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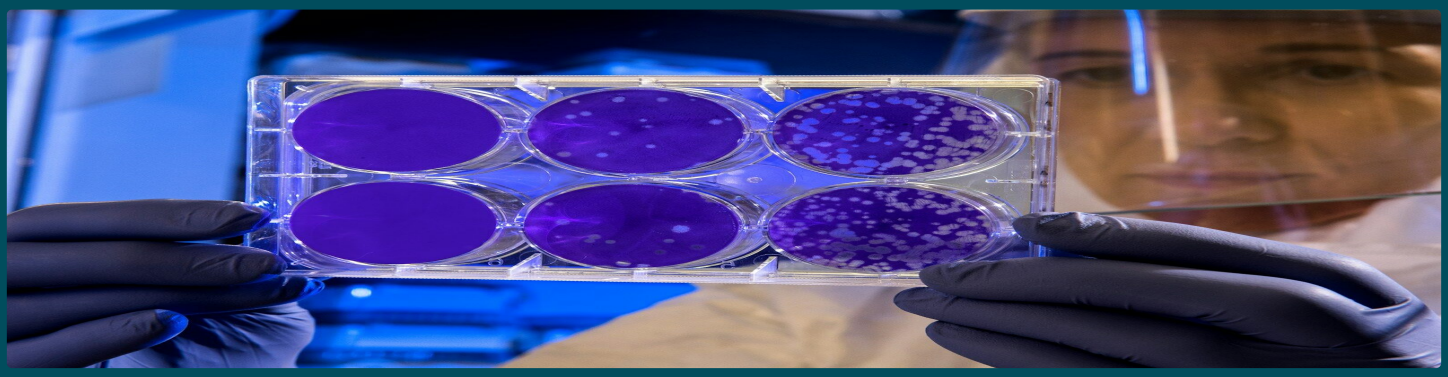

MEDICO-LEGAL

Hope Can’t Replace Evidence: The Supreme Court on Stem Cell Therapy In Yash Charitable Trust v. Union of India & Ors.

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Table of contents

- Brief Facts
- Issue Before the Court
- Arguments by the Parties
  - Submission on behalf of the Petitioner
  - Submission on behalf of the Respondents
- Courts Analysis and Decision
  - Reasonable Maintenance
  - The types of stem cell “therapies” (autistic spectrum disorder)
  - The Offer of Stem Cell Therapy
  - Service and Patient Autonomy
  - Clinical Studies and Trials
- Way Forward
- References

Brief Facts

The present public interest litigation (PIL) is in the Supreme Court of India due to the promotion of stem cell “treatment” for Autism Spectrum Disorder (ASD). The Petitioners did not object to medical research; rather, they objected to the way some clinics are presenting an experimental treatment as though it were already an accepted form of treatment and may be a cure. The reason for this concern is that families with a child who has ASD often have an urgent need for assistance and therefore seek whatever potential assistance may be available, even if they are under pressure emotionally. As such, they may easily be persuaded to consider a costly and unproven treatment as a viable option for hope. As a result, the Petitioners are seeking an order to stop the commercial use of stem cell treatments unless they are part of approved clinical trials.

Issue Before the Court

The Hon’ble Supreme Court framed the two issues for consideration:

1. Whether doctors, clinics, hospitals, or other medical institutions can offer stem cell ‘therapy’ as a routine healthcare service?
2. Whether the Drugs Act of 1940 and the NDCT Rules, 2019, provide a regulatory framework for conducting stem cell research and clinical trials in relation to ASD?

Arguments by the Parties

Submission on behalf of the Petitioner

Petitioners claimed the administration of stem cell therapy for ASD is not only not authorised but also not a safe and effective treatment method. The petitioners’ arguments were based on the National Guidelines for Stem Cell Research of 2017; the status of stem cell therapy as evidence-based in humans of 2021, and the EMRB-NMC recommendations of 06.12.2022. According to petitioners, all the above-mentioned publications indicate that the use of stem cells can be considered only within the framework of a controlled clinical study approved by ethics committees.

