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REPORTABLE

IN THE SUPREME COURT OF INDIA
ORIGINAL CIVIL JURISDICTION

WRIT PETITION (C) NO. 369 OF 2022

YASH CHARITABLE TRUST & ORS. **…PETITIONER(S)**

VERSUS

UNION OF INDIA & ORS. **…RESPONDENT(S)**

J U D G M E N T

J.B. PARDIWALA & R. MAHADEVAN, JJ.:

For the convenience of exposition, this judgment is divided into the following parts:-

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A. FACTUAL MATRIX

1. By this writ petition in public interest, the petitioners have raised certain concerns relating to the rampant promotion, prescription and administration of stem cell "therapy" for the treatment of Autism Spectrum Disorder (hereinafter, "**ASD**") by several clinics across the country. At the core of the present petition is the issue of legal permissibility of the administration of stem cells for palliative and/or curative treatment of ASD by clinics.

2. The present petition alleges that although the stem cell "therapy" could be said to be still at an experimental stage, yet the same is being touted as a 'treatment' and/or 'cure' for ASD by various clinics/hospitals/institutions in flagrant violation of the existing legal framework and guidelines. The petition claims that the individuals diagnosed with ASD and their parents/guardians/caregivers who are unaware of the scientific and legal intricacies, unsuspectingly place their implicit faith in such clinics/hospitals/institutions in the hope of there being a miraculous cure and consequently, fall victim to cost-intensive procedures such as the present one. It is alleged that stem cell therapy for ASD is illegal and does not provide for safety-nets that are available to the subjects of clinical trials under the present regulatory framework. The petition alleges that despite a framework for the regulation of such therapies being present, the enforcement of the same is not being undertaken by the respondent nos. 1-8 respectively. Therefore, in the absence of any other recourse, the present writ petition has been filed as a Public Interest Litigation (hereinafter, "**PIL**") before this Court, seeking directions for the effective implementation of the present regulatory framework.

3. In order to demonstrate the premise of its concerns, the present petition provides an illustrative list of clinics in India which are allegedly advertising and offering services of stem cell 'therapy' as a cure for ASD. To further buttress the claim that recent years have seen a mushrooming of such stem cell 'therapies' being offered by clinics/hospitals/institutions, it was highlighted that, on 04.08.2017, this issue was brought to the notice of the 16th Lok Sabha in the form of the Unstarred question no. 3448. The Minister of State, Ministry of Health and Family Welfare ("**MoHFW**"), Government of India, responded by providing a list of 59 entities that are engaged in this practice of offering stem cell therapy, but informed that the number of reported cases is not maintained centrally. The response further went on to state that, "*The Guidelines for Stem Cell Research and Therapy were released by the Indian Council for Medical Research (ICMR) in collaboration with the Department of Biotechnology. Later, the National Guidelines for Stem Cell Research (NGSCR) were issued which guide clinicians and scientists to conduct research scientifically.*"

4. It is not in dispute that, as of today, no proven cure having guaranteed efficacy has been discovered for the treatment of ASD. However, there is a significant volume of ongoing research in the field which claims that the use of stem cells can alleviate the symptoms of the condition. While the efficacy of the use of stem cells as a cure and/or for the purpose of alleviating the symptoms of ASD is still debatable, yet the question before us is whether it is legally permissible to administer stem cells on individuals diagnosed with ASD as a routine healthcare procedure.

5. The chronology of events subsequent to the filing of the present petition also hold some significance. It is pertinent to note that the present matter was first listed before this Court on 20.05.2022. However, there have been some developments in the regulatory framework regarding stem cell research and its application in India during the course of the present proceedings. The present petition was filed on 06.05.2022, hinged on the allegation that there is a serious lapse on the part of the respondent nos. 1-8 respectively, in preventing the rampant administration, promotion and prescription of stem-cell "therapy" for the treatment of ASD. The same was said to be in violation of the New Drugs and Clinical Trial Rules, 2019 (the "**NDCT Rules, 2019**") promulgated under the Drugs and Cosmetics Act, 1940 (the "**Drugs Act, 1940**") and also in violation of the National Guidelines for Stem Cell Research, 2017 (hereinafter, the "**NGSCR 2017**") published by the respondent no. 3/Indian Council of Medical Research ("**ICMR**"). Subsequently, a number of documents were released in the public domain and since they are directly concerned with the present matter, we have looked into the same. The documents are as follows:

i. The recommendations of the Committee on Stem Cell Use in ASD, dated 06.12.2022, issued by the Ethics and Medical Registration Board ("**EMRB**") of the respondent no. 2/National Medical Commission ("**NMC**")

ii. The draft dated 31.05.2023 published by the respondent no. 3/ICMR seeking inputs on the proposed dissolution of the National Apex Committee for Stem Cell Research & Therapy (the "**NAC-SCRT**").

iii. The Order dated 03.03.2024, issued by the Department of Health Research, Ministry of Health ("**DHR**"), Ministry of Health and Family Welfare ("**MoHFW**"), Government of India, dissolving the NAC-SCRT.

6. The recommendations of the Committee on Stem Cell Use in ASD dated 06.12.2022, issued by the EMRB of NMC, came to be challenged by a member of the respondent no. 13/Parents' Forum for Stem Cells in Autism and Cerebral Palsy (the "**Parents Forums**"), before the Delhi High Court in a writ petition titled ***Dalip Kaur and Anr. v. Union of India and Anr.,*** **WP(C) No. 6850/2023**. More particularly, the writ petition sought to assail the recommendation no. (ii) thereof and stated that it posed an issue for the patients who were undergoing stem cell therapy since it provided that, "In view of the above recommendation, use of Stem Cell in ASD, its promotion and advertisement will be considered as professional misconduct.". The issue raised before the Delhi High Court was that, as a consequence of the said recommendations dated 06.12.2022, the ongoing treatments were being abruptly discontinued because the doctors were unwilling to continue due to the fear of being subjected to proceedings for professional misconduct. Although the matter is still pending final adjudication before the Delhi High Court, yet vide the interim order dated 31.08.2023, it was observed 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, and also considering that the patients were fully aware of and were willing to assume potential risks, the High Court permitted the continuation of the stem cell treatment since any abrupt cessation of the treatment might not be in the

best interests of the patients involved. It is to be noted that the said interim order never came to be challenged by the respondents till date.

7. The relevant observations made by the Delhi High Court in ***Dalip Kaur*** *(supra)* are reproduced hereinbelow:

> *"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."*

8. It is in light of the aforesaid factual backdrop, that we must look into the regulatory framework governing the administration of stem cells as a routine healthcare procedure for the treatment of ASD.

B. SUBMISSIONS OF THE PARTIES

a. Submissions on behalf of the Petitioners

9. Mr. Siddharth Nath, the learned counsel appearing for the petitioners submitted that the present writ petition has been filed seeking to curb the unrestricted marketing and commercialisation of stem cell therapy for patients diagnosed with ASD. He submitted that medical experts across the world hold the view that stem cell therapy has not been proven to be safe, or effective for ASD and more research is required in controlled environements, before such treatment can be offered to patients.

10. On the issue of maintainability, it was submitted that the present writ petition has been filed as a Public Interest Litigation with the sole intent to secure the rights of those with ASD, and that the petitioners otherwise have no personal interest in the matter. The learned counsel further submitted that no relief *qua* any individual clinic has been sought by the petitioners. Yash Charitable Trust (hereinafter, the "**petitioner no. 1**") is a non-government organisation, registered as a trust in the State of Maharashtra, with its focus on providing skill development, training, livelihood opportunities and mental health support through counselling, consultations and other therapeutic interventions to persons with intellectual and developmental disabilities including ASD. Dr. Vibha Krishnamurthy (hereinafter, the "**petitioner no. 2**") is a developmental paediatrician with 22 years of combined experience both in India as well as

the United States of America. She is said to have been actively involved in several non-profit activities centering around the research, advocacy and training in the field of child rights and disabilities. The Forum for Medical Ethics Society (hereinafter, the "**petitioner no. 3**") is an organisation which focuses on spearheading public engagement around the interplay of ethics with contemporary issues in health and allied themes. Mr. K.S. Ganpathy (hereinafter the "**Petitioner no. 4**"), is the parent of a child who had received stem cell therapy for the treatment of ASD in year 2011, and the treatment is said to have been administered by one Dr. Alok Sharma in Surana Hospital, Chembur, Maharashtra. While the said hospital has not been made a party to the present proceedings, the institute of which Dr. Alok Sharma is a director, has been impleaded as Respondent no. 9 in this matter, in lieu of the Order dated 20.05.2022 of this Court.

11. The learned counsel for the petitioners submitted that the administration of stem cell 'therapies' by clinics/hospitals commercially for a fee, is in contravention of the NDCT Rules, 2019. He argued that such stem cell therapies are permitted to be undertaken only in the limited form of clinical trials. Rule 2(1)(w)(v) of the NDCT Rules, 2019 includes "stem cell derived products" and this would unambiguously imply that stem cell therapies would come to be governed by the clinical trial rules provided thereunder.

12. He also submitted that the NDCT Rules, 2019 is being violated by the clinics/hospitals administering stem cell therapies for the treatment of ASD since they are operating without any permission from the Central Licensing Authority, and without any protocol being approved by the Ethics Committee for clinical trials.

13. He further submitted that the actions of the clinics/hospitals violate Rule 74 of the NDCT Rules, 2019 which prohibits the manufacture for sale or for distribution, any new drug except in accordance with the Drugs Act, 1940 and the NDCT Rules, 2019. He pointed out that neither has there been any clinical trial for stem cell therapy in ASD, nor has any permission been granted in lieu of an application made under Rule 91 of the NDCT Rules, 2019 through which the manufacture of an unapproved new drug under clinical trial for the treatment of patients with life threatening diseases, can be undertaken.

14. The learned counsel highlighted that since the stem cell therapies are being undertaken by the clinics/hospitals as a commercial venture and not as a clinical trial under the NDCT Rules, 2019, the subjects of such therapies are not protected by the safeguards that are otherwise available to clinical trial-subjects under Chapter VI of the NDCT Rules, 2019. Such safeguards include compensation in case of injury, disability or death during the clinical trial of a new drug or investigational new drug.

15. The learned Counsel further submitted that the respondent no.3 has consistently maintained that the stem cell therapy for ASD is unapproved, unproven and not recommended. He sought to distinguish the ICMR-approved stem cell and cell-based product called ‘stempeucel’ from the stem cell therapies administered for the treatment of ASD by stating that ‘stempeucel’ is the only stem cell and cell-based product from India which has been granted a manufacturing and marketing license by the Central Drugs Standard Control Organisation (CDSCO). Further, the learned counsel drew our attention to the NGSCR 2017 and a report on the Evidence based Status of Stem Cell Therapy for Human Diseases, 2021 respectively, to submit that

these documents issued by the respondent no. 3 conclude that stem cell therapies should not be offered as a standard or routine procedure to the patients diagnosed with ASD.

16. The learned counsel also laid much emphasis on the recommendations dated 06.12.2022 issued by the EMRB of the respondent no. 2, to argue that these recommendations unequivocally state that the use, promotion and advertisement of stem cell therapy for ASD would constitute 'professional misconduct'.

17. In *arguendo*, the learned counsel for the petitioner submitted that the clarification dated 09.02.2021 issued by the respondent no. 1 states that the expression "stem cell derived product" as occurring in the NDCT Rules, 2019 does not include stem cell therapy for the treatment of ASD. If the said clarification is taken into account, then the respondent no. 1 would have to explain as to how the administration of such a therapy could be considered as 'professional misconduct' as stated by the EMRB of the respondent no. 2.

18. In the last, the learned counsel submitted that even if the stance of the respondent no.1, more particularly the stance that there are no provisions prescribed under the Drugs Act, 1940 to regulate therapies and/or treatments, is taken into account, the respondent no. 1 is under an obligation to indicate as to how such practices are to be regulated. The failure to do so would result in a regulatory grey area which may come to be exploited for commercial gain.

b. <u>Submissions on behalf of the Respondent no.1/Union of India</u>

19. Mr. Vikramjit Banerjee and Ms. Aishwarya Bhati, the learned Additional Solicitor Generals of India submitted that although a medicinal "product" derived from cells or stem cells is regulated under the Drugs Act, 1940 yet, there are no provisions prescribed under the said Act to regulate therapies or treatments.

20. It was submitted that as per Rule 100 of the NDCT Rules, 2019, the Central Licensing Authority has constituted an Expert Committee to evaluate the scientific and technical matters relating to the approval of stem cell and cell based drug 'products'.

21. It was further submitted that, *vide* letter dated 09.02.2021, a direction under Section 33P of the Drugs Act, 1940 was issued by the MoHFW to the Principal Health Secretaries of all the States and UTs respectively, clarifying the scope of the term "stem cell derived product" defined under the NDCT Rules, 2019. According to the said clarification, a "stem cell derived product" would mean "*a drug which has been derived from processed stem cells and which has been processed by means of substantial or more than minimum manipulation with the objective of propagation and/or differentiation of a cell or a tissue, cell activation and production of a cell line which includes pharmaceutical or chemical or enzymatic treatment altering biological characteristic combining with a non-cellular component, manipulation by genetic engineering including gene-editing and gene modification*".

22. It was submitted that a drug would fall within the definition of a "stem cell derived product" if there is substantial or more than minimal manipulation of the cell. It is only the cell based products and tissue based products which

have been processed by means of substantial or more than minimal manipulation, as per the criteria mentioned above, that are covered under the NDCT Rules, 2019. "Substantial or more than minimal manipulation of the cell" could be said to exist in the following situations:

i) *Ex-vivo* alteration in the cell population (T-cell depletion, cancer cell depletion); or

ii) Expansion which is expected to result in the alteration of a function.

23. The learned ASG also highlighted those instances which do not fall within the meaning of the phrase "substantial or more than minimal manipulation" and in fact, only constitute a minimal manipulation of cells, thereby falling outside the regime prescribed under NDCT Rules, 2019. Those are as follows:

i) Isolation of tissue,

ii) Washing, centrifugation, suspension in acceptable medium,

iii) cutting, grinding, shaping, disintegration of tissue,

iv) Separation of cells,

v) Isolation of a specific cell,

vi) Treatment with antibiotics,

vii) Sterilization by washing,

viii) Freezing, thawing,

ix) Stem cells removed from an individual for implantation of such cells into the same individual for use under the same surgical procedure should not undergo processing steps beyond rinsing, cleaning or sizing and these steps are not considered as processing.

24. The learned ASG also referred to the recommendations of the Committee on Stem Cell Use in ASD dated 06.12.2022 issued by the EMRB of the respondent no. 2 and the report on the Evidence Based Status of Stem Cell Therapy for Human Diseases, 2021 issued by the respondent no. 3 respectively, to submit that there exists no treatment that can cure ASD. It was submitted that these documents clearly reflect that stem cell therapy is not recommended and should not be offered as a standard or routine therapy to patients diagnosed with ASD, in clinical practice.

c. <u>Submissions on behalf of the Respondent no.2/ National Medical Commission</u>

25. Mr. Prateek Bhatia, the learned counsel appearing on behalf of the respondent no. 2/National Medical Commission submitted that the respondent no. 3/ICMR has independently evaluated the evidence-based efficacy of the therapeutic use of stem cells in the treatment of ASD by taking inputs from medical specialists and by reviewing the existing medical and scientific literature. The learned counsel pointed out that the respondent no. 3/ICMR in its report titled 'Evidence Based Status of Stem Cell Therapy for Human Diseases, 2021' has concluded that a 'critical review of the studies reported so far does not support the use of stem cell therapy over and above the behavioural and supportive therapies of ASD", and that based on this conclusion, the respondent no. 3/ICMR has recommended that stem cell therapy should not be offered as a standard or routine therapy to patients diagnosed with ASD, until there is any revision in the recommendation upon a periodic review.

