IN THE HIGH COURT OF KERALA AT ERNAKULAM

Present:

THE HONOURABLE THE CHIEF JUSTICE MR.S.MANIKUMAR

&

THE HONOURABLE MR. JUSTICE SHAJI P.CHALY

Wednesday, the 22nd day of January 2020/2nd Magha, 1941

WP(C) No.28250/2017(S)

PETITIONER

LYSOSOMAL STORAGE DISORDERS SUPPORT SOCIETY
HAVING ITS OFFICE AT TOP FLOOR DUGGAL COMPLEX, SCHOOL ROAD, KHAN PUR,
NEW DELHI-110062, REPRESENTED BY ITS STATE CO-ORDINATOR, KERALA CHAPTER,
(SUDHEER BABU K.S, RESIDING AT KARUMKKIL HOUSE, KUNDANNOOR P O,
THRISSUR DISTRICT-680590).

RESPONDENTS

1. STATE OF KERALA,
REPRESENTED BY ITS CHIEF SECRETARY, GOVERNMENT SECRETARIAT,
THIRUVANANTHAPURAM-695001.
2. THE PRINCIPAL SECRETARY,
HEALTH AND FAMILY WELFARE DEPARTMENT, GOVERNMENT SECRETARIAT,
THIRUVANANTHAPURAM-695001.
3. THE KERALA SOCIAL SECURITY MISSION,
REPRESENTED BY ITS EXECUTIVE DIRECTOR, POOJAPPURA,
THIRUVANANTHAPURAM-695012.
4. THE KERALA MEDICAL SERVICES CORPORATION LTD,
REPRESENTED BY ITS MANAGING DIRECTOR,
NEAR WOMEN AND CHILDREN HOSPITAL, HEALTH AND WELFARE FAMILY COMPOUND,
THYCAUD, THIRUVANANTHAPURAM, KERALA 695014.
5. UNION OF INDIA
REPRESENTED BY ITS SECRETARY, HEALTH AND FAMILY WELFARE DEPARTMENT,
CABINET SECRETARIAT, RAISINA HILL, NEW DELHI-110011.

ADDL. R6 IMPLEADED

ADDL.R6. SANOFI GENZYME, REPRESENTED BY ITS GENERAL MANAGER (SOUTH ASIA) &
HEAD- INDIA, SANOFI HOUSE, CTS NO.117-B, L&T BUSINESS PARK,
SAKI VIHAR ROAD, POWAI, MUMBAI-400 072.

ADDL. R6 IS IMPLEADED AS PER ORDER DATED 01/08/2019 IN
IA.3/2019 IN WPC.

Writ Petition (civil) praying inter alia that in the circumstances stated in the affidavit filed along with the WP(C) the High Court be pleased to direct the respondents to provide Enzyme Replacement Therapy, free of cost, to the children included in Ext-P2 list, pending disposal of the Writ Petition(Civil).

This petition again coming on for orders upon perusing the petition and the affidavit filed in support of WP(C) and this Court order dated 15/01/2020 upon hearing the arguments of M/S ADITHYA RAJEEV, ARJUN RAGHAVAN, JAIBY PAUL, T.R.HARIKUMAR, Advocates for the petitioner, GOVERNMENT PLEADER for R1 & R2, STANDING COUNSEL for R4, SRI.RAJAGOPALAN. A., CENTRAL GOVERNMENT COUNSEL for R5 and of SRI.SUNIL SANKER & SRI.K.N.SIVASANKARAN, Advocate for Addl. R6 and of SRI.RANJITH THAMPAN, ADDL. ADVOCATE GENERAL, the court passed the following:

P.T.O.

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S.Manikumar, C.J.
&
Shaji P.Chaly, J.

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W.A.No.2151 of 2017 &
W.P.(C)No.28250 of 2017-S

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Dated this the 22nd day of January, 2020

ORDER

S.Manikumar, C.J.

