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Regulatory Framework and Challenges of Organ Transplantation: A Critical Analysis of The Transplantation of Human Organs and Tissues Act, 1994 in India

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ABSTRACT

The Transplantation of Human Organs and Tissues Act, 1994 (THOTA) in India was enacted to regulate the transplantation of organs, prevent commercial exploitation, and promote ethical practices. This paper critically examines the provisions of THOTA, its amendments, and their effectiveness in addressing organ trafficking and promoting deceased organ donation. This paper aims to critically assess THOTA's regulatory framework, examining its provisions and amendments, enforcement challenges, and societal implications. By analyzing these factors, the study seeks to offer insights into improving THOTA's effectiveness, enhancing ethical practices, and ensuring equitable access to life-saving organ transplants in India. It discusses key provisions, including brain-stem death certification, authorization committees, and penalties for violations. Challenges such as ambiguity in 'affection or attachment' criteria and the prosecution of offenders are analyzed. The study concludes with recommendations for strengthening THOTA to meet current healthcare needs while curbing illegal organ trade.

Keywords*: Organ Transplantation, Transplantation of Human Organs and Tissues Act, Organ Trafficking.*

I. INTRODUCTION

Organ transplantation is a vital medical procedure that saves lives but also raises ethical and legal challenges, particularly concerning commercial exploitation and organ trafficking. The Transplantation of Human Organs and Tissues Act, 1994 (THOTA) was introduced in India to regulate this complex domain, defining procedures for organ retrieval, transplant coordination, and ethical guidelines. Over the years, amendments have aimed to address gaps and strengthen enforcement against illegal practices. Despite its noble intentions, THOTA faces criticism for loopholes exploited by organ traffickers and challenges in effectively promoting deceased

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organ donations.

Chronic kidney disease poses a significant worldwide health challenge, resulting in about 735,000 deaths each year. In India, between 151 and 232 people per million suffer from end-stage renal disease (ESRD), meaning nearly 220,000 individuals need kidney transplants annually. Yet, only around 7,500 transplants are performed yearly at 250 centers nationwide, with 90% of kidneys coming from living donors and 10% from deceased donors.

Spain leads the world in organ donation rates, with 35.3 donors per million inhabitants, thanks to its "opt-out" policy where everyone is considered a donor unless they choose not to be. In the United States, people must actively choose to become donors, typically when getting a driver's license, following an "opt-in" policy.

India lacks a national organ donation policy like Spain's or a structured process like the U.S. Individuals over 18 can donate their organs either during their lifetime or after death, but for cadaver donations, Obtaining consent from the next of kin is essential before proceeding with organ removal for transplantation.

II. TRANSPLANTATION OF HUMAN ORGANS AND TISSUES ACT, 1994 (THOTA)

he Transplantation of Human Organs Bill was enacted by the Indian Parliament in June 1994 and received the President's approval on July 8, 1994. It became effective on February 4, 1995, as per a Gazette notification. In 2011, an amendment expanded the Act to include "Tissues."

The Transplantation of Human Organs and Tissues Act, 1994 (THOTA), oversees the extraction, storage, and transplantation of human organs and tissues for medical treatments. Additionally, it aims to curb the commercialization of human organs and addresses associated issues.

According to the Transplantation of Human Organs and Tissues Act (THOTA), transplantation involves transferring an organ from either a living or deceased donor to a living recipient for medical treatment. Removal of organs from a person declared brain-stem dead can only occur if a Board of medical experts verifies and certifies the death. This Board includes the following members:

a. The head registered medical practitioner at the hospital where the brain-stem death took place.

b. A specialist registered medical practitioner, independently nominated by the head practitioner from a list of names sanctioned by the Appropriate Authority.

c. A neurologist or neurosurgeon, chosen by the head practitioner from an approved panel

provided by the Appropriate Authority.

d. The registered medical practitioner responsible for treating the individual who has been declared brain-stem dead.