26. Insofar as the Recommendations of the Committee on Stem Cell Use in ASD dated 06.12.2022 issued by the EMRB of the respondent no. 2 is concerned, the learned counsel submitted that it is pursuant to this Court's order dated 18.07.2022 that a committee of experts had been constituted by the EMRB of the respondent no. 2 to examine the issues related to the use of stem cell therapy for ASD. This is how the recommendations came to be given. The committee of experts, based on the available evidence, and after due deliberation and discussion, submitted the aforesaid report dated 06.12.2022. The experts concluded that, for the present, there was no evidence available to reach the conclusion that stem cell therapy is effective in treating ASD and accordingly, the committee had disapproved the administration of stem cell therapy for the treatment of ASD. The report further concluded that the prevailing practice of treating ASD using stem cells is unethical and therefore, recommended that the use of stem cell therapy for ASD along with its promotion and advertisement would be considered as 'professional misconduct'. The report however added that the aforesaid recommendation would be reviewed periodically as and when new evidence based research comes to light.

27. The learned counsel also submitted that the MoHFW, Government of India, took note of the recommendations dated 06.12.2022 issued by the EMRB of the respondent no. 2 as well as the report on the 'Evidence Based Status of Stem Cell Therapy for Human Diseases, 2021' issued by the respondent no. 3 respectively and thereby, declined to approve the use of stem cell therapy for the treatment of ASD.

28. In the last, the learned counsel submitted that the MoHFW, the respondent no. 2 and respondent no. 3 respectively have not approved the use of stem cell therapy for the treatment of ASD, and that any registered medical practitioner found indulging in the act of prescribing, recommending, administering, and advertising stem cell therapy would be liable to face disciplinary action for professional misconduct under the Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002 / National Medical Commission Registered Medical Practitioner (Professional Conduct) Regulations, 2023. He submitted that such complaints would be dealt with by the respective State Medical Councils in accordance with the procedure prescribed under the aforesaid regulation.

d. <u>Submissions on behalf of the Respondent no.9/Neurogen Brain and Spine Institute Private Limited</u>

29. Mr. Utkarsh Sharma, the learned counsel appearing for the respondent no. 9/ Neurogen Brain and Spine Institute Private Limited questioned the maintainability of the present petition. He alleged that the present petition is a result of motivated interests since the petitioner no. 2 who provides rehabilitation therapies for ASD is apprehensive about its commercial interests being adversely affected by the stem cell therapies which are the subject matter of the present petition.

30. The learned counsel emphasised on distinguishing stem cell therapy being delivered as a ‘product’ as opposed to it being delivered as a ‘procedure’. He argued that the stem cell therapy is only delivered as a ‘product’ when the ‘stem cell derived product(s)’ are manufactured by companies and sold to various hospitals/doctors, whereas, the stem cell therapy is delivered as a

'procedure' when a doctor, in a hospital, takes cells from a patient and administers them back into the same patient.

31. He submitted that it is only the 'drugs', and not the 'procedures' which are covered by the Drugs Act, 1940 and the rules thereunder, including the NDCT Rules, 2019. The direction dated 09.02.2021 issued by the MoHFW to the Principal Health Secretaries of all the States under Section 33P of the Drugs Act, 1940 clarified that stem cells removed from an individual for the purpose of its implantation back into the same individual, for use in the same surgical procedure, need not undergo steps beyond rinsing, cleaning or sizing and that these steps would not be considered as processing. As a result, an autologous cell/stem cell therapy which does not undertake any steps beyond rinsing, cleaning or sizing, cannot amount to a 'stem cell derived product' under the definition of 'new drug' given in Rule 2(1)(w) of the NDCT Rules, 2019. Thus, it was submitted that neither can such therapy be termed as a 'drug' nor can the yardsticks and parameters applicable to a drug be applied to such therapy. In this context, he submitted that the respondent no. 9 who administers an autologous bone-marrow derived cell/stem cell therapy/procedure uses the patient's own body part and is therefore, not a 'drug'.

32. He submitted that the stem cell therapy procedure that is carried out by the respondent no. 9, is being done after obtaining due approval from the Institutional Ethics Committee registered with the Central Drugs Standard Control Organisation (hereinafter, the "**CDSCO**") and in accordance with the permission granted by the Health Ministry of the State of Maharashtra vide

order dated 29.02.2024 whereby the cancellation of registration of the respondent no. 9 was set aside.

33. The counsel relied on a certain "List of Practices and Procedures involving cell or stem cell-based preparations for therapeutic purposes as identified by experts", which has been prepared by the MoHFW in year 2022, and this list is said to have purportedly categorised the use of 'bone marrow derived stem cells' as a 'clinical option' for autism.

34. The learned counsel invited our attention to the recommendation made by the Drugs Technical Advisory Body ("**DTAB**") in its 84th meeting dated 27.08.2019, wherein it was stated that the routine practices/transplantations/surgeries/therapies involving stem cells, undertaken by doctors for the treatment of their own patients, without any intention to commercialise the same outside of their own hospitals/clinics, would fall outside the purview of the 1940 Act and the 2019 Rules respectively.

35. The learned counsel further contended that the petitioners' reliance on the NGSCR 2017 guidelines issued by the respondent no. 3 is misplaced since they do not have any statutory force and are not binding in nature. In this regard, he also submitted that a clarification had been sought from the respondent no. 3 by one Nitin Khanapure, through an RTI application made under the Right to Information Act, 2005, regarding the nature of the NGSCR 2017 i.e., whether such guidelines are a 'guidance document or a regulatory document'. In response to the said RTI application, the respondent no. 2 in its reply dated 16.08.2020 stated that the NGSCR 2017 only constitute a guidance document. By placing significant reliance on the aforesaid response,

the learned counsel fortified his contention that the respondent no. 3 is a non-statutory body and hence the NGSCR 2017 do not have any binding force.

36. Moreover, the learned counsel submitted that the respondent no. 3 had withdrawn itself from all regulatory matters pertaining to stem cell research, *vide* its public notices dated 31.05.2023 and 03.03.2024 respectively. Therefore, any reliance placed on the 2017 guidelines which predate these withdrawal notices would be incorrect.

37. The counsel brought to our notice the orders of the Delhi High Court in ***Abhishek Agarwal & Anr. v. Union of India & Anr.,*** **W.P.(C) 5147/2019** and ***Dalip Kaur*** *(supra)* respectively, which in his opinion, had the occasion to deal with the issue of stem cell therapies extensively and had arrived at the conclusion to permit its continuation.

i. In the order dated 04.09.2019 passed in ***Abhishek Agarwal*** *(supra)*, the Delhi High Court had observed that,

> *"4. The position, as it emerges from the Status Note dated 14th June, 2019 filed by the Central Drugs Standard Control Organization (CDSCO), is that, while treatment using "stem cells" is permissible, treatment using "stem cells derived products" requires a licence under the Rules, 2019….*
>
> *xxx*
>
> *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.*"

38. It was submitted by the learned counsel that ***Dalip Kaur*** *(supra)* which deals with the validity of the EMRB recommendations dated 06.12.2022 issued by the respondent no. 2 is pending adjudication. However, he submitted that the

said report does not have the force of law since the EMRB is merely an autonomous board constituted under Section 16 read with Section 27 of the NMC Act. The EMRB does not have any statutory power and any recommendation of the EMRB cannot be declaratory or binding in nature, especially in the absence of an explicit acceptance by the respondent no. 2. He also submitted that in light of the proviso to Section 27 of the NMC Act, the EMRB can act only through the State Medical Councils and not otherwise.

e. <u>Submissions on behalf of the Respondent no.10/ Reelabs Pvt. Ltd.</u>

39. Mr. Nikilesh Ramachandran, the learned counsel appearing for the respondent no. 10/ Reelabs Pvt. Ltd. submitted that the respondent no. 10 is a biotech company primarily involved in Cord Blood Banking and holds the requisite licence to collect, process, test, store, bank and release umbilical cord blood stem cells. He further submitted that the respondent no. 10 is primarily engaged in the treatment of 80 disorders (excluding ASD) using stem cell therapy, as approved under Annexure III of the NGSCR 2017.

40. The learned counsel submitted that the respondent no. 10 acts in strict compliance with the NGSCR 2017 as well as the NDCT Rules, 2019. He categorically denied the petitioners' allegations that the website of the respondent no. 10 has advertised stem cell therapy as a cure for ASD. He submitted that the said website merely provides a list of the ICMR-approved treatable diseases which does not include ASD. Therefore, he would submit that respondent no. 10 does not engage in any form of false advertising including claims to cure ASD.

f. Submissions on behalf of Respondent no.11/Saffron Naturele Products Ltd.

41. Ms. Swarupama Chaturvedi, the learned senior counsel (as Her Ladyship then was) appearing for the respondent no. 11/Saffron Naturele Products Ltd., submitted that respondent no. 10 is a private limited company engaged in research-oriented development and production of different types of stem cells and primary cells. She submitted that the respondent no.10 is engaged in the processing of stem cells but is not involved in providing any therapy to the patients.

42. She argued that since the respondent no. 10 is merely engaged as a vendor in supplying the processed stem cell to the patients or the hospitals as per their requirement, the onus of compliance with any rules lies with such patients or hospitals only and does not place any obligation on the respondent no. 10.

43. She further submitted that the respondent no. 10 does not have any infrastructure. It has no medical practitioners/medical manpower on roll or any facility to carry out any medical treatment of any kind, much less of the kind as is alleged by the petitioners.

44. She submitted that since the respondent no. 10 is not engaged in the end-use of the stem cells it supplies, it is not answerable as regards to the legal permissibility of such alleged medical treatment of ASD using stem cell therapy. However, she further went on to submit that there is no law which governs stem cell therapy and the guidelines are non-judicious in nature.

g. <u>Submissions on behalf of the Respondent no.13/ Parents' Forum for Stem Cells in Autism and Cerebral Palsy</u>

45. Mr. Nitesh Ranjan, the learned counsel appearing for the respondent no. 13 submitted that the respondent no. 13 is a registered society comprising of parents and family members of children diagnosed with autism and cerebral palsy, who are undergoing autologous cell/stem cell therapy. He submitted that the respondent no. 13 had preferred to be impleaded in the present matter in order to oppose the present petition since in their opinion, allowing the present petition would lead to the denial of stem cell therapies to their children who have seen a marked improvement owing to autologous mononuclear cell/stem cell therapy. We were also informed that it is one of the members of the respondent no. 13 who had preferred the writ petition in ***Dalip Kaur*** *(supra)* before the Delhi High Court.

46. The learned counsel submitted that the autologous cell therapy is performed using the patient's own cells, without the injection of any external or foreign object. He submitted that process involves obtaining the bone marrow from the hip bone; isolation of the mononuclear cells from the bone marrow using the density gradient centrifugation method and the immediate injection of these cells intrathecally *via* lumbar puncture into the same patient. He would submit that the use of one's own body part cannot and does not fall within the definition of a 'drug' under the Drugs Act, 1940 or under any other law.

47. Furthermore, the learned counsel mirrored the submissions that were made by respondent no. 9 with respect to (a) the difference between 'stem cell derived product' and 'stem cell therapy' respectively under the scheme of the NDCT Rules, 2019; (b) the statutory clarification regarding the meaning of "stem cell derived product" issued under Section 33P of the 1940 Act; (c) the

recommendations made by the DTAB in its 84th meeting; (d) the list issued by the MoHFW whereby 'bone marrow derived stem cells' was mentioned as a 'clinical option' for autism; and (e) the challenge to the recommendations made by the EMRB report dated 06.12.2022 before the Delhi High Court in ***Dalip Kaur*** *(supra)*.

48. He further submitted that the right to life under Article 21 of the Constitution contains within its fold, the undeniable fundamental right of the patient and their care-givers to choose the best or any available treatment which could potentially lead to an improvement in the health or condition of the patient. He submitted that if the prayers in the present petition are granted, it could lead to a deprivation of the fundamental right of the patient to seek and avail medical treatment with full and free consent. He argued that the potential of risk or the lack of guaranteed efficacy cannot be made a valid ground to deny the patient a therapy or treatment, to which the patient or their guardian has given their explicit consent. To demonstrate that patients receiving stem cell therapy have witnessed improvements in their condition, the learned counsel placed before us medical records, including the copies of brain scans of those patients whose parents/guardians are members of the respondent no. 13.

C. ISSUES FOR DETERMINATION

49. Having heard the learned counsel appearing for the parties and having gone through the materials on record, the following questions fall for our consideration:

i. Whether doctors/clinics/hospitals/institutions are legally permitted to offer stem cell 'therapy' as a routine healthcare service?

ii. Whether the Drugs Act, 1940 and the NDCT Rules, 2019 provide a framework for the regulation of research in stem cell therapies which are used for the treatment of ASD?

D. ANALYSIS

a. Maintainability of the present PIL:

50. Upon a perusal of the facts on record, it is clear that the present petition raises an issue of public importance.

51. The respondents' contention that the present petition which arises out of the petitioner no.1's apprehension regarding stem cell therapies posing a potential threat to its commercial interests is untenable. Even if there is an underlying commercial competition amongst the service providers of various modes of treatment, it does not discredit the petition's main concern that there is considerable confusion among the stakeholders, those administering as well as receiving such 'therapies' regarding the regulatory framework. The facts on record indicate that the petitioners are bona fide and no personal grievance is sought to be addressed through the present petition.

52. The present petition, therefore, is held to be maintainable.

b. What are stem cell 'therapies' in ASD?

53. At the outset, it is necessary to clarify the scope of the term stem cell "therapies". It is relevant to note that there is no statutory definition of the term "therapy" under the Drugs Act, 1940 or the rules promulgated thereunder. Hence, we turn to the guidelines and related documents issued by the ICMR and DHR to understand the term in the context of the therapeutic

use of stem cells in ASD. The primarily relevant ICMR-DHR guidelines and documents in this regard are the NGSCR 2017, the Evidence Based Status of Stem Cell Therapy for Human Diseases 2021 ("**EBSSCT, 2021**"**)**, and the National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, 2017 ("**National Ethical Guidelines**").

54. While the guidelines issued by the ICMR and DHR do not define the term 'stem cell therapy', yet we find a representative overview thereof in Chapter 5 of the EBSSCT, 2021 which deals with the evidence-based status of therapeutic use of stem cells in ASD.

55. The representative studies outlined by the ICMR in the EBSSCT, 2021 indicate that research on the therapeutic use of stem cells in ASD involves administering various types of stem cells such as human embryonic stem cells, human cord blood mononuclear cells, umbilical cord derived mesenchymal stem cells, autologous umbilical cord blood stem cells, fetal stem cells, autologous bone marrow mononuclear cells and bone marrow aspirate concentrate stem cells. The routes of administration of these stem cells for therapeutic use in ASD also vary considerably, ranging from intravenous (IV), intramuscular (IM), epidural, popliteal block, brachial plexus block, intrathecal(IT), epidural catheter caudal, deep spinal muscle, combined IV and IT transplantation, peripheral IV infusion, subcutaneous, etc. This clearly underscores that therapeutic use of stem cells in ASD is undertaken in the form of administering stem cells and that there is significant variation in the type of stem cells used as well as their route of administration.

56. At this stage, we may take note of the respondents' submissions as regards the distinction between 'drugs' and 'therapies'. As noted above, the therapeutic use of stem cells in ASD involves the administration of various types of stem cells through different routes. Hence, it is necessary to determine whether the stem cells that are administered for therapeutic use in ASD fall within the definition of "drug" under the Drugs Act, 1940.

57. However, we find it apposite to clarify at the threshold that irrespective of categorization of the stem cells administered for therapeutic use as "drugs" under the Act, 1940, the issue of the permissibility of their administration as a clinical service, cannot be determined *ipso facto*. In other words, it cannot be said that merely because certain stem cells which are administered for therapeutic use in ASD may not fall within the definition of "drugs" under the Drugs Act, 1940, they would, by default, be permitted to be offered to patients as a clinical service. It is no gainsaying that to ascertain the permissibility of administering such stem cell therapies for ASD, the focus of inquiry has to primarily be from the angle of standard of care owed by medical professionals to their patients.

