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)

O R D E R

1. In our Order dated 01.09.2026, we had posed certain questions to the respondents, to ascertain whether reasonable and genuine steps are being taken by the regulatory authorities, the treating institutions and the caregivers to move existing patients, wherever appropriate, towards a duly regulated research / clinical trial framework.

2. We heard Ms. Aishwarya Bhati, the learned Additional Solicitor General appearing for the Union of India. She highlighted the steps which have been and those which are proposed to be taken, in compliance with the Judgment & Order dated 30.01.2026.

Signature Not Verified
Digitally signed by VISHAL ANAND
Date: 2026.10.16 15:22:53 IST
Reason:

3. In today's hearing, we also heard Mr. Neeraj Kishan Kaul, the learned Senior counsel appearing for the Respondent No.13

(Parents' Forum for Stem Cells in Autism and Cerebral Palsy). We also heard Mr. Prashant Bhushan, the learned counsel on the subject.

4. We also heard certain individuals present in Court today, who stated that they are appearing in-person to voice their concerns regarding the status of the ongoing stem cell therapies for Autism Spectrum Disorder (ASD) being administered to their children or wards.

5. At the outset, we consider it necessary to clarify the scope and import of our Judgment & Order dated 30.01.2026. The present proceedings are not concerned with determining the efficacy of the so-called stem cell 'therapies' for ASD, nor is it the endeavour of this Court to evaluate the scientific claims advanced by various individuals in support of such intervention. The question before us is one of law, namely, whether the administration of such therapy for ASD is permissible having regard to the applicable regulatory framework.

6. We would like to hereby reiterate that the therapeutic use of stem cells for ASD is not recognised as 'sound and relevant medical practice' by the concerned authorities in the light of the scientific knowledge and regulatory standards prevailing at present. Consequently, medical practitioners who offer such intervention as a clinical service, outside an approved and monitored research or clinical trial setting, fail to meet the reasonable standard of care owed to their patients. It is on this basis that we clarified the existing position of law. Under

the existing regulatory framework, stem cell 'therapy' for ASD cannot be offered as a clinical service outside an approved and monitored research/clinical trial setting. In such circumstances, the individuals diagnosed with ASD, or their parents/guardians/caregivers cannot demand that such a form of procedure be permitted to be administered as a clinical service. However, one would still have the liberty to participate in an approved and regulated research/clinical trial involving such medical interventions. Having said that, a research/clinical trial participant must not be under any "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.

7. At the same time, we consider it necessary to clarify that our judgment & order dated 30.01.2026 does not foreclose the possibility of such an intervention being considered permissible in the future. The prohibition on administering stem cell 'therapy' for ASD as a clinical service is founded upon the state of scientific evidence and the prevailing regulatory framework as on date. It does not amount to an immutable prohibition against any future development in this field. Should further rigorous scientific research, undertaken in a duly regulated manner and in accordance with the applicable scientific and ethical standards, establish the safety, efficacy and ethical acceptability of such an intervention, the competent regulatory authorities would

remain at liberty to consider whether, and subject to what conditions and safeguards, it may be permitted in accordance with law.

8. Now, we turn to the compliance affidavit dated 28.09.2026, which has been filed on behalf of the Union of India, duly affirmed by Dr. Tushar Karmarkar, Deputy Secretary to the Government of India, Department of Health Research, Ministry of Health and Family Welfare.

9. The compliance affidavit dated 28.09.2026 refers to the Office Order No. M-11019/5/2026-CG dated 24.03.2026, issued by the Department of Health Research, *vide* which the **National Stem Cell Research Regulation Committee ("NSRC")** been constituted to oversee and regulate research on stem cells that have undergone minimal or less than minimal manipulation. The NSRC comprises representatives of the Department of Biotechnology, the Department of Health and Family Welfare, CDSCO, and the Chairman NMC (not below the rank of Joint Secretary), seven permanent experts, along with subject experts drawn on rotation from 13 specialities as per requirement, and an ICMR-DHR Secretariat.

