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FROM PRODUCT TO PROCEDURE: RETHINKING THE LEGAL REGULATION OF STEM-CELL THERAPIES IN INDIA

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Abstract

Stem-cell therapy presents one of the most difficult problems for contemporary health law because it occupies an uncertain space between scientific research, regulated medical products and clinical procedures. India does not lack legal instruments governing this field. The Drugs and Cosmetics Act 1940, the New Drugs and Clinical Trials Rules 2019, the National Guidelines for Stem Cell Research 2017, the National Ethical Guidelines for Biomedical and Health Research, professional ethics regulations and the Clinical Establishments Act 2010 collectively regulate different aspects of stem-cell research and treatment. Yet these instruments were not designed as one coherent framework for the complete movement of a cellular intervention from laboratory research to clinical practice. The Supreme Court's decision in *Yash Charitable Trust v Union of India* in January 2026 exposed this structural difficulty while firmly rejecting the routine clinical administration of unproven stem-cell therapy for autism spectrum disorder. This article argues that the central problem is not the absence of regulation but a regulatory mismatch between product-oriented drug law and procedure-oriented medical practice. Minimally manipulated and autologous interventions demonstrate this problem particularly clearly. The article examines the classification of stem-cell interventions, the relationship between scientific evidence and the legal standard of care, the status of professional and ethical guidelines, institutional fragmentation, patient autonomy, and the implementation challenges that followed the Supreme Court's decision. It argues for a coherent, tiered regulatory pathway connecting research, clinical trials, conditional access and established clinical care while preserving strong safeguards against the commercialisation of experimental medicine.

Keywords: Stem-cell therapy; Indian health law; clinical trials; medical regulation/

I. Introduction

The regulation of stem-cell therapy presents a particularly difficult challenge for health law because the object being regulated does not fit comfortably within conventional legal categories. A stem-cell intervention may involve a biological product manufactured outside the patient's body, cells obtained from the patient's own body and minimally processed before re-administration, or a therapeutic procedure combining cell processing with a clinical intervention. The scientific distinction between these forms may be obvious to specialists, but their legal consequences are considerably less certain. Whether a treatment is characterised as a drug, a biological product, medical research or a clinical procedure determines which regulator becomes responsible, what approvals are required, what evidence must be generated and what protections are available to the patient.

The difficulty becomes more acute when experimental interventions are presented to patients as established treatment. Stem-cell science has generated considerable therapeutic expectations, but scientific possibility does not establish clinical efficacy. The legal system must therefore distinguish between legitimate experimentation and the commercial provision of treatment whose safety and effectiveness have not been adequately demonstrated. That distinction is particularly important where patients or their families are vulnerable and where the intervention is promoted as a possible cure for a serious or incurable condition.

The Supreme Court's judgment in *Yash Charitable Trust & Ors v Union of India & Ors*, delivered on 30 January 2026, provides an important judicial intervention in this field. The proceedings concerned the administration, promotion and prescription of stem-cell interventions for autism spectrum disorder (ASD). The Court was confronted not merely with the question whether stem cells were scientifically promising, but with the legal question whether such interventions could be offered as a routine clinical service. It ultimately held that stem-cell therapy for ASD could not be offered as ordinary clinical treatment and could only be administered within the legally permissible framework of research or an approved clinical trial.¹

The importance of the decision, however, extends beyond ASD. The judgment reveals the deeper structure of India's regulatory approach to stem-cell medicine. The Court examined the Drugs and Cosmetics Act 1940, the New Drugs and Clinical Trials Rules 2019 (NDCT Rules), the National Guidelines for Stem Cell Research 2017 (NGSCR), the National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, professional medical regulations and the jurisprudence governing medical standards and informed consent. In doing so, it demonstrated that India already possesses a substantial body of regulation. The

problem is that these instruments were developed through different regulatory purposes and administered by different institutions. They do not operate as a single, clearly articulated pathway governing the entire life cycle of a stem-cell intervention.

This article therefore does not treat *Yash Charitable Trust* merely as an isolated case concerning autism. It uses the decision as an important judicial lens through which to examine the broader legal regulation of stem-cell therapies in India. The central argument is that India's regulatory difficulty is best understood as a **product–procedure gap**. Drug regulation is comparatively well suited to a stem-cell-derived product that is manufactured, processed, tested and marketed as a therapeutic product. It is considerably less straightforward when the intervention involves a patient's own cells, minimal manipulation and immediate re-administration as part of a clinical procedure. At the same time, the fact that an intervention does not qualify as a “new drug” cannot logically mean that it becomes lawful standard medical care. The Supreme Court's reasoning is important precisely because it prevents this classificatory distinction from becoming a regulatory escape route.

The article argues that the next stage of Indian stem-cell regulation should therefore not be limited to adding more prohibitions. The more important task is to construct a coherent legal pathway through which an intervention can move from scientific research to clinical trials, from clinical trials to carefully controlled access where appropriate, and ultimately to established clinical practice. Such a framework must also identify the respective responsibilities of CDSCO, the Department of Health Research, ethics committees, the National Medical Commission, State authorities and clinical establishments. Regulation should protect patients without making lawful innovation legally unintelligible.

II. The Legal Character of Stem-Cell Therapy

The first difficulty in regulating stem-cell therapy arises from classification. Conventional drug regulation assumes that there is a relatively identifiable therapeutic product whose composition, manufacture, quality, safety and efficacy can be assessed. Stem-cell interventions complicate this assumption because the therapeutic object may change depending on where the cells come from, how they are processed and how they are administered.