58. Therefore, for the purpose of determining the issues before us, we would first determine whether stem cells are permitted to be administered for therapeutic use in ASD as a commercial service or not. If it is found that therapeutic use of stem cells in ASD cannot be offered as a commercial service, we would then consider whether such stem cells may nevertheless be administered in a research or clinical trial setting. In order to identify the appropriate regulatory route for undertaking such clinical trial or research, we would delve into the

question of whether stem cells administered for therapeutic use in ASD fall within the definition of "drugs" under the Drugs Act, 1940.

c. <u>Is it permissible for medical practitioners to offer stem cell 'therapy' in ASD as a service?</u>

59. We may refer to a few landmark judgments of this Court which have laid down the law on the duty of care owed by a medical practitioner towards its patient in order to determine whether stem cell 'therapy' in ASD can be offered as a clinical treatment or not. A Three-Judge Bench of this Court in ***Indian Medical Association v. V.P. Shantha and others*** reported in **(1996) 86 COMP 806**, paved the way for adopting and applying the "*Bolam Test"* in the Indian landscape of medical negligence jurisprudence to determine the standard of care which is required from medical practitioners as laid down in the landmark English case of ***Bolam v. Friern Hospital Management Committee*** reported in **(1957) 1 WLR 582**. The observations of McNair J. in ***Bolam*** *(supra)* are reproduced below:

> *"Before I turn to that, I must tell you what in law we mean by "negligence." In the ordinary case which does not involve any special skill, negligence in law means a failure to do some act which a reasonable man in the circumstances would do, or the doing of some act which a reasonable man in the circumstances would not do; and if that failure or the doing of that act results in injury, then there is cause of action. How do you test whether this act or failure is negligent? In an ordinary case it is generally said you judge it by the action of the man in the street. He is the ordinary man. In one case it has been said you judge it by the conduct of the man on the top of a Clapham omnibus. He is the ordinary man. <u>But where you get a situation which involves the use of some special skill or competence, then the</u>*

> *test as to whether there has been negligence or not is not the test of the man on the top of a Clapham omnibus, because he has not got this special skill. The test is the standard of the ordinary skilled man exercising and professing to have that special skill. A man need not possess the highest expert skill; it is well established law that it is sufficient if he exercises the ordinary skill of an ordinary competent man exercising that particular art. I do not think that I quarrel much with any of the submissions in law which have been put before you by counsel. Mr. Fox-Andrews put it in this way, that in the case of a medical man, negligence means failure to act in accordance with the standards of reasonably competent medical men at the time. That is a perfectly accurate statement, as long as it is remembered that there may be one or more perfectly proper standards; and if he conforms with one of those proper standards, then he is not negligent. Mr. Fox-Andrews also was quite right, in my judgment, in saying that a mere personal belief that a particular technique is best is no defence unless that belief is based on reasonable grounds. That again is unexceptionable. But the emphasis which is laid by the defence is on this aspect of negligence, that the real question you have to make up your minds about on each of the three major topics is whether the defendants, in acting in the way they did, were acting in accordance with a practice of competent respected professional opinion. Mr. Stirling submitted that if you are satisfied that they were acting in accordance with a practice of a competent body of professional opinion, then it would be wrong for you to hold that negligence was established."*
>
> (Emphasis supplied)

60. This Court in ***V.P. Shantha*** (*supra*) also referred an earlier decision of this Court in ***Laxman Balkrishna Joshi v. Trimbak Bapu Godbole***, reported in **1968 SCC OnLine SC 260** as follows:

> "*31. In an action for negligence in tort against a surgeon this Court, in Laxman Balkrishna Joshi v. Trimbak Bapu Godbole has held: (SCR p. 213)*
>
> > "*The duties which a doctor owes to his patient are clear. A person who holds himself out ready to give medical advice and treatment impliedly undertakes that he is possessed of skill and knowledge for the purpose. Such a person when consulted by a patient owes him certain duties, viz., a duty of care in deciding whether to undertake the case, a duty of care in deciding what treatment to give or a duty of care in the administration of that treatment. A breach of any of those duties gives a right of action for negligence to the patient. The practitioner must bring to his task a reasonable degree of skill and knowledge and must exercise a reasonable degree of care. Neither the very highest nor a very low degree of care and competence judged in the light of the particular circumstances of each case is what the law require.*"
>
> (Emphasis supplied)

61. An examination of the jurisprudence developed by this Court while dealing with cases of medical negligence has consistently recognised the standard of fiduciary duty that medical professionals owe to their patients, i.e. a duty to exercise a reasonable degree of care, skill, and knowledge expected of a prudent medical practitioner in the same field. This 'standard of care' was also recognised by this Court in ***Jacob Mathew v. State of Punjab***, reported in **(2005) 6 SCC 1**, and ***Kusum Sharma v. Batra Hospital***, reported in **(2010) 3 SCC 480**. This Court recently reaffirmed the same in ***M.A. Biviji v. Sunita and Others***, reported in **(2024) 2 SCC 242**. The following excerpt from the judgment of this Court in ***M.A. Biviji*** *(supra)*, succinctly summarises the

concept of 'duty of care' that is owed by medical practitioners towards their patients. The relevant portions of the judgment in ***M.A. Biviji*** *(supra)* are reproduced below:

> "*35. Before proceeding further, let us understand what this Court has found to constitute medical negligence. In Jacob Mathew v. State of Punjab, the Court held: (SCC pp. 32-33, para 48)*
>
> > *"48. ... (1) Negligence is the breach of a duty caused by omission to do something which a reasonable man guided by those considerations which ordinarily regulate the conduct of human affairs would do, or doing something which a prudent and reasonable man would not do. The definition of negligence as given in Law of Torts, Ratanlal & Dhirajlal (edited by Justice G.P. Singh), referred to hereinabove, holds good. Negligence becomes actionable on account of injury resulting from the act or omission amounting to negligence attributable to the person sued. The essential components of negligence are three:"duty", "breach", and "resulting damage".*
> >
> > *(2) Negligence in the context of medical profession necessarily calls for a treatment with a difference. To infer rashness or negligence on the part of a professional, in particular a doctor, additional considerations apply. A case of occupational negligence is different from one of professional negligence. A simple lack of care, an error of judgment or an accident, is not proof of negligence on the part of a medical professional.* ***So long as a doctor follows a practice acceptable to the medical profession of that day****, he cannot be held liable for negligence merely because a better alternative course or method of treatment was also available or simply*

because a more skilled doctor would not have chosen to follow or resort to that practice or procedure which the accused followed. When it comes to the failure of taking precautions, what has to be seen is whether those precautions were taken which the ordinary experience of men has found to be sufficient; a failure to use special or extraordinary precautions which might have prevented the particular happening cannot be the standard for judging the alleged negligence. So also, ***the standard of care, while assessing the practice as adopted, is judged in the light of the knowledge available at the time of the incident,*** *and not at the date of trial. Similarly, when the charge of negligence arises out of failure to use some particular equipment, the charge would fail if the equipment was not generally available at that particular time (that is, the time of the incident) at which it is suggested it should have been used.*

(3) A professional may be held liable for negligence on one of the two findings: either he was not possessed of the requisite skill which he professed to have possessed, or, he did not exercise, with reasonable competence in the given case, the skill which he did possess. The standard to be applied for judging, whether the person charged has been negligent or not, would be that of an ordinary competent person exercising ordinary skill in that profession. It is not possible for every professional to possess the highest level of expertise or skills in that branch which he practices. A highly skilled professional may be possessed of better qualities, but that cannot be made the basis or the yardstick for judging the performance of the professional proceeded against on indictment of negligence."

36. Following Jacob Mathew, the Court in Kusum Sharma v. Batra Hospital laid down the following principles that are to be considered while determining the charge of medical negligence (Kusum Sharma case, SCC pp. 506-507, para 89)

> *"89. (I) Negligence is the breach of a duty exercised by omission to do something which a reasonable man, guided by those considerations which ordinarily regulate the conduct of human affairs, would do, or doing something which a prudent and reasonable man would not do.*
>
> ***
>
> *(III) The Medical Professional is expected to bring a reasonable degree of skill and knowledge and must exercise a reasonable degree of care. Neither the very highest nor a very low degree of care and competence judged in the light of the particular circumstances of each case is what the law requires.*
>
> *(IV) A medical practitioner would be liable only where his conduct fell below that of the standards of a reasonably competent practitioner in his field.*
>
> *(V) In the realm of diagnosis and treatment there is scope for genuine difference of opinion and one professional doctor is clearly not negligent merely because his conclusion differs from that of another professional doctor.*
>
> *(VI) The medical professional is often called upon to adopt a procedure which involves higher element of risk, but which he honestly believes as providing greater*

chances of success for the patient rather than a procedure involving lesser risk but higher chances of failure. Just because a professional looking to the gravity of illness has taken higher element of risk to redeem the patient out of his/her suffering which did not yield the desired result may not amount to negligence.

(VII) Negligence cannot be attributed to a doctor so long as he performs his duties with reasonable skill and competence. Merely because the doctor chooses one course of action in preference to the other one available, he would not be liable if the course of action chosen by him was acceptable to the medical profession.

***

(IX) It is our bounden duty and obligation of the civil society to ensure that the medical professionals are not unnecessarily harassed or humiliated so that they can perform their professional duties without fear and apprehension."

37. As can be culled out from above, the three essential ingredients in determining an act of medical negligence are:
(1) a duty of care extended to the complainant,
(2) breach of that duty of care, and
(3) resulting damage, injury or harm caused to the complainant attributable to the said breach of duty.

However, a medical practitioner will be held liable for negligence only in circumstances when their conduct falls below the standards of a reasonably competent practitioner.

38. Due to the unique circumstances and complications that arise in different individual cases, coupled with the constant advancement in the medical field and its practices, it is natural

> *that there shall always be different opinions, including contesting views regarding the chosen line of treatment, or the course of action to be undertaken. In such circumstances, just because a doctor opts for a particular line of treatment but does not achieve the desired result, they cannot be held liable for negligence,* ***provided that the said course of action undertaken was recognised as sound and relevant medical practice****. This may include a procedure entailing a higher risk element as well, which was opted for after due consideration and deliberation by the doctor. Therefore, a line of treatment undertaken should not be of a discarded or obsolete category in any circumstance.*
>
> *39. To hold a medical practitioner liable for negligence, a higher threshold limit must be met. This is to ensure that these doctors are focused on deciding the best course of treatment as per their assessment rather than being concerned about possible persecution or harassment that they may be subjected to in high-risk medical situations. Therefore, to safeguard these medical practitioners and to ensure that they are able to freely discharge their medical duty, a higher proof of burden must be fulfilled by the complainant. The complainant should be able to prove a breach of duty and the subsequent injury being attributable to the aforesaid breach as well, in order to hold a doctor liable for medical negligence. On the other hand, doctors need to establish that they had followed reasonable standards of medical practice."*
>
> (Emphasis Supplied)

62. What is discernible from the aforesaid exposition is that every medical practitioner owes to his patient a duty to exercise a reasonable degree of care, skill, and knowledge expected of a prudent medical practitioner in the same field. The dictum of this Court in the aforesaid decisions also clarifies that this 'standard of care' requires a medical practitioner's conduct to be judged not

by the highest expert standard, but by that of an ordinary competent practitioner, acting with due care in the circumstances prevailing at the time of treatment. The test, therefore, is one of reasonableness, not perfection.

63. The natural corollary of the above principles is that a medical practitioner cannot be said to meet the standard of reasonable care if they administer an intervention that lacks credible scientific evidence of safety and efficacy, or where authoritative medical bodies unequivocally state that such form of treatment is not recommended. This flows directly from the requisite standard of care emphasised in ***V.P. Shantha*** *(supra)*, ***Jacob Mathew*** *(supra)*, as also reaffirmed in ***M.A. Biviji*** *(supra)*, that is, a doctor's conduct must conform to a "*practice acceptable to the medical profession of that day"* when *"judged in the light of the knowledge available at the time of the incident"*. The jurisprudence makes it clear that liability does not arise merely because an alternative approach existed, but rather, liability arises when the course adopted is one which the ordinary, reasonably competent medical practitioner would not regard as a sound and acceptable medical practice in light of the prevailing body of medical knowledge. In ***M.A. Biviji*** *(supra),* this Court reiterated that a medical practitioner is insulated from negligence liability provided that "*the said course of action undertaken was recognised as sound and relevant medical practice"* and is supported by the knowledge available at the time of the incident. Therefore, it can be deduced that if a treatment is characterised by the relevant scientific community or regulatory authorities as unproven, experimental, obsolete, or lacking justification, such a treatment cannot be defended as an exercise of due care and reasonable judgment by a medical practitioner.

64. The note of caution sounded by this Court in ***M.A. Biviji*** (*supra*) that a particular line of treatment undertaken should be regarded as a *"sound and relevant medical practice"* and that "*it should not be a discarded or obsolete category in any circumstance"* is of crucial importance. Keeping this in mind ensures that patients are treated in accordance with established, evidence-based medical norms, and prevents medical practitioners from resorting to speculative, unproven, or experimental interventions when there is absence of any credible scientific evidence or professional opinion. In other words, a practitioner who disregards this caveat and administers speculative, unproven, or experimental treatments even when credible professional bodies expressly advise against the use of such a treatment, the administration of such a treatment would fail to satisfy the standard of reasonable care necessitated under the established medical negligence jurisprudence in India. The only circumstance in which an experimental treatment may be provided is when it is administered within an approved research or clinical trial setting.

65. It is in the backdrop of these principles that we would now proceed to evaluate whether therapeutic use of stem cells in ASD meets the threshold of reasonable standard of care that medical practitioners owe towards their patients. In order to do so, we would look into the following documents which encapsulate the current state of knowledge and professional opinion on the subject matter:

i. The EMRB-NMC Recommendations dated 06.12.2022;
ii. The NGSCR 2017 and the Evidence Based Status of Stem Cell Therapy for Human Diseases, 2021 jointly published by the ICMR and the DHR;
iii. The DTAB's 84th Meeting Recommendations dated 27.08.2019; and

iv. The list of practices and procedures involving cell or stem-cell based preparations for therapeutic purposes as identified by experts (other than Standard of Care provided by ICMR), [purportedly shared by the Minister, MoFHW, Government of India *vide* email dated 19.01.2023]

(i) ***Significance of the Ethics & Medical Registration Board, National Medical Commission Recommendations dated 06.12.2022:***

66. The Ethics & Medical Registration Board ("**EMRB**") of the NMC constituted a committee of experts to examine the issues related to the prescription, recommendation or administration of stem cell treatment for ASD, and the report containing the expert committee's recommendations was published by the EMRB on 06.12.2022. The expert committee reviewed the available scientific literature in the field of stem cell research for ASD and examined the veracity of the unproven hypothesis that this treatment helps in offering neural cell protection by enhancing neural tissue repair and preventing ongoing neuronal damage, thereby reducing the severity of autistic symptoms. It noted that the quality of research in this area is poor and indicated that based on the existing research pool, it was not possible to draw any firm conclusions on the efficacy of stem cell therapy in ASD. It also emphatically highlighted that none of the current international guidelines recommend stem cell therapy as a treatment for ASD. Its observation reads as follows:

> *"Guidelines and expert opinions: National and international guidelines, including ICMR guidelines are uniform in their conclusion that there is insufficient evidence for SCT in ASD and do not recommend it as a treatment for ASD, and call for more high-quality research. Many experts in the field 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. Jessica Sun and Joanne Kurtzberg, eminent researchers in this area, have expressed concerns about predatory marketing practices, and unwarranted raising of hopes despite the absence of good quality scientific evidence and exploitation of patients and their families Similarly, Antonio Narzisi in 2022 stated that "The take home message that needs to be considered is that, to date, the scientific evidence on the use of stem cells for the treatment of ASD is insufficient,..." and that offering SCT for ASD in the current state of scientific research is clearly unethical.