Taking note of the prayers and the material on record, orders have been issued periodically. The last order was on 15.1.2020. Inviting the attention of this court to the National Policy for Treatment of Rare Diseases, Ministry of Health and Family Welfare, Government of India, in particular, creating a National and State Level Corpus, contribution required to be made by the State and Central Governments, Mr.Ranjith Thampan, learned Additional Advocate General submitted that as directed by the Government of India, a State Corpus Fund has been created in the year 2017 for treatment of rare diseases and accordingly, a sum of Rs.50 lakhs has been deposited in the said Corpus Fund every year but the Government of India has not contributed any amount towards the said Corpus. At this juncture, it is pertinent to extract the provision relating to creation of a National and State Level Corpus, which reads as under:

"m) **Creating a National and State Level Corpus**

1. The Government of India (GOI) to set up a corpus fund with the initial amount of Rs.100 Crore towards funding treatment of rare genetic diseases. Resources allocated for treatment of rare diseases can be progressively scaled up with regular improvements in availability of

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epidemiological data, cost estimation studies and measures taken to encourage development of orphan drugs and for reduction in prices of drugs.

2. The States to have a similar corpus at the State level and the GOI will contribute funds towards the State Corpus to the ratio 60:40 out of the central pool. It would be up to the States to have a corpus of a larger amount. This funding arrangement will be part of the PIP process.
3. The corpus fund will be dedicated for rare 'genetic' disorders. It will not fund treatment for rare blood disorders (hemophilia, Thalassemia and sickle cell anemia) or for rare cancers, as separate government programs for them exist already.
4. The corpus can be used for part funding of the treatment cost depending on the type of treatment (one time/long term), cost of treatment, clinical outcome or other related considerations.
5. To ensure sustainability of the corpus, the Public Sector Undertaking (PSUs) and corporate houses, to be encouraged to make contributions as per Section 135 and Schedule VII of the Companies Act as well as the provisions of the Companies (Corporate Social Responsibility Policy) Rules, 2014 (CSR Rules)."

2. Learned Additional Advocate General submitted that whatever fund collected under the 'We-care' Scheme, has been properly utilised for providing assistance to the beneficiaries under various schemes which includes education, finance, marriage, etc. and that even administrative fee is not taken from the fund collected under 'We-care' Scheme. On the submission of the learned

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counsel for the petitioner that though sufficient funds were available in the financial year 2016-17 and 2017-18 in particular excess income over expenditure, Rs.264,618,265/- (2016-2017) and Rs.232,446,514/- (2017-2018) and the grounds of appeal wherein Government of Kerala have raised a ground of financial constraint for providing assistance to those who require Enzyme Replacement Therapy and also the fact that during the relevant years, for not providing proper assistance, some children expired, Mr.Ranjith Thampan, learned Additional Advocate General submitted that not only for this disorder, Government have to provide medical assistance to other critical diseases such as cancer, kidney replantation, liver diseases, etc. and therefore, Government have to take into consideration the interest of the beneficiaries under the Scheme who require medical assistance. According to him, the entire carry forward income cannot be spent only for treatment of those who require Enzyme Replacement Therapy.

3. On the abovesaid aspect, we direct the Government to explain as to why income, though available, could not be spent for treatment of those who require Enzyme Replacement Therapy and the manner in which the said excess income was spent.

4. From the statement of the Union of India, it would be seen that Ministry of Health and Family Welfare Government of India had formulated

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National Policy for Treatment of Rare Diseases (NPTRD) in July 2017. Owing to certain difficulties expressed in implementation of the Policy, Government of India have issued Gazette notification informing the general public that the National Policy, evolved in July 2017 has been kept in abeyance. Such notification has been issued only on 18.12.2018. From the above statement of Union of India, it is clear that though National Policy was evolved in the year 2017, wherein Government of India have to set up a Corpus Fund with the initial amount of Rs.100 Crore towards funding treatment of rare genetic diseases, the same has not been done.