The Drugs and Cosmetics Act 1940 adopts a deliberately broad definition of “drug”. Section 3(b) includes substances intended for use in the diagnosis, treatment, mitigation or prevention of disease or disorder.² The breadth of this definition is significant because it allows the regulatory system to encompass therapeutic substances that were not necessarily contemplated when the legislation was enacted. Yet the breadth of the definition does not by itself answer

the more difficult question of how a particular cellular intervention should be regulated.

The NDCT Rules provide a more specific classification. Rule 2(1)(w)(v), together with its accompanying explanation, addresses cell or stem-cell-derived products intended for use as drugs and distinguishes between products involving substantial manipulation and those involving minimal manipulation or other characteristics relevant to their regulatory status.³ This distinction reflects a legitimate regulatory concern. A highly manipulated cellular product may present manufacturing, biological and safety risks that require a regulatory approach comparable to other advanced therapeutic products. A minimally manipulated autologous intervention may raise a different set of questions because the cells originate from the same patient and may be returned to that patient shortly after collection.

The difficulty arises when this classification is treated as though it determines the legality of clinical use by itself. It does not. The Supreme Court expressly recognised this point in its discussion of the ASD litigation. The Court observed that whether administered stem cells fall within the statutory definition of “drug” cannot, by itself, determine whether their administration is permissible as a clinical service.⁴ The relevant inquiry must also consider the standard of care owed by medical professionals and whether the treatment is scientifically and medically justified.

This distinction is crucial. A therapy may fall outside the definition of a “new drug” while still being experimental medicine. Conversely, a treatment may involve a regulated product but also constitute a medical procedure requiring professional and institutional oversight. The legal system therefore cannot allow the categories of “drug” and “procedure” to become mutually exclusive regulatory silos.

Autologous interventions illustrate the problem particularly well. In an autologous procedure, cells are obtained from the same individual who will receive them. Where the processing is limited, the intervention may not fit neatly within the conventional concept of a manufactured therapeutic product. Yet the patient is still being subjected to an intervention whose safety and therapeutic efficacy must be assessed. The absence of a conventional manufactured product cannot eliminate the ethical and professional obligations owed to the patient.

The classification problem is therefore not merely technical. It determines whether the intervention enters a system of pre-market review, clinical-trial approval, ethics review, professional regulation or some combination of these mechanisms. It also determines which institution can intervene when a clinic begins offering an experimental procedure commercially. A legal framework that focuses only on the product may leave the clinical act insufficiently regulated, while a framework focused only on professional conduct may

intervene too late, after patients have already been exposed to an inadequately tested treatment. The better approach is consequently to treat classification as the starting point rather than the conclusion of regulation. The relevant question should not simply be whether the cells constitute a “new drug”. It should be whether the particular intervention has reached the evidentiary and regulatory threshold necessary for the form in which it is being offered to patients.

III. India’s Regulatory Architecture Before 2026

India’s stem-cell regulatory framework developed incrementally rather than through a single comprehensive statute. The Drugs and Cosmetics Act 1940 remains the principal statutory foundation for therapeutic products. The Drugs Rules 1945 and the NDCT Rules supplement that framework by establishing regulatory mechanisms for manufacture, licensing, new drugs, clinical trials and biomedical research.⁵

The NDCT Rules are particularly important because they create a bridge between conventional product regulation and research involving human participants. Chapter IV addresses biomedical and health research involving human participants and requires institutional ethical oversight. The Rules also connect research activity with national ethical standards. Rule 16(4), in particular, requires compliance with the applicable ICMR ethical framework.⁶ This connection gives regulatory significance to ethical principles that might otherwise remain merely advisory.

The NGSCR 2017 occupies another important place in this structure. Issued by the ICMR and Department of Biotechnology, the Guidelines provide an ethical and scientific framework for stem-cell research and distinguish between areas in which research may be undertaken and areas requiring greater restriction or prohibition.⁷ They address matters such as institutional oversight, consent, scientific validity and the appropriate progression of research.

The National Ethical Guidelines for Biomedical and Health Research Involving Human Participants 2017 provide a broader ethical framework. They deal with informed consent, risk–benefit assessment, protection of vulnerable participants, compensation and responsibilities of researchers and ethics committees.⁸ These guidelines are particularly important because the ethical legitimacy of stem-cell research cannot be separated from the conditions under which individuals become research participants.

Professional regulation supplies another layer. The Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations 2002, which continued under the transitional provisions of the National Medical Commission Act 2019 until superseded, contain provisions

concerning treatment that lacks sound medical evidence. Regulation 7.22 is especially relevant because it addresses the prescription or administration of therapies that are beyond the physician's competence or unsupported by rational and medical evidence.⁹ The significance of this provision is that the regulation of stem-cell medicine is not confined to the licensing of products. A physician's professional obligations independently constrain what may be offered to a patient.

The Clinical Establishments (Registration and Regulation) Act 2010 provides yet another regulatory mechanism. Where applicable, it regulates clinical establishments and permits consequences for non-compliance. Sections 32 and 40 provide enforcement mechanisms that can become relevant where a clinical establishment facilitates unlawful or non-compliant medical practice.¹⁰ The difficulty, however, is that the Act has not created a uniformly applicable national regulatory system across all States and Union Territories. Its operation therefore illustrates a wider problem in Indian health law: central legislation may coexist with uneven State-level implementation.