10. The Union has also submitted that the following documents have been issued in furtherance of our judgment & order dated 30.01.2026, in order to widely disseminate and enforce the regulatory framework governing stem cell research in ASD:

   i. D.O. Letter No. M-11019/5/2026-CG dated 10.03.2026, issued by the Secretary DHR & to the Chairman, NMC

ii. Advisory No. CDN-20011/105/2026-COORDINATION-NMC dated 25.03.2026 issued by the National Medical Commission

iii. Advisory No. R-13014/28/2022- Ethics dated 05.09.2026, issued by the Ethics & Medical Registration Board, National Medical Commission

iv. Advisory No. C.18018/13/2026-MS dated 16.09.2026, issued by the Department of Health & Family Welfare, Ministry of Health & Family Welfare, Government of India, to the Chief Secretary/Additional Chief Secretary (Health)/Principal Secretary (Health), Secretary (Health)/Director General of Health Services/Director of Medical Education/Nodal Officer, Clinical Establishments (All States/UTs who have adopted the Clinical Establishment Act, 2010)

11. In response to our query that "*Whether, subsequent to the Judgment, the competent regulatory authority has received any application for approval or permission to conduct research/clinical trial involving stem cell therapy for ASD?*", it has been submitted that the competent regulatory authority for stem cell research depends upon the level of manipulation of the stem cells, as defined by the Central Drugs Standard Control ("**CDSCO**"). Where the stem cells have undergone more than minimal manipulation, the research is regulated by CDSCO under the New Drugs and Clinical Trial Rules, 2019 ("**NDCT Rules, 2019**"). Where the stem cells have undergone minimal or less than minimal manipulation, the research is

regulated by the DHR, and in addition to the recommendation of the Institutional Ethics Committee registered with the DHR, the trial is required to be approved by the NSRC. It was submitted that neither the CDSCO, nor the DHR or the ICMR have received any application seeking approval or permission to conduct clinical trial/research with respect to stem cell therapy for ASD.

12. It has also also been highlighted that the Union has recognized the need to provide a duly regulated avenue for patients already undergoing such therapy. Hence, a multi-center randomized controlled trial ("**RCT**") has been proposed to be initiated at two tertiary care sites in the country: one in North India and one in South India, within a period of six months with funding support from the ICMR.

13. On perusal of the compliance affidavit dated 28.09.2026, we find that, although the Union proposes to undertake consolidation of the existing rules, regulations and guidelines through appropriate amendments, the need of the hour is to clearly explain the existing regulatory framework applicable to research/clinical trial corresponding to different levels of manipulation of stem cells for ASD. There is an urgent need for a step-wise procedure to be widely disseminated amongst the public, so as to ensure ready access to all stakeholders involved.

14. The failure of the authorities to effectively curb the malpractice of illegally administering a prohibited form of medical intervention as a clinical service has led to the

proliferation of clinics and doctors offering such services. The lack of readily accessible information, which the public could consult to ascertain the legal position, has tacitly enabled such malpractice to continue. The labyrinth of rules, regulations, office orders and advisories, unless presented in a clear and coherent manner, leaves room for such malpractices to persist and enables dubious elements to exploit the lack of public awareness in this regard. In other words, even though the administration of stem cell therapy for ASD has never been permissible as a clinical service outside an approved and monitored research or clinical trial setting, the absence of a clear and accessible protocol has made it easier for such interventions to be offered under the guise of legitimate medical treatment.

15. Therefore, we hereby direct that the Ministry of Health and Family Welfare, Government of India to undertake the following steps, **within a period of 6 weeks** from the date of this order:

i. Issue a comprehensive protocol clearly explaining the regulatory regime governing the use of stem cells in research and clinical trials relating to ASD. The protocol shall set out, in a step-wise manner, the procedure for seeking the requisite permissions and approvals, the timelines applicable at each stage, and the duties and obligations of all stakeholders concerned. The statutory or regulatory basis for each step of compliance, along with the competent authority responsible for granting the requisite approval or authorisation, shall be clearly

identified and explained. Wherever practicable, it shall be supplemented by a flowchart enabling medical practitioners, institutions and members of the public to readily identify the regulatory pathway applicable to the proposed intervention. The objective is to ensure that no stakeholder is left to navigate a labyrinth of regulatory instruments without being able to ascertain the precise requirements applicable to them.

ii. Create awareness and undertake widespread dissemination of information regarding the existing regulatory framework, clearly informing the public that stem cell therapy for ASD is not permissible as a clinical service outside a duly approved and monitored research or clinical trial setting. For this purpose, the Ministry shall ensure:

a) That such information is published in a dedicated and easily identifiable section of its official website, in clear and accessible language, and is disseminated through the websites of other relevant regulatory authorities, including the DBT, the ICMR, the CDSCO and the NMC.

b) That the information reaches the public at large, particularly parents, guardians and caregivers of persons with ASD, through hospitals, medical institutions, professional medical associations and patient support organisations. The information

shall clearly distinguish between established forms of treatment and experimental interventions, explain the legal restrictions governing the administration of stem cell therapy for ASD, and caution the public against misleading claims regarding its safety, efficacy or regulatory approval.

