

ITEM NO.301

COURT NO.6

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. 235096/2026 - INTERVENTION APPLICATION
IA No. 218210/2026 - INTERVENTION APPLICATION
IA No. 67852/2026 - 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. 73433/2026 - PERMISSION TO FILE ADDITIONAL
DOCUMENTS/FACTS/ANNEXURES
IA No. 223334/2026 - 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 : 01-09-2026 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. Nishit Agrawal, AOR

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Mr. Prateek K Chadha, AOR
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Mr. Ritik Kanoujia, Adv.
Mr. Sreekar Aechuri, Adv.**

**For Respondent(s) : Ms. Aishwarya Bhati, A.S.G.
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Mr. Pratyush Shrivastava, Adv.
Ms. Shivika Mehra, Adv.
Mr. Abdesb Chaudhary, Adv.
Mr. Sachin Sharma, Adv.**

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Mr. Arman Roop Sharma, Adv.
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Mr. Vivek Tiwari, Adv.
Ms. Saumya Mishra, Adv.
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**Mr. Nikilesh Ramachandran, AOR
Mr. Lovekesh Aggarwal, Adv.**

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Mr. Mukesh Kumar, AOR
Mr. Vaibhav Manu Srivastava, AOR
Mr. Anas Tanwir, AOR

Mr. Pankaj Kumar Singh, Adv.
Mr. Pawan Kumar Shukla, Adv.
Ms. Kanika, Adv.
Mr. Raj Singh Rana, AOR

Intervenor-in-person, AOR

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, AOR

Mr. Anilendra Pandey, AOR
Mr. Rajeev Kumar Ranjan, Adv.
Mr. Kamlesh Upadhyay, Adv.

Mr. Amit Meharia, Adv.
Mr. Abinash Agarwal, Adv.
Ms. Priya S Bhalerao, Adv.
Ms. Shivangi Sengar, Adv.
Ms. Priya S B., Adv.

Ms. Rupali Francesca Samuel, AOR

UPON hearing the counsel the Court made the following
O R D E R

1. The matter has come up today to report compliance of our directions issued in the Judgment titled “Yash Charitable & Ors. vs. Union of India & Ors.” [Writ Petition (Civil) No.369/2022 decided on 30.01.2026], beyond what has been brought to our attention at the last date of hearing on 30.07.2026.
2. We are of the *prima facie* opinion that the steps taken by the Government, including the issuance of the advisory by the Department of Health Research (DHR) and the updating of the list of disease conditions in which stem cell therapy is approved or recommended as a standard of care, pursuant to the deliberations of the expert consultation convened under the Chairmanship of the Secretary, DHR, with officials from the Central Drugs Standard Control Organisation (CDSCO), Department of Biotechnology (DBT), National Medical Commission (NMC), as well as subject experts from AIIMS, New Delhi, Tata Memorial Centre, Mumbai and King George Medical University, Lucknow, are steps in the right direction and reflect an effort towards

strengthening and clarifying the regulatory framework governing research in stem cell therapy with respect to Autism Spectrum Disorder ("ASD").

3. At the same time, the working and effectiveness of the recently revised regulatory framework governing stem cell research in ASD, particularly the functioning of the National Stem Cell Research Regulation Committee constituted by the DHR, may require further examination by the Government. This assumes added significance in the present case, particularly since the matter concerns patients who were already undergoing stem cell therapy for ASD at the time of this Court's judgment dated 30.01.2026. While this Court had indicated in paragraph 153 of the judgment that such existing patients ought not to be left without appropriate medical supervision and had called upon the Government to consider the manner in which they could be transitioned into duly regulated clinical trials, the position regarding such patients, and the manner in which their ongoing treatment is proposed to be regulated or transitioned into an appropriately approved research/clinical-trial framework, remains to be clearly placed before the Court by the Respondent No. 1/Union of

India.

4. The issue, therefore, is not merely the manner in which the regulatory framework is to operate going forward, but also its application to patients who were already receiving such treatment when the judgment was delivered. It would be necessary to ascertain what steps have been taken, both by the regulatory authorities and by the institutions administering such therapy, to give meaningful effect to the course contemplated in paragraph 153.
5. In these circumstances, the Union of India shall, in its compliance affidavit, specifically disclose:
 - (i) 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;
 - (ii) if so, the number of such applications, the date(s) on which they were received, the identity of the applicant institution(s), and the present status of each such application;
 - (iii) the particulars of any clinical trials relating to stem cell therapy for ASD that are presently

approved or under consideration, together with the institutions conducting or proposing to conduct such trials and their capacity, if any, to accommodate patients presently undergoing such therapy.

- (iv) if no such application or proposal has been received from any of the institutions presently administering such therapy, whether the Government has ascertained the reasons therefor, particularly having regard to the course indicated by this Court in paragraph 153 of the judgment;
- (v) what steps the Union of India proposes to take to facilitate the transition of existing patients into duly approved clinical trials, while ensuring that the regulatory safeguards applicable to such trials are maintained.

6. The Court would also consider it appropriate to ascertain whether corresponding steps have been taken by the institutions/clinics presently administering stem cell therapy to patients with ASD, as well as by the parents, guardians or caregivers of such patients. The position in this regard shall accordingly also be placed on record by Respondent no. 13 and other concerned institutions/clinics

and the parents, guardians or caregivers, who shall disclose:

- (i) whether, subsequent to the judgment, any steps have been taken to bring the ongoing treatment within the framework of a duly approved and regulated clinical trial, including by approaching any competent regulatory authority or an institution authorised to conduct such clinical trials;
- (ii) whether any application, proposal or request has been made by the concerned institution/clinic, or by any parent, guardian or caregiver, to any competent authority, medical institution, research institution or clinical-trial centre for initiation of, or participation in, an approved clinical trial involving stem cell therapy for ASD;
- (iii) if any such step has been taken, the particulars thereof, including the date of the application/request, the authority or institution approached, the response received thereto and the present status of the proposal;

7. The aforesaid disclosures are being called for not only to ascertain the present position of the patients who were

already undergoing treatment at the time of the judgment, but also to enable the Court to assess whether the course contemplated in paragraph 153 is being translated into practice. In particular, the Court would wish to ascertain whether reasonable and genuine steps have been taken by the regulatory authorities, the treating institutions and the caregivers to move existing patients, wherever appropriate, towards a duly regulated clinical-trial framework, while ensuring that such patients are not left without appropriate medical supervision during such transition.

8. List on 29.9.2026 at 2.00 P.M.

(CHANDRESH)
ASTT. REGISTRAR-cum-PS

(POOJA SHARMA)
COURT MASTER (NSH)