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

\+ W.P.(C) 8503/2017

BABY DEVANANDA D (MINOR)
THR HER MOTHER DEEPA S AND ANR ..... Petitioners

Through Mr. Ashok Agarwal with Mr. Kumar Utkarsh, Advocates

versus

EMPLOYEES STATE INSURANCE
CORPORATION AND ORS. ..... Respondents

Through Ms. Shyel Trehan, Amicus Curiae and Advocate with Ms. Sonali Malik, Advocate.
Mr.Yakesh Anand and Mr.Nimit Mathur, Advocates with Dr.Naresh Kumar Arora, Addl. Director (Insp.) and Mr. Dhruv Prasad, UDC for ESIC.
Ms. Amrita Prakash, CGSC with Mr.Hari Shankar Sharma, Advocates for UOI/R-2 and 3.
Mr. Rajshekhar Rao with Mr. Kotla Harshavardhan, Ms. Mansi Sood and Mr. Gaurav Sansanwal, Advocates for Sanofi Genzyme.

AND

\+ W.P.(C) 699/2018

MASTER HARSHA D.S. (MINOR)
THROUGH HIS FATHER
SHANKARAPPA D.S. AND ANR ..... Petitioners

Through Mr. Ashok Agarwal with Mr. Kumar Utkarsh, Advocates

versus

EMPLOYEES STATE INSURANCE CORPORATION AND ORS. ..... Respondents

Through Ms. Shyel Trehan, Amicus Curiae and Advocate with Ms. Sonali Malik, Advocate.
Mr.Yakesh Anand and Mr.Nimit Mathur, Advocates with Dr.Naresh Kumar Arora, Addl. Director (Insp.) and Mr. Dhruv Prasad, UDC for ESIC.
Ms. Amrita Prakash, CGSC with Mr.Hari Shankar Sharma, Advocates for UOI/R-2 and 3.
Mr. Rajshekhar Rao with Mr. Kotla Harshavardhan, Ms. Mansi Sood and Mr. Gaurav Sansanwal, Advocates for Sanofi Genzyme.

Reserved On: 31st May, 2019
% Date of Decision: 17th July, 2019

CORAM:
HON'BLE MR. JUSTICE MANMOHAN

J U D G M E N T

MANMOHAN, J:

1. In the present two writ petitions, the petitioners have challenged the validity and legality of Clauses 5.1 and 5.3 of the Guidelines of the ESI Corporation titled *"ESIC Decisions on Medical Services-July, 2014"*. The impugned clauses read as under:-

"5.1 Upper limit on the expenditure for procedures not covered under CGHS package rates would be Rs. 10 lacs per beneficiaries per year.

5.3 In respect of children of IP, congenital diseases requiring referral to SST and genetic disorders would be eligible for coverage up to the ceiling mentioned earlier only in case the child is born after the IP had become eligible for SST."

2. The present writ petitions were initially tagged with a batch of matters filed by the employees who were insured under the Employees' State Insurance Act, 1948 (for short "ESI Act") but whose minor children had been denied Super Speciality Treatment on the grounds that the minors had been born prior to the employees having become eligible for Super Speciality Treatment and/or the expenditure to be incurred on their treatment was beyond the ceiling of Rupees Ten Lacs per year.

3. It is pertinent to mention that the present two petitioners are minor children who are suffering from genetic disorders, namely, Gaucher Type I (Master Harsha D.S.) and Hurler Syndrome Type I (Baby Devananda D.). Both Gaucher Type I and Hurler Syndrome Type I, which are rare diseases. The term 'rare disease' in many countries has been defined as a disease or condition which occurs so infrequently that there is no reasonable expectation that the cost of developing and making available a drug for such disease or condition will be recovered from sales of such a drug. Rare diseases have low prevalence and collectively affect approximately between six to eight per cent of the population. Globally around six thousand to eight thousand rare diseases exist and new ones are reported regularly. Around eighty per cent of rare diseases are of genetic origin, hence disproportionately impact children.

4. While issuing notice in the present batch of matters, this Court had directed ESI Corporation to commence Enzyme Replacement Therapy or any other appropriate treatment to the minor petitioners. It was further directed that in the event the ESI Corporation does not have the expertise to administer the said therapy, it would forward the case of the petitioners to a super speciality empanelled hospital and cost, if any, for such treatment would be borne by the ESI Corporation.

5. During the pendency of the present cases, the impugned Guidelines were amended from time to time by way of administrative orders issued by the ESI Corporation.

6. On 07th November, 2016, the impugned Clauses 5.1 and 5.3 were modified by the ESI Corporation. The revised Guidelines amended the conditions on which Super Speciality Treatment could be availed by the Insured Person and his family members. The relevant portion of the Circular dated 07th November, 2016 is reproduced hereinbelow:-

> *"In view of difficulties being faced by IPs for getting Super-Speciality Treatment services especially through referral system and for suggesting measures to improve medical services under ESI scheme, a Sub-Committee was constituted whose recommendations were placed in 169th meeting of ESI Corporation held on 5th September, 2016. These recommendations have been approved by the competent authority, as under:-*
>
> *xxxx xxxx xxxx xxxx*
>
> *"The IP should have been in continuous employment for last two years as on the date of diagnosis of the SST (other than cases of employment injury) and at least 156 days of contribution was paid by the IP during the immediately preceding four contribution periods with eligibility for sickness benefit in at least two benefit periods."*

After completion of the above period the IP and family will be eligible for the SST including the children of IP with congenital diseases and genetic disorder."

xxxx xxxx xxxx xxxx

……*cases where the expenditure incurred/to be incurred is more than 10 lakhs are to be examined on case to case basis by a committee constituted by ESIC Hqrs. Office and approval of the Chairman, ESI Corporation should be taken in this regard."*

(emphasis supplied)

7. Consequently, while impugned Clause 5.1 no longer survives as each case has to be examined on its merits by a Committee constituted by ESI Corporation Headquarter office, irrespective of the cost involved in the treatment, Clause 5.3 stands amended/modified. Subsequently, ESI Corporation issued a Circular dated 15th December, 2016, clarifying that the amendments introduced vide letter dated 07th November, 2016 shall operate prospectively.

8. Vide order dated 17th April, 2017, this Court directed ESI Corporation to examine the pending cases on merits, in accordance with the said amendments.

9. In its 175th Meeting held on 18th September, 2018, the ESI Corporation in supersession of its instructions dated 07th November, 2016 issued revised eligibility conditions for Super Speciality Treatment for the Insured Persons and members of his/her family. Till the eligibility conditions were made part of Regulations, the ESI Corporation issued an Office Memorandum dated 29th October, 2018 amending Clause 5.3 of *ESIC Decisions on Medical Services-July, 2014*. The said executive order was

deemed to be an interim measure till the draft notification inserting Regulation 96C under Section 59A of the ESI Act, was finalised. The relevant guidelines issued by way of the Office Memorandum dated 29th October, 2018 are reproduced hereinbelow:

> *"1. The Insured Person who has contributed for 78 days in a contribution period be allowed to avail super speciality treatment provided he/she has completed minimum of six months of insurable employment i.e. from the date of registration on IP Portal*
>
> *2. The members of family of the Insured Persons be allowed super speciality treatment if the Insured Person has contributed 156 days (78 days in each contribution period) and have completed minimum one year of insurable employment from the date of registration".*
>
> *3. In both the above cases, the employer should have filed the monthly contribution as per Section 44 read with regulation 26(a) failing which Regulation 31 of the ESI(General) Regulation, 1950.*
>
> *4. This shall be available only in the corresponding benefit period.*
>
> *5. Insured persons and their family members shall continue to avail the super speciality if the Insured Persons is in receipt of extended sickness benefits.*
>
> *6. The Insured Women shall be eligible for super speciality treatment in case it arises due to or out of maternity if she is in receipt of maternity benefit.*
>
> *7. The cases of employment injury shall not attract the aforesaid conditions.*
>
> *The aforesaid conditions shall apply only in those cases where expenditure of the treatment for reference is made outside the ESI set-up and is to be paid by the ESCI without share of the State Govt. In cases, Insured Person or their family member requires treatment*

which is not available in ESI Hospital or ESI Medical Education Institutions and aforesaid eligibility conditions are not met by the Insured Person, such cases be referred to Hospitals/Medical Colleges of the State Govt., who are duty bound to render services to a citizen."

(emphasis supplied)

10. Pursuant to the order dated 17th April, 2017, the ESI Corporation constituted a Committee to examine the cases of all the petitioners in terms of amended Super Speciality Treatment Circulars. A table indicating the names of petitioners, and the decision of the said Committee is reproduced hereinbelow:-

S. No	*Name & Age*	*Date of Birth*	*Disease*	*Date of Diagnosis*	*Whether eligible for SST treatment as per ESIC guidelines criteria notified vide circulars dated 07.11.2016 and 15.12.2016*	*If not eligible, then reason for rejection*
1.	*Master Lalit Kumar*	*28.02.2012*	*Gaucher Type 1*	*04.05.14*	*Eligible*	-
2.	*Master Harsha*	*02.02.2015*	*Gaucher Type 1*	*2016*	*Not eligible*	*Insured Persons has not been in continuous employment for the last two years as on date of diagnosis for SST*
3.	*Master Dixit Ankalagi*	*05.02.2014*	*Gaucher Type 1*	*Sept, 2016*	*Eligible*	-
4	*Master*	*17.12.2014*	*Gaucher*	*Mar-Apr*	*In order to*	-

	Rudraksh Vyas		*Type 1*	*2016*	*determine the genuineness of the Insured Person, a confirmation Report from the Regional Director, Jaipur is required before processing the case.*	
5.	*Baby Devanandha*	*29.09.2014*	*Hurler Syndrome Type 1*	*Oct 2016*	*Not eligible*	*The IP has not been in continuous employment for the last two years as the date of registration on the portal is 07.04.2017 as per available records.*
6.	*Miss Sangeetha*	*29.09.1997*	*Gaucher Type 1*	*Apr 2017*	*Eligible*	-
7.	*Baby Nisarga*	*07.04.2010*	*Gaucher Type 1*	*04.09.2014*	*Eligible*	-
8.	*Vishal Kumar*	*19.01.2008*	*Hurler Syndrome*	*Oct, 2013*	*Eligible*	-
9.	*Kumari Priya*	*01.01.2003*	*Gaucher Type 1*	*Oct-Nov 2015*	*Eligible*	-
10.	*Dharmender Singh*	*16.10.1994*	*Hurler Syndrome*	*Apr,2006*	*Not Eligible*	*Not eligible as per definition of Family as his age is exceeding 21 years*

(emphasis supplied)

11. Vide orders dated 15th April, 2019, 16th April, 2019, 10th May, 2019 and 24th May, 2019, this Court disposed of eleven of the Writ Petitions being W.Ps.(C) 8445/2014, 1493/2016, 1860/2016, 1266/2018, 7730/2016, 11866/2016, 8474/2017, 4444/2016, 2609/2016, 2945/2016 and 10554/2016 which were tagged with the present two petitions.