16. With respect to the Union's proposal to initiate multicentre Randomised Controlled Trial ("**RCT**") across the two tertiary care sites indicated in the compliance affidavit, certain concerns arise regarding the eligibility criteria for participation in such research/clinical trials. Accordingly, the Union is directed to clarify, on the next date of hearing, the eligibility criteria proposed to be adopted for participation in the RCT and, in particular, whether the process of randomisation may result in some participants, including those who are already undergoing the therapy, being excluded from the intervention under study and, consequently, being unable to avail of its potential benefits. In the event that the proposed design of the RCT may result in some eligible participants, including those already undergoing the therapy, being excluded from receiving the intervention under study, the Union shall deliberate upon and place before this Court a comprehensive plan for the continued monitoring and medical supervision of such participants, including appropriate follow-up, assessment of their clinical condition and such further measures as may be necessary to safeguard their health and well-being, in accordance with applicable scientific, ethical

and regulatory standards.

17. Having regard to the concerns raised and the lack of clarity, at this stage, regarding the eligibility criteria for participation in the proposed RCT and the precise manner in which the two tertiary care centres are to function, we permit Respondent No. 13 and any other interested individual to place their views and suggestions before the National Stem Cell Research Regulation Committee for their due consideration. We direct the Union to establish a dedicated online portal for the submission of such views and suggestions **within a period of 4 weeks**. The Committee shall duly consider the representations so received, afford an opportunity of hearing to the persons concerned wherever necessary, and take appropriate decisions in accordance with law.

18. As regards patients who had already commenced stem cell therapy for ASD on or before 30.01.2026, we direct the Union to establish a dedicated online portal for maintaining the medical records of such patients, including the particulars of the treating medical practitioners, the nature and course of the intervention administered, and such other clinical details as may be prescribed by the competent authority, subject to appropriate safeguards for the confidentiality and security of the patients' medical information. Such online portal is to be created **within a period 6 weeks** from the date of this order. Once the portal is established, it shall be mandatory for the patient or their parent/guardian/caregiver and the doctor/clinic administering such therapy, to register

themselves on the portal with the requisite information before continuing with the intervention.

19. Pending the operationalisation of the proposed tertiary care centres, patients who had commenced stem cell therapy for ASD on or before 30.01.2026 may, as a strictly temporary arrangement, continue with the ongoing procedure at the existing clinics or institutions, subject to their registration on the aforesaid portal and compliance with such monitoring, reporting and other safeguards as may be prescribed by the competent authority. This arrangement shall be confined to existing patients and shall not be construed as recognition or approval of stem cell therapy for ASD as a permissible clinical service.

20. We reiterate that no new patients shall be inducted for stem cell therapy for ASD outside a duly approved and monitored research or clinical trial setting. The temporary arrangement set out above is confined to patients who had commenced such therapy on or before 30.01.2026 and shall not be construed as diluting the regulatory position clarified in the judgment dated 30.01.2026.

21. Registry shall furnish one copy of this Order to Ms. Aishwarya Bhati, the learned ASG for its onward communication.

22. Post this matter for further hearing on 14.12.2026 at 2.00 p.m.

.....J.

(J. B. PARDIWALA)

.....J.

(R. MAHADEVAN)

New Delhi.

13th October, 2026.

ITEM NO.301(PH) COURT NO.5 SECTION X

S U P R E M E C O U R T O F I N D I A
RECORD OF PROCEEDINGS

Writ Petition(Civil) No.369/2022

YASH CHARITABLE TRUST & ORS. Petitioner(s)

VERSUS

UNION OF INDIA & ORS. Respondent(s)

[PART HEARD BY: HON'BLE MR. JUSTICE J.B. PARDIWALA AND HON'BLE MR. JUSTICE R. MAHADEVAN]
(IA No. 77306/2022 - APPLICATION FOR PERMISSION,IA No.90102/2026 - APPROPRIATE ORDERS/DIRECTIONS, IA No. 73459/2026 - APPROPRIATE ORDERS/DIRECTIONS, IA No. 8728/2023 - DELETING THE NAME OF PETITIONER/RESPONDENT, IA No. 69302/2026 - EXTENSION OF TIME IA No. 218210/2026 - INTERVENTION APPLICATION, IA No. 67852/2026 - INTERVENTION APPLICATION, IA No. 278560/2026 - INTERVENTION APPLICATION, IA No. 235096/2026 - INTERVENTION APPLICATION IA No. 80436/2026 – INTERVENTION/IMPLEADMENT, IA No. 235098/2026 - PERMISSION TO APPEAR AND ARGUE IN PERSON, IA No. 218214/2026 - PERMISSION TO APPEAR AND ARGUE IN PERSON,IA No. 67854/2026 - PERMISSION TO APPEAR AND ARGUE IN PERSON, IA No. 223334/2026 - PERMISSION TO FILE ADDITIONAL DOCUMENTS/FACTS/ANNEXURES & IA No. 73433/2026 - PERMISSION TO FILE ADDITIONAL DOCUMENTS/ FACTS/ANNEXURES)

WITH
W.P.(C) No. 731/2026 (X)
(FOR ADMISSION)
(IA No. 171710/2026 - GRANT OF INTERIM RELIEF)

Date : 13-10-2026 These matters were called on for hearing today.

