



**PARLIAMENT OF INDIA
RAJYA SABHA**

44

**DEPARTMENT-RELATED PARLIAMENTARY STANDING
COMMITTEE ON HEALTH AND FAMILY WELFARE
FORTY-FOURTH REPORT
ON
THE TRANSPLANTATION OF HUMAN ORGANS
(AMENDMENT) BILL, 2009**

**(PRESENTED TO THE RAJYA SABHA ON THE 4TH AUGUST, 2010)
(LAID ON THE TABLE OF THE LOK SABHA ON THE 4TH AUGUST,
2010)**

**RAJYA SABHA SECRETARIAT
NEW DELHI**

AUGUST, 2010/ SHRAVANA, 1932 (SAKA)

**PARLIAMENT OF INDIA
RAJYA SABHA**

DEPARTMENT-RELATED PARLIAMENTARY STANDING

COMMITTEE ON HEALTH AND FAMILY WELFARE

FORTY-FOURTH REPORT

ON

**THE TRANSPLANTATION OF HUMAN ORGANS
(AMENDMENT) BILL, 2009**

(PRESENTED TO THE RAJYA SABHA ON THE 4TH AUGUST, 2010)

(LAID ON THE TABLE OF THE LOK SABHA ON THE 4TH AUGUST, 2010)



**RAJYA SABHA SECRETARIAT
NEW DELHI**

AUGUST, 2010/ SHARAVANA, 1932 (SAKA)

CONTENTS

	PAGES
1. COMPOSITION OF THE COMMITTEE-----	(i)
2. PREFACE-----	(ii)
3. REPORT-----	
*4. OBSERVATIONS/RECOMMENDATIONS AT A GLANCE-----	
*5. MINUTES-----	

* to be appended at the printing stage

COMPOSITION OF THE COMMITTEE (2009-2010)

RAJYA SABHA

1. Shri Amar Singh - Chairman
2. Shrimati Viplove Thakur
- *3. Dr. Radhakant Nayak

4. Shri Janardan Dwivedi
5. Shri Balbir Punj
6. Dr. Prabhakar Kore
7. Shrimati Brinda Karat
8. Shrimati Vasanthi Stanley
- @9. Dr. M.A.M. Ramaswamy

- #10 Dr. Anbumani Ramadoss

LOK SABHA

11. Shri J. M. Aaron Rashid
12. Shri Ashok Argal
13. Shrimati Sarika Devendra Singh Baghel
14. Shri Vijay Bahuguna
15. Dr. Chinta Mohan
16. Shrimati Tabassum Hasan
17. Dr. Sanjay Jaiswal
18. Shri S. R. Jeyadurai
19. Dr. (Shrimati) Kruparani Killi
20. Shri N. Kristappa
21. Dr. Tarun Mandal
22. Shri Datta Meghe
23. Dr. Jyoti Mirdha
24. Shrimati Jayshreeben Patel
25. Shri R.K. Singh Patel
26. Shri M. K Raghavan
27. Dr. Anup Kumar Saha
28. Shrimati Meena Singh
29. Dr. Arvind Kumar Sharma
30. Shri Pradeep Kumar Singh
31. Shri Ratan Singh

SECRETARIAT

Shrimati Vandana Garg,	Additional Secretary
Shri R.B.Gupta,	Director
Shrimati Arpana Mendiratta,	Joint Director
Shri Dinesh Singh,	Assistant Director
Shri Satis Mesra	Committee Officer

-
- * ceased to be a member w.e.f 01/7/2010
- @ ceased to be a member w.e.f 30/6/2010
- # ceased to be member w.e.f 29/6/2010

PREFACE

I, the Chairman of the Department-related Parliamentary Standing Committee on Health and Family Welfare, after having been authorized by the Committee to present the Report on its behalf, present this Forty-fourth Report of the Committee on the Transplantation of Human Organs (Amendment) Bill, 2009*.

2 In pursuance of Rule 270 of the Rules of Procedure and Conduct of Business in the Council of States, relating to the Department-related Parliamentary Standing Committees, the Hon'ble Chairman, Rajya Sabha, referred** the Transplantation of Human Organs (Amendment) Bill, 2009 (Annexure-I), as introduced in the Lok Sabha on the 18th December 2009 and pending therein, to the Committee on the 22nd January 2010 for examination and report.

3. A Press Release inviting suggestions/comments from general public was issued on the 8th February 2010. In response thereto, the Committee received 32 memoranda.

4. The Committee considered the Bill in its meetings held on the 17th February, 20th May, 9th June, and 6th July 2010.

5. The Committee held wide ranging discussions with several stakeholders on different provisions of the Bill. Divergent views were expressed by many experts, representatives of organisations engaged in the field of deceased donor transplantation, kidney, eye and tissue transplantation etc. The Committee also interacted with the Secretary and other officers of the Department of Health and Family Welfare, Ministry of Health and Family Welfare. The list of witnesses is given in Annexure-II. The Committee sought clarifications from the above entities not only on the various viewpoints put forth before it on the Bill but also on how to make the parent Act more meaningful and in tune with the requirements of the society at large.

6. The Committee took up clause-by-clause consideration of the Bill at its meeting held on the 6th July 2010. After a detailed discussion, the Committee arrived at a consensus on the various provisions of the Bill. At its meeting held on the 21st July 2010, the Committee considered and adopted the draft Report.