12. Since pleadings were not complete in W.Ps.(C) 6865/2015, 3850/2019, 11610/2017 and 1935/2017, they were directed to be listed before the regular Roster Bench.

13. In fact, during the final hearing, this Court had repeatedly enquired from the learned counsel for ESI Corporation, the specific provision under the ESI Act, which enabled/authorised ESI Corporation to issue executive orders/circulars/office memorandums. However, no direct answer was given by the ESI Corporation.

14. In the written submissions dated 16th April, 2019, ESI Corporation enclosed a draft notification for inserting Regulation 96C in the ESIC (General) Regulations, 1950 (hereinafter referred to as "Regulations, 1950"), which is yet to be notified as per Section 97 of the ESI Act. The said draft notification reads as under:-

"EMPLOYEES' STATE INSURANCE CORPORATION
NOTIFICATION
NEW; DELHI ……., 2019

No……. WHEREAS the draft Regulation 96C to the Employees' State Insurance (General) Regulation, 1950 were issued on 26th November, 2018 vide notification no. 470 dated 6th December, 2018 in the Gazette of India, Extraordinary Part III Section 4, objections and suggestions were called by the Employees' State Insurance Corporation.

AND WHEREAS The said Gazette Notification was made available to the public on 06-12-2018 vide notification No. 470 dated 6th December, 2018 in the Gazette of India, Extraordinary Part III Section 4.

AND WHEREAS objections and suggestions were received and the same has been examined and addressed. The necessary amendment is being incorporated as proviso to the Regulation.

NOW THEREFORE, in exercise of the power conferred under Section 97 Sub Section 1 of the Employees' State Insurance Act, 1948 (34 of 1948), the Employees' State Insurance Corporation, do hereby notify Regulation 96C further to amend the Employees' State Insurance (General) Regulations, 1950 and is hereby published under section 59A of the said Act.

REGULATION

In the Employees' State Insurance (General) Regulations, 1950, a new Regulation 96C shall be inserted as under:

REGULATION 96C	*REFERREAL FOR SUPER SPECIALTY TREATMENT TO TIE-UP HOSPITALS AND EXPENDITURE TO BE INCURRED BY EMPLOYEES' STATE INSURANCE CORPORATION DIRECTLY*

Subject to the provisions of the Act and the Regulations, the Corporation or State Government may refer a beneficiary to any tie-up arranged medical facilities, where cost of such facility is borne directly by the Corporation and where the fund permits; an Insured Person should have completed a minimum of six months of insurable employment from the date of registration and have contributed not less than seventy eight (78) days in the relevant contribution period including in which registration was made. However, where the facility has been extended to his family members, an Insured Person should have completed a minimum of one year of insurable employment and have contributed for not less than seventy eight (78) days in each of the two (2) contribution period and such benefit shall be available to an Insured Person or a beneficiary in the corresponding benefit period.

Provided further that an Insured Person with employment injury or Insured Woman with complications arising out of maternity or those in receipt of extended sickness benefit under the Act shall be eligible as per the relevant contributory conditions and in case of family of extended sickness beneficiaries, they shall also be eligible as long as the benefit period corresponding to contribution period covered in extended sickness by more than half of the contribution period.

S Ravichandran

EMPLOYEES' STATE INSURANCE CORPORATION
NOTIFICATION
New Delhi, the 26th November, 2018

No. N-12/13/1/2016-P&D. – The following draft regulations further to amend the Employees' State Insurance (General) Regulations, 1950, which the Employees' State Insurance Corporation purposes to make in exercise of the powers conferred under sub-section (1) of Section 97 of the Employees' State Insurance Act, 1948 (34 of 1948), is hereby published under 59A of the said Act for information of all persons likely to be affected thereby and notice is hereby given that the said draft regulations will be taken into consideration after expiry of a period of Thirty days from the date on which copies of the Official Gazette in which this notification is published, are made available to the public:-

1. *Any objection or suggestion, which may be received from any person in respect of the said draft regulations within the period specified above, will be considered by the Employees' State Insurance Corporation.*
2. *The objections and suggestions, if any, may be addressed to Shri S. Ravinchandran, Additional Commissioner (P&D), Employees' State Insurance Corporation, Panchdeep Bhawan, CIG, Marg, New Delhi-110002 (e-mail:dir-pnd@esic.nic.in)*

DRAFT REGULATIONS
In the Employees' State Insurance (General) Regulations

1950, a new Regulation 96-C shall be inserted as under:

Regulation 96C: REFERAL FOR SUPER SPECIALITY TREATMENT TO TIE-UP HOSPITALS AND EXPENDITURE TO BE DIRECTLY INCURRED BY EMPLOYEES' STATE INSURANCE CORPORATION.

Subject to the provisions of the Act and the Regulations, the Corporation or State Government may refer a beneficiary to a tie-up arranged medical facilities, where cost of such facility is borne directly by the Corporation and where the fund permits; an Insured person should have completed a minimum of six months of insurable employment from the date of registration and have contributed not less than seventy eight (78) days in the relevant contribution period including in which registration was made. However, where the facility has been extended to the family members, an Insured Person should have completed a minimum of one year of insurable employment and have contributed for not less than seventy eight (78) days in each of the two (2) contribution period and such benefit shall be available to an insured person or a beneficiary in the corresponding benefit period.

S. RAVICHANDRAN, Addl. Commissioner (P&D)
[ADVT-III/4/Exty./392/18]"

15. Since the present cases, along with the batch of matters they were tagged with, raised important questions of law and were an offshoot of the earlier decision rendered by this Court in ***Mohd. Ahmed (Minor) Vs. Union of India, 2014 SCC OnLine Del 1508***, Ms. Shyel Trehan, Advocate was appointed as the learned Amicus Curiae.

ARGUMENTS ON BEHALF OF LEARNED AMICUS CURIAE

16. Ms. Shyel Trehan, learned Amicus Curiae stated that in view of the amendments carried out by ESI Corporation to impugned Clauses 5.1 and

5.3 of the Guidelines titled *ESIC Decisions on Medical Services-July, 2014* during the pendency of the writ petitions, the challenge to Clause 5.1 did not survive as each case had to be examined on its merits by a Committee constituted by ESI Corporation Headquarter office, irrespective of the cost involved in the treatment.

17. She further stated that the challenge to impugned Clause 5.3 survived to the extent that Guideline Nos. 1 and 2 provided a different commencement date for entitlement to Super Speciality Treatment of Insured Person viz-a-viz his/her family members and Guideline No. 3 to the extent it stipulated that neither the Insured Person nor his/her family members would be entitled to Super Speciality Treatment if the employer of the Insured Person had failed to pay the monthly contribution in terms of Section 44 of the ESI Act.

18. A chart handed over by Ms. Shyel Trehan indicating the amendments carried out to Clause 5.3 during the pendency of the present proceeding is reproduced hereinbelow:-

DEFINITION AS PER THE ACT	***AS PER ESIC DECISION ON MEDICAL SERVICES-JULY 2014***	***AMENDMENT VIDE NOTIFICATION DATED 07.11.2016***	***AS PER OFFICE MEMORANDUM DATED 29.10.2018***
FAMILY- *Family is defined under Section 2(11) of the ESI Act as follows:-* *" family " means all or any of the following relatives of an insured person, namely : —* *(i) a spouse ;* *(ii) a minor legitimate or*	***Clause 5.3*** *In respect of children of IP, congenital diseases requiring referral to SST and genetic dis-orders would be eligible for coverage up to the ceiling mentioned earlier only in case the child is born after*	***Amendment to Clause 5.3*** *The IP should have been in continuous employment for last two years as on date of diagnosis of the SST (other than cases of employment injury) and at least 156 days of*	***Guideline No. 2*** *The members of family of the Insured Persons be allowed super speciality treatment if the Insured Person has contributed 156 days (78 days in each contribution period) and have*

adopted child dependent upon the insured person ; *(iii) a child who is wholly dependent on the earnings of the insured person and who is —* *(a) receiving education, till he or she attains the age of twenty-one years,* *(b) an unmarried daughter ;* *(iv) a child who is infirm by reason of any physical or mental abnormality or injury and is wholly dependent on the earnings of the insured person, so long as the infirmity continues* *(v) dependant parents, whose income from all sources does not exceed such income as may be prescribed by the Central Government ;* *(vi) in case the insured person is unmarried and his or her parents are not alive, a minor brother or sister wholly*	*the IP had become eligible for SST.*	*contribution was paid by the Insured Person during the immediately preceding four contribution periods with eligibility for sickness benefit in at least two benefit periods.* *<u>After completion of the above period the IP and family will be eligible for the SST including the children of IP with congenital diseases and genetic disorder.</u>*	*completed minimum one year of insurable employment from the date of registration.*

