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

+ **W.P.(C) 6850/2023 & CM APPLs. 26789/2023, 40240/2023**

**DALIP KAUR & ANR.**

..... Petitioners

Through: Mr. Sandeep Sethi, Sr. Advocate with  
Mr. Akshay Sapre, Ms. Shruti  
Shivkumar and Mr. Sahel Sood,  
Advocates and Dr. Gokavarapu  
Sandhya.

versus

**UNION OF INDIA & ANR.**

..... Respondents

Through: Mr. Chetan Sharma, ASG with Mr.  
Ripu Daman Bhardwaj, CGSC and Mr.  
Amit Gupta, Mr. Kushagra Kumar,  
Mr. Ghanshyam Jha, Mr. Saurabh  
Tripathi, Mr. Vikramaditya Singh,  
Advocates & Mr. Vedansh Anand, GP  
for UOI.

Dr. Sujata Mohanty, Prof. Stem Cell  
Facility, AIIMS, Prof. Sheffali Gulati,  
who is Facility-in-charge, Child  
Neurology, Dept. of Pediatrics,  
AIIMS, New Delhi, Mr. Satya Ranjan  
Swain, Advocate, Panel Counsel and  
Mr. Kautilya Birat, Advocate for  
AIIMS.

Mr. T. Singhdev, Mr. Aabhaas  
Sukhramani, Mr. Abhijit Chakravarty,  
Mr. Bhanu Gulati, Ms. Anum Hussain  
and Mr. Tanishq Srivastava,  
Advocates for R-2.

**CORAM:**



**HON'BLE THE CHIEF JUSTICE  
HON'BLE MR. JUSTICE SANJEEV NARULA**

**ORDER  
31.08.2023**

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1. Petitioners have filed the present petition impugning recommendations dated 06<sup>th</sup> December, 2022 issued by the Committee on Stem Cell Use in Autism Spectrum Disorder constituted by Ethics and Medical Registration Board (“**EMRB**”) of the National Medical Commission (“**NMC**”).

2. The relevant portion of recommendations are detailed as under:

*“7. Two meta-analyses have been published so far on this topic, in the last 1-2 years. Both have noted that scientific quality of most studies has been inadequate. Therefore, it is not possible to draw any firm conclusions on the efficacy of SCT in ASD.*

*8. None of the current international guidelines recommend SCT as a treatment for ASD. Similarly, many eminent researchers and leaders the lack of sufficient scientific evidence. They also have noted prevailing unethical practice of offering SCT as a treatment for ASD. Further, they have expressed concern and warned about indiscriminate promotion and predatory marketing of stem cell therapies in ASD leading to creation of false hopes, unrealistic expectations, and exploitation of the affected population and their families.*

*9. Obviously, more well-designed and methodologically sound research needs to explore the safety and utility of SCT In ASD.*

**RECOMMENDATIONS:**

*i. Current Status: Stem cell therapy is not recommended as a treatment for Autism Spectrum Disorder (ASD) in clinical practice.*

*ii. In view of the above recommendation, use of Stem cell in ASD, its promotion and advertisement will be considered as professional misconduct.*

*iii. Further research needs to be conducted and encouraged in terms of well-designed Double-blind RCT's to explore the safety and efficacy of Stem Cell Therapy in ASD.*

*iv. These recommendations will be updated periodically.”*

3. Mr. Sandeep Sethi, learned Senior Counsel appearing for the Petitioners, submits that the children of the Petitioners, who have been



diagnosed with Autism Spectrum Disorder (“**ASD**”), showed marked improvement after they were administered stem cell treatment. However, on account of the impugned recommendations, their treatment has been discontinued as their doctors are unwilling to continue the treatment on account of the stipulation in the impugned recommendation that any doctor who administers stem cell therapy will be subjected to proceedings for committing professional misconduct.