* Published in Gazette of India Extraordinary Part II Section 2, dated the 18th December 2009

**Rajya Sabha Parliamentary Bulletin Part II, No 46776, dated the 22nd January 2010

7. The Committee has relied upon the following documents/information in finalizing its Report:

- (i) Background Note, Clause-by-Clause Note on the Bill, Parent Act, Report of the Transplant of Human Organs Act Review Committee constituted by the Delhi High Court, National Consultations on the Parent Act conceptualised and organised by the Rajiv Gandhi Foundation in Partnership with the Ministry, Feedbacks from State Governments and the Draft Guiding principles for organ transplantation prepared by WHO received from the Department of Health and Family Welfare;
- (ii) Presentation and clarifications by the Secretary and other officers of the Department of Health and Family Welfare;
- (iii) Memoranda received on the Bill from various experts and other stakeholders;
- (iv) Oral evidence on the Bill; and
- (v) Comments of the Department received in respect of memoranda forwarded to it for their view on various issues raised therein.

8. On behalf of the Committee, I would like to acknowledge with thanks all the stakeholders who assisted the Committee in formulating its views on the various provisions of the Bill.

9. For facility of reference and convenience, observations and recommendations of the Committee have been printed in bold in the body of the Report.

NEW DELHI;

July 21, 2010

Asadha 30, 1932 (Saka)

AMAR SINGH

*Chairman, Department-related Parliamentary
Standing Committee on Health and Family
Welfare*

(iii)

REPORT

The Transplantation of Human Organs Act, 1994 aimed at regulating the removal, storage and transplantation of human organs for therapeutic purposes and to prevent commercial dealings in human organs. Subsequent to its coming into force on 4th February, 1995 in the States of Goa, Himachal Pradesh and Maharashtra and all the Union Territories, it has been adopted by all States except Andhra Pradesh and Jammu & Kashmir, which have their own legislations in this regard. However, inspite of this legislation being in force, there have been numerous instances of organized human organ trading rackets. These cases have highlighted the loopholes in the Act that are being misused for such thriving business of illegal commercial transactions in human organs. The ultimate sufferer in all such cases is the economically weaker section of the society. Thus, on the one hand, this Act has not been able to curb commercial transactions in human organs; on the other hand, it has resulted in procedural delays in genuine cases of organ donation.

2. The Transplantation of Human Organs (Amendment) Bill, 2009, (hereinafter referred to as the "Bill") is an initiative of the Government which is aimed to plug the loopholes in the existing Act.

3. As per the Statement of Objects and Reasons appended to the Bill, the amendments proposed alongwith the reasons warranting their need, are reproduced below:-

(i) presently the said Act regulates transplantation of the human organs, it has been proposed that the said Act also regulate the transplantation of tissues of the human body. Therefore, it is proposed to amend the long title, short title of the Act and also to insert appropriate definition of "tissues" in the definition clause and consequential amendments in other sections of the Act;

(ii) to expand the definition of "near relative" in order to include the grandfather, grandmother, grandson and granddaughter as near relative;

(iii) to make mandatory for the Intensive Care Unit or Treating Medical Staff to request relatives of brain dead patients for organ donation and to provide for the enucleating of corneas by a trained technician. Further to enable a surgeon or a physician and an anaesthetist or intensivist to be included in the medical board in the event of non-availability of a neurosurgeon or neurologist for certification of brain death;

(iv) to regulate the transplantation of organs for foreign nationals, to prevent the exploitation of minors, to provide for Swap Donations of organs, to empower the Central Government to prescribe the composition of Authorisation Committees and to empower State Governments and Union territories to set up their own Authorisation Committees;

(v) to constitute the Advisory Committees to advise the Appropriate Authorities;

(vi) to empower the Appropriate Authorities to summon persons, seek production of documents, issue search warrants, etc.;

vii) to establish a National Human Organs and Tissues Removal and Storage Network;

(viii) to provide for the development and maintenance of a national registry of the recipients of human organs transplants;

(ix) to appoint a "transplant coordinator" in all hospitals registered for organ retrieval and transplantation; and to provide for the registration of non-governmental organisations working in the field of organ retrieval, banking and transplantation;

(x) to enhance the penalties provided under the Act; and

(xi) consequential amendment in section 24 in respect of the rule making power of the Central Government.

The Bill seeks to achieve the above objectives.

4. The Secretary, Department of Health and Family Welfare, during her deposition before the Committee on the 17th February 2010 gave a brief idea about the Bill and expressed the hope that the amendments proposed *vide* the Bill would not only enable efficient implementation of the Act but more importantly reduce exploitation going on through illegal transplantations. The Committee was given a brief description of the demand and supply mismatch and the illegal transplantations through commercial trading of organs. The Committee was also apprised that the Bill was based on several documents/papers like recommendations of a Committee constituted by the Delhi High Court to examine lacunae in the Parent Act, recommendations of the Rajiv Gandhi Foundation, and draft guiding principles of the organ transplantation prepared by the World Health Organisation.

5. As the Bill under consideration has far-reaching implications, the Committee decided to issue a Press Release seeking the views from all the stakeholders as well as the public at large. In response thereto, the Committee received a large number of memoranda. After scrutinizing them, the Committee concluded that it was necessary to interact with some experts and stakeholders for an in-depth examination of all relevant aspects connected with the Bill. The Committee, accordingly, heard the views of some of the experts and stakeholders during its meetings held on the 20th May and the 9th June, 2010.

6. During the aforesaid meetings in Delhi, the Committee had the opportunity to interact with quite a few witnesses representing different stakeholders. These interactions enabled the Committee to understand the complexities and problem-areas which have resulted in the failure of the parent Act in its main objective, *i.e.* regulating the removal, storage and transplantation of human organs for therapeutic purposes. It also helped the Committee tremendously to analyse whether the present amendments were good enough to deal with the identified underlying problems related to commercial dealings of human organs. The Committee also sought the views/comments of the Department on the various issues/apprehensions raised by the stakeholders/experts through point-wise reply to their memoranda.

7. Committee's observations and recommendations contained in the Report reflect an extensive scrutiny of all the viewpoints put forth before it.

8. The clauses where amendments have been suggested by the Committee or it has been found necessary to comment thereon in view of divergent views of the stakeholders, are discussed in the succeeding paragraphs.

