds for the purpose of patients with rare diseases. Since the number of patients suffering from rare diseases, though substantial, do not give sufficient exposure to corporate house, CSR funding is negligible in this sphere. There is a need to encourage special CSR funding, especially, if possible, by PSUs and pharmaceutical companies.

(ix) **Palliative care and Assistive devices:** Medicines, equipment, devices, assistive devices, such as wheelchairs, prosthetic limbs orthotics, etc. need to be incentivised for manufacturing as also for imports. There is a need to consider and grant custom duties waiver and other related exemptions.

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14 https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTE1ODI=

15 https://rarediseases.mohfw.gov.in/

(x) **National Register of Rare disease patients:** There is no proper analysis of the number of patients suffering from rare diseases. Therefore, there is a need to create a proper database and a central agency for patients with rare diseases, including their contact details, so they can be referred to the nearest Centre of Excellence for evaluation and treatment.

(xi) **Indigenous development of medicines for rare diseases:** Indigenisation, and further development and research of medicines for rare diseases, especially for patients in India needs to be undertaken.

(xii) **Revision of caps under NPRD, 2021**: The upper limit of Rs.50 lakhs fixed by NRDC may be adequate for a large number of rare diseases mainly Group 1 and Group 2, but the said cap is inadequate for some rare diseases such as DMD falling in the Group 3 category. This amount, therefore, requires to be re-considered for some rare diseases. In addition, no caps or limits ought to be fixed on funding for individual CoEs, and they ought to be granted greater autonomy in terms of their funding and operational capacity, given their crucial role in implementing the NPRD.

(xiii) **Exclusion Criteria:** Currently, the companies still have the option to exclude rare genetic disorders from insurance policies. The matter was considered by this Court in ***RFA 610/2016*** in ***'M/s. United India Insurance v. Jai Prakash Tayal' (decision dated 26th February, 2018)***, wherein the IRDAI was directed to re-look at the exclusionary clauses in the insurance contracts and ensure that insurance companies do not reject claims on the basis of the exclusions relating to genetic disorders. The said judgment is pending consideration

before the Supreme Court in ***SLP(Civil) No. 29590/2018*** titled ***'United India Insurance Co. Ltd. v. Jay Prakash Tayal'.*** Regardless, as per IRDAI's Master Circular dated 22nd July, 2020 bearing no. IRDAI/HLT/REG/CIR/193/07/2020 exclusions relating to "Internal congenital diseases, genetic diseases or disorders" cannot be allowed in health insurance policies.

347. In the light of the above, the following directions are issued in these matters.

Directions qua NRDC

348. The NRDC, which was constituted vide order dated 15th May, 2023, shall continue to function for a further period of 5 years. The constitution of the NRDC is as follows:

S.No.	Name of the Member	Capacity
1	Director General - Indian Council for Medical Research	Chairperson
2	Dr. Nikhil Tandon, Professor – AIIMS	Member
3	Secretary - Ministry of Health & Family Welfare or one of his nominee.	Member
4	Drug Controller General of India	Member
5	Dr. Madhulika Kabra, Professor - AIIMS	Member

349. The mandate of the said Committee would be as under:

i) Monitor and provide guidance on strategies for implementation of R&D policy in the country;

ii) Continue identification and recognition of rare diseases;

iii) Finalization and implementation of uniform guidelines for objective inclusion, exclusion and exit criteria for treatment of patients with rare diseases;

iv) To support MoHFW in creating a central uniform and robust system for procurement of drugs for rare diseases across COEs;

v) Ensure that procurement of drugs for treatment of rare diseases is done at a reasonable and affordable price;

vi) To negotiate prices for bulk purchase for other rare diseases drugs with companies, as majority of these drugs are manufactured by a single company and are proprietary in nature. These negotiated prices may be provided to the Rare Disease Cell, MoHFW, for doing the needful;

vii) Monitor and promote development of indigenous rare disease drugs in India by engaging and supporting various stake holders;

viii) In addition to the above mandate, the NRDC shall be the overall authority for:

a) Receiving the proposals from the CoEs in respect of patients who need to be administer therapies/treatments.

b) Reviewing and assessing the recommendations made by CoEs and, thereafter, approving the treatments/therapy.

c) The procurement of the medicines would commence immediately after the NRDC has approved a particular patient for treatment.

ix) Conduct periodic reviews of the Rare Diseases Policy and make recommendations to update or refine the policy based on

emerging research, treatments, and challenges faced by patients and healthcare providers.