dependant upon the earnings of the insured person			
Insured Person *Insured Person is defined under Section 2(14) of the ESI Act as follows :* *"insured person" means a person who is or was an employee in respect of whom contributions are or were payable under this Act and who is, by reason thereof, entitled to any of the benefits provided by this Act*		***Amendment to Clause 5.3*** *The IP should have been in continuous employment for last two years as on date of diagnosis of the SST (other than cases of employment injury) and at least 156 days of contribution was paid by the Insured Person during the immediately preceding four contribution periods with eligibility for sickness benefit in at least two benefit periods.* *<u>After completion of the above period the IP and family will be eligible for the SST including the children of IP with congenital diseases and genetic disorder.</u>*	***Guideline No. 1.*** *"The Insured Person who has contributed for 78 days in a contribution period be allowed to avail super speciality treatment provided he/she has completed minimum of six months of insurable employment i.e. from the date of registration on IP Portal"* ***Guideline No. 3*** *"In both the above cases, the employer should have filed the monthly contribution as per Section 44 read with regulation 26(a) failing which Regulation 31 of the ESI(General) Regulation, 1950".* ***Guideline No. 4*** *"This shall be available only in the corresponding benefit period".* ***Guideline No. 5*** *"Insured persons and their family members shall continue to avail the super speciality if the Insured Persons*

			is in receipt of extended sickness benefits". ***Guideline No. 6*** *"Insured Women shall be eligible for super speciality treatment in case it arises due to or out of maternity if she is in receipt of maternity benefit".* ***Guideline No. 7*** *"The cases of employment injury shall not attract the aforesaid conditions.* *The aforesaid conditions shall apply only in those cases where expenditure of the treatment for reference is made outside the ESI set-up and is to be paid by the ESCI without share of the State Govt. In cases, Insured Person or their family member requires treatment which is not available in ESI Hospital or ESI Medical Education Institutions and aforesaid eligibility conditions are not met by the Insured Person, such cases be referred to Hospitals/Medical Colleges of the State Govt., who are duty*

			bound to render services to a citizen."

19. Ms. Shyel Trehan, learned Amicus Curiae submitted that Guidelines Nos. 1 and 2 of the Executive Order dated 29th October, 2018 to the extent they introduced different set of eligibility conditions for the Insured Person and his/her family, were inconsistent with Regulation 95A(2) of Regulations, 1950, inasmuch as the said Regulation prescribes that the family of an insured person shall become entitled to medical benefit from the day the insured person himself becomes entitled to medical benefit and shall continue to be so entitled so long as the insured person is entitled to receive medical benefit for himself, or in the case of death of the insured person till such date upto which the insured person would have remained entitled to medical care had he survived.

20. She pointed out that in terms of Guideline No. 3 of Office Memorandum dated 29th October, 2018, the condition precedent for the Insured Person and his family members to avail Super Speciality Treatment, was that the Employers necessarily had to file their respective monthly contribution in terms of Section 44 of ESI Act read with Regulation 26(a) and Regulation 3 of Regulations, 1950. In other words, according to her, a failure on part of the employers to pay their contribution, in terms of the said memorandum would disentitle the Insured Person as well as his family members to avail the medical benefit under ESI Act.

21. She submitted that the Guideline No. 3 was inconsistent with Sections 85 and 85 B of the ESI Act, inasmuch as the said provisions prescribe only certain damages/punishment/penalty to be inflicted on the person who had

failed to pay the contribution. The relevant portion of the aforesaid Sections, is reproduced hereinbelow:-

*"**85. Punishment for failure to pay contributions, etc.** — If any person —*

(a) fails to pay any contribution which under this Act he is liable to pay, or

(b) deducts or attempts to deduct from the wages of an employee the whole or any part of the employer's contribution, or

(c) in contravention of section 72 reduces the wages or any privileges or benefits admissible to an employee, or

(d) in contravention of section 73 or any regulation dismisses, discharges, reduces or otherwise punishes an employee, or

(e) fails or refuses to submit any return required by the regulations or makes a false return, or

(f) obstructs any Inspector or other official of the corporation in the discharge of his duties, or

(g) is guilty of any contravention of or non-compliance with any of the requirements of this Act or the rules or the regulations in respect of which no special penalty is provided,

[he shall be punishable —

[(i) where he commits an offence under clause (a), with imprisonment for a term which may extend to three years but—

(a) which shall not be less than one year, in case of failure to pay the employee's contribution which has been deducted by him from the employee's wages and shall also be liable to fine of ten thousand rupees ;

(b) which shall not be less than six months, in any other case and shall also be liable to fine of five thousand rupees :

Provided that the Court may, for any adequate and special reasons to be recorded in the judgment, impose a sentence of imprisonment for a lesser term ;

(ii) where he commits an offence under any of the clauses (b) to (g) (both inclusive), with imprisonment for a term which may extend to one year or with fine which may extend to four thousand rupees, or with both.]]

xxxx xxxx xxxx xxxx

85-B. Power to recover damages. *— (1) Where an employer fails to pay the amount due in respect of any contribution or any other amount payable under this Act, the Corporation may recover 3 [from the employer by way of penalty such damages, not exceeding the amount of arrears as may be specified in the regulations]:*

Provided that before recovering such damages, the employer shall be given a reasonable opportunity of being heard:

[Provided further that the Corporation may reduce or waive the damages recoverable under this section in relation to an establishment which is a sick industrial company in respect of which a scheme for rehabilitation has been sanctioned by the Board for Industrial and Financial Reconstruction established under section 4 of the Sick Industrial Companies (Special Provisions) Act, 1985 (1 of 1986), subject to such terms and conditions as may be specified in regulations.].

(2) Any damages recoverable under sub-section (1) may be recovered as an arrear of land revenue 1 [or under section 45-C to section 45-I].”

ARGUMENTS ON BEHALF OF THE PETITIONERS

22. Mr. Ashok Aggarwal, learned counsel for the petitioners submitted that the impugned Clauses 5.1 and 5.3 of the *ESIC Decision on Medical Services July, 2014* and subsequent amendments thereto are violative of the Articles 14, 21, 39, 41 and 47 of the Constitution of India. He emphasised that in the case of ***Mohd. Ahmed (Minor) Vs. Union of India*** (supra) dealing with similar facts, this Court has already held that State is under a duty to provide medical aid on fair, reasonable, equitable and affordable basis. Thus, according to him, ESI Corporation was bound to provide the treatment to the two petitioners.

ARGUMENTS ON BEHALF OF ESI CORPORATION

23. Per contra, Mr. Yakesh Anand, learned counsel for ESI Corporation submitted that the objective of ESI Act was to provide certain benefits to employees in cases of sickness, maternity and employment injury. He emphasised that the ESI Act provides for *"Reasonable Medical Services"* only.

24. He pointed out that Health is a State subject under the Constitution of India and the State Government has the primary responsibility to provide quality health care services to the people. He stated that though ESI Corporation can support the State Governments by infusing funds, yet the primary duty of providing medical services to the people remains with the State Governments. He submitted that the ESI Corporation cannot act as a "State" for the purpose of providing medical services.

25. Mr. Yakesh Anand further stated that ESI Corporation is a self aided/funded organisation deriving its funds primarily from the statutory contributions collected from the employers and the employees (Insured Persons) as per the provisions of the ESI Act. He contended that ESI Corporation holds the funds so derived from the contributions in the capacity of a trustee and is therefore responsible for ensuring that the said funds are not misused. He emphasised that though ESI Corporation is not an insurance company, yet it works on the basic principle of insurance and it is the duty of ESI Corporation to check the misuse of the limited funds derived from the contributions made by the employers and the employees.

26. Mr. Yakesh Anand stated that as the process for registration with ESI Corporation is relatively easy and does not involve stringent scrutiny, the funds of ESI Corporation are very vulnerable. He stated that the medical

benefits under Super Speciality Treatment had been misused by some of the Insured Persons and also by some persons who were otherwise not entitled to claim the benefits under ESI Corporation Scheme. He pointed out that in the case of ***Baby Nisha and Anr. Vs. Employees State Insurance Corporation and Another, W.P.(C) 1506/2016*** the father of the patient had manipulated the records to avail the Super Speciality Treatment for his minor daughter. He stated that the amended Clause 5.3 intends to filter out the frivolous cases wherein the insured person deliberately register themselves under the ESI Act just to avail the medical treatment.

27. He submitted that the eligibility criteria of minimum period of service, i.e., six months (in case of insured persons) and period of one year (in case of family of the insured persons) had been kept to ensure judicious and rational utilization of the funds and to ensure that the costly treatment is availed by the genuine insured persons who had been registered and had paid minimum contributions. He pointed out that the treatment such as Enzyme Replacement Therapy costs over Rupees One Crore Eighty Lacs per year per patient and that the ESI Corporation had already spent a sum of Rupees Thirteen Crores on the treatment of ten patients.

REJOINDER ARGUMENTS ON BEHALF OF PETITIONERS

28. In rejoinder, learned counsel for the petitioners submitted that in order to come within the ambit of the ESI Act, all that an individual has to do is to join employment, which is as much a necessity as a fundamental right under Article 19(1)(g) of the Constitution of India. He stated that the ESI Act does not stipulate that if an employee is aware that his/her family member has an ailment which requires Super Speciality Treatment, the employee would be

precluded from joining employment or availing the benefits under the ESI Act. He further stated that it could not be said that joining employment of such an employee would amount to a "fraud". He contended that in all probability if such an employee were to get a job, he/she would be more driven by the direct benefits of employment and less by the benefit for his family members' treatment. He contended that in any event there is no means to gauge the relative weight of consideration that would have prompted the Insured Person to join employment and also availing of such a benefit would at best be "utilization" and not "misuse" of the funds of the ESI Corporation.

