$~70,55,56,57,58,59,64,71 to 75,62 and 78

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

Date of Decision: 23rd March, 2021

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

MASTER ARNESH SHAW ..... Petitioner

Through: Mr. Rajshekhar Rao, Senior Advocate with Mr. Rahul Malhotra and Mr. Asif Ahmed, Advocates. (M:9899218215)

versus

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

Through: Mr. Chetan Sharma ASG, Mr. Ripu Daman Bhardwaj, CGSC with Mr. Amit Gupta, Mr. Vinay Yadav, Mr. Akshay Gadeock, Mr. Sahaj Garg and Mr. R. Venkat Prabhat, Advocates with Dr. Pulkesh Kumar, Deputy Secretary, MoHFW for R-1 (M: 9818030700).

Mr. Satvik Varma, Senior Advocate and Mr. Tanveer Oberoi, Advocate for R-2 (M: 9958935556).

55 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 Aggarwal & Mr. Kumar Utkarsh, Advocates.

versus

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

Through: Mr. Shankar Kumar Jha, Senior Panel Counsel for UOI. (M:9811706171)

Ms. Mrinalini Sen Gupta, ASC for GNCTD. (M:9873367274 & 8826331177)

56 WITH

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

DHANANJAY BHARDWAJ, 11 YEARS OLD, THROUGH: HIS NEXT FRIEND AND NATURAL FATHER SH. AMIT KUMAR ..... Petitioner

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

versus

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

Through: Mr. Sanjeev Uniyal, Advocate with Mr. Dhawal Uniyal, Advocate for R-1. (M:9560806614)

Ms. Mrinalini Sen Gupta, ASC for GNCTD. (M:9873367274

57 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 Aggarwal & Mr. Kumar Utkarsh, Advocates.

versus

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

Through: Mr. Sanjib Kumar Mohanty, Senior Panel Central Govt. Counsel with Mr. Amit Acharya, Advocate for UOI. (M:9667222694 & 9873024619, 9818236472)

Ms. Mrinalini Sen Gupta, ASC for GNCTD. (M:9873367274

58 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 Aggarwal & Mr. Kumar Utkarsh, Advocates.

versus

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

Through: Mr. Siddharth Khatana, Senior Panel Counsel for R-1/UOI. (M:9811132326)

Ms. Mrinalini Sen Gupta, ASC for GNCTD. (M:9873367274

59 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 Aggarwal & Mr. Kumar Utkarsh, Advocates.

versus

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

Through: Mr. Raj Kumar Yadav and Mr. Amit Acharya, Advocates for R-1/UOI. (M:9818836222)

Ms. Mrinalini Sen Gupta, ASC for GNCTD. (M:9873367274

64 WITH

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

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

Through: Mr. Ashok Aggarwal & Mr. Kumar

Utkarsh, Advocates.

versus

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

Through: Mr. Raj Kumar Yadav and Mr. Amit Acharya, Advocates for R-1/UOI. (M:9818836222)

Ms. Mrinalini Sen Gupta, ASC for GNCTD. (M:9873367274

71 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 and Mr. Kumar Utkarsh, Advocates. (M:9811101923)

versus

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

Through: Ms. Amrita Prakash, CGSC with Dr. Pulkesh Kumar and Mr. Harishankar Sharma, Advocates for R-1. (M:9818667963)

Mr. Satvik Varma, Senior Advocate and Mr. Tanveer Oberoi, Advocate for R-2.

Ms. Mrinalini Sen Gupta, ASC for GNCTD. (M:9873367274

72 WITH

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

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

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

versus

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

Through: Mr. Chetan Sharma, ASG with Mr. Ajay Digpaul, CGSC, Mr. Amit

Gupta, Mr. Vinay Yadav, Mr. Akshay Gadeock, Mr. Sahaj Garg and Mr. R. Venkat, Advocates with Mr. Kamal R. Digpaul, Advocate for UOI (M: 9811157265).
Mr. Satvik Varma, Senior Advocate and Mr. Tanveer Oberoi, Advocate for R-2.
Ms. Mrinalini Sen Gupta, ASC for GNCTD. (M:9873367274

73 WITH

\+ **W.P.(C) 1491/2021 & CM APPL. 4291/2021**

MASTER MEDHANSH JHAWAR @ MADHAV ..... Petitioner
Through: Mr. Rahul Malhotra, Advocate.
versus

UNION OF INDIA & ANR. ..... Respondents
Through: Mr. Nawal Kishore Jha, Sr. Panel Counsel for UOI.
Mr. Satvik Varma, Senior Advocate, and Mr. Tanveer Oberoi, Advocate for R-2.

