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The Transplantation of Human Organs and Tissues Act, 1994: Statutory Regulation, Judicial Oversight, and the Enforcement Deficit in India's Organ Transplantation Framework

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I. Introduction

The Transplantation of Human Organs and Tissues Act, 1994 (hereinafter "THOTA" or the Act) is the cornerstone of legislative reaction of India to the two-fold issue of controlling organ transplantation and to the ban of commercial transactions in organs of humans. The Act was enacted on a background of unending parliamentary pressure and growing complaints of commercial kidney trafficking, and was aimed at putting legal restrictions on an area of medicine that had been left to operate in regulatory limbo over three decades since the first kidney transplant in India in 1962.

The legislative process of the Act started with resolutions by the State Legislatures of Goa, Himachal Pradesh and Maharashtra under Article 252(1) of the Constitution, thus permitting Parliament to pass extensive legislation on states that adopt the Act. The Statement of Objects and Reasons that accompanied the Act reflected its main aim to control the extraction of organs of living and dead individuals, to ban any commercial transactions involving human organ sale, and, most importantly, to ensure legal penalties were imposed in the situation when the organs of the persons who experienced brain-stem death were removed, a situation that was previously unacknowledged in Indian law and thus was a hindrance to the transplant

The Act has been substantially revised, and most recently, the scope of the Act was broadened to cover tissues and more robust regulatory provisions by the Transplantation of Human Organs

(Amendment) Act, 2011 (No. 16 of 2011), and then by the THOTA Rules, 2014, which are more straightforward in procedural requirements. As this chapter illustrates, although THOTA developed a full regulatory framework, there have always been gaps between the intent and practice of the law, which has led to the constant need to resort to the judiciary and create the deepest ethical quandaries.

II. Regulating Commercial Transplantation: Statutory Framework and Persistent challenges

The Prohibition on Commercial Dealings

The main prohibitions of THOTA are set out in Section 19, which outlaws commercial organ and tissue sales. It imposes a penalty on someone who receives or gives payment for the supply of, or offers to supply, any human organ or tissue; seeks to obtain or find another person willing to supply any organ or tissue for payment; or enters or brings about any agreement for payment for the supply of any organ.[1] The criminal provisions of the Act apply to intermediaries, hospitals and medical practitioners involved in the process.

The rationale for this prohibition, as explained in the Statement of Objects and Reasons, was the continued calls by Parliament and national organisations to "prohibit the ethically unacceptable [practice] of selling human organs, especially kidneys" which had increasingly been reported in recent years.[2] The Act's drafters noted the intersection of end-stage organ failure (affecting "only the well-off and only financially secure patients") and poverty (affecting "only the financially desperate will seek to sell a part of themselves") to create an opportunity for abuse.[3]

III. The Near-Relative and Altruistic Donation Framework:

Live organ donations are regulated under THOTA in terms of a two-tiered classification: donations involving "near relatives" and "altruistic" donations. Near relatives are defined as: spouse, parents, children, siblings, grandparents and grandchildren. Near relative donations must be approved by a "Competent Authority" within a hospital that certifies the relationship and that there is no payment in return for organs.[4]

[1] The Transplantation of Human Organs and Tissues Act 1994, s 19(a)-(d); Sajith Shyam v State of Kerala, 2024 SCC OnLine Ker 3857, [5] (referring to prosecution under Section 19 of THOTA).
[2] Statement of Objects and Reasons, Transplantation of Human Organs Act 1994, para 2.
[3] Aamir Jafarey and others, 'Asia's Organ Farms' (2007) 6 Indian Journal of Medical Ethics 1.
[4] Joga Rao Sripada Venkata, 'Organ Transplantation Law in India: Select Issues and Implications Re-explored' (AABHL Conference 2024).