29. Learned counsel for the petitioners clarified that it was not the petitioners case that a person who was not eligible under law should be benefitted. He contended that the question in the present case was with regard to who was eligible and the ESI Corporation's argument regarding misuse of its funds was unfounded. He stated that the only case that the ESI Corporation had cited was that of ***Baby Nisha and Anr. Vs. Employees State Insurance Corporation and Another, W.P.(C) 1506/2016*** which had no nexus to the controversy in the present case.

30. Learned counsel for the petitioners stated that the ESI Corporation had not brought on record anything to indicate that it was facing any shortage of funds. He pointed out that according to information received vide letter dated 20thFebruary, 2019 under the RTI Act, presently ESI Corporation had a surplus revenue of Rs. 15151.89 cores (Rupees Fifteen Thousand One Hundred and Fifty One Crore) in 2017-18.

31. In any event, he contended that the ESI Corporation had statutory means available to it, to avert financial crisis. He submitted that in

accordance with Section 26(2) of the ESI Act, the ESI Corporation could accept grants, gifts and donations from the Central Government, State Governments, local authorities and individuals or bodies.

32. Learned counsel for the petitioners submitted that the ESI Act, was an ideal legislation which took into its ambit a population of around fifty crore. He stated that due to improper implementation of the ESI Act, presently only thirteen crore beneficiaries with two crore insured persons were registered with ESI Corporation.

COURT'S REASONING

AS THE POLICY VACUUM, AS FAR AS RARE DISEASES GO, STILL CONTINUES, THIS COURT IS OF THE VIEW THAT IT IS OPEN TO IT TO PASS NECESSARY ORDERS TO PROTECT THE RIGHT OF LIFE OF CITIZENS.

33. This Court in the case of ***Mohd. Ahmed (Minor) Vs. Union of India*** (supra) after relying upon the judgment of the Apex Court in ***Paschim Bengal Khet Mazdoor Samity & Anr. Vs. State of Bengal, 1996 4 SCC 37*** has held as under:-

> *" 57. ……The Supreme Court observed that the obligation to provide medical care was an obligation of the welfare state and held "The Constitution envisages the establishment of a welfare State at the federal level as well as at the State level. In a welfare State the primary duty of the Government is to secure the welfare of the people. Providing adequate medical facilities for the people is an essential part of the obligations undertaken by the Government in a welfare State. The Government discharges this obligation by running hospitals and health centres which provide medical care to the person seeking to avail of those facilities. Article 21 imposes an obligation on the State to safeguard the*

right to life of every person. Preservation of human life is thus of paramount importance. The government hospitals run by the State and the medical officers employed therein are duty-bound to extend medical assistance for preserving human life. Failure on the part of a government hospital to provide timely medical treatment to a person in need of such treatment results in violation of his right to life guaranteed under Article 21. .....It is no doubt true that financial resources are needed for providing these facilities. But at the same time it cannot be ignored that it is the constitutional obligation of the State to provide adequate medical services to the people. Whatever is necessary for this purpose has to be done.....In the matter of allocation of funds for medical services the said constitutional obligation of the State, has to be kept in view. It is necessary that a time-bound plan for providing these services should be chalked out keeping in view the recommendations of the Committee as well as the requirements for ensuring availability of proper medical services in this regard as indicated by us and steps should be taken to implement the same." (emphasis supplied).

58. Consequently, right to health and health care access are a part of Articles 21, 38 and 46 of the Constitution. Accordingly, every person has a fundamental right to quality health care -- that is affordable, accessible and compassionate.

xxxxx xxxx xxxx xxxx

80. This Court is of the view that Government needs to seriously consider expanding its health budget if their right to life and right to equality as enumerated in Articles 14 and 21, are not to be rendered illusionary. If poor patients are to enjoy benefit of recent innovations in the medical field, like robotic surgery, genome engineering the Government must immediately think of increasing its investment in the health sector.

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*85. To conclude, today, on account of lack of Government planning, there is **'pricing out'** of orphan drugs for rare and chronic diseases, like Gaucher. The enzyme replacement therapy is so expensive that there is a breach of constitutional obligation of the Government to provide medical aid on fair, reasonable, equitable and affordable basis. By their inaction, the Central*

and the State Governments have violated Articles 14 and 21 of the Constitution.

86. Just because someone is poor, the State cannot allow him to die. In fact, Government is bound to ensure that poor and vulnerable sections of society have access to treatment for rare and chronic diseases, like Gaucher especially when the prognosis is good and there is a likelihood of the patient leading a normal life. After all, health is not a luxury and should not be the sole possession of a privileged few.

87. Although obligations under Article 21 are generally understood to be progressively realizable depending on maximum available resources, yet certain obligations are considered core and non-derogable irrespective of resource constraints. Providing access to essential medicines at affordable prices is one such core obligation."

(emphasis supplied)

34. As despite the directions rendered in ***Mohd. Ahmed (Minor) Vs. Union of India*** (supra), the Union of India had not taken any step towards formulating a policy for tackling rare diseases and promoting the development of orphan drugs, this Court directed the Ministry of Health and Family Welfare (hereinafter referred to as "Ministry") to convene a meeting with the Secretary, Ministry of Labour, Secretary, Ministry of Corporate Affairs, and Director General, ESI Corporation.

35. In pursuance to the said order, minutes of meeting dated 13th October, 2016 were placed on record, wherein it was stated that a national policy on treatment of rare diseases shall be prepared within six to eight months.

36. Subsequently, the Ministry formulated the National Policy for Treatment of Rare Diseases (for short "Policy") to provide for treatment of patients suffering from rare diseases, who were not eligible for financial assistance under any other health scheme being run by the Central

Government or State Government. The Policy after receiving the approval from the Hon'ble Union Minister for Health and Family Welfare, was directed to be implemented vide Office Memorandum dated 27th July, 2017. The relevant portion of the said Policy, is reproduced hereinbelow:-

> *"**EXECUTIVE SUMMARY***
>
> ***Rare Diseases***
>
> *A rare disease is a health condition of particularly low prevalence that affects a small number of people compared with other prevalent diseases in the general population. It is estimated that globally around 6000 to 8000 rare diseases exist with new rare diseases being reported regularly in the medical literature. The prevalence distribution of rare diseases is skewed – 80% of all rare disease patients are affected by approximately 350 rare diseases.*
>
> *Paradoxically, though rare diseases are of low prevalence and individually rare, collectively they affect a considerable proportion of the population in any country, which according to generally accepted international research is – between 6% and 8%. Rare diseases include genetic diseases, rare cancers, infectious tropic diseases and degenerative diseases. 80% of rare diseases are genetic in origin and hence disproportionately impact children.*
>
> *There is no universally accepted definition of a rare disease and the definitions usually vary across jurisdictions. However, the common considerations in the definitions are primarily, disease prevalence and to varying extent – severity and existence of alternative therapeutic options. India will have to arrive at its own definition suited to its need, based on a careful consideration of prevalence, disease and study-ability.*
>
> ***Rare Diseases as a public health in India***
>
> *So far only about 450 rare diseases have been recorded in India. The field of rare diseases is complex, heterogeneous, continuously evolving and suffers from a deficit of medical and scientific knowledge. Rare diseases pose a significant challenge to public health systems in terms of – difficulty in collecting epidemiological data impeding burden and cost estimations, making correct and*

timely diagnosis, challenges in research and development, unavailability and prohibitive cost of treatment.

Rare diseases constitute a major economic burden independent of a country's size and demographics arising from increased healthcare spending. As resources are limited, there is a macroeconomic allocation dilemma: on one hand, health problems of a much larger number of persons can be addressed by allocating a relatively smaller amount, on the other, for funding treatment of rare diseases, much greater resources will be required for addressing health problems of a relatively smaller number of persons.

Need for a Policy

Rare diseases are, in most cases, serious, chronic, debilitating and life threatening, often requiring long and specialised treatments. In addition, they often result in some form of handicap, sometimes extremely severe. 50% of new cases are in children and are responsible for 35% of deaths before the age of 1 year, 10% between the ages of 1 and 5 years and 12% between 5 and 15 years.

Further, the impact on families is often catastrophic in terms of emotional as well as financial drain, as the cost of treatment is prohibitively high. This has resulted in parents of children suffering from rare diseases, whose treatment cost were not being covered by insurance or otherwise not being reimbursed, in approaching the courts seeking directions that the government provide the drugs for free. The Hon'ble High Court of Delhi in W.P.(C) No.4444/2016, W.P.(C) No.7730/2016 and W.P.(C) No.7729/2013, directed the Ministry of Health & Family Welfare to frame a "national policy on treatment of rare diseases."

Furthermore, a policy is required to devise a multipronged approach to building India's capacity to tackle rare diseases comprehensively, in areas of – epidemiological data for estimating burden, arriving at a definition and for cost estimation of treatment; research and development for treatment and diagnostic modalities, including through international collaboration; training of health care providers; awareness generation; creating conducive

environment for drug development and measures for affordability of treatment etc.

Policy Direction

The GOI appointed committees to make recommendations towards formulation of 'Policy on treatment of rare diseases'. The committees made a gamut of recommendations, which were incorporated in this Policy. The Policy highlights the measures and steps, both in the short as well as in the long term, that need to be taken to deal comprehensively with rare diseases. However, recognizing the exorbitant cost of treatment for rare diseases, the policy seeks to strike a balance between access to treatments with health system sustainability.