The Act also includes the following key provisions:

- Recognises "cadaver transplantation".
- Recognises "brain-stem death".
- Prohibits "unrelated live donors".
- Allows preservation of harvested organs for the purposes of transplantation.
- The donor must provide clear written consent for organ removal after death, in the presence of at least two witnesses, one of whom must be a near relative.
- Individuals must be at least 18 years old to authorize organ donation, while parents or guardians can provide consent for minors.
- If a body remains unclaimed in a hospital for over 48 hours, the hospital's head can approve the removal of organs from such bodies.
- If a body is undergoing post-mortem for legal or pathological reasons, the authorized doctor can permit organ removal if they believe the organs will not be needed for the post-mortem purpose and if the deceased did not object to organ removal before death.
- Organs can only be transplanted into recipients who are "near relatives" of the donor. According to the 2011 amendment, "near relatives" include spouse, child, parent, sibling, grandparent, or grandchild.
- Organs from live unrelated donors can be transplanted into any recipient in need, provided prior approval from the Authorization Committee[3] has been secured.
- Hospitals involved in the removal, storage, or transplantation of organs must be registered. Failure to comply with regulations may result in cancellation of their registration following an investigation.
- Unauthorized organ removal by individuals or hospitals can result in imprisonment of up to ten years and fines up to twenty lakh rupees.
- A registered medical practitioner convicted of unauthorized organ removal may have

[3] In most of the states, the Authorization Committee consists of the Director of Medical Education, Director of Medical Services and either Dean or Professor from the government teaching hospitals.

their name removed from the medical register for three years for a first offence and permanently for repeat offences.

- Engaging in commercial transactions involving human organs is punishable by imprisonment for a minimum of five years, extending up to ten years, and fines ranging from twenty lakh to one crore rupees.

III. KEY FEATURES OF THE AMENDMENT IN THE LAW BROUGHT WITH EFFECT FROM 2011

1. For the purposes of coordinating the transplant an office of "transplant coordinator" is appointed. A transplant coordinator is designated by the hospital to oversee all aspects of human organ and tissue removal and transplantation. Hospitals authorized to conduct these procedures are required to have a transplant coordinator on staff. According to the Act, registered medical practitioners must consult with the transplant coordinator, if one is present, to:
    i. Verify if the individual admitted to the Intensive Care Unit or their immediate family had given prior consent for the removal of any organs or tissues before their death. If so, the hospital must obtain the necessary documentation as prescribed.
    ii. If no previous consent has been provided, inform the individual or their close relative about the opportunity to either approve or refuse organ or tissue donation, in accordance with the regulations.
    iii. Send written notification to the Human Organ Retrieval Centre regarding the donor identified in points (i) and (ii), as required for the removal, storage, or transplantation of organs or tissues.
2. Section 9 addresses limitations on organ transplants and was amended to:
    - Prevent the exploitation of foreign nationals or financially vulnerable locals through monetary incentives.
    - Ensure that individuals with disabilities, such as minors or those with mental illness, cannot become live donors.
    - Allow for organ swapping to ensure compatibility if two donors and two recipients are identified, but the donor's consent does not align with the intended recipient.

It deals with the following cases:

i. If either the donor or the recipient, who are close relatives, is a foreign national, prior approval from the Authorization Committee is mandatory before any removal or transplantation of human organs or tissues can take place. The Authorization Committee will not grant approval if the recipient is a foreign national and the donor is an Indian national, except when they are close relatives.

ii. Organ transplantation involving live donors who are minors, mentally challenged, or diagnosed with conditions such as schizophrenia or mental retardation is prohibited.

iii. If a donor wishes to donate an organ or tissue to a close relative before their death, but they are not biologically compatible with the recipient, and another donor agrees to donate to the same recipient but faces the same biological incompatibility, then the first donor, who is biologically compatible with the second recipient, and the second donor, who is compatible with the first recipient, along with both recipients, enter into a joint agreement to exchange their organs or tissues accordingly. This exchange must be approved by the Authorisation Committee before any removal or transplantation takes place.