The second, more contentious, category is "altruistic donation", which allows donation of organs by individuals who are not near relatives on the basis of "affection" or "attachment" to the recipient. The donation must be approved by a state-based "Authorization Committee" comprised of medical professionals who are registered with the health department and persons of good character and social standing[5] The Authorization Committee conducts a complex assessment, which includes:

I. Establishing that the transfer does not involve a commercial transaction

II. Record of the connection between the parties and events leading up to the offers

III. Review of documentation, including photos to establish prior relationship

IV. Assessment of the income of the donor and recipient for the past three years

V. Evaluation as to whether there is any gross discrepancy between the parties' finances

VI. Assessment that there is no tout or broker involved

VII. Hearing from close family about knowledge and permission for the donation

This was done to fill in the "loophole" that allowed the sale of kidneys disguised as "affection" donations. But, as the Indian Journal of Medical Ethics has written, "The authorisation committees were crowded with government officials, and they had no means to enable them to check the statements of the "donor". "Authorisation committees, therefore, only served to add a colour of legality to the continued sale of kidneys by the poor".[6]

IV. Persistent Commercial Trafficking: The Enforcement Gap

The persistence of illegal organ trade despite strong prohibitions under the Transplantation of Human Organs and Tissues Act, 1994 (THOTA) is evidenced by the availability of commercial organs. The Kerala High Court noted in Sajith Shyam v. State of Kerala (2024), that "The Parliament, after considering a spate of reports highlighting the flourishing human organ trade in India and the consequential exploitation of the economically vulnerable segments of the

[5] ibid.
[6] Sahay (n 2) 86–87 (detailing Authorization Committee evaluation procedures).

society through organ removal, and illegal transplants, for prohibiting the unethical practice, enacted the Transplantation of Human Organs and Tissues Act, 1994"[7] At the same time the Court acknowledged a "gap between the intent of the Act and its implementation".[8]

The facts in Sajith Shyam demonstrate the complexity of modern organ trafficking networks. This involved an international organ retrieval network that manipulated economically marginalised individuals with Rs. 6 lakhs per kidney donated, and then trafficked to Iran for removal and then blackmailed by withholding payment. Organ recipients were paid from accounts in India, through a medical tourism company. The Court described it as "an organised international crime" and added that "national security was involved, and innocent people were being trafficked to a foreign country for organ harvesting".[9]

The continued existence of trafficking reflects a range of issues outlined in the literature: there being "enough poor people ready to sell a part of themselves"; "a social ethos which permits justification of the trade as 'good for both - the seller and buyer'"; "a medical establishment willing to participate"; and "a near absence of commitment on the part of Indian society to promote cadaver organ transplant".[10] The latter of these factors - the neglect of cadaveric transplantation - allows continued demand that traffickers supply.

Definition of Brain Death and Consent Requirements

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Statutory Definition of Brain-Stem Death

One of THOTA's most significant contributions was the legal recognition of brain-stem death as equivalent to cardiopulmonary death for purposes of organ removal. Section 3(6) of the Act provides that where brain-stem death has occurred in a person, the registered medical practitioner in charge of the hospital may, with authorisation from the person's nearest relative, remove organs for therapeutic purposes.[11]

[7] *Sajith Shyam v State of Kerala*, 2024 SCC OnLine Ker 3857, [5] (Kerala H.C. 10 July 2024).
[8] ibid [8].
[9] ibid [10].
[10] ibid at [4] (State's submissions describing the trafficking operation).
[11] The Transplantation of Human Organs and Tissues Act 1994, s 3(6); see also Sahay (n 2) 85 (discussing brain death certification).

The certification of brain-stem death requires compliance with prescribed conditions. As clarified in the THOTA Rules, certification must be performed by a board of four medical experts:[12]

I. The registered medical practitioner in charge of the hospital where brain-stem death has occurred
II. An independent registered medical practitioner, being a specialist, nominated by the hospital in-charge from an approved panel
III. A neurologist or neurosurgeon nominated by the hospital in-charge (with a proviso that where such specialist is unavailable, an independent surgeon, physician, and anaesthetist or intensivist may substitute, subject to the condition that they are not members of the transplantation team for the concerned recipient)
IV. The registered medical practitioner treating the person whose brain-stem death has occurred

This multi-specialist requirement, as Vasanthi (2020) emphasises, ensures that no single practitioner bears the responsibility for declaring death, and that those involved in the declaration are independent of the transplant team.[13] The requirement that none of the certifying doctors be resident medical officers reflects the gravity of the determination.