Submission on behalf of the Respondents

Union of India: Respondent Union of India claims that stem cell-based products are regulated under the Drugs Act, 1940, and the New Drugs and Clinical Trials Rules, 2019. However, it was earlier mentioned that to fall within the definition of “New Drugs”, the procedures are not to be carried out by using Autologous stem cells.

Respondent Clinics and Parent Organizations: Respondents claimed that neither the consent nor the rights and free will of patients or parents, believing that the therapy had positively impacted them, could be forcibly taken away. Additionally, a stem cell-based product was different from a stem cell-based procedure.

Courts Analysis and Decision

Reasonable Maintenance

The Court determined that this Public Interest Litigation was reasonable in its maintenance and included patient safety, involving medical ethics, and enforcing regulations. The allegation of commercial competition was not persuasive to the Court. The focus for the Court was to determine whether or not the rights of vulnerable and less fortunate people were being respected and protected through this situation of alleged stem cell therapies.

The types of stem cell “therapies” (autistic spectrum disorder)

The Court recognized that there were many different types of stem cells and methods for administering those cells through stem cell “therapy”. The Court further clarified that the lack of a clear statutory definition of “therapy” does not mean that stem cell therapies can be freely marketed to the general public. The determination of whether stem cell therapies are acceptable is carried out according to the reasonable standard of care, which is expected to be provided by a qualified medical professional.

The Offer of Stem Cell Therapy

The Court referenced V.P. Shantha, Jacob Mathew and M.A. Biviji to comment on the respective standard of care that a physician is to provide to their patients. All three members of the Court stated that physicians have a duty to conduct themselves according to accepted medical practices that have been determined by the current knowledge of the medical community. Based on the evidentiary record available to the Court, stem cell therapy for ASD is not established as an acceptable standard of practice within the current medical community. The ICMR, DHR and EMRB-NMC have all established that the ongoing therapy for patients is an experimental procedure which can only be provided through approved clinical trials. Accordingly, the Court determined that a physician who provides stem cell therapy to patients with ASD is providing care that is below the normal standards of care and may also constitute a breach of the medical professional’s ethical obligations.

Service and Patient Autonomy

The Court found that families facing ASD do encounter many challenges. But autonomy does not possess any right to demand an experimental or unproven treatment. In referencing Samira Kohli, the Court explained that there is a need for informed consent. Patients have the right to be informed about both procedures and related information, including risks, benefits, alternatives and outcomes related to said procedures.

The primary barrier here is the lack of established safety and efficacy; therefore, consent alone is not sufficient in addressing this barrier. The Court is mindful of the risk of developing a therapeutic misconception, wherein an individual assumes that an experimental treatment is an accepted form of treatment.

Clinical Studies and Trials

The Court held that stem cells would be classified under the broad definition of “drugs” as outlined in Section 3(b)(i) of the Drugs Act, 1940 (as stem cells are used to treat/ alleviate a diseased condition). Autologous stem cells that are not substantially altered do not constitute “new drugs” according to the NDCT Rule, 2019.

Regardless, research involving humans cannot proceed without proper regulatory oversight; thus, it must adhere to the guidelines outlined in Chapter IV of the NDCT Rules, 2019 and the National Ethical Guidelines, and may only be conducted in accordance with approved clinical trials that provide the required ethical and regulatory oversight.

Way Forward

This ruling creates a distinction between researching and treating an individual with Autism Spectrum Disorder (ASD). It did not stop the proceeding of testing stem cell therapies for ASD; however, it required that all continuing studies/tested therapies be done under a credentialed and overseen/supervised structure.

The ruling did not allow for the application of any experimental procedure to be sold as a standard of care. Thus, the ruling prevents the exploitation of individuals with ASD and their families while providing an avenue for continued medical advancements. Therefore, the message is clear: Although hope is valid, evidence must be used for both science and medical treatments of any patient with ASD. Autonomy has limits when an experimental procedure has not yet been determined to be safe, efficacious, or reasonable by the medical community.

References

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