The resulting structure is therefore extensive but fragmented. CDSCO and State drug authorities regulate products and licensing within the drugs framework. The Department of Health Research and ICMR operate within the research and ethical sphere. Ethics committees supervise research at the institutional level. The NMC and State medical councils regulate professional conduct. State health authorities regulate clinical establishments where the applicable statutory framework is in force. These institutions may all become relevant to a single stem-cell intervention.

The existence of multiple regulatory instruments is not itself a defect. Complex medical technologies often require multiple forms of oversight. The difficulty arises when the legal relationship between these institutions is unclear. A patient does not experience a stem-cell therapy as a collection of regulatory categories. The patient experiences one intervention, one physician, one clinic and one set of risks. Regulation, by contrast, may divide responsibility between several institutions without identifying which authority bears ultimate responsibility for the legality of the intervention as a whole.

This institutional fragmentation becomes especially important when a therapy occupies the boundary between research and treatment. If a cellular intervention is not a "new drug", but is also not accepted standard care, the law must still identify its lawful route into human use. The NDCT Rules and ethical guidelines provide parts of that route, but the regulatory architecture has historically depended heavily on interpreting several instruments together.

IV. Scientific Evidence and the Legal Standard of Care

The regulation of stem-cell therapy cannot be separated from the legal concept of medical standard of care. The law does not ordinarily require every doctor to practise the most advanced form of medicine available. It does, however, require a reasonable level of professional competence and care consistent with accepted medical knowledge.

Indian medical negligence jurisprudence establishes this principle through a series of decisions. In *Laxman Balkrishna Joshi v Trimbak Bapu Godbole*, the Supreme Court identified duties concerning the decision whether to undertake a case, the choice of treatment and the administration of treatment.¹¹ *Indian Medical Association v VP Shantha* brought the Bolam principle into Indian medical jurisprudence, while *Jacob Mathew v State of Punjab* developed the standard of reasonable professional competence in the context of medical negligence.¹² More recently, *M.A. Biviji v Sunita* reaffirmed the importance of assessing medical conduct against contemporary professional knowledge and practice.¹³

These principles matter greatly for experimental medicine. The legal problem is not that medical science must remain static. Medical advancement necessarily requires doctors and researchers to investigate treatments that are not yet established. The crucial distinction is between **researching an experimental treatment** and **presenting an experimental treatment as established clinical care**.

A clinical trial accepts uncertainty as an inherent part of medical research. The participant is informed that the intervention is being studied, the research is subjected to ethical and regulatory scrutiny, and outcomes are collected systematically. Routine clinical practice rests on a different premise: the intervention has accumulated sufficient evidence to be regarded as an acceptable treatment for the relevant condition.

The danger of commercialised experimental medicine arises when that distinction disappears. A patient may be told that a stem-cell intervention is “promising” or “advanced” without being adequately informed that its clinical efficacy remains uncertain. The legal problem is therefore not resolved merely by obtaining a signature on a consent form. The patient’s decision must occur within a truthful evidentiary context.

The ICMR’s *Evidence Based Status of Stem Cell Therapy for Human Diseases* is important in this regard. Its assessment of stem-cell therapy for ASD treated the evidence as insufficient to establish the intervention as standard care.¹⁴ Such scientific assessments do not automatically become statutes merely because a court refers to them. Their legal significance instead derives from the ways in which regulatory rules incorporate them, professional bodies rely upon them, and courts use them to understand contemporary medical knowledge.

This relationship between science and law is particularly important in emerging technologies.

Legislation cannot realistically specify the scientific standard for every new cellular therapy. The regulatory system must therefore be capable of incorporating evolving expert knowledge while preserving legal accountability. Guidelines, professional standards and expert evidence can perform this function, but their precise legal status must remain clear.

The significance of the Supreme Court's 2026 decision lies partly in its recognition that scientific evidence and medical standard of care cannot be treated as separate questions. A therapy does not become acceptable standard medical care merely because a patient desires it, a doctor believes in its potential or a clinic can technically administer it. The intervention must occupy a defensible position within contemporary medical knowledge.

V. Yash Charitable Trust v Union of India: A Judicial Clarification of the Regulatory Framework

The Supreme Court's January 2026 decision must be situated within this broader legal architecture. The case arose from concerns regarding the promotion and administration of stem-cell "therapy" for ASD. The Court recorded the central problem in terms that are important for the entire field: there was already a regulatory framework, but considerable confusion existed among those administering and receiving such therapies regarding the applicable law.¹⁵

The Court's reasoning proceeded in a manner that is significant beyond the immediate ASD context. It first distinguished the question of whether stem-cell therapy could be offered as a routine clinical service from the separate question of how stem-cell interventions should be regulated when undertaken as research or clinical trials. That distinction prevented the case from being reduced to a technical question about the meaning of "drug".

The Court relied extensively on medical standard-of-care jurisprudence. It concluded that the legality of offering stem-cell therapy as routine care could not be determined simply by establishing that the intervention was technologically possible or desired by patients. Medical professionals owe patients a duty to exercise reasonable skill, knowledge and care.¹⁶ Where a treatment lacks sufficient scientific evidence to qualify as accepted care, its commercial administration cannot be justified simply by describing it as an alternative therapy.

The Court's treatment of informed consent is equally important. *Samira Kohli v Dr Prabha Manchanda* established that valid consent requires adequate disclosure and understanding of material information concerning the proposed treatment.¹⁷ In the stem-cell context, that principle acquires particular force because experimental interventions involve uncertainty that must be disclosed accurately.

The Court rejected the proposition that patient consent could independently authorise the routine administration of an unproven therapy. This is not a rejection of autonomy in general. Rather, it reflects the distinction between the patient's authority to make an informed decision and the physician's independent professional obligation to offer treatment that falls within legally and medically acceptable practice. Consent cannot transform an experimental intervention into established therapy.