A. Immediate Measures

- *Constituting a Consultative Committee (inter-ministerial) at National Level*
- *Constituting a Technical cum Administrative Committee at Central as well as State levels for management of and release of corpus funds*
- *Creating a corpus fund at Central and State Level for part funding treatment of rare diseases*
- *Creating a Web-based application for online application process*
- *Developing materials for generating awareness in the general public, patients and their families and health care providers*

B. Long term measures; deliberate, concrete steps towards progressive realisation

- *Creating a patient registry for rare diseases*
- *Putting systems in place for reporting and data collection*
- *Conducting epidemiological study to estimate prevalence of rare diseases*

- *Arriving at a definition of rare diseases based on epidemiological study and reporting*
- *Taking measures to improve research and development for treatment, diagnostic modalities, care and support, drug development of orphan drugs etc.*
- *Taking measures, legislative or otherwise, to create a conducive environment for encouraging local manufacturing of orphan drugs and to control the prices of drugs to make them more affordable*
- *Encouraging funding support from PSUs and corporate sector and exploring other options for sustainable funding for the corpus*
- *Ensuring insurance coverage for rare diseases, including genetic disorders*
- *Allowing import of ERTs and removing import duty on them*

Multi-sectoral convergent approach to tackling rare diseases

The Policy delineates the role of several ministries in achieving the measures envisaged. Each Ministry and concerned department is required to develop an implementation framework on measures to be taken by them on their sector wise response to tackling rare diseases.

xxxx xxxx xxxx xxxx

4.1. Implementation Mechanism

The Policy highlights the measures and steps that ought to be taken immediately and also those that can be implemented progressively in phases. It also highlights the role of various ministries and departments, which at present is indicative and can be further extended based on adequate evidence and data gathered from epidemiological studies and research.

The Policy envisages setting up a Consultative Committee for implementing the policy in coordination with various ministries and departments. There will also be a Technical cum Administrative Committee within MoHFW, both at the Central and State Levels,

for handling the corpus fund and technical issues related thereto. The ministries, including MoHFW will design their own roadmap for implementation of the activities indicated below.

4.2. Strategies for implementation

A. Immediate Measures

- *Constituting a Consultative Committee (inter-ministerial) at National Level*
- *Constituting a Technical cum Administrative Committee at Central as well as State levels for management of and release of corpus funds and developing various technical requirements for identification and treatment of rare diseases*
- *Creating a corpus fund at Central and State Level for treatment of rare diseases*
- *Creating a web-based application for online application process*
- *On the basis of the current knowledge, developing materials for generating awareness in the general public, patients and their families and health care providers. To be revised with availability of new information and knowledge*

B. Long term measures for progressive realisation through a roadmap with phases and benchmarks

- *Creating a patient registry for rare diseases*
- *Putting systems in place for reporting and data collection*
- *Conducting epidemiological study to estimate prevalence of rare diseases*
- *Arriving at a definition of rare disease based on epidemiological study and reporting*

- *Taking measures to improve research and development for treatment, diagnostic modalities, care and support, drug development of orphan drugs etc.*
- *Taking measures, legislative or otherwise, to create a conducive environment for encouraging local manufacturing of orphan drugs and to control the prices of drugs to make them more affordable*
- *Encouraging funding support from PSUs and corporate sector and exploring other options for sustainable funding for the corpus*
- *Ensuring insurance coverage for rare diseases, including genetic disorders*
- *Allowing import of ERTs and removing import duty on them*
- *Strengthening/establishing laboratories for supporting technical activities required for rare diseases.*

4.3 Role of ministries and departments

The activities indicated below are indicative and can be expanded depending on improvement in our knowledge and understanding of rare diseases and the type of response it will require, based on availability of data an evidence generated through research and studies.

4.3.1 Ministry of Health and Family Welfare

a) Health Ministry to create a cell on rare diseases within itself, to be headed by a Joint Secretary and constituting 2 consultants. It will act as a nodal agency and coordinate all the activities of the Health Ministry on rare diseases.
b) Indian Council of Medical Research (ICMR) to constitute a division or identify one of its existing divisions, to promote research and development in the field of rare diseases for diagnosis and treatment of rare diseases, including through international/regional collaborations.
c) Define TOR and responsibilities of Consultative Committee and also of the Technical cum Administrative Committee for Corpus funds (discussed below).

d) Create a patient registry with information to practitioners and a reporting system of any patient diagnosed with a rare disease. This will be housed in ICMR. Patient registries may serve as appropriate tool to aid in understanding the natural history and clinical characteristics of rare diseases and assess the long-term outcomes of treatment.

e) Take measures to collect epidemiological data on rare diseases.

f) Take measures to create awareness among medical professionals, patients and their families and general public on rare diseases.

g) Drug Controller General of India (DCGI) to consider feasibility of amending Drugs and Cosmetics Act or otherwise taking measures under it, to include appropriate provisions on orphan drugs including provisions to facilitate clinical trials and import of ERTs.

h) For patients in BPL category who get identified with rare diseases, make available for free and supportive services, whether in private or government hospital.

i) ICD 11 classifies about 5000 rare diseases. The centres identified by the Central/State government for categorising rare diseases in India, need to group/put rare diseases under already identified disease classification under ICD 11. If any new rare disease is identified, steps will be taken by the Ministry for sending required evidence to WHO for inclusion of the disease under ICD classification.

j) Central/State Governments will support in strengthening/establishing laboratories required for various technical activities related to rare diseases.

k) As a preventive measure, consider feasibility of providing pre-conception and ante-natal genetic counseling and screening programmes for diagnosing genetic disorders, which would provide a choice to parents about giving birth to children with genetic disorders, especially to families that have a diagnosed genetic disorder or a high risk for it.

l) Central/State Government shall utilize existing new born screening programme for early detection of treatable rare diseases, to the extent considered feasible.

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 crores 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 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 of 60:40 out of the central pool. It would be upto 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 (haemophilia, thalassemia and sickle cell anemia) or for rare cancers, as separate governments 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 Undertakings (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).*

n) Creating a web-based application for online application process

To ensure timely decisions and release of funds, a web-based application would be developed for creating online mechanism for applying to the corpus. Central government will create this web-based application within 6-12 months of

the release of this policy. It will have the details of the corpus and instructions and mechanism for applying for funding. It would be open to both individuals as well as institutions as well as state government to apply for funds by entering details on the web application as per instruction provided.

4.3.2 Ministry of Chemicals and Fertilizers, Department of Pharmaceuticals

a) Constitute a Cell within Dept. of Pharmaceuticals to promote drug development and affordability of drugs for rare diseases.

b) Consider mechanisms, legislative or otherwise, for creating a conducive environment for indigenous manufacture of drugs for rare diseases at affordable prices.

4.3.3. Ministry of Corporate Affairs

Encourage PSUs and corporate houses to contribute to the corpus as per the 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). Preventive and promotive health care is included in the list in the Schedule for CSR activities.

4.3.4 Ministry of Finance

a) Department of Revenue to consider removing import duty on ERTs.

b) Department of Financial Services to explore on the basis of actuarial studies, whether insurance sector should cover cost of treatment of rare diseases and amend the Insurance Act accordingly. It is necessary to bring in health insurance reforms through IRDA (Insurance Regulatory and Development Authority of India) and government intervention.

4.3.5 Ministry of Labour and Employment

Employees State Insurance Corporation (ESIC) to explore whether the ceiling limit on funding treatment for rare diseases can be increased through suitable amendments.

4.4 Implementation Framework on way forward

Each Ministry and concerned department should develop an implementation framework on actions points to be taken by them on their sector wise response to tackling rare diseases. The implementation framework should have a clear targeted approach, complete with indicators and benchmarks (where applicable) and progressive realisation through phases.

4.5 Setting Up of Committees

4.5.1 Constitution of Consultative Committee

Government of India (GOI) to constitute a Consultative Committee headed by Secretary Health to coordinate the initiatives taken by the different ministries and departments. Its meetings could be held at least once in a year.

4.5.2 Constitution of Technical cum Administrative Committee

a) There will be a Central Technical cum Administrative Committee for the national corpus. It will be chaired by the Additional Secretary/Joint Secretary and have such members as considered necessary.

b) There will be Technical cum Administrative Committee at the State level for the State Corpus. It will be chaired by the Secretary and have such members as considered necessary.

c) The Committees will meet once in three months.

d) The State corpus could be operated at the State level under the oversight of the Central Committee.

4.5.3 The Broad Role of the Technical cum Administrative Committees

a) Central Committee will develop a priority list of rare disorders for which funding support will be considered, on the basis of – disease severity, availability of treatment, reasonably proven clinical outcome, cost data, cost effectiveness. It will develop the priority list with due regard to the recommendations of the government appointed committees.

b) Central Committee will develop objective inclusion/exclusion criteria on the basis of which applications for funding support will be decided and the extent of funding to be provided will be determined. The inclusion/exclusion criteria will include household income of patient, curability of condition and cost effectiveness etc. This will also be developed according to the recommendations of the committee.

c) The Central Committee will also develop criteria on the basis of which the progress of the patients whose treatment is part funded, will be reviewed.

d) The Central and State Committees will identify and accredit institutions that will carry out diagnosis of rare diseases, and institutions that will provide treatment for rare diseases, and institutions that will both diagnose and treat rare diseases.

e) The State Committees will review the applications received on the website and decide on the applications – whether to fund and fund to what extent – as per the details entered and the criteria developed by the Central Committee.

f) The State committees will also review the progress of the case and evaluate whether the clinical condition of the patient is being improved by the therapy."

37. On 11th August, 2017, Mr. Luv Aggarwal, Joint Secretary, Ministry of Health and Family Welfare made a presentation with regard to the Policy. This Court recorded its appreciation for the services rendered by Mr. Luv Aggarwal and observed that the presentation had been helpful in understanding the intricate issues involved in the cases. This Court on the

said date also directed the Ministry to file an affidavit indicating the steps undertaken by it to implement the Policy at the ground level. The Govt. of NCT of Delhi was also directed to follow up with the Union of India and submit a proposal for utilising the funds from the available corpus and ensure that the State Level Committee as envisaged is formed and treatment of patients commences at the earliest.