B. <u>Directions to Union of India</u>

B.1. The Union of India shall establish the National Fund for Rare Diseases (*'NFRD'*) for which a sum of Rs. 974 crores, as per the recommendation of the NRDC, and pending approval of the MoHFW, shall be allocated for the financial years 2024-25, 2025-26. Similarly, the same amount if not a higher amount, shall be allocated for the next two financial years of 2026-27 and 2027-28. The Court is conscious that the said fund may not be fully sufficient for the number of patients. But as the UOI's data reveals, not all patients are yet approaching CoEs for treatment. This Court expresses confidence that once the fund is created, over the next few years, efforts would be made to reduce the price of drugs and make them more accessible. In addition, crowd funding & CSR funding would also bring in additional funds for tackling rare diseases. The UOI, however, ought not to be deterred from accepting the recommendation of NRDC and releasing the Rs. 974 Crores.

B.2. Approval for the transfer of said funds to be granted and the amounts to be transferred to the NFRD within 30 days by the concerned Ministries and competent authorities. The Union of India shall mandate monthly progress reviews of the NFRD to ensure 100% fund utilization. This shall include a mandatory monthly meeting between the MoHFW, CoEs, and NRDC to monitor the disbursement of funds and identify any delays. The first such meeting should be scheduled within 30 days.

B.3 The said amount shall be utilized for providing treatment to all the Petitioners, who are suffering from rare diseases. The medicines shall be procured by the MoHFW at the prices negotiated by the NRDC.

B.4. **The NDRF shall be administered by the National Rare Diseases' Cell consisting of one or more Nodal Officers in the MoHFW, who shall release the funds for treatment of patients under the National Policy for Rare Diseases', 2021, as directed by the NRDC**. The fund would not lapse or revert due to under-utilisation. Monthly reports of utilization of the fund and the number of patients receiving treatment shall be submitted to the NRDC.

B.5. The upper limit of Rs.50 lakhs under NRDP, 2021 for the treatment of rare diseases shall be flexible in case of rare diseases in Group 3 category such as DMD, SMA, Gaucher etc. as per the recommendation of NRDC. No ceiling shall be imposed *qua* funding of individual CoEs.

B.6. Within a period of 3 months, the Union of India shall develop and operationalize a centralized National Rare Disease Information Portal that includes a patient registry, available treatments, nearest CoEs, and updates on fund utilization. This portal should be accessible to patients, doctors, and the general public.

B.7. The crowdfunding platform, already operational, shall be under the supervision of the Nodal Officer, Ministry of Health and Family Welfare. The details of the platform shall be publicized in print and electronic media as also on online platforms within a period of two weeks. The funds coming into the said platform shall be automatically transferred to the NDRF.

B.8. Requisite notifications for granting customs, GST waivers and exemptions under Income Tax Act, 1961 in respect of imports of rare diseases medicines etc., shall be processed and issued within 30 days.

B.9. Donations for rare diseases shall be added in Schedule VII of the Companies Act, 2013 to enable CSR contribution by companies, including PSUs.

B.10. The Union of India shall direct the DCGI and the CDSCO to create a dedicated fast-track approval process for rare disease drugs and therapies within 60 days. All applications for rare disease therapies should be processed within 90 days from submission.

B.11. The Union of India is directed to expand the existing number of CoEs, considering patient density.

B.12. Union of India ought to collaborate with CoEs and the companies to provide free genetic screening for all rare disease patients at risk of requiring therapies. Screening is to be conducted for all enrolled patients at CoEs, as that is the first step towards developing a comprehensive prevention and control strategy for rare diseases.

B.13. The DCGI and the CDSCO shall coordinate on the issue whether orphan drugs for the treatment of rare diseases ought to be regulated under the DPCO. DCGI and CDSCO are directed to keep a watch out for clinical trials – both global and local, so that more and more patients can be enrolled, especially when the medicines are unaffordable. They may also consider granting exemptions from conducting clinical trials in terms of the extant Rules, prior to approval or even post-facto approval may also be explored.