CORAM :
HON'BLE MR. JUSTICE J.B. PARDIWALA
HON'BLE MR. JUSTICE R. MAHADEVAN

For Petitioner(s) :
Mr. Nalin Kohli, Sr. Adv.
Mr. Ankur Khandelwal, Adv.
Mr. Nishit Agrawal, AOR
Mr. Chirag Sharma, Adv.
Mr. Alok Nayak, Adv.
Mr. Yash Jain, Adv.
Mr. Prashant Shivam, Adv.

Mr. Siddharth Nath, Adv.
Mr. Prateek K Chadha, AOR
Mr. Anunay Chowdhury, Adv.
Mr. Asjad Hussain, Adv.
Mr. Ritik Kanoujia, Adv.
Mr. Sreekar Aechuri, Adv.
Ms. Surbhi Soni, Adv.
Mr. Aniket Chauhaan, Adv.

For Respondent(s) :

Ms. Aishwarya Bhati, A.S.G.
Ms. Madhulika Upadhyay, AOR
Mr. Ketan Paul, Adv.
Mr. Ashok Panigrahi, Adv.
Mr. Piyush Beriwal, Adv.
Mr. Pratyush Shrivastava, Adv.
Ms. Shivika Mehra, Adv.
Mr. Abdesh Chaudhary, Adv.
Mr. Sachin Sharma, Adv.

Mr. Prateek Bhatia- 3289 , AOR

Mr. Omkar Deshpande, Adv.
Mr. Siddharth Dharmadhikari, Adv.
Mr. Aaditya Aniruddha Pande- 3259, AOR
Mr. Shrirang B. Varma, Adv.

Mr. Anand Sharma, Adv.
Mr. Arman Roop Sharma, Adv.
Ms. Shimpy Arman Sharma, Adv.
Ms. Priya Pachouri, Adv.
Ms. Shivangi Goel, Adv.
Mr. Nishkarsh Kumar Pharswal, Adv.
Ms. Deepika Ojha, Adv.
Dr. Vinod Kumar Tewari- 1866, AOR

Mr. Nikilesh Ramachandran- 1406, AOR
Mr. Shubham Seth, Adv.
Mr. Aditya Krishnan, Adv.

Mr. Neeraj Kishan Kaul, Sr. Adv.
Mr. Prashant Bhushan, Adv.
Mr. Akshay Sapre, Adv.
Mr. Yash S. Vijay- 3775, AOR
Mr. Toshiv Goyal, Adv.
Mr. Anmol Aggarwal, Adv.
Mr. Shikhar Aggarwal, Adv.
Mr. Joshua Tom Thomas, Adv.

Mr. Shyam Mehta, Sr. Adv.
Mr. Ashish Wad, Adv.
Mr. Manoj Wad, Adv.
Ms. Swati Arya, Adv.

Mr. Deepanshu Verma, Adv.
For M/s.J S Wad And Co- 1288, AOR

Mr. Amit Meharia, Adv.
Mr. Abinash Agarwal, Adv.

Intervenor-in-person

Mr. Nalin Kohli, Sr. Adv.
Mr. Ankur Khandelwal, Adv.
Mr. Nishit Agrawal, AOR
Mr. Chirag Sharma, Adv.
Mr. Alok Nayak, Adv.
Mr. Yash Jain, Adv.
Mr. Prashant Shivam, Adv.

Mr. Ritesh Patil- 3820, AOR

Mr. Anilendra Pandey- 2501, AOR
Mr. Ambrish Kumar Mishra, Adv.

Mr. Vaibhav Manu Srivastava- 2447, AOR
Mr. Anas Tanwir- 2963, AOR

Mr. Pankaj Kumar Singh, Adv.
Mr. Pawan Kumar Shukla, Adv.
Ms. Kanika, Adv.
Mr. Raj Singh Rana, AOR
Mr. Shyam Singh Chauhan, Adv.
Mr. V.S. Dubey, Adv.

UPON hearing the counsel the Court made the following

O R D E R

1. Post this matter for further hearing on 14.12.2026 at 2.00 p.m.

2. Signed Order (in original) is placed on the file.

(VISHAL ANAND)
DEPUTY REGISTRAR

(POOJA SHARMA)
COURT MASTER (NSH)

(Signed Order is placed on the file)