38. On 08th December, 2017, this Court was informed that the National Health Mission had earmarked Rupees One Hundred crore towards Central assistance to the States as Central Share of sixty per cent of the approved cost for treatment of rare and genetic diseases. This Court was also informed that the Central Government had appointed a Central Technical-cum-Administrative Committee vide order dated 13th September, 2017 and Inter-Ministerial Coordination Committee under the Chairmanship of Additional Secretary (Public Health) for inter-ministerial co-ordination.

39. Thereafter, the Government of National Capital Territory of Delhi constituted a Rare Diseases Board as well as Technical-cum-Administrative Committee at the State level and set up an initial corpus of Rupees One Hundred Crores.

40. This Court on 16th March, 2018 after hearing arguments was of the *prima facie* opinion that not many patients even Above Poverty Line (for short "APL") could afford the treatment for rare diseases. This Court pointed out that in accordance with its judgment in ***Mohd. Ahmed (Minor) Vs. Union of India*** (supra) patients suffering from the rare diseases constitute a separate class irrespective of the fact whether they belong to below or above poverty line inasmuch as the price of drugs for 'Orphan Diseases' are exorbitant. Consequently, this Court directed the Central

Government to consider grant of financial assistance even to patients belonging to APL. This Court further directed that in future whenever Govt. of National Capital Territory of Delhi forwarded any application of patients suffering from rare diseases to Central Technical Committee, it would also forward the name of the doctors who had processed the case of the patient along with their mobile number so that the members of the Central Technical Committee could speak to the concerned doctors in case they had any doubt.

41. However, as the petitioners on subsequent dates were raising grievances that their cases were not being processed in accordance with the Policy, this Court vide order dated 31st August, 2018 directed the Member Secretary, Central Technical Committee as well as Director (NHM), Ministry to make a "walk through presentation", i.e. as of that day how a patient's application was being processed by different authorities at the different stages and what interaction the patient was having with the authorities and hospitals in accordance with the Policy.

42. Surprisingly, on 30th November, 2018 the Joint Secretary, Ministry in its presentation highlighted major lapses in the existing Policy. In fact, the sum and substance of his presentation was that the Policy had been illegally and erroneously framed. This Court in the order dated 30th November, 2018 recorded that, *"the sum and substance of his presentation is that the National Policy had been illegally and erroneously framed inasmuch as public health is a State subject and concurrence of most states had not been obtained prior to the framing of the policy. He further states that though the work of rare diseases has been transferred from the Public Health Division to the National Health Division, yet it is difficult for the National Health*

Mission (for short "NHM") to support the treatment of the rare diseases as the same falls under the Tertiary Sector and the mandate of the NHM is only for primary and secondary care. In response to a query, he states that no funds leave alone Rs. 100 Crores had been allocated for the said National Policy. He contends that a decision has been taken to re-frame the policy and for this purpose, an Expert Committee has been appointed".

43. Consequently, this Court directed the Ministry to place on record a fresh affidavit to explain the withdrawal of the previous affidavits dated 05th December, 2017 and 14th March, 2018.

44. Accordingly, the affidavit of the Union of India dated 15th December, 2018 came to be filed in which the following reasons for withdrawal of the said Policy were given:-

a. Though vide affidavit dated 14th March, 2018, it was stated that a corpus of Rs. 100 Crore had been created under NHM, yet no such corpus had been created. The affidavit dated 14th March, 2018 was rendered under an honest mistaken belief that funds had been earmarked.

b. In the Affidavit dated 14th March, 2018, it was submitted that States had been asked to seek central assistance of the 60% of the approved cost of the treatment through State PIPs. However, as per para 4.3.1.(o), the role of the Central Government was to contribute 60:40 ratio in the corpus created by the States. The provision of 60:40 under the Policy was for contribution to the corpus for Central and State Governments and it did not mean that the entire cost of treatment of the individual patient would be borne by the Central and State Governments in the ratio of 60:40.

c. The limiting factor for the implementation of the policy was that it had to be implemented under NHM, which did not cover tertiary care and Rare Disease management essentially fall under Tertiary Care.

d. Public Health and Hospitals is a State Subject. Most of the States were either ignorant about the Policy or had started questioning the feasibility of it.

e. Government of Kerala asked the Ministry to defray the total interventions, which was not cost effective, or to resort to compulsory licensing of these drugs so that the cost was reasonable or to amend the Policy stating that health is a state subject.

f. Only six states had constituted the State Technical Committees and two of those states namely State of Tamil Nadu and Delhi had objected to the financial burden imposed on the States vide letter dated 05th December, 2018 and 12th December, 2018 respectively.

g. The policy was not feasible to implement due to issues of cost effectiveness and lack of resources.

h. Given the challenges in implementing the Policy, an expert committee had been constituted vide order dated 16th November, 2018 to reframe the Policy.

i. Pending final decision on the Policy, the Policy had been kept in abeyance on 29th November, 2018 with the approval of the Union Minister of Health and Family Welfare.

45. The following interim measures were also proposed by Union of India in its affidavit dated 15th December, 2018:-

a. To add a new sub-scheme under the already existing Rashtriya Arogya Nidhi, (for short "RAN"), for providing one-time assistance to poor patients of Rare Disease living Below Poverty Line (BPL), which would be a centrally administered scheme of Central Government.
b. States would be free to develop their mechanism for supporting the rare disease patients.
c. Based on the priority list of known rare disease for financial assistance for BPL Patients, as submitted by CTC in 2017, diseases amenable to a one time treatment had been proposed under the proposed sub-scheme under RAN for rare diseases.
d. Till the approval of sub-scheme of Rare Disease under RAN was obtained, in case of diseases amenable to one time treatment that were not coming under the illustrative list of categories annexed to the existing RAN Scheme, the same would be considered under the Miscellaneous head of RAN scheme as per RAN guidelines, subject to the Technical Committee of RAN recommending the same.
e. Recognizing the need for secondary care and tertiary care, the Pradhan Mantri Jan ArogyaYojna component of Ayushman Bharat already provided a cover of Rs. 5 lakh per year.
f. Ministry had requested the Department of Pharmaceuticals to explore the feasibility of capping the price for the drugs used for treatment of Rare Diseases vide letter dated 29th November, 2018.

46. Vide order dated 17th December, 2018, the affidavit dated 15th December, 2018 was taken on record and the Secretary of the Ministry was directed to be personally present in Court on the next date of hearing.

47. Subsequently, the Ministry filed another affidavit dated 07th February, 2019, stating the following: -

a. Prognosis of two patients, namely, Baby Arshi and Master Ubed was not good and that ERT alone was unlikely to have a significant effect on their life quality. It was recommended that both the patients could be offered cervical spinal cord decompression surgery, but the prognosis was guarded. A Writ Petition filed by the mother of Baby Arshi and Master Ubed is pending before the regular Roster Bench and is listed for hearing on 11th September, 2019;

b. Vide notification dated 18th December, 2018, the general public was informed that the Policy had been kept in abeyance till a revised policy was issued;

c. A new expert committee had been constituted to draft a revised policy;

d. To ensure that in the interim there was no vacuum, Ministry had approved a sub-component under the RAN, which would provide one-time financial assistance to the patients below BPL suffering from specific rare diseases, which require one time treatment. The said specific rare diseases were as suggested by the technical committee headed by Directorate General of Health Services.

e. In a bid to speed up assistance to the needy, under RAN, Revolving funds could be placed at the disposal of all government hospitals in Delhi to provide treatment upto Rs. 5 lakhs;

f. In cases of treatment beyond Rs. 5 lakhs in hospitals with revolving funds, such cases could be referred to Department of Health and Family Welfare;

g. Provision of Rs. 200 Crore under the umbrella scheme of RAN had been made for FY 2019-2020;

h. The Ministry had no scheme under which financial assistance on recurring basis could be provided for treatment of rare diseases like Gaucher, MPS etc. which require exorbitant expenditure. It was stated that the drugs were not manufactured domestically and the cost of imported drugs was very high. In light of resource constraints, there were compelling reasons to prioritize the available resources and the Ministry was constrained to assist patients for specified rare diseases requiring only one time assistance;

i. To create awareness about rare diseases, the Ministry had also proposed to tie up with ASHA workers;

48. On 08th February, 2019, pursuant to the directions of this Court, the Secretary of the Ministry was personally present in Court. She informed the Court that a notification dated 18th December, 2018 had been issued by the Ministry, indicating that the Policy had been kept in abeyance till a revised policy was issued. Ms. Preeti Sudan, the Secretary, Ministry undertook as follows:-

i) To notify a new policy within nine months after taking into consideration the judgment of this Court in ***Mohd. Ahmed (Minor) v. Union of India*** (supra) and US Orphan Drug Act, 1983 and other policies prevalent in other countries.

ii) To convene a meeting of all stakeholders within two weeks.

49. Accordingly, a meeting of all stakeholders was convened by the Ministry on 20th February, 2019.

50. This Court is of the view that with the withdrawal of the Policy, there continues to be a policy vacuum, similar to the circumstances which prompted the decision of this Court in the case of ***Mohammed Ahmed (Minor) v. Union of India*** (supra). In fact, the interim measures suggested by the Union of India are one time payments, which do not address the unique nature of the diseases suffered by the Petitioners, which require lifelong treatment.