3. The strong criticism regarding insufficient resources for detecting fraud and conducting essential activities of the Authorisation Committee has been tackled by establishing a new advisory body and enhancing the Committee's powers akin to those of a civil court through additional provisions in section 13.

4. The Central Government is empowered to create a National Network for the Removal and Storage of Human Organs and Tissues, along with several Regional Networks. Consequently, a National Organ and Tissue Transplant Organization (NOTTO) has been established in Delhi to serve as the central agency for procuring, allocating, and distributing organs and tissues across the country. It includes five regional centers (ROTTO) covering each region, and every state now has a State Organ and Tissue Transplant Organization (SOTTO). These centers aim to address the imbalance between demand and supply of various tissues while ensuring quality assurance.

5. The penalties for violations of the Act have been strengthened. The penalty for the unauthorized removal of organs or tissues has been increased to 10 years of imprisonment. Additionally, medical practitioners involved may face removal from the medical council register for at least three years. Illegal trafficking of human tissues is now a distinct offense carrying fines ranging from five lakhs to 25 lakhs. Failure to

register hospitals or services can lead to imprisonment for up to five years and fines of up to 25 lakhs, compared to the previous penalty of three years and five thousand rupees.

IV. THOTA RULES, 2014

Three years later, in 2014, amendments and new rules were introduced under the THOTA Rules. These rules provided more detailed definitions of specific terms and introduced 21 mandatory forms for live and deceased donor submissions to the authorization committee. Additionally, they outlined the following functions for regulatory bodies:

(A) Duties and Responsibilities of Appropriate Authority

The Appropriate Authority is responsible for several key functions:

- Approving, renewing, suspending, or canceling hospital registrations, ensuring compliance with established standards for conducting transplantation activities and overseeing tissue banks that test, store, or distribute tissues.
- Addressing complaints alleging violations of the act and taking necessary actions.
- Performing regular inspections of tissue banks and hospitals to ensure adherence to regulations.

(B) Advisory Committee

Established for a term of 2 years. The Advisory Committee was comprised to assist the Appropriate Authority in carrying out its duties. It comprises a representative from a non-governmental organization with expertise in organ or tissue donation.

(C) Additional provisions of The THOTA RULES, 2014

1. **Eligibility Requirements for a Transplant Coordinator**: According to Rule 29 of the THOTA Rules, 2014, a transplant coordinator must be employed by a registered hospital and possess qualifications in fields such as medicine, nursing, social work, psychiatry, sociology, social science, or public health.
2. **Duties Regarding Brain Death Certification**: Registered medical practitioners are responsible for declaring brain death, assisted by a transplant coordinator as part of the procedure.
3. **Panel Appointment for Brain Death Certification**: The Designated Authority has the option to establish a panel of experts to certify brain death in compliance with legal standards.

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4. **Form 7** : It is used for pledging organ donations prior to death.
5. **Form 8** : It is for declarations made by close relatives or parents (in cases involving minors).
6. **Form 9** : It deals with procedure required to obtain consent for handling unclaimed bodies.
7. The THOTA 2014 guidelines specify the format for issuing brainstem death certificates, which mandates two examinations conducted six hours apart.
8. **Zonal Transplant Coordination Center (ZTCC)** : Established in 2001, the Zonal Transplant Coordination Center (ZTCC) serves as the coordinating body for Mumbai and its suburbs, operating under the guidelines set by the Maharashtra State for cadaver transplants issued in 1999. Registered with the charity commissioner's office, the ZTCC operates in accordance with the Human Organ Transplantation Act of 1994, which was adopted by Maharashtra in 1995. The center manages a computerized waiting list for organs like kidneys, livers, hearts, and lungs, categorized by blood group and adhering to the priority criteria outlined in Maharashtra state guidelines. Patients must register through hospitals, as direct registration with ZTCC is not allowed.
9. **Green Corridors[4] :** Delays in transportation have often resulted in the loss of valuable organs. A green corridor is a specially designated as a cleared route for ambulances transporting harvested organs, aimed at expediting their journey to the destination. In India, organ transport primarily uses roadways, with commercial airlines utilized for longer distances. Implementing green corridors has been successful in minimizing cold ischemia time and improving the outcomes of organ transplants.