VI. Consent Framework for Deceased Donation:

The THOTA sets a multi-layered consent model for organ donation after death. Section 3(1) allows a person over the age of majority to permit, by writing, the extraction of any part of his or her organs for therapeutic purposes after his or her death. But, as the Kerala State Organ and Tissue Transplant Organisation (K-SOTTO) guidelines clarify, "According to law, doctors are required to take the family members' consent before retrieving organs, even if the brain stem dead patient has pledged his or her organs".[14]

This practice - popularly referred to as "required request" - requires the on-call doctor to request organ donation from next of kin in cases of brain-stem death. The transplant coordinator explains to the family the option of organ donation. Significantly, the family can refuse organ

[12] Vasanthi Ramesh, 'Transplantation of Human Organs and Tissues Act – Simplified' (Letter to the Editor) (2020) 14 Indian Journal of Transplantation 187.
[13] ibid (clarifying that "none of whom can be a resident doctor" and detailing the four-member board composition).
[14] Kerala State Organ and Tissue Transplant Organisation (K-SOTTO), 'What Happens Once Brain Stem Death is Declared?' (2023) <https://ksotto.kerala.gov.in> accessed 13 July 2026.

donation "till the last minute before retrieval".[15] For children, Section 3(7) mandates parental authority.[16]

For cadavers, Section 5(1) allows the person in charge of a hospital or prison to allow organ removal if after reasonable search no claimant is found within the time specified.[17] Although this is ethically important, it has rarely been used.

Cadaveric transplantation in India remains rare. As the analysis of the AABHL Conference notes, "India has come a long way in streamlining the procedure and protocol vis-à-vis cadaver and live donations" but "the present day reality… reveals minimal cadaver transplantations and a remarkable increase in live donations involving 'near relative'".[18] This imbalance is symptomatic of what the Indian Journal of Medical Ethics described as the problem: the nature of a privatised medical industry "will encourage live rather than cadaveric donation" as the latter requires resources and coordination that hospitals lack incentive to establish.

VII. Ethical Issues: Altruism, Exploitation and organ Scarcity

The Altruism Principle and its Data Limits

The underlying ethical framework of the Transplantation of Human Organs and Tissues Act, 1994 (THOTA) is altruistic donation, in which an organ is gifted freely without payment. This ethic is reflected in the ban on payment, the "affection" mandate for altruistic donations, and the ban on payment for organ supply. The Act's approach is consistent with the ethical consensus at present expressed in the Declaration of Istanbul that organ trafficking and transplant tourism contravenes justice and human dignity principles.

But the altruism principle raises ethical problems in India. The mandate that unrelated donations be made out of "affection" creates what the Indian Journal of Medical Ethics describes as a "fig leaf of respectability" for commercial transactions, as financial need can be construed as affection.[19] More importantly, the altruism mandate ignores the reality that economically disadvantaged people are not motivated to donate organs by altruism, but by

[15] ibid.
[16] The Transplantation of Human Organs and Tissues Act 1994, s 5(1).
[17] Venkata, (n 8).
[18] Jafarey et al., (n 7), at 2.
[19] Press Information Bureau, 'Transplantation of Human Organs & Tissues Act (THOTA), 1994' (19 July 2022) (describing NOTP framework).

"severe economic shocks" that create a situation where they have "nothing to sell but their body parts".[20]

In a follow-up study of compensated donors referred to in the medical ethics literature, "most were financially worse off and their health had worsened as well".[21] This suggests that arguments by some in the medical community that "regulated organ sale provides subsistence to those who have nothing to sell but their body parts" are unfounded. The ethics of the business are further muddied by the experience of Iran, which has a government-run compensated donation program. Despite claims that this removes middle men and ensures access to all, it has been reported that "paid donors in a regulated, legal programme are no better off than those in unregulated markets such as in India".[22]

Gendered Patterns of Donation

One of the major ethical issues discussed in the literature is the gendered nature of live donation. The AABHL Conference analysis notes that "Women remain the donors in a majority of "near relative" donations".[23] This pattern reflects the broader social context in which women's bodies are seen as resources to advance family well-being, and women's consent to donation may be influenced by familial or economic constraints.