51. While in terms of settled law, keeping in view the separation of powers as incorporated in the Constitution, the formulation of policy is within the exclusive domain of the executive and the Court should refrain from issuing directions for formulation of a policy, which has financial/ economic and other implications, [See ***J.K. Sawhney v. Punjab National Bank, 2010 VII AD (Delhi) 765)***] yet at the same time, the Supreme Court, while addressing the argument with respect to lack of resources, put forth by the State in case of ***Paschim Bengal Khet Mazdoor Samity & Anr.*** (supra), has held that it is the constitutional obligation of the State to provide adequate medical services to the people.

52. This Court, in case of ***Mohammed Ahmed (Minor) v. Union of India*** (supra) while balancing the Right to Health under Article 21 of the Constitution and the corresponding obligations of State under Articles 14 and 21, held that while the availability of finance with the Government is a relevant factor, but, at the same time, no Government ought to be allowed to say that it will not treat patients with chronic and rare diseases due to financial constraints, especially when their prognosis is good. It held:-

> *"69. Government cannot cite financial crunch as a reason not to fulfil its obligation to ensure access of medicines or to adopt a plan of action to treat rare diseases. In the opinion of this Court, no government can wriggle out of its core obligation of ensuring the right of access to health facilities for vulnerable and marginalised section of society, like the petitioner by stating that it cannot afford to provide treatment for rare and chronic diseases."*

53. As the policy vacuum, as far as rare diseases go, still continues, this Court is of the view that it is open to it to pass necessary orders to protect the right of life of citizens before it.

THE ESI ACT AND ITS REGULATIONS DO NOT EXCLUDE ANY SPECIFIC DISEASE, OR CREATE DISTINCTION BETWEEN PRIMARY, SECONDARY AND TERTIARY CARE. SOCIAL WELFARE LEGISLATIONS SUCH AS THE ESI ACT, HAVE TO BE CONSTRUED LIBERALLY, AND IN CASE OF ANY DOUBT, THE ISSUE HAS TO BE RESOLVED IN FAVOUR OF THE CLASS OF PERSONS FOR WHOSE BENEFIT THE STATUTE HAS BEEN ENACTED. FURTHER, ESI CORPORATION, BEING A STATUTORY CORPORATION AND A CREATURE OF ESI ACT, IS BOUND BY ITS PARENT ACT AND CANNOT CHALLENGE ITS VIRES. CONSEQUENTLY, THE ESI CORPORATION'S ARGUMENT THAT IT CAN PROVIDE ONLY REASONABLE MEDICAL SERVICES OR THAT IT IS NOT A STATE FOR THE PURPOSE OF PROVIDING SUPER SPECIALITY TREATMENT TO

INSURED PERSON AND/OR HIS/HER FAMILY MEMBERS, IS UNTENABLE IN LAW.

54. The ESI Corporation's argument that *"health being a State subject"* is State Governments' responsibility and that ESI Corporation cannot be held liable to provide Super Speciality Treatment to the Insured Person and to his/her family members, is fallacious.

55. The ESI Corporation by emphasising that health is a State subject, seems to be suggesting, rather vaguely and oddly that the obligations to provide Super Speciality Treatment to the Insured Person and/or his/her family members is ultra-vires its parent Act, or that ESI Act itself is ultra-vires the Constitution, for want of subject-matter competence on the part of the Union Legislature. This Court is of the view that ESI Corporation, being a statutory corporation and a creature of ESI Act, is bound by its parent Act and cannot challenge its vires.

56. In fact, the object of ESI Act is not to provide primary care only. Section 56 of the ESI Act does not distinguish between primary and tertiary care while defining 'medical benefit'. Section 56(1) states "*An insured person or (where such medical benefit is extended to his family) a member of his family whose condition requires medical treatment and attendance shall be entitled to receive medical benefit.*"

57. This Court is of the view that the ESI Act and its regulations provide for regulation of scales (Section 57) but they do not exclude any specific disease, or create distinction between primary, secondary and tertiary care. In fact, tertiary care is being provided by ESI Corporation including Paediatric Surgery, Cardiology, Oncology and Onco Surgery.

58. This Court is further of the opinion that ESI Act is a social welfare legislation. The self-proclaimed objective of the said Act is *"to provide for certain benefits to employees in case of sickness, maternity and employment injury and to make provision for certain other matters in relation thereto."* Consequently, this Court is of the opinion that social welfare legislations such as the ESI Act, have to be construed liberally, and in case of any doubt, the issue has to be resolved in favour of the class of persons for whose benefit the statute has been enacted.

59. In ***Bombay Anand Bhavan Restaurant vs. Dy. Director ESI Corporation & Another, (2009) 9 SCC 61*** the Supreme Court has held as under :-

> *"20. The Employees' State Insurance Act is a beneficial legislation. The main purpose of the enactment as the Preamble suggests, is to provide for certain benefits to employees of a factory in case of sickness, maternity and employment injury and to make provision for certain other matters in relation thereto. The Employees' State Insurance Act is a social security legislation and the canons of interpreting a social legislation are different from the canons of interpretation of taxation law. The courts must not countenance any subterfuge which would defeat the provisions of social legislation and the courts must even, if necessary, strain the language of the Act in order to achieve the purpose which the legislature had in placing this legislation on the statute book. The Act, therefore, must receive a liberal construction so as to promote its objects."*
>
> (emphasis supplied)

60. The same principle has been reiterated in ***M/s Cochin Shipping Co. Vs. ESI Corporation, (1992) 4 SCC 245, Transport Corporation of India vs. Employees' State Insurance Corpn. & Another, (2000) 1 SCC 332*** and ***Delhi Gymkhana Club Limited Vs. Employees' State Insurance***

Corporation, (2015) 1 SCC 142.

61. It is also wrong to suggest – as submitted by ESI Corporation – that a claim for life-saving treatment, or any valid treatment for any ailment, which is medically proper to be prescribed, is unreasonable. At the most, what can be termed unreasonable is the cost of treatment, medicines, consumables etc. In fact, the cost of treatment does not concern the beneficiary of the ESI Corporation as it is solely within the power of ESI Corporation and instrumentalities of the State to regulate cost of the treatment through policy interventions, price controlling and capping measures.

62. Even though rare genetic diseases like Gaucher and Hurler Syndrome are treatable, yet because of the prohibitively expensive treatment majority of the patients do not have access to the same. The burden of the rare genetic diseases like Gaucher and Hurler Syndrome disease is disproportionately borne by low and middle-income countries as the individuals most vulnerable to them in India are the poor, illiterate, minorities who marry between close relations. These groups often do not have access to testing and treatment services and lack awareness about the nature of the diseases and preventive techniques. Consequently, this public health crisis is driven by social and economic factors.

63. This Court suggests to Union of India that Human Rights based approach to rare diseases and Super Speciality Treatment may be adopted. A human rights-based approach to rare genetic diseases like Gaucher and Hurler Syndrome would uphold the rights of such patients including the right to life, health and non-discrimination. This approach would focus on the social and medical determinants of the disease and would articulate the domestic and international legal obligations of governments and non-state

actors to ensure that good quality treatment for rare diseases is available and accessible at reasonable prices without discrimination. The human rights approach would create an enabling legal environment for the research and development of new, more effective drugs and diagnostics, and to lower the prices of existing drugs, including new medicines and advanced diagnostics.

64. One will have to operationalize human rights approach to Enzyme Replacement Therapy at the grass root level and for this the State as well as Civil Society and large pharmaceutical companies will have to come forward.

65. The suggested approach is in consonance with the approach adopted by the global rights campaigns against HIV which has helped galvanize public support spurred research and improved access to medicine.

66. Recently, the Stop TB Partnership, KELIN and the International Human Rights Clinic, University of Chicago Law School has formed the TB and Human Rights Consortium and drafted the Nairobi Strategy to develop and implement a human rights-based approach to TB.

67. Consequently, ESI Corporation is under an obligation to take care of the insured person and his/her family members and ensure that every life counts. Further, the ESI Corporation's argument that it can provide only reasonable medical services or that it is not a State for the purpose of providing Super Speciality Treatment to Insured Person and/or his/her family members, is untenable in law.

MANDATORY PROCEDURE PRESCRIBED IN SECTION 97 HAS NOT BEEN FOLLOWED BY THE ESI CORPORATION WHILE ISSUING THE ESIC DECISION ON MEDICAL SERVICES-JULY 2014 OR THE SUBSEQUENT AMENDMENTS THAT FOLLOWED VIDE CIRCULARS

DATED 07TH NOVEMBER, 2016 AND 29TH OCTOBER, 2018. CONSEQUENTLY, THE CREATION OF A SEPARATE CLASS OF TREATMENT i.e. SUPER SPECIALITY TREATMENT, BY WAY OF AN ADMINISTRATIVE CIRCULAR, IS WITHOUT AUTHORITY OF LAW.

68. Upon examination of ESI Act and accompanying regulations, this Court finds that its Section 97 empowers the ESI Corporation to make regulations. In terms of said Section, every Regulation has to be published in the gazette. Further, it is required to be forwarded to the Central Government, and laid before the Parliament. This mandatory procedure has not been followed by the ESI Corporation while issuing the *ESIC Decision on Medical Services-July 2014* or the subsequent amendments that followed vide circulars dated 07th November, 2016 and 29th October, 2018.

69. It is settled law that when a power is given to do a certain thing in a certain way, the thing must be done in that way or not at all and other methods of performance are forbidden. [See ***Taylor Vs. Taylor, (1875) 1 Ch.D.426; Nazir Vs. King Emperor, AIR 1936 PC 253***, ***Babu Verghese Vs. Bar Council of Kerala, (1999) 3 SCC 422***]

70. Consequently, the creation of a separate class of treatment i.e. Super Speciality Treatment, by way of an administrative circular, is without authority of law.

THE RESPONDENT-ESI CORPORATION'S ARGUMENT THAT IT PERFORMS FUNCTIONS ANALOGOUS TO A PRIVATE INSURANCE COMPANY OR ACTS LIKE A TRUSTEE IS UNTENABLE IN LAW AND CONTRARY TO FACTS.