The Court also considered the phenomenon of therapeutic misconception. Where an experimental treatment is offered in a clinical setting, patients may understand participation as though they were receiving established therapeutic care rather than contributing to research involving uncertain outcomes. The danger is especially serious where commercial incentives and therapeutic claims are involved. A consent document cannot cure a structural misunderstanding created by the way the intervention is presented.

The judgment then turned to the statutory classification of stem cells. Section 3(b) of the Drugs and Cosmetics Act contains a broad definition of "drug", and the Court held that stem cells administered for therapeutic purposes could fall within that definition.¹⁸ At the same time, the Court did not collapse the distinction between being a "drug" and being a "new drug". Certain minimally manipulated autologous interventions might not satisfy the specific criteria applicable to "new drugs" under the NDCT Rules.

That distinction is one of the most important aspects of the judgment. The Court expressly cautioned that the classification question does not itself determine whether the intervention may be offered as clinical care.¹⁹ Thus, "not a new drug" cannot be equated with "approved treatment". This reasoning is central to closing the product-procedure gap.

For ASD specifically, the Court concluded that stem-cell therapy could not be offered as a routine clinical service and could instead be administered within an approved research or clinical-trial framework.²⁰ The significance of this holding extends beyond the specific disease because it reinforces the legal principle that experimental medicine must remain identifiable as research until sufficient evidence exists to support its transition into standard care.

The judgment also addressed the institutional framework governing stem-cell research. The Court considered the 2024 dissolution of the National Apex Committee for Stem Cell Research and Therapy and examined its relationship with the NDCT Rules.²¹ It relied upon the broader principle that executive instructions cannot override statutory or delegated legislation. That principle is well established in *State of Madhya Pradesh v GS Dall & Flour Mills* and was reaffirmed in *Jaiveer Singh v State of Uttarakhand*.²²

This part of the decision demonstrates that stem-cell regulation is not simply a question of

substantive standards. It is also a question of institutional legality. A regulator cannot acquire or lose statutory authority merely because the executive rearranges administrative responsibilities. Where the statutory framework assigns responsibilities through rules, administrative restructuring must remain consistent with those rules.

The Court's later observations regarding the need for clearer regulation, monitoring, institutional responsibility and mechanisms for dealing with existing patients should be understood carefully. These observations are important recommendations arising from the regulatory difficulties exposed by the case, but they should not be treated as though every recommendation constituted a new statutory rule. The distinction matters because judicial recognition of a regulatory deficiency does not itself confer legislative authority upon the Court to redesign the entire regulatory regime.

The judgment therefore performs two functions. It provides binding clarification concerning the legality of unproven ASD stem-cell therapy and the role of consent, while also exposing broader weaknesses in India's regulatory architecture. Its lasting significance lies not only in what it prohibits but in the regulatory questions it leaves visible.

VI. The Product–Procedure Gap

The most significant structural problem in Indian stem-cell regulation is the gap between product regulation and procedure regulation. Conventional drug law asks whether a therapeutic product is safe, effective and properly manufactured. Medical regulation asks whether a professional has acted competently and whether the treatment offered to the patient is consistent with accepted standards. Stem-cell therapy may require both forms of oversight simultaneously.

Consider a conventional stem-cell-derived product that has undergone extensive laboratory processing. It can be characterised as a therapeutic product, subjected to manufacturing standards, clinical investigation and regulatory approval. The legal pathway is comparatively intelligible because the product can be identified and assessed before it reaches the patient.

Now consider a minimally manipulated autologous intervention. Cells are collected from the patient, processed to a limited extent and returned to that patient. There may be no conventional commercial “product” in the ordinary sense. Yet the intervention can involve invasive procedures, significant biological risks and substantial uncertainty about therapeutic efficacy. If drug law does not classify the intervention as a “new drug”, a regulatory system focused exclusively on product approval could leave an important part of the therapeutic act outside its principal mechanism.

The opposite problem is equally significant. If every autologous intervention were treated as though it were a conventional pharmaceutical product, the law might fail to account for the procedural and professional dimensions of the intervention. The risks of collection, processing, administration and clinical decision-making may not be captured by a product-centred model. The solution cannot therefore be to choose one category and eliminate the other. India requires a regulatory framework that recognises the continuum between products and procedures.

The Supreme Court's reasoning is valuable because it prevents the classification distinction from producing a regulatory vacuum. Its observation that permissibility as a clinical service cannot be determined merely from whether the intervention falls within the definition of "drug" provides an important doctrinal foundation.²³ The legal inquiry must remain connected to the standard of care.

Yet judicial interpretation cannot permanently substitute for legislative design. A legal system should not require patients, doctors, researchers and regulators to reconstruct the regulatory pathway by combining definitions, ethical guidelines, professional regulations and judicial decisions. The law should itself identify the pathway.

This is particularly important because scientific development will continue to produce interventions that do not fit existing categories. Cellular therapies may involve gene editing, tissue engineering, ex vivo expansion, combination products and personalised manufacturing. A regulatory framework that responds only after litigation will inevitably remain behind scientific innovation.

The product-procedure problem therefore supports a broader proposition: India's advanced-therapy regulation should be based on the **regulatory character of the intervention**, rather than on a rigid choice between "drug" and "procedure". The extent of manipulation, source of cells, intended use, route of administration, evidence base and stage of development should determine the applicable level of oversight.