In conclusion, there is as yet insufficient and inadequate scientific evidence on efficacy of the SCT in ASD. Therefore, SCT cannot be recommended as it treatment for ASD."

67. Based on its review, the expert committee made certain recommendations that are critical to the present adjudication. The expert committee's recommendations published in the EMRB report dated 06.12.2022 are as follows:

"RECOMMENDATIONS:
i. Current Status: Stem cell therapy is not recommended as a treatment for Autism Spectrum Disorder (ASD) in clinical practice.
ii. <u>In view of the above recommendation, use of Stem cell in ASD, its promotion and advertisement will be considered as professional misconduct</u>.

> *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."*
> (Emphasis supplied)

68. These recommendations of the EMRB expert committee 06.12.2022 were approved by the NMC in its meeting dated 28.03.2024 and thereafter published on the NMC website.

69. The EMRB is constituted by the Central Government as an Autonomous Body under Section 16(d) of the NMC Act, 2019. As per Section 27(1)(b), the EMRB has the power to regulate professional conduct and promote medical ethics in accordance with the regulations framed under the NMC Act, 2019. Moreover, as per Section 27(2) of the NMC Act, 2019, the EMRB may, in the discharge of its functions, make such recommendations to, and seek such directions from, the NMC, as it deems necessary. Sections 27(1)(b) and 27(2), respectively, read thus:

> *"27. Powers and functions of Ethics and Medical Registration Board.- (1) The Ethics and Medical Registration Board shall perform the following functions, namely:-*
> ***
> *(b) regulate professional conduct and promote medical ethics in accordance with the regulations made under this Act:*
> *Provided that the Ethics and Medical Registration Board shall ensure compliance of the code of professional and ethical conduct through the State Medical Council in a case where such State Medical Council has been conferred power to take disciplinary actions in respect of professional or ethical*

> *misconduct by medical practitioners under respective State Acts;*
>
> ***
>
> *(2) The Ethics and Medical Registration Board may, in the discharge of its duties, make such recommendations to, and seek such directions from, the Commission, as it deems necessary."*
>
> (Emphasis supplied)

70. The EMRB is a statutory body under the NMC Act, 2019, responsible for regulating professional conduct and promoting medical ethics, therefore, its recommendations, once approved by the NMC, serve as authoritative guidance on what constitutes ethical and professionally acceptable conduct for medical practitioners in India. The EMRB's recommendations expressly state that stem cell therapy for ASD is not recommended, for lack of adequate evidence, and that its use or promotion amounts to professional misconduct. In such view of the matter, could it be said that the administration of stem cell for therapeutic use in ASD constitutes a *"sound and relevant medical practice"* or a "*practice acceptable to the medical profession of that day"* when *"judged in the light of the knowledge available at the time of the incident"*? In light of this Court's dictum in ***M.A. Biviji*** *(supra)* and ***V.P. Shantha*** *(supra)*, our answer to this question must be an emphatic 'No'. There is no manner of doubt left in our minds that if any medical practitioner offers such stem cell therapy in ASD as a clinical service, he/she would fail to meet the reasonable standard of care which the law requires a medical practitioner to discharge.

(ii) ***Significance of the National Guidelines for Stem Cell Research, 2017 and the Evidence Based Status of Stem Cell Therapy for Human Diseases, 2021***

71. The NGSCR 2017 as well as the EBSSCT 2021 are documents which have been published by the ICMR on behalf of the Secretary DHR, MoHFW & DG, ICMR. According to the Government of India (Allocation of Business) Rules, 1961 ("**Business Allocation Rules, 1961**"), the DHR is responsible for the promotion and coordination of basic, applied and clinical research including clinical trials and operational research in areas related to medical, health, biomedical and medical profession and education through development of infrastructure, manpower and skills in cutting edge areas and management of related information thereto. The DHR is also responsible for promoting and providing guidance on research governance issues, including ethical issues in medical and health research. Moreover, even though the ICMR is an autonomous body registered under the Societies Registration Act, 1860, yet as per the Business Allocation Rules, 1961, the Indian Council of Medical Research is also listed as a business allocated to the DHR.

72. Given this framework, it is limpid that the documents published by the ICMR as authorized by the DHR represent the well-researched scientific and ethical position of the apex bodies entrusted with the responsibility of overseeing biomedical research in the country. Thus, we find that the said documents, though not binding by themselves, yet can certainly be relied upon as credible source to assess whether a certain *practice* is *acceptable to the medical profession of that day"* when *"judged in the light of the knowledge available at the time of the incident"* and whether a line of treatment undertaken should

be regarded as a *"sound and relevant medical practice"* and not as a "*discarded or obsolete category in any circumstance"*. The relevance of these ICMR publications lie not in their binding force in a standalone manner, but in the role they play in evidencing the contemporary scientific and ethical baseline of the medical profession.

73. Chapter 5 of the EBSSCT 2021 which deals with therapeutic use of stem cells in ASD has already been referred to by us hereinabove. This document clearly and emphatically states that critical review of the studies reported so far do not support the use of stem cell therapy over and above the behavioural and supportive therapies for ASD. The ICMR in this document further states that based on the review of available scientific evidence, stem cell therapy should not be offered as a standard or routine therapy to patients with ASD. The relevant paragraphs from the said Chapter 5 of the EBSSCT 2021 are reproduced below:

> *"Have stem cells been used in ASD?*
>
> *Along with supportive therapies and drug treatment, few studies have tested the use of various forms of stem cells to improve the outcome in children with Autism. We are aware that many Indian patients with ASD have been offered different types of stem cell therapies as a standard treatment option and not as part of any approved clinical trial / research. ICMR with inputs from medical specialists in this field has reviewed the existing scientific and medical literature and submissions from practicing doctors and their professional societies regarding any evidence-based safety and efficacy of stem cells in ASD. Critical review of the studies reported so far do not support the use of stem cell therapy over and above the behavioural and supportive therapies for ASD.*

Recommendations (2021): Based on the review of available scientific evidence, stem cell therapy should NOT be offered as a standard or routine therapy to patients with Autism. These guidelines will be periodically reviewed for any new evidence showing benefit or harm with the use of stem cells for Autism Spectrum Disorder. Therapeutic use of any type of stem cell in Autism should be restricted to clinical trials only after obtaining necessary regulatory approval as defined in National Guidelines for Stem Cell Research-2017. The patients participating in these clinical trials should be closely monitored for the possibility of any harm with use of stem cells. As per the National Ethical Guidelines for Biomedical and Health Research Involving Human Participants - 2017, trial participants should have read and signed the informed consent form which explains them the alternative therapies, possible benefits as well as harm due to experimental treatments like stem cell therapy. Participants should not be made to pay for any expenses incurred beyond routine clinical care and which are research related including tests, investigations and any interventions (such as stem cells). This is applicable to all participants,

including those in comparator/control groups. Participants in a clinical trial should be provided compensation in the event of any harm or permanent injury or death due to the use of experimental stem cell therapy.

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Summary of Evidence and Recommendations for Medical / Scientific Professionals (2021)

Based on the review of available scientific evidence, stem cell therapy should NOT be offered as a standard or routine therapy to patients with Autism Spectrum Disorder.

CAUTIONARY NOTE

The experts observed that severe autism can have a major impact on the quality of life of the affected child and the family. There is therefore a need to undertake research into the causes and more effective management of ASD. Since conventional management fails to control

symptoms in many cases, such families see hope in some miraculous recovery with the use of stem cells without understanding the risks versus benefit ratio. It is therefore imperative that use of any type of stem cells in ASD should be restricted to clinical trials with necessary approval from regulatory authorities in India and as per the National Guidelines on Stem Cell Research – 2017.

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These guidelines will be periodically reviewed for any new evidence showing benefit or harm with the use of stem cells for Autism Spectrum Disorder."

(Emphasis supplied)

74. The NGSCR 2017 goes as far as to state that the use of stem cells in patients (other than for hematopoietic stem cell reconstitution for approved indications) outside an approved clinical trial is unethical and shall be considered as malpractice. The observations from the NGSCR 2017 reads thus:

"We *are committed towards stem cell treatments that are safe and have proven efficacy. The Guidelines for Stem Cell Research and Therapy in 2007 was a step towards this commitment, which were revised after public consultations and released as National Guidelines for Stem Cell Research (NGSCR-2013). The National Guidelines for Stem Cell*

Research, 2017 is an outcome of concerted efforts of different stakeholders. It has been formulated taking into account several new scientific and technical advancements as well as the perceived challenges in the field. Efforts were made to bring together all concerned ministries/agencies to chalk out strategies to curb rampant unethical practices of banking and therapeutic application. The recommendations of the Inter-Ministerial/Inter-Agency meetings have helped to shape these guidelines. Detailed and extensive consultation with stakeholders were held and their suggestions taken into account before finalization. Most importantly, the guidelines have been harmonized with existing rules and regulations resulting in a comprehensive document.

The 2017 guidelines, reiterate that any stem cell use in patients, other than that for hematopoietic stem cell reconstitution for approved indications, is investigational at present. Accordingly, any stem cell use in patients must only be done within the purview of an approved and monitored clinical trial with the intent to advance science and medicine, and not offering it as therapy. In accordance with this stringent definition, every use of stem cells in patients outside an approved clinical trial is unethical and shall be considered as malpractice."

(Emphasis supplied)

75. The ICMR publications clearly set out the contemporary scientific position on therapeutic use of stem cells in ASD, and that regardless of the binding nature of the guidelines, these documents published by the ICMR would function as authoritative indicators of what constitutes sound medical practice and what falls outside the realm of defensible clinical judgment. These documents published by the ICMR and endorsed by the DHR, unequivocally

state that the therapeutic use of stem cells in ASD, outside an approved clinical trial is unethical and shall be considered as malpractice, since there is lack of reliable conclusive research on the efficacy and safety of such procedures. Therefore, if a medical practitioner, in blatant disregard of such authoritative guidelines choose to offer stem cell therapies for ASD, as a clinical service, outside of an approved clinical trial, then such medical practitioner would be considered as having failed to act in accordance with reasonable standard of care.

(iii) ***Significance of the DTAB's 84th Meeting Recommendations dated 27.08.2019:***

76. We now turn to the 84th DTAB Meeting Recommendations dated 27.08.2019, which have been relied upon by the respondent nos. 9 and 13. The Drugs Technical Advisory Body ("**DTAB**") is a statutory body constituted by the Central Government under Section 5(1) of the Drugs and Cosmetics Act, 1940 which reads thus,

> "*5. The Drugs Technical Advisory Board.- (1) The Central Government shall, as soon as may be, constitute a Board (to be called the Drugs Technical Advisory Board) to advise the Central Government and the State Governments on technical matters arising out of the administration of this Act and to carry out the other functions assigned to it by this Act.*"

77. It was recommended therein that it was stated that the routine practices/transplantations/surgeries/therapies involving stem cells, undertaken by doctors for the treatment of their own patients, without any intention to commercialise the same outside of their own hospitals/clinics, would fall outside the purview of the Drugs Act, 1940 and the NDCT Rules, 2019 respectively.

78. Further, one of the agendas for deliberation was consideration of the proposal to incorporate a definition for the term "*stem cell derived product"* under the NDCT Rules, 2019. The DTAB accepted the proposal and recommended a clarification of the term *"stem cell derived product*", which was subsequently reproduced verbatim in the abovementioned direction dated 09.02.2021 issued by the Drugs Regulation Section, Department of Health & Family Welfare, MoHFW, Government of India under Section 33P of the Drugs Act, 1940.

79. However, there is another crucial aspect of the 84th DTAB meeting that warrants attention. At the 84th meeting itself, the DTAB further deliberated on the agenda and went on to recommend that the routine practices/transplantations/surgeries/therapies undertaken by doctors involving stem cell for treatment of their own patients, and not for commercialisation of the same outside their own hospitals/clinics, would fall outside the purview of Drugs Act, 1940 and the NDCT Rules, 2019 and should therefore be dealt outside the said regulation. The said additional recommendations made by the DTAB at its 84th meeting dated 27.08.2019 are as follows:

> "*DTAB deliberated the matter in length and in principle, agreed to the proposal and <u>further recommended</u> that it is given to understand that ICMR/ DHR is making guidelines for this and therefore, while considering the issuance of such clarification on stem cell derived products, those guidelines to be published by the ICMR may be considered.*
>
> *<u>DTAB also recommended that, the routine practices/ transplantations/ surgeries/therapies undertaken by doctors involving stem cell for treatment of their own patients and not for commercialization of the same outside their own</u>*

> *hospitals/clinics fall outside the purview of Drugs and Cosmetics Act, 1940 and the New Drugs and Clinical Trials Rules, 2019. Therefore, shall be dealt outside the said regulation.*
>
> *Further, DTAB recommended that, till such time the clarification about stem cell derived product is brought out by ICMR etc., communication should be issued to the State Licensing Authorities and other stake holders that the overall issue is under process and it is inappropriate to intervene from regulatory angle on routine practices/therapies/surgeries/transplantations undertaken by Registered Medical Practitioners/ physicians / doctors in their clinics/hospitals involving such stem cells for the treatment of their patients based on their medical expertise."*
>
> (Emphasis supplied)

80. However, what is significant to note is that unlike the clarification on the definition of the term "*stem cell derived products*", the above-quoted further recommendations made by the DTAB at its 84th meeting on this agenda itself, were not incorporated in the clarification dated 09.02.2021 issued under Section 33P of the Drugs Act, 1940. Moreover, no communication was issued to the State Licensing Authorities or other stakeholders to restrain them from intervening in routine practice/therapies/surgeries/transplantations undertaken by Registered Medical Practitioners/ physicians / doctors in their clinics/hospitals involving such stem cells for the treatment of their patients based on their medical expertise.

81. Given that the DTAB is merely an advisory body, its recommendations are not binding unless formally accepted and published by the Central Government. Hence, the respondents' reliance on the unadopted recommendations of the DTAB's 84th meeting, which were reproduced

neither in the Central Government's direction dated 09.02.2021 nor in any other subsequent direction, is misplaced. In the absence of any governmental acceptance or adoption of the DTAB's recommendations, these recommendations remain merely minutes of internal deliberation and do not constitute authoritative guidance conferring legitimacy upon commercialisation of routine therapeutic use of stem cells in ASD outside clinical trials.

82. Moreover, what further weakens the weight of the DTAB's recommendations is the inconsistency inherent in its recommendation that, *"the routine practices/ transplantations/ surgeries/therapies undertaken by doctors involving stem cell for treatment of their own patients and not for commercialization of the same outside their own hospitals/clinic fall outside the purview of Drugs and Cosmetics Act, 1940 and the New Drugs and Clinical Trials Rules, 2019. Therefore, shall be dealt outside the said regulation."* The DTAB does not explain how it arrives at the distinction between commercialisation within and outside one's own hospital/clinic. The DTAB does not even clarify what would amount to commercialization outside one's own hospital/clinic. In our opinion, the basis for arriving at such a touchstone of determination is arbitrary and lacks any rational basis. Such distinction dilutes the position taken by the ICMR against the therapeutic use of stem cells in ASD other than in clinical trials as there is, till date, no body of scientific literature that supports the efficacy of such therapy.

iv) Significance of the "List of practices and procedures involving cell or stem-cell based preparations for therapeutic purposes as identified by experts (other than Standard of Care provided by ICMR)," [purportedly shared by the Minister, MoFHW, Government of India vide email dated 19.01.2023]:

83. Respondent no. 9 and 13 have submitted that in 2022, in a short document titled "*List of practices and procedures involving cell or stem-cell based preparations for therapeutic purposes as identified by experts (other than Standard of Care provided by ICMR)"* prepared by the the MoHFW, Government of India, "*bone-marrow derived stem cells*" has been listed as a "*clinical option*". However, in order to ascertain the significance of the document, we have to first determine whether the list has been formally adopted by the MoHFW or not.