9. **CLAUSES 2, 3 AND 4**

9.1 Presently, the Act regulates transplantation of human organs. Transplantation of tissues of the human body is also proposed to be brought under the ambit of the Act. Accordingly, clauses 2, 3 and 4 seek to amend the Long Title of the Act as well as make consequential amendments in other sections of the Act.

9.2 The Committee was informed that with the advancement in medical technology, apart from human organs, even tissues and cells were being transplanted. While a separate law would be required for regulating cell transplantation and therapy, tissues with the exception of blood can be brought under the Act.

9.3 During the course of its interaction with experts, it was emphasised again and again that human organs and tissues cannot be treated on the same footing so far as their removal, storage and transplantation and other allied aspects were concerned. Accordingly, there was a need for specific provision for tissues wherever required in the Act. **The Committee is inclined to agree with the contention of the experts relating to tissues. The Committee, therefore, recommends that instead of having a general provision for inclusion of tissues along with human organs in the entire Act, as suggested in Clause 4 of the Bill, specific provisions relating to tissues, keeping in view the characteristics of tissues as distinct from human organs, may be incorporated in the Act.**

10. CLAUSE-5

10.1 Section 2 of the Act deals with 'definitions'.

Clause 5(a) of the Bill seeks to expand the definition of the term "near relative" to include grandparents and grandchildren as follows:

'(i) "near relative" means spouse, son, daughter, father, mother, brother, sister, **grandfather, grandmother, grandson or granddaughter;**'

10.2 Majority of the stakeholders who furnished memoranda on the subject or who appeared before the Committee suggested further expansion of the term "near relative". It was emphasized that mere addition of grandparents and grandchildren would not prove to be beneficial especially due to their age factor. It was also pointed out that joint family system was still prevalent in our society. Accordingly, the term 'near relative' needed to be made both more flexible and broader so as to include uncle/s and aunt/s both from maternal and paternal side along with their children.

10.3 Attention of the Committee was also drawn to the impact of inclusion of wife in the "near relative" category. It was stated that keeping "wife" as an option under this term was prone to misuse as a female, more so a wife, is vulnerable to being forced to donate her organs in our social set up. Another suggestion came in the form of using the term "blood relative" instead of "near relative" so that only relatives like 'biological' son, 'biological' daughter, 'biological' father, 'biological' mother etc. are covered under it thereby eliminating the risk of persons being adopted or married with the sole purpose of getting their organs.

10.4 The Committee was, however, presented with an altogether different point of view by medical experts involved in the transplantation work who appeared before the Committee. It was impressed upon the Committee that further expansion of the term was not desirable as it would lead to commercial exploitation and unfair dealings. Committee's attention was drawn to the fact that at present also, cases of all donors falling under the category of 'near relative' were being closely scrutinised by the doctors involved in organ transplantation work. Not only this, at most of the transplantation centres, near relatives were being allowed to donate their organs only after getting the clearance from the Authorisation Committee, although it was not statutorily required. It was, accordingly, contended that it was not advisable to further expand the definition as it would result in

complexities where the relationship cannot be established even through genetic testing and beyond doubt. Further, it could also lead to undue pressure on the maternal side of the family, exposed by widening of the term, for donating the organ for the recipient of the groom family. Another significant impact pointed out to the Committee was that further expansion of the term 'near relative' would indirectly result in cadaveric transplantations not being encouraged, which was the need of the hour, especially due to comparatively easier availability of the same in our country.

10.5 After a careful analysis of the opinion of the stakeholders, the Committee is inclined to agree with the view of the medical experts who have shown their reservations against inclusion of more relatives within the ambit of the term "near relative". The Committee opines that even though there is no dearth of technology like DNA tests etc. to prove a blood relation, yet the same is a very complex and time consuming process. Besides, it also involves moral questions and cannot cover adopted relatives. Inclusion of more relatives may also lead to paying to potential donor relative either in cash or through a share in property. Thus, it may indirectly lead to commercialisation of organ donation, thereby defeating the very purpose of the Act. Further, expansion by inclusion of relations from the maternal side is likely to result in their being unnecessarily harassed and being forced to donate organs.

10.6 The Committee is also of the opinion that the purpose of inclusion of relatives under "near relative" is to facilitate the donation of organs by the close relatives to their immediate family members by not making the clearance of Authorisation Committee mandatory in such cases. Nothing stops the 'other' relatives not covered under the definition to come forward and donate their organs 'out of love and affection' by following the duly prescribed process as laid down in the Act. The Committee, accordingly, recommends that apart from the proposed inclusion of grandparents and grandchildren no further expansion is required in the definition of "near relative".

10.7 Clause 5(c) seeks to insert the definition of the term 'tissue' in the following manner:

'(oa) "tissue" means a group of cells except blood performing a particular function in the human body.'

10.8 The Committee observes that with the specific inclusion of tissues under the Act, definition of the term also needs to be incorporated in the Act, which is proposed to be provided under Section 2 relating to 'Definitions'. However, the representative from a reputed Tissue Bank, while appearing before the Committee suggested the following definition of the term 'tissue':

"Tissue means a portion of the human body other than an organ. It includes corneas, musculoskeletal tissues (e.g. bone, cartilage, fascia lata, tendon), cardiovascular tissues (e.g. heart valves, blood vessels), soft tissues (e.g. skin, dura mater) and cells (e.g. sperms and ova)".

10.9 The Committee notes that in respect of the aforesaid suggestion, the Department is of the view that this aspect can be further firmed up and taken up while carrying out amendments in the Rules and as such no amendment in the Act is required.

10.11 The Committee is inclined to agree with the Department's view that the issue of specifying various types of tissues can be taken up in the Rules as including them in the Act itself may be a short-sighted approach as with every medical technological innovation in this field, an amendment would be required to be made in the Act. Therefore, the proposed definition of "tissue" will serve the purpose.