VII. Soft Law, Professional Standards and Legal Enforceability

The role of ICMR guidelines illustrates another central problem in Indian health law: the relationship between soft law and binding legal obligations.

The NGSCR and National Ethical Guidelines are not parliamentary statutes. Their authority derives from their scientific and ethical expertise, their institutional origin and, in some circumstances, their incorporation into binding regulatory frameworks. It would therefore be inaccurate to describe every requirement contained in an ICMR guideline as legislation.

At the same time, it would be equally inaccurate to dismiss these documents as legally

irrelevant. The NDCT Rules expressly connect biomedical and health research with the ICMR ethical framework.²⁴ Once a binding rule requires compliance with an external ethical standard, the legal significance of that standard changes. The underlying document may remain a guideline in form, but compliance with it can become mandatory within the regulatory context created by the rule.

The guidelines also have evidentiary significance. A court assessing whether a doctor acted consistently with contemporary medical practice may reasonably consider authoritative scientific guidance. A professional body determining whether conduct was supported by sound medical evidence may similarly rely upon expert standards. The legal effect therefore operates through multiple channels: direct incorporation, professional regulation and evidentiary assessment.

This model has practical advantages. Medical science changes rapidly, and requiring Parliament to amend primary legislation whenever scientific standards change would make regulation inflexible. Guidelines can be updated more quickly. However, flexibility must not become uncertainty. Doctors should be able to understand which provisions are legally mandatory, which constitute professional guidance and which merely represent emerging scientific opinion.

The distinction becomes particularly important when professional discipline is involved. Regulation 7.22 of the IMC Regulations addresses treatment lacking sound rational and medical evidence.²⁵ A professional disciplinary proceeding should not depend upon the assumption that every ICMR document is automatically binding. Rather, the regulator must establish the relevant professional standard and demonstrate how the doctor's conduct departed from it.

The Supreme Court's approach is useful precisely because it does not require treating guidelines as legislation. Instead, it places them within the wider evidentiary and regulatory framework. This approach should be preserved. India should resist the temptation to solve every regulatory problem by declaring guidelines to be "binding" in the abstract. The better solution is to identify through legislation or delegated legislation the circumstances in which compliance is mandatory, while preserving guidelines as scientifically responsive instruments.

VIII. Institutional Fragmentation and the Question of Regulatory Authority

The second major structural problem concerns institutional responsibility. A stem-cell intervention may simultaneously implicate drug regulation, clinical research, professional conduct, hospital regulation and research ethics. The question is therefore not simply whether

rules exist, but whether a clearly identifiable institution is responsible for ensuring that the entire regulatory chain functions.

The history of the National Apex Committee for Stem Cell Research and Therapy illustrates the difficulty. The NGSCR contemplated national-level oversight for stem-cell research. During the litigation, however, the Department of Health Research issued an order dated 3 March 2024 dissolving the NAC-SCRT.²⁶ The Supreme Court subsequently examined whether this executive action was consistent with the statutory and regulatory framework established under the NDCT Rules.

The Court's reasoning drew upon the orthodox administrative-law principle that executive instructions may supplement statutory rules but cannot contradict or supersede them. In *GS Dall & Flour Mills*, the Supreme Court held that executive instructions cannot be used to amend or override statutory rules.²⁷ *Jaiveer Singh* similarly emphasised the limits of administrative instructions where statutory rules occupy the field.²⁸

The significance of this reasoning for stem-cell regulation is broader than the particular committee. Regulatory institutions derive legitimacy from legal authority. If responsibility for a technologically sensitive area is transferred from one institution to another without a clear statutory basis, the resulting uncertainty can affect the validity of decisions taken by the new body.

At the same time, institutional fragmentation cannot be solved simply by creating another committee. A new committee without clearly defined statutory powers may reproduce the same problem. The regulatory framework must identify who authorises research, who evaluates scientific validity, who regulates products, who supervises clinical establishments and who disciplines medical professionals. More importantly, it must establish how these functions interact.

A central authority may be appropriate for advanced cell-based products because manufacturing and product standards require national uniformity. Research oversight may require both central and institutional mechanisms. Professional discipline necessarily involves medical regulatory bodies. Clinical establishment regulation may remain substantially within State structures. The answer is therefore not complete centralisation but **coordinated allocation of authority**.

The Centre-State dimension is especially important. A central advisory may establish the national policy concerning unproven stem-cell therapy, but enforcement may require State drug controllers, State medical councils, health departments and local authorities. Where the Clinical Establishments Act is not uniformly operational, the availability of establishment-level

sanctions will vary. This creates the possibility of different enforcement outcomes for substantially identical conduct.

A mature national framework should therefore distinguish between substantive standards, which should be nationally consistent, and administrative implementation, which may remain decentralised. Doctors and patients should not face different substantive rules merely because the clinic happens to be located in a different State.

IX. Patient Autonomy and the Limits of Consent

Patient autonomy creates perhaps the most difficult normative question in experimental medicine. If a competent patient or the guardian of a child understands that a treatment is uncertain and nevertheless wishes to assume the risk, why should the State prevent the treatment?

The answer cannot simply be that the State knows what is best for every patient. Modern medical law rightly places considerable weight on autonomy. *Samira Kohli* established the importance of informed consent and adequate disclosure in medical treatment.²⁹ Constitutional jurisprudence also recognises decisional autonomy as an important dimension of personal liberty.

But autonomy does not operate in a legal vacuum. A patient's decision to accept risk does not automatically authorise a doctor to practise outside accepted professional standards. The doctor has independent duties arising from professional regulation and the law of medical negligence. The relationship is therefore not symmetrical: the patient may decide whether to accept a lawful treatment, but that does not necessarily create a legal entitlement to any treatment that the patient requests.