84. Respondent no. 9 has submitted that the said list was sent as an attachment by the erstwhile Minister of Health and Family Welfare, Government of India, vide email dated 19.01.2023, to respondent no. 9's director Dr. Alok Sharma. The body of the said email dated 19.01.2023 which has been brought to our attention by respondent no. 9 reads thus:

> "*Sir,*
>
> *This is in reference to your mails and receipts dated 10.01.2023 regarding suggestions and recommendations for stem cell SOP/ Guidelines finalization. This is to acknowledge that the list of documents, research papers, thesis, global publications on cell and stem cells procedures as well as the list of practices and procedures involving cell and stem cell based preparations for therapeutic purposes as identified are attached for information.*"

85. There are multiple issues with relying on this private communication to assess the reasonable standard of care to be undertaken by a medical practitioner. First, neither the body of the email, nor the list itself clearly states whether such a list has been formally adopted and published by the MoHFW or not. Apart from the title of the list merely mentioning "*as identified by experts (other than Standard of Care provided by ICMR)*", the document does not even go on to mention who these 'experts' are, and is silent on how the list is to be construed vis-à-vis the ICMR's guidelines.

86. Respondent no. 13 argued that the MoHFW has recognised administration of "*Bone marrow derived Stem Cells"* as a "*Clinical option*" for ASD on the basis of the said list. However, in the same breath, it has also relied *inter alia*, on an open platform petition on the website "change.org". The said online petition dated 01.03.2023 titled "*Support & Facilitate Stem Cell Therapy as a treatment for Autism and other disabilities*" states that the said list has been prepared and 'finalized' but not approved or released to the public. Therefore, there is gross inconsistency between the submission and the supporting documentation sought to be relied upon by the respondent no.13 on this aspect.

87. Moreover, the said list has not been addressed by the respondent no. 1 or respondent no. 2 in their submissions.

88. Since the veracity of the status of the list could not be established by the respondents, the said list cannot be said to have any bearing on a medical practitioner's decision on the suitability of offering therapeutic use of stem cells in ASD as a clinical service. Be that as it may, there is no gainsaying that

any novel therapy utilizing stem cells ought to undergo clinical trial before being offered as a clinical service.

89. Therefore, based on a careful perusal of the above-mentioned documents, we arrive at the conclusion that the ICMR publications elaborately set out the contemporary scientific position on the therapeutic use of stem cells in ASD and therefore, function as authoritative indicators of whether such use of stem cells is recognised as sound and relevant medical practice. The DTAB recommendations and the purported MoHFW list, both of which have not been formally published or adopted by the government, are not authoritative documents which could alter this position to confer any legitimacy upon therapeutic use of stem cells in ASD outside of clinical trial settings. When determining whether a practitioner has acted in accordance with the reasonable standard of care, the authoritative weight lies with the evidence-based guidance of the ICMR , endorsed by the DHR which is entrusted with the scientific and ethical governance of biomedical research.

90. Therefore, we arrive at the conclusion that, since therapeutic use of stem cells in ASD is not recognised as 'a sound and relevant medical practice' as per the knowledge available at present, the medical practitioners who offer the same as a clinical service, outside of an approved and monitored research/clinical trial, fail to meet the reasonable standard of care owed by them towards their patients. Hence, until there is further research which establishes this as a sound and relevant medical practice, stem cell 'therapies' for ASD cannot be offered by medical practitioners as a clinical service, outside an approved and monitored clinical trial/research setting.

d. <u>Right to choose a 'treatment' in light of 'consent' and 'patient autonomy'</u>

91. We are, however, cognizant of the profound difficulties faced by the individuals diagnosed with ASD and their caregivers which often drive them to explore experimental or unproven interventions in the hope that even partial symptomatic relief may be achieved. Respondent no. 13 submits that many of its members, who are themselves medical practitioners, have opted for stem cell interventions for ASD offered by various clinics as a paid medical service. These parents/guardians claim to have taken these decisions after giving due consideration to the purported benefits and associated risks, and they believe they are providing 'informed consent' on behalf of their children. We respect the choice of the parents/guardians, however, it remains to be seen whether the individuals or their parents/guardians/caregivers can demand a right to choose a medical intervention merely because they claim to have consented to undergo such therapies on the basis of an informed understanding of its risk-benefit analysis. Therefore, we find it apposite to address ourselves on what is a valid consent for the purpose of undergoing a medical treatment.

92. A Three-judge Bench of this Court in ***Samira Kohli v. Dr. Prabha Manchandra and Another*** reported in **(2008) 2 SCC 1** had dealt with the information that is required to be furnished by a doctor to secure consent. In order to delineate what would be the threshold of "adequate information" to be furnished by the doctor to obtain consent, this Court in ***Samira Kohli*** *(supra)* summarised the principles as follows:

> "*49. We may now summarise principles relating to consent as follows:*

(i) A doctor has to seek and secure the consent of the patient before commencing a "treatment" (the term "treatment" includes surgery also). The consent so obtained should be real and valid, which means that: the patient should have the capacity and competence to consent; his consent should be voluntary; and his consent should be on the basis of adequate information concerning the nature of the treatment procedure, so that he knows what he is consenting to.

(ii) The "adequate information" to be furnished by the doctor (or a member of his team) who treats the patient, should enable the patient to make a balanced judgment as to whether he should submit himself to the particular treatment or not. This means that the doctor should disclose (a) nature and procedure of the treatment and its purpose, benefits and effect; (b) alternatives if any available; (c) an outline of the substantial risks; and (d) adverse consequences of refusing treatment. But there is no need to explain remote or theoretical risks involved, which may frighten or confuse a patient and result in refusal of consent for the necessary treatment. Similarly, there is no need to explain the remote or theoretical risks of refusal to take treatment which may persuade a patient to undergo a fanciful or unnecessary treatment. A balance should be achieved between the need for disclosing necessary and adequate information and at the same time avoid the possibility of the patient being deterred from agreeing to a necessary treatment or offering to undergo an unnecessary treatment.

(iii) Consent given only for a diagnostic procedure, cannot be considered as consent for therapeutic treatment. Consent given for a specific treatment procedure will not be valid for conducting some other treatment procedure. The fact

that the unauthorised additional surgery is beneficial to the patient, or that it would save considerable time and expense to the patient, or would relieve the patient from pain and suffering in future, are not grounds of defence in an action for negligence or assault and battery. The only exception to this rule is where the additional procedure though unauthorised, is necessary in order to save the life or preserve the health of the patient and it would be unreasonable to delay such unauthorised procedure until patient regains consciousness and takes a decision.

(iv) There can be a common consent for diagnostic and operative procedures where they are contemplated. There can also be a common consent for a particular surgical procedure and an additional or further procedure that may become necessary during the course of surgery.

(v) The nature and extent of information to be furnished by the doctor to the patient to secure the consent need not be of the stringent and high degree mentioned in Canterbury but should be of the extent which is accepted as normal and proper by a body of medical men skilled and experienced in the particular field. It will depend upon the physical and mental condition of the patient, the nature of treatment, and the risk and consequences attached to the treatment."

(Emphasis supplied)

93. The aforesaid exposition clearly states that a pre-condition for a valid consent to be obtained is the disclosure of adequate information concerning the nature of the medical treatment, so that the patient knows what he is consenting to.

It was further clarified that the "adequate information" must enable the patient to make a balanced judgment and should be of the extent which is accepted as normal and proper by a body of medical men skilled and experienced in the particular field. This would mean that such adequate information has to be present in the first place. If the available information itself is not adequate, there cannot logically be a disclosure of such a nature that could enable a patient to give their consent.

94. The therapeutic use of stem cells in ASD falls in such a category of treatments as there is a dearth of established scientific evidence on its efficacy and safety. As a result, the doctors do not have "adequate information" to provide to their patients in the first place. Where scientific evidence is absent or inconclusive, and where neither efficacy nor risk profile is established in a manner that would be accepted as normal and proper by a body of medical practitioners skilled and experienced in the particular field, the pre-requisite of disclosure of adequate information to obtain a valid consent cannot be satisfied. In the absence of such necessary data, the very foundation of the "adequate information" standard laid down by the Three-judge Bench of this Court in ***Samira Kohli*** *(supra)* collapses.

95. While dealing with the scope of consent, we may refer to a crucial observation made by Chandrachud J., in his concurring opinion in ***Common Cause (A Registered Society) v. Union of India and Another***, reported in **(2018) 5 SCC 1**. It was clarified and underscored therein that consent is recognised to the extent that it gives an individual the ability to opt in or opt out of a treatment that is offered, but such autonomy cannot be taken to mean that the right to

demand a particular form of treatment has been conferred on the patient. The relevant observation reads thus:

> "*398. […] Consent gives an individual the ability to choose whether or not to accept the treatment that is offered.* ***But consent does not confer on a patient the right to demand that a particular form of treatment be administered,*** *even in the quest for death with dignity. […]*"
>
> (Emphasis supplied)

96. Consent is a mode of exercising patient autonomy. Since consent does not confer on a patient the right to demand a particular form of treatment, patient autonomy cannot be stretched to seek an entitlement to subject oneself to a clinical procedure that is scientifically unvalidated, ethically impermissible, and outside the bounds of reasonable medical practice. Seen in such light, consent for undergoing a medical procedure cannot be equated with a mere exercise of choice. 'Consent' is an informed authorisation, grounded in adequate disclosure of the nature, procedure, purpose, benefits, effects, alternatives, substantial risks; and adverse consequences of refusing treatment. 'Choice' reflects what an individual or its parents/guardians/caregivers may desire to opt for, but 'consent' in the context of a medical procedure requires that such choice be shaped and supported by adequate information. Where the requisite information in unavailable, a choice cannot mature into a valid consent. We have already arrived at the finding hereinabove that therapeutic use of stem cells in ASD cannot be offered as a service by medical practitioners until there is further research which establishes this as a sound and relevant medical practice. In such

circumstances, the individuals diagnosed with ASD, or their parents/guardians/caregivers cannot demand that such a form of procedure be administered as a clinical service.

97. However, although one cannot demand that a form of medical intervention be permitted to be administered, one would still have the liberty to participate in an approved and regulated research/clinical trial involving such medical interventions. Having said that, we would like to add a word of caution to it as well. The ICMR in its National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, 2017 warns about the risk of "therapeutic misconception", i.e. a misconception by participants believing that the purpose of clinical trials/research is to administer treatment rather than to conduct research, and therefore potential participants should be mindful of the same.

e. <u>Permissibility of administering stem cells for therapeutic use in ASD for the purpose of research/clinical trial:</u>

98. In order to determine the regulatory pathway applicable to any research or clinical trial involving the administration of stem cells for therapeutic use in ASD, it is necessary to ascertain whether the stem cells proposed to be administered for such use, fall within the definition of "drug" under the Drugs Act, 1940. This inquiry is determinative because the answer to that in turn would govern the procedural requirement for undertaking a research or clinical trial in this regard.

(i) Do 'stem cells' administered for therapeutic use in ASD fall within the definition of "drug" under the Drugs Act, 1940?

99. The term "drugs" has been defined in Section 3(b) of the Drugs Act, 1940 as follows:

> "*Definitions. —In this Act, unless there is anything repugnant in the subject or context, —*
>
> *xxx*
>
> *(b) "drug" includes-*
>
> *(i) all medicines for internal or external use of human beings or animals and all substances intended to be used for or in the diagnosis, treatment, mitigation or prevention of any disease or disorder in human beings or animals, including preparations applied on human body for the purpose of repelling insects like mosquitoes;*
>
> *(ii) such substances (other than food) intended to affect the structure or any function of the human body or intended to be used for the destruction of [vermin] or insects which cause disease in human beings. animals, as may be specified from time to time by the Central Government by notification in the Official Gazette;*
>
> *(iii) all substances intended for use as components of a drug including empty gelatin capsules; and*
>
> *(iv) such devices intended for internal or external use in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or animals, as may be specified from time to time by the Central Government by notification in the Official Gazette, after consultation with the Board;"*
>
> (Emphasis supplied)

100. Clause (i) of Section 3(b) of the Drugs Act, 1940 is of particular relevance for determining whether stem cells, proposed to be administered for therapeutic use in ASD, fall within the definition of a 'drug'. A bare textual reading of the provision indicates that the term 'drug' includes not only 'medicines' but also '*all substances intended to be used for or in the diagnosis, treatment, mitigation or prevention of any disease or disorder in human beings or animals*'. We may refer to a few landmark judgments of this Court, in order to understand the scope of the broad term "substances" appearing in Section 3(b)(i).

101. This Court in ***Chimanlal Jagjivan Das Sheth v. State of Maharashtra*** reported in **1962 SCC OnLine SC 16**, had observed that the definition of "drugs" under Section 3(b) of the Drugs Act, 1940 is comprehensive enough to include within its ambit not only medicines but also substances intended to be used for or in the treatment of diseases of human being or animals. It was observed that the wide scope of the term "drug" extended beyond medicines, and that by use of the term 'substances', the definition introduces a distinction between medicines and those other things which are not medicines strictly so but are used for the purpose of treatment. The relevant observation of this Court in **C*himanlal*** (*supra*) reads as follows:

> *"3. ... The said definition of "drugs" is comprehensive enough to take in not only medicines but also substances intended to be used for or in the treatment of diseases of human beings or animals. This artificial definition introduces a distinction between medicines and substances which are not medicines strictly so-called. The expression "substances", therefore, must be something other than medicines but which are used for treatment. The part of the definition which is material for the present case is "substances intended to be used for or in the*

> *treatment". The appropriate meaning of the expression "substances" in the section is "things". It cannot be disputed, and indeed it is not disputed, that absorbent cotton wool, roller bandages and gauze are "substances" within the meaning of the said expression. If so, the next question is whether they are used for or in "treatment". It is not necessary for the purpose of this appeal to define exhaustively "the substances" falling within the definition of "drugs"; and we consider that whether or not surgical instruments are "drugs", the articles concerned in this case are."*
>
> (Emphasis supplied)

102. This aforesaid observation was further clarified by a three-Judge Bench of this Court in ***Ishwar Singh Bindra and Others v. State of U.P.*** reported in **1968 SCC OnLine SC 98**, wherein it was observed that the dictum in **C*himanlal*** (*supra*) construes the term "substances" as corporeal matter that is used for treatment but constitutes a class of items different from "medicine". However, for the term to be read so, it becomes imperative to understand the word "and" in the expression "*all medicines for internal or external use of human beings or animals and all substances intended to be used for or in the diagnosis, treatment, mitigation or prevention of any disease or disorder in human beings or animals*" used in Section 3(b)(i) and the same has to be read in a disjunctive manner. The relevant observation of this Court in ***Ishwar Singh Bindra*** (*supra*) read thus:

> "10. […] *The dictionary meaning of the words "medicines and substances" may be noticed. In Shorter Oxford English Dictionary the appropriate meaning of "medicine" is "medicament especially one taken internally- medicament generally". The meaning of "substance" relevant for our purposes is "any particular kind of corporeal matter-a species of matter of a definite chemical position-a piece or a mass of*

> *particular kind of matter-a body of a specified composition or texture".*
>
> *11. Now if the expression "substances" is to be taken to mean something other than "medicine" as has been held in our previous decision it becomes difficult to understand how the word "and" as used in the definition of drug in Section 3(b)(i) between "medicines" and "substances" could have been intended to have been used conjunctively. It would be much more appropriate in the context to read it disjunctively [sic]. In Stroud's Judicial Dictionary, 3rd Edn. it is stated at p. 135 that "and" has generally a cumulative sense, requiring the fulfilment of all the conditions that it joins together, and herein it is the antithesis of or. Sometimes, however, even in such a connection, it is, by force of a contexts, read as "or". Similarly in Maxwell on Interpretation of Statutes, 11th Edn., it has been accepted that "to carry out the intention of the legislature it is occasionally found necessary to read the conjunctions 'or' and 'and' one for the other".*
>
> (Emphasis supplied)

103. What is discernible from the aforesaid is that though stem cells may not, strictly speaking, qualify as 'medicines' yet, they would fall within the purview of "drugs" as 'substances' under Section 3(b)(i). We say so because stem cells can be said to be corporeal matter, a species of matter of a definite chemical position, a piece or a mass of particular kind of matter, a body of a specified composition or texture, and is intended to be used for or in the treatment of diseases of human beings or animals. Accordingly, stem cells satisfy the statutory description of "*substances intended to be used for or in the treatment of diseases*".