B.14 Exemption for orphan drugs from price control under the DPCO shall be reviewed at the earliest.

B.15. Union of India is directed to review its policies in relation to local manufacturing of medical equipment for patients suffering from rare diseases such as wheelchairs, Prosthetic limbs, orthotics, Mobility scooters and walking aids.

B.16. Union of India is also directed to consider extension of waiver of customs duty for all imports[16] - individual use and imports for commercial purposes by companies, so that companies are incentivised to import larger quantities of drugs for rare diseases, to ensure robust supplies.

B.17. Concrete steps be taken to encourage PSUs and pharmaceutical companies to increase their contribution to CSR in rare diseases.

B.18. Direct the IRDAI to comprehensively re-look into exclusion criteria in relation to genetic disorders in health insurance contracts.

B. 19. Nodal Official, who shall be responsible to coordinate between the NRDC and the MoHFW, shall be identified and notified in one week.

C. <u>Directions to the pharmaceutical companies, including Roche, Sarepta and other such companies.</u>

C.1 Companies shall ensure the adequate availability of therapies and medicines in India for rare diseases, whether through manufacturing or imports. A proper distribution network, established by these companies, shall be in place to ensure continuous supplies. Procedures and timelines must be fixed to guarantee adequate and sufficient provision of these medicines and therapies.

C.2 Pharmaceutical companies currently importing rare disease therapies shall submit a detailed plan to the Ministry of Health and Family Welfare and the NRDC within 90 days for establishing local manufacturing or distribution facilities in India for therapies/medicines relating to rare diseases.

C.3 Companies shall provide the therapies at the price agreed with the NRDC, without delay after placing of purchase orders. Considering the time-sensitive nature of the matter, companies ought to ensure that once a patient is approved for treatment, the required medication must be delivered to the designated CoE within 14 business days of placing the order.

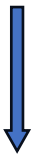
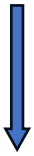
350. First meeting of the NRDC shall take place in the week beginning from 21st October, 2024, so that immediate directions can be issued in terms of the mandate prescribed above. The DG, ICMR shall be the Chairperson of the NRDC, whose office shall coordinate all meetings with the Nodal Officer from the Ministry. On the said date, the case of all the Petitioners shall be placed before the NRDC for approval and commencement of treatment.

351. Treatment for all the eligible & amenable patients, as per AIIMS' report dated 21st July, 2024, who are before the Court in these batch of petitions, shall commence within 45 days, as per recommendation of NRDC.

352. To ensure coordination between different authorities such as the NRDC, MoHFW, CoEs and the companies, for the procurement of

[16] https://pib.gov.in/PressReleasePage.aspx?PRID=1912095

medicines and for treatment of the Petitioners, the following flow-chart shall be followed:

Protocol	*Authority in-charge*
Patients approach CoEs 	***CoEs***
CoEs review, examine patients, and recommend treatment. 	***CoEs to send recommendation to the NRDC***
Recommendation to be reviewed by NRDC on a monthly/fortnightly basis. ***Approvals based on criteria fixed by NRDC be given for procurement of assistive medicines or any equipment/devices. Such approvals to be sent to the concerned CoE and MOHFW.*** 	***NRDC to send approvals of treatment/course of action to CoE & Nodal Officer, Rare Diseases Cell, MoHFW***
CoEs to place purchase order on companies as per agreed prices. 	***CoEs to place purchase order. Information to be sent to the NRDC and Nodal Officer, Rare Diseases Cell, MoHFW.***
Supplies to be made by companies directly to CoEs. 	***CoEs + companies + Nodal Officer, Rare Diseases Cell, MoHFW.***

	Any difficulties in the procurement to be overseen by the NRDC
Payment to companies from the National Fund for Rare Diseases.	***MoHFW, shall release the payments as directed by the NRDC from the NFRD.*** ***Responsibility is of the Nodal Officer, Rare Diseases Cell, MoHFW.***