74 WITH

\+ **W.P.(C) 1511/2021 & CM APPLs. 4331-32/2021**

MASTER KENIT JHAWAR @ KESHAV ..... Petitioner
Through: Mr. Rahul Malhotra, Advocate.
versus

UNION OF INDIA & ANR. ..... Respondents
Through: Mr. Prakash Kumar, CGSC for R-1/UOI. (M:9810164350)
Mr. Nawal Kishore Jha, Sr. Panel Counsel for UOI.
Mr. Satvik Varma, Senior Advocate, and Mr. Tanveer Oberoi, Advocate for R-2.

75 WITH

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

LAKSHYA KUMAR GOYAL, 8 YRS OLD, THROUGH: HIS

NEXT FRIEND AND NATURAL FATHER SH. VIPIN KUMAR ..... Petitioner

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

versus

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

Through: Mr. Chetan Sharma ASG, Mr. Ripu Daman Bhardwaj, CGSC with Mr. Amit Gupta, Mr. Vinay Yadav, Mr. Akshay Gadeock, Mr. Sahaj Garg and Mr. R. Venkat Prabhat, Advocates with Dr. Pulkesh for R-1 (M: 9818030700).

Mr. Shankar Kumar Jha, Sr. Panel Counsel for UOI (M: 9811706171).

Mr. Satvik Varma, Senior Advocate, and Mr. Tanveer Oberoi, Advocate for R-2.

Ms. Mrinalini Sen Gupta, ASC for GNCTD. (M:9873367274

62 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 and Mr. Kumar Utkarsh, Advocates.

versus

UNION OF INDIA THROUGH ITS SECRETARY ..... Respondents

Through: Mr. Chetan Sharma ASG, Mr. Ripu Daman Bhardwaj, CGSC with Mr. Amit Gupta, Mr. Vinay Yadav, Mr. Akshay Gadeock, Mr. Sahaj Garg and Mr. R. Venkat Prabhat, Advocates with Dr. Pulkesh for R-1 (M: 9818030700).

Mr. Shankar Kumar Jha, Sr. Panel

Counsel for UOI (M: 9811706171).
Mr. Satvik Varma, Senior Advocate, and Mr. Tanveer Oberoi, Advocate for R-2.
Ms. Mrinalini Sen Gupta, ASC for GNCTD. (M:9873367274)

78 WITH

\+ **W.P.(C) 3662/2021 & CM APPLs. 11103/2021, 11104/2021, 11105/2021**

PAYEL BHATTACHARYA ..... Petitioner

Through: Aditya Chatterjee, Nitya Kaligota, Sumer Dev Seth and Abhirup Ghosh, Advocates.

versus

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

Through: Anju Gupta and Mr. Roshan Lal Goel, Advocates for R-1 (M: 9654169406.
Mr. Anuj Aggarwal, Advocate for R-2

CORAM:
JUSTICE PRATHIBA M. SINGH

Prathiba M. Singh (Oral)

1. The Petitioners in these cases, who are mostly children, are suffering from the following Rare Diseases:

Rare Diseases	**Petitioners**	**Age**	**Writ Petition Number**
Duchenne Muscular Dystrophy (*hereinafter*,	1) Master Arnesh Shaw	7 years	WP(C) 5315/2020
	2) Master Aviraj Garg	4 years	WP(C) 10782/2020
	3) Master Harshit Soni	16 years	WP(C) 3682/2021

"DMD")	4) Master Dhananjay Bharadwaj	11 years	WP(C) 3689/2021
	5) Master Khushwant Bhardwaj	7 years	WP(C) 3706/2021
	6) Master Aarav Garg	5 years	WP(C) 3707/2021
	7) Master Manish	8 years	WP(C) 3729/2021
	8) Master Chirag	6 years	WP(C) 3729/2021
	9) Master Shourya Maru	7 years	WP(C) 3737/2021
	10) Master Keshav Sharma	12 years	WP(C) 322/2021
	11) Master Lakshya Kumar Goyal	8 years	WP(C) 1611/2021
	12) Master Siddharth Swarnkar	9 years	WP(C) 3859/2021
MPS II (Hunter Syndrome)	1) Master Medhansh Jhawar	2 years	WP(C) 1491/2021
	2) Master Kenit Jhawar	3 years	WP(C) 1511/2021
Hippel- Linau	1) Payel Bhattacharya	41 years	WP(C) 3662/2021

2. 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.