104. The Drugs Act, 1940 along with the Rules thereto make a further sub-categorization of "new drugs". It is worth noting that there is a sub-set within the category of stem cells, that falls within the category of "new drugs". Rule 2(1)(w) of the NDCT Rules, 2019, defines the term "new drug" and sub-clause (v) of the said provision categorizes *"stem-cell derived product…intended to be used as drug*" within the said definition. The Explanation to Rule 2(1)(w) goes on to state that drugs referred to in sub-clauses (iv) and (v) shall always be deemed to be new drugs. Rule 2(1)(w)(v) along with the corresponding Explanation reads as follows:

> *"2. Definitions*
>
> *(1) In these rules, unless the context otherwise requires,—*
>
> ***
>
> *(w) "new drug" means,—*
>
> ***
>
> *(v) a vaccine, recombinant Deoxyribonucleic Acid (r-DNA) derived product, living modified organism, monoclonal anti-body, cell or stem cell derived product, gene therapeutic product or xenografts, intended to be used as drug;*
>
> *Explanation: The drugs, other than drugs referred to in sub-clauses (iv) and (v), shall continue to be new drugs for a period of four years from the date of their permission granted by the Central Licencing Authority and the drugs referred to in sub-clauses (iv) and (v) shall always be deemed to be new drugs;*
>
> (Emphasis supplied)

105. It is important to note that the Explanation to Rule 2(1)(w) of the NDCT Rules, 2019, places a deeming provision due to which drugs referred to in sub-clauses (iv) and (v) shall always be deemed to be new drugs. Due to this deeming provision, stem-cell derived products shall always be deemed to be 'new drugs'. The perpetual nature of this categorization is particularly important from a regulatory point of view. The legislature, through the deeming provision in the Explanation, has expressed its intention to keep stem-cell derived products under the licensing purview of the Central Licensing Authority only when such products are being used for commercial purposes. A perusal of the statutory scheme of the NDCT Rule, 2019 indicates that such higher threshold of scrutiny is present only for stem-cell derived products and not for stem cells in general.

106. With a view to obviate any confusion amongst the stakeholders dealing with stem cells, we may clarify the meaning of the term "stem cell derived product". We may refer to the directions issued by the Drugs Regulation Section, Department of Health & Family Welfare, MoHFW, Government of India Section 33P of the Drugs Act, 1940 along with the clarification dated 09.02.2021 ("**MoHFW Clarification"**) , which reads thus:

> *"It is clarified that "stem cell derived product" means a drug which has been derived from processed stem cells and which has been processed by means of substantial or more than minimal manipulation with the objective of propagation and / or differentiation of a cell or tissue, cell activation, and production of a cell-line, which includes pharmaceutical or chemical or enzymatic treatment, altering a biological characteristic, combining with a non- cellular component, manipulation by genetic engineering including gene editing & gene modification.*

For the above purpose:

i. Substantial or more than minimal manipulation means ex-vivo alteration in the cell population (T-Cell depletion, cancer cell depletion), expansion, which is expected to result in alteration of function.

ii. The isolation of tissue, washing, centrifugation, suspension in acceptable medium, cutting, grinding, shaping, disintegration of tissue, separation of cells, isolation of a specific cell, treatment with antibiotics, sterilization by washing or gamma irradiation, freezing, thawing and such similar procedures are regarded as minimal manipulation and are not considered as processing by means of substantial or more than minimal manipulation.

iii. Stem cells removed from an individual for implantation of such cells only into the same individual for use during the same surgical procedure should not undergo processing steps beyond rinsing, cleaning or sizing and these steps shall not be considered as processing.

Further, the cell based products and tissue based products which have been processed by means of substantial or more than minimal manipulation as per criteria mentioned above are also covered under the New Drugs and Clinical Trials Rules, 2019."

(Emphasis supplied)

107. The aforesaid clarification dated 09.02.2021 indicates that not all types of stem cells would amount to "stem-cell derived product" under Rule

2(1)(w)(v) of the NDCT Rules, 2019. Whether a particular type of stem cell qualifies as a "stem-cell derived product" would depend on (i) the stem cell being "processed", and (ii) the degree of manipulation that such stem cell is subjected to. If a stem cell has been processed by means of substantial or more than minimal manipulation, only then will such stem cell become a stem-cell-derived product and fall within the definition of "new drugs" under Rule 2(1)(w) of the NDCT Rules, 2019. The MoHFW Clarification also provides what amounts to processing and substantial or more than minimal manipulation.

108. We find it apposite to note that clause (iii) of the MoHFW Clarification places a restriction on the processing that a stem cell could be subjected to, when it is removed from an individual for implantation of such cells in the same individual, for use during the same surgical procedure (autologous stem cells). Such processing is limited to the extent of rinsing, cleaning or sizing which are not considered to be "processing" itself for the purposes of the NDCT Rules, 2019. What can be discerned from the MoHFW Clarification and the definition of stem-cell derived products therein, is that autologous stem cells for the purpose of implantation during the same surgical procedure would not qualify as stem-cell derived products in terms of the Drugs Act, 1940 and NDCT Rules, 2019. Naturally, such stem cells would not be considered a "new drug" under the NDCT Rules, 2019.

109. However, we may clarify with a view to obviate any confusion, that though autologous stem cells such as those used for the therapy provided to persons with ASD, do not meet the criteria of being a new drug under the NDCT Rules, 2019, yet they fall under the broader definition of "drugs" in the Drugs

Act, 1940. Therefore, the protections available under the scheme of the said Act is available even in respect of such medicines or substances that do not qualify as new drugs governed by the NDCT Rules, 2019.

110. In such view of the matter, it cannot be said that the standard of adequate scientific evidence as regards the efficacy of a drug or treatment is inapplicable to the stem cell therapies merely because such therapies are not governed as "new drugs" by the NDCT Rules, 2019. Though such therapies may not be "new drugs", yet their novel and evolving nature remains undisputed. For this reason, we may say without any manner of doubt that the therapeutic use of stem cells for treatment of ASD cannot be recognized as 'a sound and relevant medical practice' unless there is scientific material on record to indicate its efficacy and safety standards.

111. In our considered view, the only situation in which administration of stem cells for therapeutic use in ASD may be permissible is within the research/clinical trial setting. To do so, it is imperative for us to delineate a regulatory pathway for the same.

(ii) <u>Regulatory pathway to be followed for administering stem cells for therapeutic use in ASD in Clinical Trial/Research setting</u>

112. We have already concluded that since therapeutic use of stem cells in ASD is not recognised as 'a sound and relevant medical practice' on the basis of present scientific knowledge, medical practitioners who offer the same as a clinical service, outside an approved and monitored research/clinical service, fail to meet the reasonable standard of care owed by them towards their patients. However, this does not prevent research in the field of stem cell for

potential therapeutic use in ASD, provided that the same is undertaken strictly within the confines of an approved and monitored clinical trial/research setting. The regulatory framework for conducting such research or clinical trial would vary, depending on whether the stem cell proposed to be administered amount to being "stem-cell derived product" or not.

113. In case of administration of "stem-cell derived products", the regulatory framework applicable to clinical trials of "new drugs" under the NDCT, 2019 read with the Drugs Act, 1940 and the Drugs Rules, 1945 is attracted. The NDCT Rules, 2019 mandate the creation of an Ethics Committee (the "**EC**") at an institutional level under Rule 7 thereof and such Committee is required to apply for registration in terms of Rule 8. The Central Licensing Authority, upon a scrutiny of the information and documents furnished along with the application, may either register the EC or reject the application. Such registration, when granted, remains valid for a period of five years from the date of issuance, unless suspended or cancelled by the Central Licensing Authority. Once the EC is registered, it becomes competent to grant approval to any clinical trial being conducted by the institution which falls under the Committee's purview. This stipulation is limpid from the perusal of Rule 6 of the NDCT Rules, 2019. In other words, whoever intends to conduct clinical trial of a stem-cell derived product, would necessarily be required to have approval of an EC to do so.

114. In the process of granting such approval, the EC, by virtue of Rule 11 of the NDCT Rules, 2019, is tasked with the function to review and accord approval to a clinical trial study protocol and other related documents, and to oversee the conduct of clinical trials to safeguard the rights, safety and wellbeing of

trial subjects in accordance with the NDCT Rules, 2019, the CDSCO Good Clinical Practices guidelines and other applicable regulations. The host of functions which the EC has been tasked with under Rule 11, indicates that the it plays a pivotal role in monitoring and ensuring regulatory compliance and stakeholder safety. Such role is further underscored by Rule 20 of the NDCT Rules, 2019 which states that the work of every clinical trial site shall be overseen by the EC before the initiation and throughout the duration of such clinical trial.

115. The EC in turn is under the supervision of the Central Licensing Authority, which has been empowered under Rule 14 of the NDCT Rules, 2019 to take action against an EC that fails to comply with any provision of the Drugs Act, 2019 or the NDCT Rules, 2019. Once the clinical trial protocol is approved by the EC, the person/institution/organisation which intends to conduct the clinical trial would have to make an application to the Central Licensing Authority seeking prior permission to conduct clinical trial of the new drug, as per Rule 21 of the NDCT Rules, 2019. If such permission is granted under Rule 22 of the NDCT Rules, 2019, then the entire regulatory framework applicable to clinical trials, including the safeguards put in place for the trial subjects would be applicable to the clinical trial involving administration of stem cell derived products. Rule 25(xvi) of the NDCT Rules, 2019 also empowers the Central Licensing Authority to exercise its discretion in order to impose any other condition in writing with justification, in respect of specific clinical trials, regarding the objective, design, subject population, subject eligibility, assessment, conduct and treatment of such specific clinical trial.

116. Therefore, a bare perusal of the scheme of the NDCT Rules, 2019 indicates that there is a robust mechanism in place to govern the clinical trials of "new drugs" including "stem-cell derived products". However, as we have pointed out in the aforesaid, the stem cells employed for therapeutic use in the treatment of ASD do not fall under the category of stem-cell derived products. Such cells being autologous cells that are to be implanted during the same surgical procedure, do not undergo processing that meets the threshold of substantial manipulation [See: MoHFW Clarification dated 09.02.2021].

117. On a plain reading of the NDCT Rules, 2019, it is clear that the stem cells which have not undergone processing by means of substantial or more than minimal manipulation, would not be considered as a "new drug". In such view of the matter, any research involving such stem cells is to be governed by the regulatory framework in place for "biomedical and health research" under Chapter IV of the NDCT Rules, 2019. Rule 2(1)(g) of the NDCT Rules, 2019 defines "biomedical and health research" in the following terms:

> "*2. Definitions*
>
> *(1) In these rules, unless the context otherwise requires,—*
> ***
> *(g) biomedical and health research" means research including studies on basic, applied and operational research or clinical research, designed primarily to increase scientific knowledge about diseases and conditions (physical or socio-behavioural); their detection and cause; and evolving strategies for health promotion, prevention, or amelioration of disease and rehabilitation but does not include clinical trial as defined in clause (j)"*

118. What is discernible from the aforesaid definition is that clinical trials prescribed for the investigation of a "new drug", are excluded from the ambit of "biomedical and health research". Though such a position is apparent from the bare textual reading of Rule 2(1)(g), yet it cannot be said that clinical trials have been given a go by entirely. We say so upon a reading of Rules 15 and 16(4) of the NDCT Rules, 2019. These provisions make the National Ethical Guidelines for Biomedical and Health Research Involving Human Participants (referred to as the "**National Ethical Guidelines**") binding on the conduct of any research that falls under the scope of Chapter IV of the NDCT Rules, 2019. Clauses 4.2.4 and 7.9 of the National Ethical Guidelines, issued by the ICMR, are of significance to the regulatory framework for biomedical and health research because of the legal enforceability accorded to these provisions by the NDCT Rules, 2019. Clauses 4.2.4 and 7.9 of the National Ethical Guidelines read thus:

> *"4.2.4. Stem cell proposals should be reviewed and approved by the institutional committee for stem cell research (IC-SCR) before being submitted to the EC for consideration, in accordance with the National Guidelines for Stem Cell Research (2017).*
>
> **---xxx---**
>
> "*7.9.1 <u>Except haemopoietic stem cell transplantation for haematological disorders, any other uses of stem cells are categorized as research and must be conducted as clinical trials, needing the approval of the EC, IC-SCR (permissible research), National Apex Committee for Stem Cell Research and Therapy (NAC-SCRT) (restricted research) and CDSCO (IND products and drugs) as the case may be." Use of stem cells outside the domain of a clinical trial for any purpose is considered unethical and hence not permissible.</u>*"
>
> (Emphasis supplied)

119. Clauses 4.2.4 and 7.9.1 lend clarity as regards the regulatory regime for any research in stem cells that do not undergo processing by means of substantial or more than minimal manipulation, while carving out an exception for haemopoietic stem cell transplantation for haematological disorders. In other words, Rules 15 and 16(4) of the NDCT Rules, 2019, by giving binding effect to the National Ethical Guidelines, mandate that any research involving stem cells would have to be undertaken as a clinical trial. The natural corollary of this stipulation is that the therapeutic use of such stem cells cannot be offered as a medical treatment for ASD.

120. Having conclusively established that stem cell therapy for ASD can be administered only in clinical trial/research setting, we may look at the binding nature of the ICMR guidelines from one another angle. Regulation 7.22 of the Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002 (the "**IMC Regulations, 2002**") promulgated under the Indian Medical Council Act, 1956 ("**IMC Act, 1956**") enjoin upon the medical practitioners, the duty of following the ICMR guidelines while undertaking research that involves patients or volunteers. Since the administration of stem cells would necessarily have to be undertaken in the form of research, Regulation 7.22 gains significance as it has the effect of making *inter alia*, the NGSCR, 2017 as well as the National Ethical Guidelines, binding on medical practitioners.

121. It may be argued by the respondents herein that the IMC Regulations, 2002 cease to place any legal obligations after the enactment of the National Medical Council Act, 2019 (the "**NMC Act, 2019**") which repeals the IMC

Act, 1956. However, Section 61(2) of the NMC Act, 2019, which is a transitory provision, lends much clarity in this regard. Section 61(2) provides that till new standards or requirements are specified under the NMC Act, 2019 or the rules and regulations are made thereunder, the provisions under the Erstwhile IMC Act, 1956 or regulations thereunder, *viz.* IMC Regulations, 2002, shall continue to remain in force.

122. It can be clearly discerned from the aforesaid that Regulation 7 of the IMC Regulations, 2002 shall continue to be in force. Regulation 7 provides a list of acts, commission or omission that constitute professional misconduct and render a medical practitioner liable for disciplinary action. We may refer to Regulation 7.22 which relates to actions that constitute professional misconduct during conduct of research. The said provision reads thus:

> "*7.22: Research: Clinical drug trials or other research involving patients or volunteers as per the guidelines of ICMR can be undertaken, provided ethical considerations are borne in mind. Violation of existing ICMR guidelines in this regard shall constitute misconduct. Consent taken from the patient for trial of drug or therapy which is not as per the guidelines shall also be construed as misconduct.*
>
> (Emphasis supplied)

123. The aforesaid rules and regulations promulgated under the Drugs Act, 1940 and the IMC Act, 1956 respectively, leave no manner of doubt in our minds that the ICMR Guidelines, more particularly, the NGSCR 2017 and the National Ethical Guidelines, are statutory mandates and not mere guiding principles for the purpose of research in the field of therapeutic use of stem cells for treatment of ASD. Therefore, there is no gainsaying that the guideline requiring the administration of stem cells to be done in a clinical trial/research

setting are binding in nature and any failure to do so would constitute professional misconduct.