4. Considering the gravity of the situation, we requested the All-India Institute of Medical Sciences (“**AIIMS**”) to depute senior doctors/doctors who are subject-matter experts in the field of stem cell therapy for assisting this Court. In furtherance of our directions Dr. Sujata Mohanty, Prof. Stem Cell Facility, AIIMS and Prof. Sheffali Gulati, Facility-in-charge, Child Neurology, Dept. of Pediatrics, AIIMS, have appeared today.

5. It turns out that Dr. Mohanty and Prof. Gulati were members of the Committee which made the impugned recommendations. They have been heard extensively for the Court to understand their perspective. They have shed light on ASD and the scientific community’s views on stem cell treatment. They emphasise that the Committee arrived at the decision after careful and deep consideration of studies conducted globally. They point out that while several studies have been conducted regarding the use of stem cell treatment for ASD, the results have been inconclusive and meta-analyses of these studies observe poor design and quality of the methodology, non-deployment of double-blind randomized control trials, poor sample size, etc. across all the studies. No standardized established protocol for elements such as suitable stem cell type, administration method, dosage, etc. have been established, suggesting that the scientific study of stem cell therapy for



treatment of ASD is still at a nascent and experimental stage. Another impediment in the development of this field of study is the nature of ASD; it is multifactorial and complex in origin, and the precise nature of the genetic and environmental triggers remain enigmatic, despite decades of research in the field. No known cure exists, however, the symptoms and effects of ASD can be tempered using holistic treatment involving physiotherapy, behavioural therapy, etc. In order to prevent exploitation of desperate families by giving false hopes regarding the efficacy of stem cell treatment, the Committee recommended against administration and promotion of stem cell treatment for ASD.

6. We have carefully considered the submissions made by both parties. As it stands, we are only presented with the Committee's recommendations. To date, neither the National Medical Commission nor the Government of India has issued a definitive order prohibiting stem cell therapy for ASD. Furthermore, no statutory provision has been presented before us explicitly forbidding the use of stem cell therapy in cases of ASD.

7. In a judgment delivered on 04<sup>th</sup> September, 2019 by a coordinate bench of this Court, clinics were permitted to administer stem cell treatments to certain children diagnosed with Cerebral Palsy. This permission was granted pending a final determination by the Central Drugs Standard Control Organization concerning stem cell therapy under the New Drugs and Clinical Trial Rules, 2019. The rationale behind this allowance was the Court's belief that even a day's interruption in treatment could have severely detrimental effects on the patients. The relevant portions of the said order read as under:

*“5. The petitioners, in these cases, are, however, presently undergoing treatment using "stem cell therapy" from the clinic. It is an admitted*



*position that discontinuance of the said treatment, even for a day, will have severely deleterious effects on their health. Till such time a final decision is, therefore, taken, by the CDSCO, regarding the issue of whether the clinic is providing therapy using "stem cells", or "stem cells derived products", we are of the opinion that the treatment presently being administered to these petitioners cannot be allowed to be discontinued, as such discontinuance is likely to have life-threatening consequences.*

*6. We, therefore, allow the petitioners to continue such treatment, from the clinic, till a final decision is taken, by the CDSCO, regarding the aspect of coverage, or otherwise, of the clinic, under the Rules, 2019.*

*7. We also clarify that no decision, adverse to the clinic regarding the aspect of its coverage under the Rules, 2019, would be taken, save and except in accordance with due law and due procedure and after giving the clinic an adequate opportunity of being heard.*

*8. With these observations, these writ petitions are hereby disposed of."*

8. Dr. Sandhya Gokavarapu, a distinguished oncologist and the mother of a child currently undergoing stem cell treatment for ASD, passionately impressed upon us the remarkable progress her child has made due to the therapy. Specifically, she observed a significant 4 percentage point reduction in the Childhood Autism Rating Scale (CARS) within merely two months of initiating the treatment. Dr. Gokavarapu firmly believes that any disruption in the treatment now would result in irreparable damage to her child's health. Given that the NMC is yet to render a decision concerning the recommendations as set forth in Section 27(2) in conjunction with Section 10 of the NMC Act, 2019, she ardently appeals for the continuation of the therapy.