71. The respondent-ESI Corporation's argument that it performs functions analogous to a private insurance company or acts like a Trustee is untenable in law and contrary to facts. For instance, in private insurance

contracts, the relationship between the Insured Person and the insurer is not statutory, but contractual. Further, in private insurance contracts, the relationship is at the option of the contracting parties, whereas in the case of the ESI Corporation, the relationship is a mandatory one.

72. Also, in private insurance contracts, there are certain duties attached to the insured regarding disclosure of facts and certain concomitant rights available to the insurer in case a relevant fact is concealed. But in the case of the ESI Corporation, the Insured Person and his/her family members, are covered by insurance merely by virtue of registration of the Insured Person. Lastly, and most importantly, the objective of private insurance companies is commercial while in the case of the ESI Corporation, the objective is to give benefit to the employees.

CERTAINLY, IT IS OPEN TO THE STATE AND AUTHORITIES TO PREVENT OR CHECK MISUSE OF A SOCIAL WELFARE LEGISLATION, BUT TO DELAY OR DEFER THE IMPLEMENTATION OF A STATUTORY PROVISION JUST TO PREVENT MISUSE, WOULD AMOUNT TO ACTING CONTRARY TO THE LEGISLATIVE MANDATE – A COURSE OF ACTION WHICH IS NOT OPEN TO THE STATE AND/OR ITS INSTRUMENTALITIES, LIKE THE ESI CORPORATION.

73. This Court is also of the view that the effectiveness of a social welfare legislation cannot be undermined or whittled down by unfounded and unsubstantiated fear of misuse. Under Section 38 of the ESI Act, all employees to which the ESI Act applies are to be compulsorily insured. The perception that persons "deliberately" get themselves registered with the ESI Corporation "only to avail benefit", is erroneous.

74. To suggest that a law shall not be misused or misutilised is to suggest the impossible. Certainly, it is open to the State and authorities to prevent or

check misuse of a social welfare legislation, but to delay or defer the implementation of a statutory provision just to prevent misuse, would amount to acting contrary to the legislative mandate – a course of action which is not open to the State and/or its instrumentalities, like the ESI Corporation.

PRESCRIBING DIFFERENT COMMENCEMENT DATES FOR ENTITLEMENT TO SUPER SPECIALITY TREATMENT OF INSURED PERSON VIZ-A-VIZ HIS/HER FAMILY MEMBERS IS INCONSISTENT WITH THE EXISTING REGULATION 95A(2) OF REGULATIONS, 1950 AND WILL NEITHER CHECK MISUSE OF THE ESI ACT NOR ENSURE THAT COSTLY TREATMENTS ARE AVAILED BY GENUINE PERSONS.

75. It is a well-recognised principle of interpretation of a statute that a rule to have statutory force, must conform to the provisions of the statute under which it is framed and it must also come within the scope of the rule making power of the authority framing the rule. The Supreme Court has repeatedly held that if these twin conditions are not satisfied, the rule is void. Some of the judgments germane to the issue are reproduced hereinbelow:-

A) In ***Gen Officer Commanding-in-Chief and Another v. Dr. Subhash Chandra Yadav and Another, (1988) 2 SCC 351***, the Supreme Court has held as under:-

> *"14. ……It is well settled that rules framed under the provisions of a statute form part of the statute. In other words, rules have statutory force. But before a rule can have the effect of a statutory provision, two conditions must be fulfilled, namely, (1) it must conform to the provisions of the statute under which it is framed; and (2) it must also come within the scope and purview of the rule-making power of the authority framing the rule. If either of these two conditions is not fulfilled, the rule so framed would be void……"*
>
> (emphasis supplied)

B) In ***Additional District Magistrate (Rev.) Delhi Admin Vs. Siri Ram, (2000) 5 SCC 451,*** the Supreme Court has held as under:

> *"16. It is a well-recognised principle of interpretation of a statute that conferment of rule-making power by an Act does not enable the rule-making authority to make a rule which travels beyond the scope of the enabling Act or which is inconsistent therewith or repugnant thereto……"*
>
> (emphasis supplied)

C) In ***State of T.N. and Another, v. P. Krishnamurthy and Others, (2006) 4 SCC 517,*** the Supreme Court has held as under:-

> *"15. There is a presumption in favour of constitutionality or validity of a subordinate legislation and the burden is upon him who attacks it to show that it is invalid. It is also well recognised that a subordinate legislation can be challenged under any of the following grounds:*
>
> *(a) Lack of legislative competence to make the subordinate legislation.*
> *(b) Violation of fundamental rights guaranteed under the Constitution of India.*
> *(c) Violation of any provision of the Constitution of India.*
> *(d) Failure to conform to the statute under which it is made or exceeding the limits of authority conferred by the enabling Act.*
> *(e) Repugnancy to the laws of the land, that is, any enactment.*
> *(f) Manifest arbitrariness/unreasonableness (to an extent where the court might well say that the legislature never intended to give authority to make such rules).*
>
> *xxxx xxxx xxxx xxxx*
>
> *17. In Indian Express Newspapers (Bombay) (P) Ltd. v. Union of India [(1985) 1 SCC 641] this Court referred to several grounds on which a subordinate legislation can be challenged as follows:*
>
> *"75. A piece of subordinate legislation does not carry the same degree of immunity which is enjoyed by a statute*

passed by a competent legislature. Subordinate legislation may be questioned on any of the grounds on which plenary legislation is questioned. In addition it may also be questioned on the ground that it does not conform to the statute under which it is made. It may further be questioned on the ground that it is contrary to some other statute. That is because subordinate legislation must yield to plenary legislation. It may also be questioned on the ground that it is unreasonable, unreasonable not in the sense of not being reasonable, but in the sense that it is manifestly arbitrary."

(emphasis supplied)

xxxx xxxx xxxx xxxx

20. In St. John's Teachers Training Institute v. Regional Director, NCTE [(2003) 3 SCC 321] this Court explained the scope and purpose of delegated legislation thus:

"10. A regulation is a rule or order prescribed by a superior for the management of some business and implies a rule for general course of action. Rules and regulations are all comprised in delegated legislations. The power to make subordinate legislation is derived from the enabling Act and it is fundamental that the delegate on whom such a power is conferred has to act within the limits of authority conferred by the Act. Rules cannot be made to supplant the provisions of the enabling Act but to supplement it. What is permitted is the delegation of ancillary or subordinate legislative functions, or, what is fictionally called, a power to fill up details……"

(emphasis supplied)

76. Keeping in view the aforesaid mandate of law, this Court is in agreement with the learned Amicus Curiae's submission that Guideline Nos. 1 and 2 of the Executive Order dated 29th October, 2018 and proposed Regulation 96C are inconsistent with the existing Regulation 95A(2) of

Regulations, 1950 inasmuch as the existing Regulation stipulates that the entitlement date for medical benefits for the Insured Person and his/her family members shall be the same. The Regulation 95A(2) is reproduced hereinbelow:-

> ***"95A. Medical benefit to families of insured persons.—***
>
> *xxxxx xxxx xxxx xxx*
>
> *(2) The family of an insured person shall become entitled to medical benefit from the day the insured person himself becomes entitled to medical benefit and shall continue to be so entitled so long as the insured person is entitled to receive medical benefit for himself, or in the case of death of the insured person till such date upto which the insured person would have remained entitled to medical care, had he survived."*
>
> (emphasis supplied)

77. This Court is further of the opinion that prescribing different commencement dates for entitlement to Super Speciality Treatment of Insured Person viz-a-viz his/her family members will neither check misuse of the ESI Act nor ensure that costly treatments are availed by genuine persons. Consequently, the classification of Insured Person as distinct from his/her family members is neither founded on an intelligible differentia nor the differentia has any rational nexus to the object sought to be achieved, i.e., to prevent/curtail misuse.

GUIDELINE NO. 3 OF OFFICE MEMORANDUM DATED 29TH OCTOBER, 2018 AND THE PROPOSED REGULATION 96C TO THE EXTENT THEY PENALIZE THE INSURED PERSON AND/OR HIS/HER FAMILY MEMBERS ON ACCOUNT OF NON-DEPOSIT OF PREMIUM BY THE EMPLOYER, ARE LIKE PENALISING A VICTIM RATHER THAN THE PERPETRATORS OF THE CRIME.

78. Further, the Guideline No. 3 of Office Memorandum dated 29th October, 2018 and the proposed Regulation 96C to the extent they penalize

the Insured Person and/or his/her family members on account of non-deposit of premium by the employer, are like penalising a victim rather than the perpetrators of the crime. As suggested by learned Amicus Curiae, the said Guideline/proposed Regulation is inconsistent with Section 85 and 85B of the ESI Act.

79. Before parting with this case, this Court places on record the fact that it was ably assisted throughout by Ms.Shyel Trehan, learned Amicus Curiae. The assistance was of a high calibre and quality.

CONCLUSION

80. Keeping in view the aforesaid, this Court is of the view that the Office Memorandum dated 29th October, 2018 is directly inconsistent with the provisions of the ESI Act and the regulations framed thereunder. The proposed draft notification is also repugnant to Regulation 95A(2) of the Regulations, 1950. Assuming that the proposed Regulation 96C is notified as well as published in the Gazette of India, and laid before the Parliament, in conformity with Section 97 of the ESI Act, even then the said Regulation shall be inconsistent with Regulation 95A(2) of the Regulations, 1950. Accordingly, Guideline Nos. 1, 2 and 3 of the Office Memorandum dated 29th October, 2018 and provisions similar thereto in the proposed Regulation 96C are declared illegal and void.

MANMOHAN, J

JULY 17, 2019
rn/js