3. On 17th August, 2020, notice was issued in WP(C) 5315/2020, to the Respondent- Union of India, and a counter affidavit had initially been called for from the Union of India. An affidavit was placed on record in W.P.(C) 5315/2020 stating that various health policies are under consideration by the Union of India, in respect of such Rare Diseases. As per the said affidavit, a Draft National Policy for Rare Diseases has been released by the Government in 2020, which was in the stage of consultation. The said draft policy of 2020 was preceded by an earlier policy of 2017 which was kept in abeyance vide notification dated 18th December, 2018.

4. On 12th January, 2021, this Court had observed that the various Rare Diseases have been grouped by the Union of India, in their Draft National Policy for Rare Diseases, as Group 1, 2 and 3. Further, the draft policy also prescribed the manner in which each of the said diseases was to be dealt with.

5. This Court after considering the matter observed as under:

> *"…4. This Court is of the opinion that just because of the exorbitant price of the drug or treatment, patients, especially children, suffering from a rare disease ought not to be deprived of treatment for their condition. The draft policy of the government, which was introduced in 2020 for consultation, has still not seen the light of the day. Considering the fact that `Right to Health and Healthcare' is a Fundamental Right which has been recognised by the Supreme Court to be a part of the `Right to life' under Article 21 of the Constitution, it is incumbent on society in general and authorities in particular to ensure that the life of such children is not compromised, even if there is a small window of improving their chances of survival or even providing a*

better quality of life.

…

8. This court is of the opinion that the finalisation of the Draft Health Policy for Rare Diseases cannot be kept pending indefinitely, especially when common human lives are at stake. The earlier Policy having been kept in abeyance, it is incumbent for the Government to finalise and notify the Policy at the earliest. Accordingly, it is directed as under:

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

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

6. Thus, this Court had called for a specific timeline from the Union of India, for the finalization of the Draft National Policy for Rare Diseases, and also called for proposals in respect of crowdfunding, in order to meet the exorbitant costs involved. On 28th January, 2021, an affidavit was filed by the Ministry of Health, Union of India, stating that the Draft National Policy for Rare Diseases 2020 has been put in the public domain for comments by stakeholders. Vide the said affidavit, it was confirmed that the National Policy for Rare Diseases is likely to be finalized by 31st March, 2021, and a

digital platform would also be operational for the purposes of crowdfunding by the said date of 31st March 2021.

7. This Court, after accepting the affidavit of the Ministry of Health and Family Welfare, Union of India, directed vide order dated 28th January 2021 that the Policy ought to be finalized and put in the public domain on or before 31st July, 2021. This court also directed the Government to ensure that the digital platform *qua* crowdfunding is made operational by 31st March, 2021, to enable patients like the Petitioners to avail of funding for medicines and treatment.

8. Parallelly, certain proposals were also being considered for arranging therapies and medicines for some of the Petitioners involved in these cases.

9. On 4th February, 2021, this Court heard detailed submissions on behalf of all the parties. By this time, further writ petitions had also been filed concerning other Petitioners suffering from Rare Diseases.

10. On 24th February, 2021, certain further material was placed on record by the ld. Counsel for the Petitioner, indicating the availability of treatments and medicines for DMD in India, and even generic versions of treatments under development by various organisations. After perusing the said material, this Court impleaded the Department of Biotechnology - Government of India, Drugs Controller General of India (*hereinafter 'DCGI'*) and three other institutes, which appeared to be involved in research and development for therapies *qua* Rare Diseases.