The problem becomes even more complicated where the patient is a child or a person who depends on a parent or caregiver to make medical decisions. The possibility of therapeutic misconception becomes greater where families are desperate for improvement and clinics market experimental procedures as promising therapies.

The Court's approach in the 2026 decision should therefore be understood as a limitation on the **regulatory function of consent**, rather than a rejection of autonomy. Consent is indispensable within legitimate clinical research. It cannot, however, supply the missing scientific evidence required to convert an experimental intervention into standard care.

This distinction also protects autonomy in a deeper sense. Genuine autonomy requires meaningful information. If a patient is told that a therapy is "experimental" but is simultaneously presented with claims suggesting that it is effective or accepted, formal consent

may exist without substantive understanding. Regulation against misleading commercialisation can therefore be understood not merely as paternalistic interference but as a condition for meaningful autonomy.

The appropriate legal response is consequently not to eliminate patient choice but to structure it. Patients should have access to accurate information about approved clinical trials, known risks, uncertainty, alternatives and the distinction between research and treatment. Where an intervention remains experimental, the lawful route should be participation in a properly regulated research framework rather than purchase of an unapproved therapy in the ordinary clinical market.

X. Regulation after January 2026: From Judicial Clarification to Implementation

The real test of stem-cell regulation begins after a court has declared what the law requires. A judgment can clarify legal principles, but implementation depends upon regulators, professional bodies, clinical establishments and State authorities.

Developments during 2026 indicate movement toward greater regulatory specificity. Amendments to the Drugs Rules have strengthened central licensing arrangements for advanced biological products, including cell and stem-cell-derived products and related advanced therapies.³⁰ This development is significant for the product side of the regulatory framework because it strengthens the role of central licensing for sophisticated cellular products.

The National Medical Commission also issued an advisory reinforcing the requirement that stem-cell therapy should not be offered as standard treatment where it has not received appropriate scientific and regulatory recognition.³¹ Such professional communication is important because a court ruling concerning the legality of treatment must ultimately influence everyday medical practice.

The Union Government's subsequent advisory to States and Union Territories in September 2026 further demonstrates the movement from judicial clarification to administrative enforcement. The advisory emphasised that unproven stem-cell therapy should not be offered as routine care and specifically addressed the status of stem-cell interventions for ASD.³² Its significance lies less in creating a new substantive prohibition than in communicating the existing regulatory position to the authorities responsible for implementation.

Yet these developments do not eliminate the central structural problem. They primarily

strengthen individual components of the regulatory framework. Central licensing improves product regulation. NMC advisories strengthen professional communication. State advisories improve enforcement awareness. None, by itself, creates a complete pathway for minimally manipulated autologous interventions.

The continuing judicial proceedings concerning implementation are particularly revealing. In September 2026, the Supreme Court continued to seek information regarding applications for ASD clinical trials, the number of applications received, the status of approvals and whether existing patients could be accommodated within approved research arrangements.³³ This indicates that the transition from prohibition to lawful research access remained an unresolved practical problem even after the substantive legal position had been clarified.

That problem deserves greater attention than it has received. A regulatory prohibition may protect future patients from unproven treatment, but patients already undergoing an intervention cannot simply be treated as though they do not exist. Abrupt termination may create medical, psychological and practical difficulties. At the same time, allowing continued unapproved treatment merely because it has already begun would undermine the regulatory principle that experimental interventions require lawful oversight.

The appropriate response is a statutory transition mechanism. Where a treatment is determined to be experimental, existing patients should be assessed through an independent clinical and ethical process. Where scientifically and ethically justified, they should be given a pathway into an approved clinical trial or another lawful form of monitored access. Where continued treatment is unsafe or unsupported, the patient should receive appropriate alternative care. Responsibility for this process should not depend upon repeated judicial directions.

This is also where the distinction between regulation and enforcement becomes important. A prohibition without an accessible lawful alternative can drive experimental medicine underground. Doctors may continue offering treatments covertly; patients may travel between jurisdictions; clinics may rebrand experimental interventions as “wellness” or “regenerative” procedures. Effective regulation must therefore combine prohibition with a credible route for lawful research and innovation.

XI. Towards a Coherent Regulatory Model for Stem-Cell Therapies

India does not necessarily require a completely separate statute for every emerging biomedical technology. The more immediate requirement is a coherent regulatory architecture capable of identifying the legal status of a cellular intervention at each stage of its development.

The first stage should be research. Laboratory research involving stem cells should remain

subject to the applicable scientific, biosafety and ethical requirements. Once an intervention moves into human subjects, however, the regulatory framework should clearly identify it as research unless it has already received approval for established clinical use. This would prevent the ambiguous category in which an experimental intervention is commercially administered while being described as “therapy”.

The second stage should be regulated clinical research. The legal framework should clearly allocate responsibility between CDSCO, the Department of Health Research and institutional ethics committees. The distinction between products and procedures should remain relevant to the type of scientific assessment required, but neither category should escape ethical and regulatory oversight merely because of its classification.

The third stage should address limited access to promising interventions. India could develop a carefully controlled mechanism for conditional or expanded access where an intervention has demonstrated sufficient preliminary evidence but has not completed the entire evidence-generation process. Such access should be exceptional rather than a substitute for clinical trials. It should also require outcome reporting, informed consent, independent oversight and transparent disclosure of uncertainty.