9. Mr. Chetan Sharma, learned ASG, informs this Court that there is also a petition pending before the Hon'ble Supreme Court of India<sup>1</sup> wherein a prayer has been made to ban administration and promotion of such therapy for treating ASD. Mr. Sethi states that although the Petitioners have been



impleaded in the said petition, being only the Respondents therein, they are unable to steer the said petition; nonetheless, no interim orders have been passed by the Hon'ble Supreme Court in this regard, and therefore, the treatment should not be allowed to discontinue.

10. While we do not profess expertise on the subject, the impugned report has not indicated any significant safety concerns regarding the continuation of treatment. In fact, the report touches on the issue of safety, noting as follows:

*'Regarding safety, no major safety issues have been noted. However, fever, headache, vomiting, hyperactivity and seizures have been observed.'*

[Emphasis supplied]

11. The report also acknowledges that *"Adult stem cells, after obtaining clearance from Institutional Ethics Committees for adherence to ethical standards, have been utilized in clinical trials due to their established safety."* While Dr. Gulati did remark on witnessing adverse effects in one patient following stem cell therapy, it is pertinent to note that this patient was not receiving treatment for ASD, and this particular case was not documented in the report. Importantly, Mr. Sethi, on instructions from the Petitioners, has unequivocally expressed their desire to proceed with the treatment. He asserts their willingness to continue with the treatments fully acknowledging and accepting any potential risks, at their own discretion. He further emphasizes that they will undertake this therapy without any financial support from the State. Likewise, Dr. Sandhya Gokavarapu submitted that they shall complete the treatment at their own cost, being fully ware of the potential risks.

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<sup>1</sup> Yash Charitable Trust & Ors. vs. Union of India & Ors. [W.P.(C) 369/2022]



12. Upon reviewing the evidence and testimony presented, several factors weigh heavily on this Court's decision. First and foremost, the anecdotal evidence, notably from Dr. Sandhya Gokavarapu, underscores potential benefits of the stem cell treatment, especially when early discontinuation might result in detrimental setbacks. The cautionary account from Dr. Gulati, though valid, pertains to a non-ASD case and lacks thorough documentation in the report, making it less directly applicable to the matter at hand. We must also acknowledge that medical advancements often encompass both known and unforeseen risks, and individual autonomy in making informed decisions about treatment options is the cornerstone of patient rights. In the spirit of patient autonomy, it is noteworthy that the Petitioners are not seeking financial assistance from the State and are fully aware of and willing to assume potential risks. Their choice underscores their conviction in the treatment's benefits for their loved ones. Given these considerations, it becomes clear that an abrupt cessation of the treatment might not be in the best interests of the patients involved. Thus, while the Petitioners are granted permission to continue the stem cell treatment, they must do so with full knowledge and at their own risk. Simultaneously, the urgency of this situation calls upon the NMC to expedite its review process and come to a conclusive decision, bearing in mind the Committee's recommendations

13. Though AIIMS is not a party to the present petition, and no specific relief is sought against them, the nature of the controversy before us suggests that the input from one of India's foremost research institutes would be invaluable. This is especially true given the public interest ramifications stemming from the issues at hand. Consequently, AIIMS is hereby impleaded as a Respondent. They are directed to file a comprehensive counter-affidavit



within a span of four weeks. This should be prepared in consultation with the experts present in today's Court session to provide their perspectives on the matter. NMC (Respondent No. 2) as well as Union of India (Respondent No. 1) are to file a detailed counter-affidavit in the matter.

14. This Court expresses its gratitude to Dr. Sujata Mohanty and Prof. Sheffali Gulati, who have spared their valuable time to assist this Court in the matter.

15. List on 03<sup>rd</sup> October, 2023.

**SATISH CHANDRA SHARMA, CJ**

**SANJEEV NARULA, J**

**AUGUST 31, 2023/ns**