11. On 2nd March, 2021, the Court was informed that clinical trials are already underway in India in relation to drugs/therapies for the treatment of some of the Rare Diseases including DMD. Some of the institutions which were involved in the said research were also recognised and mentioned in

the order. Considering the urgent need for indigenous development of treatment/therapies for Rare Diseases, this Court, vide order dated 2nd March 2021, constituted an expert committee consisting of nine members headed by Ms. Renu Swarup, Secretary, Department of Biotechnology, Government of India. The said Committee was asked to submit a report on the following aspects, on or before 12th March 2021:

> *"…(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.*
>
> *…*
>
> *9. Further, a specific affidavit shall be filed by the Union of India specifying the budget for health in the last five years, as also whether any part of the budget has been unused and can be used for the purpose of treatment of the Petitioners or the indigenous development of therapies for the treatment of rare diseases."*

12. As per the above order, a meeting had to be convened by the committee and a report was to be submitted *qua* the queries indicated by the court. Further, the Union of India was directed to submit an affidavit specifying the budget for health and also as to whether any part of the budget was unused, and could be used for the purpose of treatment of patients of Rare Diseases or the indigenous development of therapies for

these Rare Diseases.

13. The report of the Committee, dated 12th March, 2021, has now been received by this court. Various facts and recommendations have been set out on the queries put by this court, in the said report. The conclusions and recommendations in the Report are as under:

- 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 Department of Biotechnology (*hereinafter*,

"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.

14. Insofar as the Ministry of Health and Family Welfare, Union of India, is concerned, in terms of the order dated 2nd March 2021, a short affidavit in respect of the budget that was allocated for Health and specifically directed for Rare Diseases has been filed. The relevant extract from the said affidavit which has been deposed by Mr. Pulkesh Kumar, Deputy Secretary, Ministry of Health & Family Welfare, are set out below:

> "*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**.”’*

15. This court has perused the Report filed by the Committee as well as the Affidavit filed by the Ministry of Health and Family Welfare, Union of India. This Court has also interacted with the Chairperson of the Committee – Ms. Renu Swarup, Secretary, Department of Biotechnology, Government of India, and Mr. Pulkesh Kumar, Deputy Secretary, Ministry of Health and Family Welfare, Govt. of India, as also various representatives from other organizations. It is worth mentioning that ld. Counsels appearing for the parties have also rendered enormous assistance to the Court by placing on record relevant materials, and giving very practical and sustainable suggestions for dealing with this mammoth human issue, being faced by children and other people suffering from Rare Diseases.

16. A perusal of the report filed by the Expert Committee appointed by this court, as also the affidavits filed on behalf of the Ministry of Health and Family Welfare, Union of India, shows that there are broadly two aspects that needs to be taken care of:

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.

17. Insofar as the first aspect is concerned, as per the report of the Expert

Committee, there are various organisations which are already working on mechanisms and therapies for dealing with Rare Diseases. The Research and Development in this area needs to be made completely robust, in order to ensure that the indigenisation and local development of medicines and therapies takes place in a time bound manner.

18. Secondly, the affidavit of Ministry of Health and Family Welfare, Union of India, also reveals that almost Rs. 200 crores were budgeted for the purpose of expenditure in respect of Rare Diseases. The affidavit shows that the expenditure that has already been incurred is only to the tune of Rs.7 crores over the last three years.

19. Considering the fact that budgets have already been sanctioned for dealing with Rare Diseases, it is 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.

20. This court is also of the opinion that while creating a fund for Rare Diseases, the same ought not to be made accessible only to those patients who approach the Court, but rather, a streamlined and sustainable mechanism ought to be in place, so that the case of each patient suffering from Rare Diseases can be examined in a timely manner. In cases of those patients for whom treatment is recommended, the same ought to be made available expeditiously, without the need for such patients to approach Courts from time to time.

21. In view of the above, the following directions are issued by this Court:

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.

25. A copy of this order be communicated to Prof. (Dr.) Randeep Guleria, Director, AIIMS [director@aiims.edu], Prof. (Dr.) Madhulika Kabra, [madhulikakabra@hotmail.com] and Prof. (Dr.) P. Ramesh Menon [rpmpgi@gmail.com] by the Registry through email forthwith.

26. A copy of this order be also communicated to Ms. Renu Swarup, Secretary, Department of Biotechnology, Government of India [secy@dept.nic.in] and Dr. Pulkesh Kumar, Deputy Secretary, Ministry of Health and Family Welfare, Government of India [dr.pulkesh@gov.in] by the Registry through email.

27. List on 19th April, 2021.

PRATHIBA M. SINGH
JUDGE

MARCH 23, 2021
Rahul/Ak