The fourth stage would be established clinical care. An intervention should enter routine practice only after adequate evidence of safety and effectiveness has been generated and the relevant regulatory approvals have been obtained. At this stage, professional standards and ordinary clinical regulation would become the principal safeguards.

Such a tiered model would also solve an important conceptual problem. It would make clear that “experimental” is not synonymous with “illegal”. Properly regulated experimentation is essential to medical progress. What is legally objectionable is the commercialisation of experimentation as though it were established treatment.

The framework should also define the meaning of minimal and substantial manipulation more clearly. At present, technical distinctions relating to manipulation can have significant regulatory consequences, yet their legal treatment is distributed across rules, notifications and guidance. The law should establish clear criteria that reflect not only the amount of physical processing but also biological alteration, expansion, genetic modification, intended use and route of administration.

A dedicated regulatory authority for advanced cellular therapies may also be appropriate, but only if its legal powers are clearly established. Its role should not duplicate CDSCO, ICMR or NMC functions. Instead, it should coordinate the regulatory life cycle of advanced therapies and ensure that a sponsor, researcher, physician or patient can identify the correct regulatory

pathway without navigating several disconnected institutions.

Patient protection must remain central to this model. Every approved clinical research pathway should require meaningful informed consent, clear disclosure of experimental status, compensation mechanisms for research-related injury, independent ethics review and systematic adverse-event reporting. Advertising should also be regulated. A treatment cannot be adequately controlled if the intervention is formally classified as research but commercially advertised to patients as a proven cure.

Transparency is equally important. A national registry of approved stem-cell trials and authorised clinical applications would allow patients and doctors to distinguish between legitimate research and commercial experimentation. The registry should identify the intervention, indication, sponsoring institution, regulatory status and trial stage. Such transparency would reduce the information asymmetry that currently allows clinics to market scientifically uncertain therapies to vulnerable patients.

Finally, the law must establish a transition mechanism. Patients who receive an intervention before its regulatory status changes should not be abandoned when enforcement begins. A lawful framework should provide for clinical assessment, continuation where justified, referral into approved trials where possible and alternative care where necessary. Such a mechanism would reconcile patient protection with the realities of ongoing medical treatment.

The objective of regulation should therefore not be to create a system in which every innovative therapy is prohibited until it becomes entirely conventional. Nor should it create a market in which patients purchase experimental medicine on the assumption that consent removes regulatory restrictions. The objective should be to construct a legally intelligible pathway between the two.

XII. Conclusion

Stem-cell therapy exposes a basic weakness in India's approach to regulating advanced medicine. The problem is not that India has no law. It has a substantial collection of statutes, rules, professional standards, ethical guidelines and institutional mechanisms. The problem is that these instruments were developed for different purposes and have not yet been integrated into a coherent regulatory architecture for cellular medicine.

The Supreme Court's January 2026 decision in *Yash Charitable Trust v Union of India* represents an important point in that development. Its immediate contribution was to reject the routine clinical administration of unproven stem-cell therapy for ASD and to make clear that patient consent cannot, by itself, convert experimental medicine into lawful standard care. Its

broader significance lies in demonstrating that classification under drug law cannot answer every question concerning the legality of a medical intervention.

The judgment's treatment of minimally manipulated autologous cells is particularly important. The fact that an intervention may not qualify as a "new drug" does not mean that it is automatically lawful as a clinical service. The legal standard of care, professional ethics, scientific evidence and research regulation remain relevant. This principle prevents the product–procedure boundary from becoming a regulatory loophole.

At the same time, judicial interpretation cannot be the permanent foundation of advanced-therapy regulation. The continuing need to combine the Drugs and Cosmetics Act, NDCT Rules, ICMR guidelines, NMC regulations, clinical-establishment law and administrative advisories demonstrates the need for greater legislative and regulatory coherence. The institutional questions surrounding stem-cell research further demonstrate that the identity of the regulator matters as much as the content of the rule.

The post-2026 developments show that India has begun to respond. Central licensing has become more explicit for advanced cellular products; professional regulators have reinforced the restrictions on unproven therapies; government advisories have sought to standardise enforcement; and judicial proceedings have continued to examine the transition of existing patients into lawful research pathways. Yet these measures remain parts of a larger regulatory puzzle.

The long-term solution should be a tiered framework that distinguishes research, clinical trials, carefully controlled conditional access and established clinical care while maintaining common principles of scientific validity, ethics, informed consent, professional responsibility and patient protection. Such a framework should clarify the legal significance of minimal and substantial manipulation, allocate institutional responsibility, regulate advertising and commercialisation, establish transparent registries and create a workable transition mechanism for patients already receiving experimental interventions.

The central question for Indian stem-cell law is therefore not whether innovation should be permitted. Innovation is indispensable to the development of medicine. Nor is the answer to permit patients to assume any therapeutic risk they choose. Medical autonomy operates within professional and regulatory boundaries. The real question is whether the law can distinguish **innovation from commercialised experimentation** and provide a lawful route from one to the other.

A mature regulatory system should make that route visible. It should allow researchers to investigate promising therapies, protect participants during clinical experimentation, permit

carefully controlled access where justified, and ensure that only adequately supported interventions become ordinary clinical care. Until that structure is achieved, stem-cell regulation will continue to depend on judicial interpretation to connect fragmented legal instruments.

The enduring lesson of the 2026 Supreme Court decision is therefore broader than the particular dispute before it. India's challenge is to move from a regulatory system that asks whether stem cells are products or procedures towards one that asks what regulatory safeguards the particular intervention requires at its particular stage of development. The future of Indian stem-cell law lies not in choosing between regulation and innovation, but in constructing a legal framework capable of governing both.