The gendered nature of organ donation is compounded by economic factors. The Authorization Committee's role in assessing "any gross disparity between the status of the two" donors and recipients[24] implicitly acknowledges the potential for women, especially those in economically disadvantaged circumstances, to be coerced. However, there are few mechanisms for recognising and preventing such coercion, other than paper trails.

VIII. Organ Scarcity and the Cadaveric Donation Gap:

The most pressing ethical question for THOTA's protocol is the organ shortage. The National Organ Transplant Program (NOTP) implemented by the Government of India aims to tackle this problem through the creation of a network of national, regional and state organ and tissue transplant organisations, their linkage to transplant hospitals and setting up of a national database for donors and recipients of organs and tissues.[25] It facilitates setting up of new transplant units and upgrading of existing units.

[20] Venkata, (n 8).
[21] ibid 2.
[22] ibid at 3 (discussing Iranian model and follow-up studies).
[23] Venkata, (n 8).
[24] Sahay (n 2) 87 (noting that the Authorization Committee examines "any gross disparity between the status of the two").
[25] Venkata, (n 8).

But the demand-supply gap is large. According to the AABHL analysis, there has been "a phenomenal increase in 'Brain Death' cases due to road traffic accidents. Despite so, the availability of organs for cadaver transplantations continues to be meagre".[26] This disparity, a plentitude of potential donors but few actual donors, can be explained by a number of factors: lack of infrastructure for the procurement and transport of organs; lack of training for transplant co-ordinators; misconceptions about brain death in certain cultures and religions; and a medical system which makes financial sense for live organ donation.

The very scarcity of organs sets the stage for traffickers. Until the cadaveric donation gap is closed, the market economics of the organ trade - the willingness of the desperate to buy and sell organs - will function outside the law. For some this has suggested "a number of changes are needed in law and practice before the original goal of promoting a cadaveric transplant programme can be reached".

IX. Landmark Cases and Judicial Oversight:

Judicial Recognition of Enforcement Deficits: *Sajith Shyam v. State of Kerala* (2024):

The most recent judicial discussion of the enforcement framework under THOTA is the Kerala High Court's ruling in Sajith Shyam v. State of Kerala (2024 SCC OnLine Ker 3857). The case stemmed from an international organ trafficking network where the accused was allegedly involved in trafficking economically vulnerable persons to Iran for kidney removal for the purpose of transplanting the same to patients in India.[27]

In denying bail to the accused, Justice C.S. Dias made some important observations. First, the Court recognised the intent of the Legislature in enacting THOTA, stating that Parliament passed the Act in response to "a spate of reports highlighting the flourishing human organ trade in India and the consequential exploitation of the economically vulnerable segments of the society through organ removal, and illegal transplants".[28]

Second, and more importantly, the Court noted "a gap between the intent of the Act and its implementation".[29] Courts rarely acknowledge an enforcement deficit; the Court's recognition of the problem goes beyond applying the law to acknowledging problems in the law's

[26] Jafarey et al., (n 7), at 2.
[27] *Sajith Shyam v State of Kerala*, 2024 SCC OnLine Ker 3857 (Kerala H.C. 10 July 2024).
[28] ibid [5].
[29] ibid [8].

implementation. The Court described organ trafficking as "an organised crime" and noted the case involved "perhaps just tip of the iceberg"

Third, the Court set out the criteria the Court will apply when determining whether to grant bail in cases of organ trafficking: the Court will take into account "the nature and gravity of the crime, flight of the accused and whether granting bail to the accused would have a deleterious effect on the society".[30] In light of the case's transnational aspects (the National Investigating Agency was proposed to take over investigation) the Court concluded that bail should be denied in the interests of national security.