124. Though the legal obligation as regards the regulation of stem cells that are not stem-cell derived products is clearly traceable to the NDCT Rules, 2019 as well as the IMC Regulations, 2002, yet it is imperative to note that the provisions thereunder do not directly address the requirement of clinical trials. The NDCT Rules, 2019 provide that for the categories of stem cells that qualify as "new drugs" under the NDCT Rules, 2019, the requirement to follow the clinical trial pathway flows as a matter of statutory mandate. On the other hand, stem cells that do not meet the threshold of a "new drug" are presently subjected to the clinical trial regulatory framework by virtue of Clause 4.2.4 and Clause 7.9.1 of the Ethical Guidelines, 2017. In other words, the normative source for the regulation of stem cells that do not undergo substantial or more than minimal manipulation is found in the Guidelines of ICMR rather than the NDCT Rules, 2019 or the IMC Regulations, 2002. These ICMR Guidelines, such as the National Ethical Guidelines are susceptible to change at an institutional level, unlike parliamentary enactments or delegated legislations.

125. Section 38 of the Drugs Act, 1940 mandates that every rule made under the Act shall be laid as soon as may be after it is made, before each House of Parliament. Therefore, amendments made to the NDCT Rules, 2019 are required to be presented before the Parliament for approval. However, there is no corresponding requirement for an amendment brought about in the Ethical Guidelines, thereby making it more readily amendable. What follows from the aforesaid is that the regulatory framework for clinical trials in cases

of administering of stem cells other than stem-cell derived products, is dependent on and subject to any changes in the National Ethical Guidelines and such amendments thereto are not afforded the same statutory safeguards as the Rules themselves that make the Guidelines legally enforceable.

126. Further, the distinction in normative source is crucial because there is a sharp difference in the safeguards that are available to subjects of a clinical trial as opposed to those of a biomedical and health research. While the NDCT Rules, 2019 emphatically provide for safety measures such as medical management and compensation in case of serious adverse events, there is no corresponding mandatory liability in case of biomedical and health research, and it has been left to the discretion of the respective ECs to decide the appropriate quantum, if any, of the same.

127. The normative basis would also assume importance because it places a practical obligation on the medical practitioner, institution, or organisation to correctly determine whether the stem cells proposed to be administered have undergone processing by means of substantial or more than minimal manipulation that would render them as a new drug. This evaluative step is fundamental to identifying the applicable regulatory pathway, i.e. whether to be regulated as a clinical trial or as a biomedical and health research. While it would not be a concern in the present state of things, if, at a subsequent point in time, the National Ethical Guidelines were to be modified in a manner that no longer renders all stem cell research as clinical trials, this distinction would also need a provision to keep in check any attempt to circumvent the applicable regulatory framework through non-disclosure or misrepresentation of the degree of processing. While penalty can be imposed under Section

27(d) read with Section 18 of the Drugs Act, 1940 for manufacture of stems cell amounting to drugs in contravention of the Drugs Act, 1940 or any rule made thereunder, there is no corresponding deterrent beyond suspension or cancellation of the EC registration for any violation of applicable provision with respect to biomedical and health research.

128. It is as clear as a noon day that the lack of safeguards for biomedical and health research in therapeutic use of stem cells is stark. However, even in light of such glaring differences in how stem cells are regulated depending on their manipulation, could it be said that those stem cells that do not undergo substantial manipulation do not attract obligations arising from ethical considerations in medicine? The answer to this question must be an emphatic 'No'. As discussed in the aforesaid parts of this judgment, consent based on adequate information is the bedrock of any medical decision made by both the doctor and patient. This has been underscored in the National Ethical Guidelines which warns about ethical problems like 'therapeutic misconception'. In our considered opinion, the manner in which the stem cell therapies are being offered for treatment of ASD is illustrative of such 'therapeutic misconception'.

129. We say so because the treatment is provided by clinics commercially and suggested in alternative to other treatments available for ASD. As a consequence, the parents and guardians who are presented with this treatment option form the mistaken expectation that the goal of the treatment is their direct personal benefit, much like routine medical care. However, for a novel treatment method that has minimal scientific support, the standard of care that ought to be provided in routine care and treatment can never be achieved. The

only result that is possible to be achieved from performing novel treatments is the production of generalizable knowledge. The benefits of conventional medical treatment stand on the substructure of knowledge accumulated from empirical analysis of the effects of such treatment. To lead patients and their guardians to put faith in treatments wherein this substructure itself is absent is, in our view, wholly unethical and against the tenets of medical jurisprudence on 'informed consent'.

130. We may refer to the broad principles laid down by this Court in ***Samira Kohli*** *(supra)* while addressing the essentials of informed consent:

(i) *First,* consent obtained by a medical practitioner must be real and valid. It is imperative that the following three conditions are met for a patient's consent to be valid:

- the patient should have the capacity and competence to consent;
- consent should be voluntary; and
- consent should be on the basis of adequate information, concerning the nature of the treatment procedure, so that the patient knows what the consent is for.

(ii) *Secondly,* "adequate information" about a procedure or treatment must necessarily consist information about

- the nature and procedure of the treatment;
- its purpose and benefits;
- its likely effects and complications;
- any alternatives, if available;
- an outline of the substantial risks; and
- adverse consequences of refusing the treatment.

131. Keeping the above principles in mind and the description and recommendations of the ICMR as regards the therapeutic use of stem cells for the treatment of ASD, we are of the view that the requirement of "adequate information" about the said treatment method is not fulfilled simply because sufficient information is not available regarding the same. Therefore, the requirement of clinical trials and research in respect of a novel and unconventional treatment method that is yet not supported by scientific evidence, flows from core ethical considerations in medicine. The lack of a clear regulatory framework is an issue of implementation of these core ethical considerations. Any use of such lacunae to offer stem cell therapy as a routine treatment in alternative to other options, is a contorted understanding of the legal and ethical framework and hence, impermissible.

132. Be that as it may, in the instant case, the regulatory framework laid by the NDCT Rules, 2019 and IMC Regulations, 2002, which make the NGSCR, 2017 and National Ethical Guidelines binding, provides adequate statutory basis for us to hold that the use of stem cell therapy for treatment of ASD is to be done only in a clinical trial/ research setting. What remains to be seen is the workability of this regulatory framework.

133. Clause 7.9.1 of the National Ethical Guidelines mandates that use of stem cells in a clinical trial/research setting requires the approval of the National Apex Committee for Stem Cell Research and Therapy (NAC-SCRT). However, the Order dated 03.03.2024 issued by the DHR dissolved the NAC-SCRT and made it mandatory for the ethics committee for stem cell research involving

human participants to have a minimum of two stem cell experts in the ethics committee. The dissolution of the sole national level body for the regulation of research in stem cells is a major setback, especially when there is no corresponding amendment to the National Ethical Guidelines that may offer clarity in this regard. Even if we attempt to trace the regulatory powers to the DHR, which is the parent institution under which the Erstwhile NAC-SCRT was functioning, yet, Clause 2(vi) of the Order dated 03.03.2024 makes it difficult for us to do so. The Order dated 03.03.2024 reads thus:

> *"Sub: Dissolving the National Apex Committee for Stem Cell Research and Therapy -reg*
> *In supersession of this Department's order No. Q-11011/15/2020- HR(ICMR)/eoffice -8076452 dated 25th September 2020 on reconstitution of National Apex Committee for Stem Cell Research and Therapy, it has been decided by the competent authority to dissolve the National Apex Committee for Stem Cell Research and Therapy (NAC- SCRT).*
>
> *2. The undersigned is directed to convey that:*
>
> *(i) The National Apex Committee for Stem Cell Research and Therapy (NAC-SCRT has been dissolved and the requirement of registration of IC- SCR with NAC-SCRT is no longer required.*
>
> *(ii) Stem cell research involving human participants, their biological material and data will be reviewed by Ethics committees (EC) with minimum two stem cell experts in the Ethics committee.*
>
> *(iii) The stem cell experts who attend the meeting may be free from conflict of interest. They need not be permanent members of IEC but may be co-opted whenever there are*

> *stem cell related proposals. These stem cell experts should be considered as part of quorum for the meeting and at least one expert should be external.*
> *(iv) EC will continue to be registered mandatorily with DHR.*
> *(v) EC must also be registered with CDSCO if its clinical Trial.*
> *(vi) No regulatory role is anticipated to be carried out by DHR related to stem cell research.*
> *(vii) Other stem cell related studies including basic/non clinical /animal related studies may be reviewed at institutional level.*
>
> *3. This issues with the approval of Competent Authority."*

(Emphasis supplied)

134. A plain reading of the above-mentioned Order dated 03.03.2024 indicates that there is a lacuna resulting in regulatory ambiguity for research involving stem cells which are not stem-cell derived products. Though the National Ethical Guidelines mandate that any research in the use of stem cells shall necessarily be by way of a clinical trial, yet the larger regulatory framework within which such Guidelines also function is provided by the Chapter IV of the NDCT Rules, 2019 governing biomedical and health research. Rules 17 and 18 envisage a central role for the DHR in exercising an oversight on the ECs. Rule 17 mandates an Ethics Committee constituted for such biomedical and health research, to register with the authority designated by the DHR, and empowers such designated authority to issue warning, suspend, debar or cancel the registration of an ethics committee in case of any failure in compliance. The offshoot of such oversight is the role of regulating biomedical and health research through the Ethics Committees.

135. The National Ethical Guidelines provide that for biomedical and health research in the field of stem cells that involves human participants, the NAC-SCRT would be the body granting approval for restricted research in stem cells. However, the Order dated 03.03.2024, for reasons unknown to us, dissolved the NAC-SCRT and the regulatory oversight of stem cell research was completely transferred to the institution specific ECs. In view of these developments, the role of the DHR as envisaged by Rules 17 and 18 of the NDCT Rules, 2019, gains prominence. We say so because, after the dissolution of the NAC-SCRT, the results of stem cell research involving human participants is to be reviewed by the ECs and in terms of the NDCT Rules, 2019, the DHR exercises oversight on the ECs.

136. Having discussed the role of DHR as per the NDCT Rules, 2019, we may now refer once again to the Order dated 03.03.2024, more particularly Clause 2(vi) thereof which states that "*no regulatory role is anticipated to be carried out by DHR related to stem cell research*". Therefore, the said Order not only dissolves the NAC-SCRT but also carves an exception as regards research in stem cell in order to remove the DHR from performing any regulatory role in the field. This presents an evident conflict between the NDCT Rules, 2019 and the Order dated 03.03.2024. Further, such conflict, if permitted to subsist, would virtually amount to allowing an Executive Order to cut down the scope of statutory rules and creating a regulatory vacuum in respect of stem cell research.

137. We may refer to this Court's dictum in ***State of M.P. v. G.S. Dall and Flour Mills***, reported in **1992 Supp (1) SCC 150** wherein it was held that Executive

instructions can only supplement a statute to address areas that are within the statute's purview but have not been covered thereby. However, in no situation can such instructions run contrary to statutory provisions or whittle down their effect. In ***Jaiveer Singh v. State of Uttarakhand*****,** reported in **(2024) 15 SCC 227**, this principle has been reiterated to establish the supremacy of statutory rules. The relevant portion of the judgment in ***Jaiveer Singh*** *(supra)* is reproduced below:

> *"45. It can thus be seen that it is a trite law that the Government cannot amend or supersede statutory rules by administrative instructions, but if the rules are silent on any particular point, it can fill up the gaps and supplement the rules and issue instructions not inconsistent with the rules already framed. It is a settled proposition of law that an authority cannot issue orders/office memorandum/executive instructions in contravention of the statutory rules. However, instructions can be issued only to supplement the statutory rules but not to supplant it."*
>
> (Emphasis supplied)

138. The aforesaid exposition lends much clarity as regards the applicability of Clause 2(vi) of the Order dated 03.03.2024. We are of the considered view that, in light of the Rules 17 and 18 of the NDCT Rules, 2019, excepting research relating to stem cells from the regulatory purview of the DHR is not possible. Therefore, the conduct of ECs in reviewing clinical trials for biomedical and health research in stem cells has to be monitored closely and regularly by the DHR or any authority appointed by it for this purpose.

139. Having gone through the NGSCR, 2017 and National Ethical Guidelines, we find it apposite to note that stem cell research requires proper regulation

backed by legislative mandate. Though the scheme of the NDCT Rules, 2019 and IMC Regulations, 2002 enable oversight, yet it would not be improper to say that such scheme is far from ideal. In our considered view, there must be a dedicated regulatory pathway for stem cell research including the therapeutic use of the same for ASD along with a dedicated monitoring authority. We insist on this for the sole reason that ambiguity in law should not result in such lack of awareness amongst the public that it can be capitalized on by persons interested in commercialization and profits. Therefore, we call upon the MoHFW to reconsider this position and to clearly specify the regulatory mechanism as well as the authority that shall exercise regulatory oversight over biomedical and health research on stem cells involving humans.

(iii) Consequences of non-compliance:

140. As per Section 27(1)(b) of the NMC Act, 2019, the EMRB has the power to regulate professional conduct and promote medical ethics in accordance with the regulations framed thereunder, provided that the EMRB ensures compliance of the code of professional and ethical conduct through the State Medical Council in a case where such State Medical Council has been conferred power to take disciplinary actions in respect of professional or ethical misconduct by medical practitioners under the respective State Acts. Moreover, as per Section 27(2) of the NMC Act, 2019, the EMRB may, in the discharge of its functions, make such recommendations to, and seek such directions from, the NMC, as it deems necessary.

141. Sections 27(1)(b) and 27(2), respectively, read thus:

> "*27. Powers and functions of Ethics and Medical Registration Board.- (1) The Ethics and Medical Registration Board shall perform the following functions, namely:-*
>
> *...*
>
> *(b) regulate professional conduct and promote medical ethics in accordance with the regulations made under this Act:*
>
> *Provided that the Ethics and Medical Registration Board shall ensure compliance of the code of professional and ethical conduct through the State Medical Council in a case where such State Medical Council has been conferred power to take disciplinary actions in respect of professional or ethical misconduct by medical practitioners under respective State Acts;*
>
> *...*
>
> *(2) The Ethics and Medical Registration Board may, in the discharge of its duties, make such recommendations to, and seek such directions from, the Commission, as it deems necessary."*
>
> (Emphasis supplied)

142. A perusal of Section 27(1)(b) & (2) of the NMC Act, 2019 would indicate that though the EMRB has been conferred with the power to regulate professional conduct and to promote medical ethics, yet such powers will have to be exercised in accordance with the regulations framed under the NMC Act itself, under Section 57 thereof. Section 57 of the NMC Act, 2019 reads as follows:

> "*57. Power to make regulations.—(1) The Commission may, after previous publication, by notification, make regulations consistent with this Act and the rules made thereunder to carry out the provisions of this Act.*
>
> *(2) In particular, and without prejudice to the generality of the foregoing power, such regulations may provide for all or any of the following matters, namely:—*
>
> *...*

> *(zd) the manner of regulating professional conduct and promoting medical ethics under clause (b) of sub-section (1) of section 27;*
> *...*
> *(zi) the act of commission or omission which amounts to professional or ethical misconduct under clause (b) of the Explanation to section 30;"*

143. It is worth noting that no regulations under Section 57 have been promulgated. In such view of the matter, we may refer to Section 61(2) of the NMC Act, 2019 which provides for transitory provisions and ensures that the rules and regulations promulgated under the Erstwhile IMC Act, 1956 continue to occupy the field till the time regulations under the new NMC Act, 2019 are introduced. Section 61(2) of the NMC Act reads as follows:

> *"61. Transitory provisions.-*
> *...*
> *(2) Notwithstanding the repeal of the Indian Medical Council Act, 1956 (102 of 1956), the educational standards, requirements and other provisions of the Indian Medical Council Act, 1956 and the rules and regulations made thereunder shall continue to be in force and operate till new standards or requirements are specified under this Act or the rules and regulations made thereunder:*
> *Provided that anything done or any action taken as regards the educational standards and requirements under the enactment under repeal and the rules and regulations made thereunder shall be deemed to have been done or taken under the corresponding provisions of this Act and shall continue in force accordingly unless and until superseded by anything done or by any action taken under this Act."*
>
> (Emphasis supplied)

144. Since Section 61(2) states that the regulations made under the Indian Medical Council Act, 1956 would continue to be in force and operate till new standards

or requirements are specified under the NMC Act, 2019, the IMC Regulations, 2002 promulgated under the Erstwhile IMC Act, 1956, would continue to be in force till the new regulations are in place.