10.12 A suggestion was also made to the Committee for the inclusion of following definition of the term 'Tissue Bank':

“Tissue Bank” means a facility that is registered and regulated under law to engage in the recovery, screening, testing, processing, storage or distribution of tissue or cells. It does not include blood banks.”

10.13 The Committee opines that tissue being one of the focal points of the present amendment Bill aiming at giving it a distinctly separate category *vis-a-vis* an organ, it would be advisable to include the definition of “Tissue Bank” under the Act. Accordingly, definition of the term as suggested above may be included in this clause for clarity.

10.14 The Committee also takes note of the following definition of the term ‘transplant co-ordinator’ proposed to be inserted in the Act:

“transplant co-ordinator means a person of the hospital appointed for co-ordinating all matters relating to removal or transplantation of human organs or tissues or both.”

10.15 The Committee feels that appointment of a hospital employee as transplant coordinator would prove to be beneficial for better coordination of all matters relating to removal/transplantation of human organs. The Committee is, however, of the view that a person who is assigned the job of transplant co-ordinator needs to possess all the specialised qualifications for such a crucial responsibility. The Committee, accordingly, recommends that specific rules in this regard under the Act may also be formulated.

10.16 The Committee also recommends to the Department to assign the transplant co-ordinator the task of ‘required request’ which is proposed by the Department to be given to a registered medical practitioner. This task should be specifically spelt out in the definition itself for the purpose of clarity.

11 CLAUSE-6

11.1 Section 3 deals with ‘Authority for removal of human organs’.

Clause 6 (a) seeks to insert the following sub-sections after sub-section (1):

"(1A) In respect of such human organs or tissues or both, as may be prescribed, it shall be the duty of a registered medical practitioner working in a hospital registered under this Act, for the purpose of removal, storage or transplantation of human organs or tissues or both,-

(i) to ascertain from the person admitted to the Intensive Care Unit or from his near relative that such person had authorised at any time before his death the removal of any human organ or tissue or both of his body under sub-section (2), then the hospital shall proceed to obtain the documentation for such authorisation;

(ii) where no such authority as referred to in sub-section (2) was made by such person, to make aware to that person or near relative for option to authorise or decline for donation of human organs or tissues or both;

(iii) to require the hospital to inform in writing to the Human Organ Removal Centre for removal, storage or transplantation of human organs or tissues or both, of the donor identified in clauses (i) and (ii) in such manner as may be prescribed.

(IB) The duties mentioned under clauses (i) to (iii) of sub-section (1A) from such date, as may be prescribed, shall also apply in the case of a registered medical practitioner working in an Intensive Care Unit in a hospital which is not registered under this Act for the purpose of removal, storage or transplantation of human organs or tissues or both."

11.2 The amendment proposes introduction of the concept of "Required Request" in respect of hospitals already registered under the Act or which are not registered for the purpose of removal, storage or transplantation of human organs or tissues or both.

11.3 The Committee notes that the Review Committee set up by the Delhi High Court had recommended that every hospital should make it mandatory for the ICU/ Treating Medical staff to request relatives of brain dead patients for organ donation. The Committee was informed that after the Uniform Anatomical Gift Act, 1987 came into force in USA, incorporating a required request clause, both awareness about organ donation and the number of organ donors increased considerably. Justification given by the Department was that the condition of "required request" could be enforced in respect of hospitals registered as Centres for Retrieval or Transplantation of Organs. Not only this, it was also being proposed to make the condition of "required request" mandatory for registration of clinical establishments subsequent to the enacting of the Clinical Establishments (Registration and Regulation) Act. Accordingly, all hospitals with ICUs were targeted to be brought under this category.

11.4 The Committee held extensive deliberations on this sensitive issue with quite a few experts. The Committee also had the opportunity to go through written memoranda received from many stakeholders highlighting the pros and cons of this proposed amendment. The predominant view which emerged after this exercise highlighted very strong reservations on the involvement of attending / treating doctors in counselling of the patient/ attendants for organ donation. The grounds for their reservation included very low doctor: patient ratio; adverse impact on the patient/attendant's mind leading to serious doubts being raised about quality care and last but not the least indirect encouragement of unethical organ trading. Equally strong apprehensions were voiced against the involvement of doctors engaged in organ removal and transplantation in counselling the patient/attendant(s) for organ donation which may lead to conflict of interest.

11.5 Therefore, it was argued that the family should be approached only after a patient has been declared brain dead. A view was put forth that the Transplant Co-ordinator or the para-medical staff may be involved in this exercise. Some stakeholders from the eye discipline were of the opinion that for eye-donation, required request can be made after death and not necessarily at the ICU admission stage.

11.6 Further, with even unregistered hospitals being covered under the proposed Amendment may encourage organs trading. It was also pointed out that very few ICU admissions ultimately result in brain death.

11.7 When attention of the Department was drawn to these serious reservations, it was clarified that not all ICU patients would be requested for donation but only those with 'brain stem death' or with imminent death (non heart beating donor).

11.8 The Committee fully shares the concerns raised by various experts regarding the efficacy of counselling the patient or his near relatives during patient's stay in ICU. The Committee strongly feels that even if the Department brings clarity by amending the Rules that not all ICU patients would be covered, it would fail to achieve the desired objective. What is required to be ensured is that "trust" of a patient or his relatives does not take a beating with the introduction of 'required request' concept, that too when the

patient is battling for his life. Further, chances are that the conflict of interest might lead to allegations of deliberate medical negligence against the treating doctors.