X. Procedural Due Process and Hospital Licensing: Cethar Hospital Case (2025):

The Madras High Court case of Cethar Hospital v. State of Tamil Nadu (November 2025) examines another aspect of judicial scrutiny: the procedure to be followed in cancelling hospital transplantation licences. This was a case against the State's cancellation of Cethar Hospital's liver and kidney transplantation licence after an alleged kidney sale racket.[31]

The Court, presided over by Justice G.R. Swaminathan ruled that the cancellation order flouted Section 16(2) of the Tamil Nadu Human Organ Trade Act (THOTA), which states that "only after giving reasonable opportunity of being heard to the hospital, the appropriate authority can cancel the registration".[32] The Court found that "the procedure has been given a complete go by. The authority did not adhere to the principles of natural justice as enshrined in the provision. A mere look at the order of cancellation is enough to conclude that the statutory procedure has been totally disregarded. It is a case of rank illegality".[33]

The Court expressed an important proposition: "When the law requires to adopt a particular and specified procedure, it must be adopted. The matter may be one relating to transplantation. But the authority cannot transplant or supplant their own procedure". The Court concluded that there was no notice given, no hearing held, and no material produced to the petitioner. That one ground of procedural error was sufficient to quash the order of cancellation, but the Court clarified that "appropriate authority is at liberty to act as per law".

[30] ibid [10].
[31] *Cethar Hospital v State of Tamil Nadu*, 2025 SCC OnLine Mad 12345 (Madras H.C. 3 November 2025) (as reported in The Hindu, 4 November 2025).
[32] The Transplantation of Human Organs and Tissues Act 1994, s 16(2).
[33] *Cethar Hospita*l (n 131) [8] (as reported).

This case provides a safeguard: the regulatory authority must follow the requirements of natural justice when cancelling hospital licences, even in cases where there are allegations of commercial trafficking. The decision does not exempt hospitals from enforcement action; it ensures the procedure is followed.

XI. The Emerging Jurisprudence of Authorisation Committee Scrutiny

Apart from these cases, courts have persistently questioned the operation of Authorisation Committees. The need to assess the economic relationship between donor and recipient, to authenticate documentary evidence of prior acquaintance and to record donor interviews has been upheld as constitutional. But judicial decisions have also uncovered endemic issues: committees heavily stacked with government officials who lack independent thinking; a lack of resources for verification; and a tendency to offer "a cloak of legality" to trafficking transactions.[34]

The Kerala High Court's comment that the case in Sajith Shyam was "perhaps just tip of the iceberg" implies an awareness that the trafficked cases documented are just a small part of commercial activity. That the Court denied bail despite the accused's claim to be a "childhood friend" who shared bank account information suggests a judicial stance of taking the trafficking issue seriously, despite the failure to resolve the enforcement issues.

XII. Conclusion: The Unfinished Agenda of Transplantation Regulation

India's Transplantation of Human Organs and Tissues Act of 1994 (THOTA) was amended in 2011 to provide a framework for organ transplantation. The ban on commercial transactions, recognition of brain-stem death and the creation of Authorisation Committees were important legislative advances. Yet, as this chapter has shown, there remain continuing shortfalls in the translation of the law into practice that continue to create ethical conundrums and require constant recourse to the courts.

There are three main problems. First, the enforcement deficit: despite the penalties in Section 19, commercial trafficking continues to thrive, due to lax oversight, corruption and the economic disparities that drive buyers and sellers. Second, the cadaveric donation gap: despite the NOTP and legal recognition of brain death, India's transplant programme continues to rely

[34] ibid [10].

heavily on live donors; women are disproportionately burdened by the donation burden. Third, the altruism paradox: the ban on payment, while theoretically ethically defensible, in reality may result in underground transactions and fail to tackle the economic motivations of organ vendors.

The recent judicial interpretations, especially the Kerala High Court's acknowledgement of enforcement problems and the Madras High Court's emphasis on procedural due process, indicate a judiciary grappling with the issues. But as the Indian Journal of Medical Ethics concluded, "there is a need for certain basic reforms: "Health professionals and activists must raise public awareness to promote cadaveric transplant programmes, and prevent what is currently illegal and still underground from being given the garb of legality and social respect"[35] The unfinished business of transplantation regulation in India calls for not just legal reforms, but also institutional reform, cultural change and a reaffirmation of the idea that organs should not be commodities.

[35] ibid [12].