V. CONSENT FOR TRANSPLANTATION

To prevent legal complications, it is essential to accurately certify brain death and secure consent from the donor or their legal successors. Diagnosis of brainstem death should rely on the clinical judgment of the physician, supplemented as needed by diagnostic aids such as electrocardiography (ECG) and electroencephalography (EEG). In rare cases like brain stem injuries from compressive or non-compressive cerebral conditions, hepatic coma, hypoglycemia, or drug overdoses resulting in acute cerebral oxygen deprivation, an EEG may show a flat line (isoelectric), which could potentially be reversible, allowing the person to

[4] Patel A, Balwani M, Patel H, et al., Deceased Organ Donation in India – Current Challenges and Scenario, 12 INDIAN J. TRANSPLANT 174-176 (2018), https://doi.org/10.4103/ijot.ijot_26_18.

survive. It's important to note that in cases of drug overdose, isoelectric EEG patterns can persist for up to twenty-three hours before recovery occurs."[5]

An episodic instance when the pronouncement of death was challenged in Court was in the case of *Bruce Tucker*[6], After confirming the death of Tucker, who sustained severe, irreversible head injuries and had his heart and kidneys removed for transplantation, a legal action was initiated by his brother, William Tucker, in the State of Virginia against four doctors. The court ruled that the doctors had not acted improperly. Following the court's instructions, the jury determined based on the facts that an individual with irreversible brain damage, whose bodily functions cannot be maintained without constant artificial support, is legally considered deceased

VI. ORGAN TRADE IN INDIA AND EFFECTIVENESS OF THOTA IN ORGAN DONATION

Even three decades after the passage of THOTA in 1994, it has not effectively curbed illegal organ trafficking or significantly promoted deceased donation programs to address the global organ shortage. Factors such as the expanding middle class, the absence of a national health insurance scheme, widening income disparities, and technological advancements have made organ commodification an enticing business opportunity for some and a perceived solution for others. In India, organ trade mirrors other societal issues such as child labor and prostitution, by exploiting individuals in financial distress through promises of significant monetary rewards to address their immediate needs. Unlike other forms of exploitation, organ trade involves invasive surgery with serious physical and psychological consequences.

Research indicates that commercial motives drive some organ donations. A significant study examining the economic and health impacts of kidney sales in India revealed that 96% of the over 300 participants sold their kidneys mainly to pay off debts, with an average compensation of $1070. The majority of the funds were used for settling debts, purchasing food, and buying clothing. At the time of the survey, three-quarters of the participants were still in debt. About 86% reported health deterioration following nephrectomy, and 79% would not recommend kidney selling to others.

VII. REASONS FOR THE FAILURE OF THOTA

1. Section 9: Ambiguous interpretation of affection and attachment

Section 9 of the Act addresses restrictions on the removal and transplantation of organs and

[5] H. Mathhews, British Medical Journal, 6 March 1971, p 520.
[6] *WE Tucker v. Dr. Cower et al., Medical Journal, pt. 1, 1973, at 36-37, see also 1 British Medical Journal 251-255 (1975).*

tissues. According to Section 9(1), organs cannot be removed from a donor's body before their death and transplanted unless they are near relatives of the recipient. Section 9(3) allows for an exception, permitting organ donation to non-relatives based on affection, attachment, or other special reasons with prior approval from the Authorisation Committee. However, Section 9(3) lacks clarity on defining what constitutes 'affection' or 'attachment'. This ambiguity has led to exploitation, where economically disadvantaged individuals are coerced into selling their organs under the guise of donating them for reasons of affection or attachment.