11.9 The Committee would like to point out that required request can prove to be a positive step if taken in the right earnest and judiciously. Keeping in view sheer lack of awareness about organ donation, the Committee is of the view that the task of counselling need not be assigned to the treating doctor not only due to the reservations stated above but also because of the fact that counselling is a professional exercise and the doctor might not be suitable for that task. The Committee recommends that the task of required request and counselling may be assigned to the Transplant Co-ordinator having the required qualifications and professional training for the purpose.

11.10 The Committee recommends that as eyes can easily be harvested even post-death and it is not a time taking exercise, required request procedure in respect of eye donation may be done after death of a patient.

11.11 The Committee observes that although the amendments make it mandatory for the hospital with ICU to inform in writing to the Human Organ Removal Centre for removal, storage or transplantation of human organs or tissues or both, of the donor identified, neither the term 'Human Organ Removal Centre' has been defined nor specific functions assigned to it indicated. The Committee, accordingly, recommends proper definition and functions of such a Centre to be specified in the Act itself.

11.12 The Committee does not find any merit in entrusting the 'required request' condition in hospitals with ICUs which are not registered. The Committee opines that it is really out of place to allow a hospital with ICU facilities to remain unregistered. With the Department admitting itself that a condition for registration may be set up during enforcement of the Clinical Establishments (Registration & Regulation) Act, there is no point in keeping Section 3 (1B). The Committee, accordingly, recommends a review of this and provide compulsory registration of all hospitals with ICU facility for the purposes of THOA in order to maintain minimum medical standards.

11.13 Clause 6 (b) seeks to insert the following proviso in sub-section (4) which provides that the task of organ removal can only be carried out by a registered medical practitioner:-

"Provided that a technician possessing such qualifications and experience, as may be prescribed, may enucleate a cornea.";

11.14 This clause seeks to authorize trained eye technicians possessing such qualification and experience to be prescribed, to remove corneas. Non- availability of eye-surgeons and ability of trained eye-technicians in the removal of cornea have been cited as justification for this proposed amendment by the Department. It has also been emphasized that such a move would have a positive impact on the number of corneas collected in the country.

11.15 All the experts and other stakeholders seemed to be unanimous on this issue of allowing trained eye technicians to enucleate a cornea. However, Committee was given to understand that the provision needed to be extended to tissues also. Specific suggestion given in this regard was to further modify the proposed proviso as follows:

"Provided that a technician possessing such qualifications and experience, as may be prescribed, may enucleate a cornea or retrieve musculoskeletal tissues and/ or cardiovascular tissues and/ or soft tissues or cells".

11.16 The Department in its feedback to the Committee was also agreeable to the inclusion of tissues in the proviso.

11.17 The Committee finds merit in the suggestion for a qualified and experienced technician handling the removal of corneas and tissues as indicated above. The Committee, accordingly, recommends amendment of proviso to sub-section (4). The Committee would also appreciate if the exercise of necessary amendments in the Rules is expedited after the proposed amendments come into effect.

11.18 Clause 6 (c) seeks to insert the following proviso in clause (iii) of sub-section (6) of Section 3 :

"Provided that where a neurologist or a neurosurgeon is not available, the registered medical practitioner may nominate an independent registered medical practitioner, being a surgeon or a physician and an anaesthetist or intensivist subject to the condition that they are not members of the transplantation team for the concerned recipient and to such conditions as may be prescribed;"

11.19 Section 3 (6) of the Act provides for the composition of the Board of Medical Experts which can certify a person as brain-stem dead for the purpose of organ removal. The composition of the Board besides having the registered Medical Practitioner in-charge of the hospital, also includes an independent registered medical practitioner (specialist) and a neurologist/neurosurgeon to be nominated by the in-charge from the panel of names approved by the Appropriate Authority. However, the Committee is given to understand that the THOA Review Committee and the national consultations held by the Department had come out with a view that due to shortage of neuro-surgeons and neurologists, brain-death certification has not picked up in the country. It was suggested that in the event of non-availability of a neuro-surgeon/ neurologist, a surgeon/ physician and an anaesthetist/ intensivist could be nominated from a panel already approved by the Appropriate Authority, subject to their not being involved in the removal/ transplantation of organ. Accordingly, proviso to sub-section (6) is proposed to be introduced.

11.20 Divergent views were expressed on this issue by the experts appearing before the Committee. It was pointed out that as brain death is diagnosed by clinical assessment, the registered medical practitioner should have specialized training for assessment and diagnosis of brain death. Apprehensions have been expressed by some stakeholders about the need to have doctors on the Board from the panel of names approved by the Appropriate Authority due to the prolonged process of approval for empanelment resulting in undue delay in arranging the panel to jointly declare a brain-death. Attention of the Committee was drawn to the existing practice in most of the countries where any registered medical practitioner who is permitted to certify cardio-pulmonary death is permitted to certify brain death as well. The requirement of joint certification of brain stem death itself provides adequate safeguard for this. It was, accordingly, emphasised to do away with the system of keeping two doctors whose names are to be duly approved by the Appropriate Authority and instead the Rules may provide for hospitals sending monthly reports specifying names and registration numbers of doctors who have certified brain death. This would be an adequate safeguard.

11.21 The Committee finds merit in Department's proposal of substituting the requirement of neurologist or a neurosurgeon, in the event of their non-availability, with a surgeon or a physician and an anaesthetist or intensivist. The Committee opines that there is dearth of neurologists and neurosurgeons in the country and it is not possible to ensure their availability round the clock in the Board of Medical Experts to certify a patient as brain dead. The Committee notes that the Department has tried to take due precaution in the form of providing a condition that the surgeon or a physician and an anaesthetist or intensivist so

substituted would not be members of the transplantation team for the concerned recipient. This would, to a great extent, be a safeguard against conflict of interest.