Endnotes

1. *Yash Charitable Trust & Ors v Union of India & Ors*, Writ Petition (Civil) No 369 of 2022, 2026 INSC 96 (SC, 30 January 2026), especially paras 57–58, 140–150 and 151.
2. Drugs and Cosmetics Act 1940, s 3(b).
3. New Drugs and Clinical Trials Rules 2019, r 2(1)(w)(v), as amended by GSR 14(E), 13 January 2022.
4. *Yash Charitable Trust* (n 1) paras 57–58.
5. Drugs and Cosmetics Act 1940; Drugs Rules 1945; New Drugs and Clinical Trials Rules 2019.
6. New Drugs and Clinical Trials Rules 2019, rr 15–18.
7. ICMR and Department of Biotechnology, *National Guidelines for Stem Cell Research* (2017).
8. ICMR, *National Ethical Guidelines for Biomedical and Health Research Involving Human Participants* (2017).
9. Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations 2002, reg 7.22; National Medical Commission Act 2019, s 61(2).
10. Clinical Establishments (Registration and Regulation) Act 2010, ss 32 and 40.
11. *Laxman Balkrishna Joshi v Trimbak Babu Godbole* AIR 1969 SC 128.
12. *Indian Medical Association v VP Shantha* (1995) 6 SCC 651; *Jacob Mathew v State of Punjab* (2005) 6 SCC 1.
13. *M.A. Biviji v Sunita* (2024) 2 SCC 242.
14. ICMR, *Evidence Based Status of Stem Cell Therapy for Human Diseases* (2021), discussion concerning autism spectrum disorder.

15. *Yash Charitable Trust* (n 1) paras 49–58.
16. *ibid* paras 59–65.
17. *Samira Kohli v Dr Prabha Manchanda* (2008) 2 SCC 1.
18. *Yash Charitable Trust* (n 1) paras 129–139; Drugs and Cosmetics Act 1940, s 3(b).
19. *Yash Charitable Trust* (n 1) paras 56–58.
20. *ibid* paras 140–158.
21. *ibid* paras 148–150 and discussion concerning the NAC-SCRT and the 2024 Department of Health Research order.
22. *State of Madhya Pradesh v GS Dall & Flour Mills* AIR 1991 SC 772; *Jaiveer Singh v State of Uttarakhand* (2024) 15 SCC 227.
23. *Yash Charitable Trust* (n 1) paras 56–58.
24. New Drugs and Clinical Trials Rules 2019, r 16(4).
25. Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations 2002, reg 7.22.
26. Department of Health Research, Ministry of Health and Family Welfare, Order dated 3 March 2024 concerning dissolution of the National Apex Committee for Stem Cell Research and Therapy.
27. *State of Madhya Pradesh v GS Dall & Flour Mills* AIR 1991 SC 772.
28. *Jaiveer Singh v State of Uttarakhand* (2024) 15 SCC 227.
29. *Samira Kohli* (n 17).
30. Ministry of Health and Family Welfare, Drugs (Eighth Amendment) Rules 2026, GSR 530(E), 29 June 2026, insofar as they concern central licensing of cell and stem-cell-derived products and related advanced therapeutic products.
31. National Medical Commission, Advisory concerning stem-cell therapy and compliance with the Supreme Court’s January 2026 decision, March 2026.
32. Ministry of Health and Family Welfare, advisory to States and Union Territories concerning regulation of unproven stem-cell therapies, September 2026.
33. Supreme Court of India, compliance proceedings concerning *Yash Charitable Trust v Union of India*, order dated 1 September 2026.
34. ICMR and Department of Biotechnology, *National Guidelines for Stem Cell Research* (2017).
35. Constitution of India, art 21; see also *Justice KS Puttaswamy (Retd) v Union of India* (2017) 10 SCC 1.

36. *Dalip Kaur v Union of India*, WP(C) No 6850 of 2023 (Delhi High Court, interim order dated 31 August 2023), as discussed in *Yash Charitable Trust* (n 1).
37. Drugs and Cosmetics Act 1940, s 33P; New Drugs and Clinical Trials Rules 2019.
38. ICMR, *Evidence Based Status of Stem Cell Therapy for Human Diseases* (2021).
39. ICMR and Department of Biotechnology, *National Guidelines for Stem Cell Research* (2017).
40. ICMR, *National Ethical Guidelines for Biomedical and Health Research Involving Human Participants* (2017).
41. National Medical Commission Act 2019, s 61(2).
42. Clinical Establishments (Registration and Regulation) Act 2010.
43. Drugs Rules 1945; New Drugs and Clinical Trials Rules 2019.
44. *Jacob Mathew* (n 12).
45. *Indian Medical Association v VP Shantha* (n 12).
46. *M.A. Biviji* (n 13).
47. *Samira Kohli* (n 17).
48. *Yash Charitable Trust* (n 1).
49. Department of Health Research, Ministry of Health and Family Welfare, materials concerning the institutional framework for stem-cell research, 2026.
50. Ministry of Health and Family Welfare, advisory concerning unproven stem-cell therapies, September 2026.
51. Supreme Court of India, compliance proceedings in *Yash Charitable Trust v Union of India*, 2026.
52. Drugs (Eighth Amendment) Rules 2026, GSR 530(E), 29 June 2026.
53. *State of Madhya Pradesh v GS Dall & Flour Mills* (n 22).
54. *Jaiveer Singh* (n 22).
55. *Yash Charitable Trust* (n 1), paras 145–150.