2. Cumbersome procedure for taking cognizance by the court.

Section 22 of the Transplantation of Human Organs and Tissues Act, 1994 specifies that the court cannot initiate proceedings for an offence under the Act unless a complaint is filed by the Appropriate Authority or by an individual who has given a notice of at least sixty days to the relevant authority, detailing the alleged offence and their intention to file a complaint in court. The current procedural requirements before a court can act on offences under the Act need simplification to ensure easier access to justice for individuals whose rights may be violated, especially in cases involving commercial transactions of human organs and exploitation.

3. Absence of provisionsto expedite trial procedures

The Transplantation of Human Organs and Tissues Act, 1994 does not specify a specific timeframe for resolving issues before the various authorities established under the Act. However, Rule 23 Clause 2 of the Transplantation of Human Organs and Tissues Rules, 2014 mandates the Authorisation Committee to expedite decisions, especially when urgent transplantation is necessary. Despite this, there is no stipulated time limit for deciding on matters related to organ donations involving near relatives, unrelated individuals, or foreigners. Given the critical nature of organ transplantation, there is a pressing need for swift decision-making by authorities, particularly in cases requiring urgent medical intervention. The current lack of provisions addressing these concerns leaves decisions to the discretion of Authorisation Committees, potentially resulting in inconsistent practices and delays that could endanger patients' lives.

4. Ignorance of people with no near relatives or altruistic donor

The Transplantation of Human Organs and Tissues Act fails to address the rights of people who neither have a near relative nor an altruistic donor. Every person need not necessarily have a near relative or a person who is willing to donate his/her organs purely on altruistic motives. Section 9 of the Act only deals with the organ donations from a near relative, someone out of affection or attachment or due to any other special reasons. As mentioned above, altruistic

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donors have been brought under ‘special reasons’ by the Courts. A patient waiting for organ transplantation without any near relatives is left at the mercy of an altruistic donor and if such a donor does not turn up, the person has no other option but to succumb to the illness. Even when a person has near relatives, it is not necessary that such potential donors are fit candidates to donate their organs to the patient and it is always possible that none of his near relatives are matching donors.[7]

5. Prosecution of violators

Organ trade in India is an open secret and large-scale organ sale rackets have been often reported despite the criminalisation of commercial dealings, however, only a handful of them have been reported to be prosecuted for violating the provisions under the Transplantation of Human Organs and Tissues Act, 1994. Though the Act was enacted in 1994, the National Crime Records Bureau did not record data on cases under the Act till 2014. In the subsequent years, very few cases were filed under the Act and taken to trial as per the data available.[8]

VIII. CONCLUSION

If illegal organ trade continues unchecked in the country, it could lead to further crimes such as kidnapping, human trafficking for organ removal, and organ theft. Given India's large population and significant number of economically disadvantaged people, it is crucial to protect them from exploitation through such illicit practices. Ending the commercialization of human organs and strongly discouraging their commodification is imperative. As discussed earlier, the Transplantation of Human Organs and Tissues Act, 1994 is significantly flawed and contains loopholes that allow organ traffickers to exploit and manipulate the law. The Act's implementation has also been ineffective, failing to curb the commercial trade in organs and increase donations from deceased individuals.

The Act's provisions create ambiguity regarding the legality of certain practices, allowing for misuse and misinterpretation to facilitate commercial organ dealings under the guise of legal donations. To achieve the Act's objectives, clarity is needed on terms such as 'affection or attachment' and 'special reasons'. Ambiguity in defining death should be addressed, and procedures for filing complaints under the Act should be simplified. Introducing specific time limits for decisions by authorities, reducing waiting periods for organ removal from unclaimed bodies, and other reforms are necessary to prevent exploitation and uphold the Act's integrity.

[7] Sapna Khajuria & Saugata Mukherjee, Organ Transplantation: Legal Framework Examined, 39 JILI 299-311 (1997).
[8] Dhvani Mehta et al., *Organ Transplant Law: Assessing Compatibility with the Right to Health*, Vidhi Centre for Legal Policy 2-3 (Sept. 2017).