11.22 The Committee, however, finds that the proposed proviso does not specify that the surgeon or a physician and an anaesthetist or intensivist would be from an approved panel of the Appropriate Authority. Such an important aspect should be part of the Act itself and cannot be left unspecified for being covered in the Rules. The Committee, accordingly, recommends insertion of the words “from a panel already approved by the Appropriate Authority” at the end of the proviso to remove any ambiguity in this regard. The Committee also recommends to the Department to modify the Rules/Act appropriately to keep a larger pool of such experts, duly approved by the Appropriate Authority, in order to ensure that the Board of Medical Experts does not face manpower crunch in its functioning and remains fully operational.

12. CLAUSE-7

12.1 Section 9 of the Act deals with ‘Restrictions on removal and transplantation of human organs’.

Clause 7 (a) seeks to insert the following sub-section after sub-section (1): -

“(1A) Where the donor or the recipient being near relative is a foreign national, prior approval of the Authorisation Committee shall be required before removing or transplanting human organ or tissue or both:

Provided that the Authorisation Committee shall not approve such removal or transplantation if the recipient is a foreign national and the donor is an Indian national unless they are near relatives.”

12.2 This clause seeks to make it mandatory for all cases involving a foreign national as a donor or recipient to be routed through the Authorization Committee even if the donor and recipients are near relatives. This sub-clause also seeks to provide that the Authorization Committee shall not approve removal or transplantation of organs or tissues or both if the recipient is a foreign national and the donor is an Indian national unless they are near relatives.

12.3 Attention of the Committee was drawn to various reports appearing in the media regarding India becoming the hub for organ transplant tourism. Recent revelations in several such cases have confirmed this alarming trend. Therefore, it was contended that in order to protect the vulnerable sections of the society from exploitation as well as to prevent India from becoming centre of this unethical and highly commercialised activity, the new provision has been proposed in the Act. As the law stands today, cases of near relatives are not required to be processed through the Authorisation Committee.

12.4 The Committee is aware that vulnerable sections of the society are falling prey to middlemen and due to poverty, are being exploited to provide their organs to foreigners in the garb of their near relatives. This practice needs to be curbed effectively at the earliest. The Committee hopes that this amendment will, to a great extent, help in plugging the loopholes in the Parent Act. The Committee, therefore, welcomes the inclusion of this amendment.

12.5 Clause 7 (a) also seeks to insert the following sub-section after sub-section (1): -

“(1B) No human organs or tissues or both shall be removed from the body of a minor before his death for the purpose of transplantation except in the manner as may

be prescribed.”

12.6 The Committee was given to understand that the above amendment was based on the following Guiding Principle of WHO:

“ No cells, tissues or organs should be removed from the body of a living minor for the purpose of transplantation other than narrow exceptions allowed under national law. Specific measures should be in place to protect the minor and wherever possible the minor’s assent should be obtained before donation.”

12.7 On being asked to clarify the circumstances under which human organ/ tissue could be removed from the body of a minor before his death, the Committee was informed that exceptions can be familial donation of regenerative cells when therapeutically compatible adult donor was not available or kidney transplant between identical twins. Fast developing medical technology and availability of newer treatment options in future were cited for non-specification of circumstances in the Act, especially due to the time-consuming process of bringing in an amendment in the Act.

12.8 While not contesting the prolonged process of bringing in amendments in an Act, the Committee is of the view that full protection needs to be provided to the most vulnerable section of the society. Accordingly, exceptional circumstances necessitating organ donation by minor need to be enumerated in the Act itself. The Committee also feels that in order to remove any sort of ambiguity, the definition of “minor” needs to be given in the Act itself.

12.9 The Committee also takes note of the fact that mentally challenged persons also need similar protection. The Committee, accordingly, recommends that the provision may be extended to mentally challenged people also.

12.10 Clause 7 (b) seeks to insert the following sub-section after sub-section (3): -

"(3A) Notwithstanding anything contained in sub-section (3), where

(a) any donor has agreed to make a donation of his human organ or tissue or both before his death to a recipient, who is his near relative, but such donor is not compatible biologically as a donor for the recipient; and

(b) the second donor has agreed to make a donation of his human organ or tissue or both before his death to such recipient, who is his near relative, but such donor is not compatible biologically as a donor for such recipient; then

(c) the first donor who is compatible biologically as a donor for the second recipient and the second donor is compatible biologically as a donor of a human organ or tissues or both for the first recipient and both donors and both recipients in the aforesaid group of donor and recipient have entered into a single agreement to donate and receive such human organ or tissue or both according to such biological compatibility in the group, the removal and transplantation of the human organ or tissue or both, as per the agreement referred to above, shall not be done without prior approval of the Authorisation Committee”.

12.11 The Committee is given to understand that, as of now, the law permits donation of an organ only by a near relative without requiring the approval of the Authorization Committee. All other cases are required to be routed through this Committee. Proposed sub-section (3A) is based on the recommendations of the Review Committee set up by Hon’ble Delhi High Court which seeks to permit swap donations between one set of willing but incompatible “near relative” donors and a similar other donor-recipient incompatible relative pair. The intention is to permit donation of organs in exchange without any commercial interest and only due to the reason that despite willingness, their organ was not found medically

compatible to the intended recipients. Swap donations are proposed to be considered by the Authorization Committees on a case-to-case basis as per existing provisions in the Act and the Rules.

12.12 The proposal has been welcomed by all the stakeholders and is stated to be a positive step towards solving the miseries of many patients who have a willing but biologically incompatible "near relative" donor. However, a suggestion was made that instead of restricting it to two donor-recipient pairs, it needed to be expanded further. It was pointed out that the task of identifying and matching potential donors and recipients for a large number of pairs could be easily accomplished through the proposed National Registry.