352. WP(C) No. 5315/2020, WP(C) No. 10782/2020, WP(C) No. 322/2021, WP(C) No. 1611/2021, WP(C) No. 3682/2021, WP(C) No. 3689/2021, WP(C) No. 3706/2021 WP(C) No. 3707/2021 WP(C) No. 3729/2021 WP(C) No. 3737/2021 WP(C) No. 3859/2021 WP(C) No. 4045/2021 WP(C) No. 4067/2021 WP(C) No. 4259/2021 WP(C) No. 4304/2021 WP(C) No. 4551/2021 WP(C) No. 4812/2021 WP(C) No. 5394/2021 WP(C) No. 5395/2021 WP(C) No. 14317/2021 WP(C) No. 1054/2023 WP(C) No. 4536/2023 WP(C) No. 4495/2023 WP(C) No. 4539/2023 WP(C) No. 4591/2023 WP(C) No. 4535/2023 WP(C) No. 4526/2023 WP(C) No. 4538/2023 WP(C) No. 4502/2023 WP(C) No. 1079/2023 WP(C) No. 5753/2023 WP(C) No. 5726/2023 WP(C) No. 5102/2023 WP(C) No. 2614/2023 WP(C) No. 7549/2023 WP(C) No. 7553/2023 WP(C) No. 7644/2023 WP(C) No. 7756/2023 WP(C) No. 8200/2023 WP(C) No. 8947/2023 WP(C) No. 8948/2023 WP(C) No. 8973/2023 WP(C) No. 8996/2023 WP(C) No. 10031/2023 WP(C) No. 10063/2023 WP(C) No. 10064/2023 WP(C) No. 6089/2023 WP(C) No. 10606/2023 WP(C) No. 10867/2023 WP(C) No. 10870/2023 WP(C) No. 12222/2023 WP(C) No. 13172/2023 WP(C) No. 13173/2023 WP(C) No.

13174/2023 WP(C) No. 13175/2023 WP(C) No. 13179/2023 WP(C) No. 13186/2023 WP(C) No. 13187/2023 WP(C) No. 13188/2023 WP(C) No. 13190/2023 WP(C) No. 13191/2023 WP(C) No. 13192/2023 WP(C) No. 13193/2023 WP(C) No. 13196/2023 WP(C) No. 13197/2023 WP(C) No. 13236/2023 WP(C) No. 13237/2023 WP(C) No. 13239/2023 WP(C) No. 13240/2023 WP(C) No. 13259/2023 WP(C) No. 13260/2023 WP(C) No. 13304/2023 WP(C) No. 13379/2023 WP(C) No. 13389/2023 WP(C) No. 13417/2023 WP(C) No. 13449/2023 WP(C) No. 13453/2023 WP(C) No. 13456/2023 WP(C) No. 13469/2023 WP(C) No. 13475/2023 WP(C) No. 15263/2023 WP(C) No. 15301/2023 WP(C) No. 15302/2023 WP(C) No. 15315/2023 WP(C) No. 15334/2023 WP(C) No. 15336/2023 WP(C) No. 15618/2023 WP(C) No. 15639/2023 WP(C) No. 16267/2023 WP(C) No. 16361/2023 WP(C) No. 14141/2023 WP(C) No. 14150/2023 WP(C) No. 55/2024 WP(C) No. 9684/2021 WP(C) No. 1182/2022 WP(C) No. 2943/2020 WP(C) No. 1491/2021 WP(C) No. 1511/2021 WP(C) No. 3662/2021 WP(C) No. 11610/2017 WP(C) No. 8986/2023 WP(C) No. 13180/2023 WP(C) No. 436/2024 WP(C) No. 479/2024 are allowed and disposed of in the above terms. ***CONT.CAS(C) 415/2022*** is also disposed of in the above terms. All pending applications in the above petitions are also disposed of. All interim orders stand vacated.

353. Let ***W.P.(C) 3662/2021*** be treated as a representation to the NRDC for deciding whether Von-Hippel-Lindau syndrome be considered as a rare disease under NPRD, 2021.

354. List ***WP(C) No. 5315/2020*** for compliance of directions on 10th December, 2024. ***WP(C) No. 5315/2020*** is treated as a part-heard matter for the purpose of filing a Status Report in respect of the directions given above.

355. Let the present judgment be communicated to Chairperson, NRDC, and Secretary, MoHFW.

PRATHIBA M. SINGH
JUDGE

OCTOBER 04, 2024
Dj/dk/dn