5. Government of kerala said to have created a separate Corpus at the state level have contributed 50 lakhs in the year 2017 and subsequently also representing 40% of the share as per the National Policy but Government of India have not contributed any amount. Though Mr. Imthiyaz Ahammed M.S, representing learned Central Government Counsel for Union of India, submitted that there was no request from the State Government and that there were other difficulties at the Union level as stated in the affidavit filed on behalf of the Government of India, we are not inclined to accept the said contention for the reason that having evolved the National Policy, which the State Government have also acted upon contributing Rs.50 lakhs towards 40% of its share, Union of India ought not to have discharged duty by contributing 60% of their share to

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the State Corpus. 60% of the said Corpus works out to Rs.75 lakhs. State Government on its part have contributed Rs.50 lakhs each for the years 2017, 2018 and 2019. Having regard to the prompt treatment which is required for the abovesaid rare diseases and the number of death of children, we are of the view that there is a failure on the part of Union of India in contributing 60% of the share as per the National Policy. Therefore, we direct respondent No.5 to deposit a sum of Rs.1.5 crores in the State Corpus which is due, as per the then existing National Policy, within 15 days from the date of receipt of a copy of this order.

6. Though Union of India has kept the 2017 Policy in abeyance, there is attempt to evolve a new Policy. Union of India is a party signatory to the resolution No.44/25 passed by the UN General Assembly. It is trite law that the universal declaration, agreements/treaties to which a country is party, is bound to honour and abide by the decisions taken.

7. Article 253 of the Constitution of India reads thus:

> "253. Legislation for giving effect to international agreements Notwithstanding anything in the foregoing provisions of this Chapter, Parliament has power to make any law for the whole or any part of the territory of India for implementing any treaty, agreement or convention with any other country or countries or any decision made at any international conference, association or other body."

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8. Article 24 of the Convention on the Rights of the Child reads as under:

"Article 24

1. States Parties recognize 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. States Parties shall strive to ensure that no child is deprived of his or her right of access to such health care services.

2. States Parties shall pursue full implementation of this right and, in particular, shall take appropriate measures:

(a) To diminish infant and child mortality;

(b) To ensure the provision of necessary medical assistance and health care to all children with emphasis on the development of primary health care;

(c) To combat disease and malnutrition, including within the framework of primary health care, through, inter alia, the application of readily available technology and through the provision of adequate nutritious foods and clean drinking-water, taking into consideration the dangers and risks of environmental pollution;

(d) To ensure appropriate pre-natal and post-natal health care for mothers;

(e) To ensure that all segments of society, in particular parents and children, are informed, have access to education and are supported in the use of basic knowledge of child health and nutrition, the

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advantages of breastfeeding, hygiene and environmental sanitation and the prevention of accidents;

(f) To develop preventive health care, guidance for parents and family planning education and services.

3. States Parties shall take all effective and appropriate measures with a view to abolishing traditional practices prejudicial to the health of children.

4. States Parties undertake to promote and encourage international co-operation with a view to achieving progressively the full realization of the right recognized in the present article. In this regard, particular account shall be taken of the needs of developing countries."

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9. Pending evolution of a new Policy, Union of India is expected to substantially assist the State Government in meeting out the expenditure. The rights and liberties of the children are to be protected in terms of Article 24 of the Convention on the Rights of the Child and Articles 50 and 253 of the Constitution of India.

10. Mr.Ranjith Thampan, learned Additional Advocate General submitted that instructions have already been given for negotiations of the price of the drugs with the 5th respondent and the outcome of the same will be reported by next hearing. Learned Additional Advocate General is also requested to furnish

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the details of Pilot Project initiated in Kannur District for generating additional resources from the public, NGOs and others.

11. Profession of Advocate is noble and it is known that many designated Senior Advocates contribute their knowledge and money for charitable purposes. Therefore, we are of the view that Associations can also contribute to the fund for providing treatment to the needy children. Registry is directed to forward a copy of this order to the Kerala High Court Advocates Association, Lady Lawyers Association, Senior Advocates Association and Kerala High Court Staff Associations.

Post the cases on 14.2.2020.

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Sd/- S.MANIKUMAR, CHIEF JUSTICE
Sd/- SHAJI P.CHALY, JUDGE

24/1/2020

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24/1/20

ASSISTANT REGISTRAR

24.1.20

vpv

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