12.13 The Committee infers that the whole concept of "Swap" donation with the approval of the Authorisation Committee will prove to be a boon for millions of patients, who, inspite of having a willing near relative cannot have organ transplantation due to biological incompatibility. Due to strict provisions of the Act and with only one other condition laid down for donations, i.e. "out of love and affection", such patients are forced to go through a silent death. The Committee also recommends that viability of expanding two donor-recipient pairs may also be explored by the Department. With the proposed National Registry becoming functional and well-coordinated network both at national and regional level, such an initiative can be carried forward in an effective and transparent manner.

12.14 The Committee was given to understand that in the case of tissues, compatibility was not required. Accordingly, swap donation may be restricted for human organs only. The Committee, however, does not find merit in excluding tissues altogether from the ambit of the swapping provision especially with the advancement in the field of medical science. The Authorisation Committee can well decide on a case-to-case basis whether a particular tissue swapping is justified or not.

12.15 Clause 7 (c) seeks to substitute sub-section (4) as follows: -

"(4)(a) The composition of the Authorisation Committees shall be such as may be prescribed by the Central Government from time to time.

(b) The State Governments and the Union territories shall constitute, by notification, one or more Authorisation Committees consisting of such members as may be nominated by the State Governments and the Union territories on such terms and conditions as may be specified in the notification for the purposes of this section."

12.16 The Parent Act empowers the Central Government to constitute Authorisation Committees in case of Union Territories and the State Governments for their respective States. The proposed amendment seeks to provide for the Central Government to prescribe the composition and broad framework including the eligibility criteria for the persons to be nominated to the Authorization Committees. Actual nomination is to be done by the State Governments and the Union Territories

12.17 The Committee notes that the Review Committee set up by the Delhi High Court was of the view that the practice of hospital based Authorisation Committee was workable and practical in Metro cities and large capital cities of States. But in non-metro and smaller capital cities, a single Authorization Committee for the entire district or a Division comprising several districts would serve the purpose.

12.18 Most of the stakeholders have welcomed the move of the Department. However, one pertinent issue has been raised regarding jurisdiction of Authorisation Committee when the

donor and recipient belong to different States or donor and recipient belong to other States and transplantation is taking place in a different State. The Department, in response to this issue has stated that this would be taken care of while amending the Rules and until then Supreme Court order of March 2005 was being followed.

12.19 Apprehensions were also voiced about too much involvement of Central Government in deciding the composition of the Authorisation Committees. It was, accordingly, suggested that composition of such Committees should entirely be left to the discretion of States/Union Territories. The Committee would like to point out that the States and Union Territories would continue to have the powers for actual constitution of such Committees. Only broad framework and eligibility criteria for members of Authorisation Committees is sought to be prescribed so as to ensure uniformity and high standard of these Committees.

12.20 The Committee fully shares its concerns over the issue of jurisdiction of Authorisation Committees. After careful deliberations, the Committee finds merit in giving jurisdictional powers to the Authorisation Committee of a particular State/District/ Hospital where organ transplantation is being carried out. The Committee, accordingly, recommends to the Department to settle this issue of jurisdiction of Authorisation Committee in the Act itself to remove any sort of ambiguity and confer all such related powers to that Committee of the State/District/Hospital where transplantation is being carried out.

13. CLAUSE 8

Clause 8 seeks to insert new sections after Section 13 as follows:

13A. Advisory Committees to advise Appropriate Authority.

"13A. (1). The Central Government and the State Governments, as the case may be, by notification, shall constitute an Advisory Committee for a period of two years to aid and advise the Appropriate Authority to discharge its functions.

(2) The Advisory Committee shall consist of-

- (a) one administrative expert not below the rank of Secretary to the State Government, to be nominated as Chairperson of the Advisory Committee
- (b) two medical experts having such qualifications as may be prescribed;
- (c) one officer not below the rank of a Joint Director to represent the Ministry or Department of Health and Family Welfare, to be designated as Member-Secretary;
- (d) two eminent social workers of high social standing and integrity, one of whom shall be from amongst representatives of women's organisation;
- (e) one legal expert who has held the position of an Additional District Judge or equivalent.

(3) The terms and conditions for appointment to the Advisory Committee shall be such as may be prescribed by the Central Government."

13.1 On being asked to justify the need for having an Advisory Committee to the Appropriate Authority, the Department clarified that the poor conviction rate under the Act has often been attributed to the inability of State Health Officer, designated as the Appropriate Authority, to find time for a methodical and systematic discharge of duties assigned under the Act. It has, therefore, been proposed to provide for the constitution of an Advisory Committee to aid and assist the Appropriate Authority to discharge its functions.

13.2 Consultations with various experts and suggestions received from various other stakeholders have brought forward several issues like questioning the gender bias with

inclusion of representative from a woman's organisation, inclusion of NGOs, qualifications of the legal expert, inclusion of experts from different specialities and inclusion of a legal advisor in crime therapeutic procedure.

13.3 The Committee is of the view that the purpose of the clause should be to give a broad framework about the composition of the Advisory Committee, with States being entrusted with the responsibility of deciding actual membership thereof. The Committee would like to point out that although such a Committee need not be a big body, yet it needs to be made more representative. Accordingly, the Committee recommends inclusion of representatives of reputed NGOs working in the field of Organ Donation and Human Rights Groups. The representation of medical experts may also be suitably enhanced to cover experts of more specialities, with the binding condition that they are not members of any transplantation team.

13.4 Following powers of Appropriate Authority are proposed to be specified through insertion of section 13B as indicated below:

"13B. The Appropriate Authority shall for the purposes of this Act have all the powers of a civil court trying a suit under the Code of Civil Procedure, 1908 and, in particular, in respect of the following matters, namely:-

(a) summoning of any person who is in possession of any information relating to violation of the provisions of this Act or the rules made thereunder;

(b) discovery and production of any document or material object;

(c) issuing search warrant for any place suspected to be indulging in unauthorised removal, procurement or transplantation of human organs or tissues or both; and

(d) any other matter which may be prescribed."