145. Accordingly, Regulation 7 read with Regulation 8 of the IMC Regulations, 2002, which provide that commission of a professional misconduct would render a medical practitioner liable for disciplinary action, govern conduct in providing treatment or furthering research through clinical trial. Regulations 7 and 8 are squarely attracted if a medical practitioner administers, promotes or advertises the therapeutic use of stem cells, outside of a clinical trial/biomedical and health research setting, or if the ICMR guidelines are violated in respect of the same.

146. As regards the errant clinics/organisations, we are of the firm view that action must be taken against them by the appropriate authority, under Section 32 and Section 40 respectively, of the Clinical Establishments (Registration and Regulation) Act, 2010, which provide for the cancellation of registration and penalty.

147. We also find it apposite to clarify that the regulatory framework under the Drugs Act, 1940, read with the NDCT Rules, 2019, the National Ethical Guidelines and the NGSCR, 2017, extends to the commercial banking and processing of stem cells. According to Clause 14 of the NGSCR, 2017, commercial banking of only Umbilical Cord Blood stem cells is permitted, and licenses have to be issued for the same by the CDSCO. It must be noted that commercial banking of all other biological materials is prohibited until

there is further notification in this regard. Moreover, Rule 52 of the NDCT Rules, 2019 prohibits manufacture of a new drug even for the purpose of clinical trial or for examination, test and analysis without obtaining prior permission from the Central Licensing Authority. Section 3(f) of the Drugs Act, 1940 defines 'manufacture' broadly to include any process or even part of a process for making, altering, ornamenting, finishing, packing, labelling, breaking up or otherwise treating or adopting any drug with a view to its sale or distribution. Consequently, any entity that intends to undertake even a part of the processing of stem cells, would be required to obtain necessary prior approvals which are to be undertaken for biomedical and health research, or clinical trial, depending on the degree of processing involved. Therefore, respondent no. 11's contention that it is not bound by any regulation because it does not administer the stem cells but merely processes them for procurement by end-users such as hospitals/clinics/doctors or patients, is held to be incorrect

E. SOME MEANINGFUL SUGGESTIONS

148. The discussion in the aforesaid is indicative of the shortfalls and faultlines in the regulatory mechanism for stem cell research. Considering the nature of such research and its potential, it is imperative to ensure that the law in this regard is accessible and clear. As things currently stand, the legal framework pertaining to stem cell research is fragmented and spread out across legislations with little harmony. This makes both compliance and enforcement an uphill task. The obscurity in the legal regime also enables manipulation of patients' vulnerabilities by errant medical practitioners. Such obscurity, whether conscious or unintended, has arisen directly from legislative shortsightedness.

149. In such view of the matter, we find it apposite to suggest the consolidation of the rules, regulations and guidelines to govern stem cell based clinical trials and research. The legislation ought to address the following points[1]:

i. Clearly define stem cells and their derivates.

ii. Lay down a specific procedure for application for clinical trials, including a flexible yet definite list of standards or guidelines that need to be adhered to. Ideally, the NGSCR, 2017 and the National Ethical Guidelines should be given a clearer statutory recognition through these provisions.

iii. Set up a protective net for the safety and welfare of human subjects in these trials through a rights-based approach through patient disclosure and consent protocols. If the patient is opting for an unproven therapy in a clinical trial setting, then higher standard of voluntary free informed consent and associated protocols must be set. The patients undergoing experimental therapies in clinical trial setting should not be charged any amount for 'treatment', rather their participation is voluntary. In case of injury or death, there should be a provision for interim compensation on immediate basis.

iv. Provide a reasonable timeline for the completion of the licensing and approval procedures.

v. Provide for periodic inspections of the clinical trial site.

[1] Vaishnav M., "*The Indian regulatory framework and the surge of unproven stem cell therapies—a call for diagnosis*", 12 (2) *Journal of Law and the Biosciences* (2025), available at: https://academic.oup.com/jlb/article/12/2/lsaf027/8329365

vi. Specify the procedure for approval and licensing of stem cell banks, along with the list of standards and guidelines that need to be complied with.

vii. Lay down the penalties for violation of the law, with imprisonment in cases where the health of the patient/trial subject is endangered.

150. For the aforesaid points to be addressed in a meaningful manner, it is also important that a dedicated authority that has clear and well-defined powers of regulatory oversight is created. We suggest that the NAC-SCRT is constituted once again to ensure proper and coherent monitoring and regulation of stem cell research.

F. CONCLUSION:

151. We may summarize the conclusions that we have reached in the aforesaid:

i. Although, the stem cells administered for therapeutic use in ASD are characterised as "drugs" under the Drugs Act, 1940, yet the same by itself is not determinative of the fact that it is permissible to be administered as a clinical service.

ii. Every medical practitioner owes to his patient a duty to exercise a reasonable degree of care, skill, and knowledge expected of a prudent practitioner in the same field. A medical practitioner cannot be said to meet the standard of reasonable care if he administers an intervention that lacks credible scientific evidence of safety and efficacy, or where authoritative medical bodies unequivocally state that such form of treatment is not recommended. This flows directly from the requisite

standard of care emphasised by this Court in ***V.P. Shantha*** *(supra)*, ***Jacob Mathew*** *(supra)* respectively, as reaffirmed in ***M.A. Biviji*** *(supra)*, that a doctor's conduct must conform to a "*practice acceptable to the medical profession of that day"* when *"judged in the light of the knowledge available at the time of the incident".* The jurisprudence makes it clear that if an intervention is characterised by the relevant scientific community or regulatory authorities, as unproven, experimental, obsolete, or lacking justification, such an intervention cannot be defended as exercise of due care and reasonable judgment by a medical practitioner.

iii. The note of caution sounded by this Court in ***M.A. Biviji*** (*supra*) that a line of treatment undertaken should be regarded as a *"sound and relevant medical practice"* and that "*it should not be a discarded or obsolete category in any circumstance"* ensures that patients are treated in accordance with established, evidence-based medical norms, and prevents medical practitioners from resorting to speculative, unproven, or experimental interventions when there is absence of any credible scientific evidence or professional opinion. In other words, a medical practitioner who disregards this and administers speculative, unproven, or experimental treatments even when credible professional bodies have expressly advised against the use of such an intervention, may be held liable on count of professional misconduct. We say so because the administration of such a treatment would fail to satisfy the standard of reasonable care necessitated under the established medical negligence jurisprudence in India.

iv. The only circumstance in which an experimental treatment may be provided is when it is administered within an approved research or clinical trial setting.

v. Such documents published by the ICMR as authorized by the DHR represent the well-researched scientific and ethical position of the apex bodies entrusted with the responsibility of overseeing biomedical research in the country. Such documents may not be binding by themselves, yet can certainly be relied upon as credible source to assess whether a particular "*practice* is *acceptable to the medical profession of that day"* when *"judged in the light of the knowledge available at the time of the incident"* and whether a particular line of treatment undertaken should be regarded as a *"sound and relevant medical practice"* and not as a "*discarded or obsolete category in any circumstance"*. The relevance and importance of these ICMR publications lie not in their binding force in a standalone manner, but in the role they play in evidencing the contemporary scientific and ethical baseline of the medical profession.

vi. A perusal of the EMRB-NMC Recommendations dated 06.12.2022, read with the EBSSCT, 2021, the NGSCR, 2017 and the National Ethical Guidelines respectively, formulated by the ICMR indicates that the therapeutic use of stem cells for treatment of ASD is not recommended as routine clinical treatment. These documents indicate that the therapeutic use of stem cells for the treatment of ASD is not recognized as a sound and relevant medical practice due to the lack of

scientific support and empirical evidence regarding its efficacy. It is categorically mentioned therein that any stem cell use in patients must only be done within the purview of an approved and monitored clinical trial with the intent to advance science and medicine, and not offering it as therapy. Therefore, every use of stem cells in patients outside an approved clinical trial is unethical and shall be considered as malpractice. Therefore, medical practitioners who offer such stem cell therapy as a routine clinical service and not in a research/clinical trial setting, could be said to be failing to meet the reasonable "standard of care" owed by them towards the patients as expounded by this Court in ***M.A. Biviji*** *(supra)* and ***V.P. Shantha*** *(supra)*.

vii. As regards the question whether patient autonomy enables a person to give consent to an unproven treatment, we are of the considered view that a treatment cannot be demanded by a patient as a matter of right. This Court's dictum in ***Samira Kohli*** *(supra)* underscores that adequate information as regards a particular treatment, is the bedrock and the consent thereto should be on the basis of such adequate information. It is undisputed that stem cell therapy for treatment of ASD does not fulfil the essentials of 'adequate information'. The validity of consent stems from the nature and information available about the treatment. In the absence of such knowledge, the patients may remain under therapeutic misconception and anticipate such results from an unproven treatment as may be expected from routine treatment and care. Following through with the medical treatment even when patients are under such misconception is, in our view, a gross violation of medical ethics. Therefore, even though the patient may have voluntarily opted for such

procedure, yet, such choice does not amount to a valid consent to undergo the treatment due to the lack of 'adequate information' to form its basis. Having said so, we clarify that one would still have the liberty to participate in an approved and regulated research/clinical trial involving stem cell therapy for ASD.

viii. The reasons presented in the aforesaid discussion establish that stem cell 'therapies' for ASD cannot be offered by medical practitioners as a clinical service, outside an approved and monitored clinical trial/research setting. In such a scenario, the regulation of such research gains primacy.

ix. With a view to ascertain the regulatory pathway in respect of stem cell therapies, we may clarify at the threshold that though autologous stem cells such as those used for the therapy provided to persons with ASD, may not meet the criteria of being a 'new drug' under the NDCT Rules, 2019, yet they fall under the broader definition of "drugs" in the Drugs Act, 1940. We say so because all stem cells fall within the purview of "drugs" as 'substances' under Section 3(b)(i) of the Drugs Act, 1940. Therefore, there is no gainsaying that the scheme of the Drugs Act, 1940 envisages providing protections being available in respect of stem cell therapy for ASD. We find that Chapter IV of the NDCT Rules, 2019, which relates to Biomedical and Health Research, provides such safeguards and the necessary regulatory pathway in respect of stem cell therapy for ASD.

x. We may summarize the regulatory regimes for both "stem cell derived products" as well as "stem cell therapies" respectively, as follows:

- In case of administration of "stem-cell derived products", the regulatory framework applicable to clinical trials of "new drugs" under the NDCT, 2019 read with the Drugs Act, 1940 and the Drugs Rules, 1945 is attracted.
- On the other hand, the stem cells which have not undergone processing by means of substantial or more than minimal manipulation, would not be considered as "new drug" under the NDCT Rules, 2019. In such circumstances, any research involving such stem cells is to be governed by the regulatory framework in place for "biomedical and health research" under Chapter IV of the NDCT Rules, 2019. Rules 15 and 16(4) respectively, thereof provide binding effect to the National Ethical Guidelines, which in turn provides in Clause 7.9.1 that any use of stem cells involving human participants (except for haemopoietic stem cell transplantation for haematological disorders) shall be undertaken as a clinical trial. Furthermore, Clause 4.2.4 of the National Ethical Guidelines mandates that review of proposals for research in stem cells must be in accordance with the NGSCR, 2017. Since, Rules 15 and 16(4) respectively, of the NDCT Rules, 2019 make the National Ethical Guidelines legally enforceable, we are of the considered view that all stem cell research involving human participants must necessarily be in a clinical trial setting.

xi. Clauses 4.2.4 and 7.9.1 respectively, of the National Ethical Guidelines mandate the constitution of Ethical Committees (ECs) to oversee stem cell research. Further, approval from such ECs as well as the Institutional Committee for Stem Cell Research (IC SCR) is also required. Clause 7.9.1 provides that approval shall also be obtained from the National Apex Committee for Stem Cell Research and Therapy (NAC-SCRT). However, the Order dated 03.03.2024 issued by the DHR dissolved the NAC-SCRT and made it mandatory for the ECs overseeing stem cell research involving human participants to have a minimum of two stem cell experts therein. Therefore, the entire regulatory purview was given to the institution specific ECs.

xii. In the aforesaid view of the matter, the Rules 17 and 18 respectively, of the NDCT Rules, 2019, which deal with the oversight of the ECs by the Department of Health Research (DHR), are significant. We say so because Rule 18 empowers the DHR or any body authorized by it to suspend or cancel the registration of an EC in cases of the ECs' failure to comply with the Rules and National Ethical Guidelines. However, Clause 2(vi) of the Order dated 03.03.2024 carves an exception for stem cell research, to remove the DHR from exercising a regulatory role in respect thereof. Clause 2(vi) of the said Order is in conflict with Rules 17 and 18 respectively, of the NDCT Rules, 2019. It is a settled position of law that executive orders/ instructions/ office memorandum cannot operate in contravention to statutory rules with the effect of supplanting the statutory mandate. Therefore, in our considered view, the removal of regulatory role of DHR in the field of stem cell research by way of Clause 2(vi) of the Order dated 03.03.2024 is *non est*.

xiii. Therefore, we are of the firm view that non-compliance of the aforesaid statutory mandate must attract consequences *viz.* professional misconduct under Regulation 7.22 of the IMC Regulations, 2002 as well as action under Sections 32 and Section 40 respectively, of the Clinical Establishments (Registration and Regulation) Act, 2010, which provide for the cancellation of registration and penalty.

152. It is unfortunate that the Union has let the matter worsen without any suitable and timely intervention. Such inaction has led to several parents/guardians seeking an unproven method of treatment for their children suffering from ASD incurring huge financial cost and in alternative to other approved treatments. It cannot be denied that various clinics, in flagrant violation of the aforesaid statutory mandate, continued to recommend and perform stem cell therapy as a routine clinical treatment for ASD because there was lack of executive action against the same. Therefore, we urge the Union to consolidate and clarify the position of law for enabling better implementation of the same in this regard at the earliest and insist on the creation of a dedicated authority for the regulatory oversight of stem cell research all across the country. In this regard, we have suggested the enactment of a legislation that may clarify several issues that plague the research in stem cells.

153. Before we close this judgment, we may address the issue as regards the continuation of treatment which the patients might have already started receiving prior to this judgment. Though we have held that stem cell therapy is required to be undertaken in a clinical trial format, yet we are aware that

starting such trials may take a significant amount of time and may not even be conducted by the clinics that have been providing this therapy as a treatment. We do not wish to leave the patients who are already undergoing the therapy in any apprehension that discontinuing the same may prove to be detrimental to their wellbeing. However, at the same time, we are also sure of our decision that stem cell therapy for ASD cannot continue as a commercial endeavour in the form of routine clinical treatment. Therefore, we direct the Secretary, Ministry of Health and Family Welfare in consultation with the officials of AIIMS and the National Medical Council, to provide the best possible solution in this regard so as to ensure that such patients are able to continue receiving the therapy till the time they can be re-routed to the institutions that are conducting clinical trials. The Secretary, MoHFW shall file submissions in compliance with this direction within a period of four (4) weeks from the date of pronouncement of this judgment.

154. We treat this matter as part heard. The Registry shall notify this matter once again after 4 weeks before this very Bench for the purpose of looking into the submissions that the Secretary, MoHFW shall submit in compliance with the aforesaid.

155. Once the Union's stance is clear, we shall proceed to issue final directions.

156. The Registry shall circulate one copy each of this judgment to all the High Courts and to the Secretary, Ministry of Health and Family Welfare.

…….J.

(J. B. PARDIWALA)

…….J.

(R. MAHADEVAN)

New Delhi.

30th January, 2026.