13.5 The Committee is of the view that fully empowered Authorisation Committee would go a long way in curbing the commercialisation of process of donation of human organs and also enabling the reach of much-needed organs to the rightful recipients.

13.6 National Human Organs and Tissues Removal and Storage Network.

"13C. The Central Government may, by notification, establish a National Human Organs and Tissues Removal and Storage Network at one or more places and Regional Network in such manner and to perform such functions, as may be prescribed."

13.7 The Department has stated that a need has been felt for the establishment of nationwide network on the lines of the Organ Procurement and Transplantation Network of USA or UK to include transplant centres, retrieval centres, certified HLA testing labs and in future trauma centres, dialysis centres and hospitals with ICUs. An efficient network that links organ retrieval and transplant centres to facilitate exchange information about availability of organs and data base of recipients holds the key to the success of any transplant programme. Accordingly, the Department has come up with the proposal of establishing a National Human Organs and Tissues Removal and Storage Network.

13.8 The Committee has received several suggestions from stakeholders like, the word 'may' in Section 13C must be replaced by the word 'shall'; Government must spell out a time-bound commitment to establish such network and a National Registry of Donors and Recipients; Hospital networking and registry maintenance to be permitted as State level initiatives and therefore in the new section 13C and 13D, the words "Central Government" to be replaced by the words "Central and State Governments". Committee's attention has

also been drawn to such Networks already set up in Maharashtra, Tamil Nadu and Karnataka.

13.9 The Committee welcomes the initiative of establishing a National Human Organs and Tissues Removal and Storage Network as also Regional Networks. However, the Committee is of the view that too much control at central level may not prove to be beneficial and result in practical difficulties. The Committee would like to recommend to the Department to establish the Network on the lines of "National Register of Clinical Establishments" proposed under the Clinical Establishments (Registration and Regulation) Act along with a replica of the same at State level to be termed as State Human Organs and Tissues Removal and Storage Network. This would facilitate in gathering and dissemination of information from the hospital and district level. For this the Department needs to assign powers to State Governments by replacing the word "Central Government" with Central and State Governments".

13.10 Similarly, the Committee recommends use of the word 'shall' in place of 'may' to give it a mandatory structure. The Committee also recommends to the Department to have a thorough study of such Networks set up in States like Maharashtra, Tamil Nadu and Karnataka. Based on the experience of these States, a model framework can be circulated to all the States. Such Networks need to be set up within a definite time-frame.

13.11 The Committee further recommends that all such information related to the Network may be put out on a dedicated website of all the State Health Departments at the State level and the Ministry of Health and Family Welfare at the Central level so that the same is available to the public at large.

13.12 The Committee would also like to recommend to the Department to work out a proposition wherein critical patients (recipients) may be considered on priority basis. It is also suggested that priority of recipient may be given to a patient (intended recipient) of the same Hospital/ District as it is not possible to manage the priority list at State or National level. However, due checks may be incorporated so that such provisions are not subjected to misuse.

13.13 While deliberating on the proposed National Human Organs and Tissues Removal and Storage Network in its meeting held on the 17th February, 2010, the Committee was apprised that the Network was going to be essentially IT-based. ERNET, an organisation under the Department of Information Technology was conducting a feasibility study of the proposal which was likely to be completed within three months.

13.14 The Committee hopes that by the time the proposed amendments to the Act would come into effect, a feasibility model for the National Network would also be ready to be launched. The Committee would, however, be failing in its duty if a mention about the status of the Organ Retrieval Banking Organisation of AIIMS is not made. The Committee was of the view that ORBO would have stood out as a role model for the proposed National and Regional Network for human organs and tissues. However, on a pertinent query in this regard, the Committee was given to understand, both by the Ministry officials and the Head of ORBO, that due to inherent constraints relating to lack of infrastructure and trained manpower, the Organisation has so far failed to achieve its objective. As a result, its mandate has remained confined to deceased organ donors of AIIMS only.

13.15 The Committee takes note of the fact that the purpose behind the proposed amendments is to make ORBO-like organizations grow out of AIIMS and have a nationwide reach. Likewise, a National Programme for Promotion of Organ Donation is also being worked out which would conceptualise a structure that would have a national as well as a state-wise reach so as to facilitate and replicate ORBO-like set-ups. While

welcoming all these ambitious plans, which would definitely contribute in extending the reach of needy patients for required organs, the Committee would like to emphasize that every conceivable effort needs to be made to make ORBO fully functional so that it can play the lead role for other similar set-ups. The Committee hopes that as assured by the Secretary, Health and Family Welfare, all the necessary procedural exercise for having the required funds, infrastructure and manpower for ORBO would be completed by the year end.

13.16 National Registry.

"13D. The Central Government shall maintain a registry of the donors and recipients of human organs and tissues and such registry shall have such information as may be prescribed to an ongoing evaluation of the scientific and clinical status of human organs and tissues".

13.17 The Department proposes the development and maintenance of a scientific registry called "National Registry" which will contain information of donors and recipients for ongoing evaluation of the scientific and clinical status of organ transplantation.

13.18 The draft guiding principles for Organ Transplantation prepared by WHO *inter-alia* state that the long-term outcomes of cell, tissue and organ donation and transplantation should be assessed for the living donor as well as the recipient in order to document benefit and harm. The Committee welcomes the proposal of establishing a National Registry and in its opinion it will help in achieving the aforesaid objective.

13.19 The Committee, however, recommends setting up of State Registries, with due powers and duties to States similar to the National Registry as suggested in case of National Human Organs and Tissues Removal and Storage Network above.

13.20 The Committee finds that no provision seems to have been made for keeping a record of donors who have pledged organ donation and of patients who need an organ donation for transplantation. The National Registry seems to suggest that it will contain only names of those who have already donated their organs and those who have already received organs through transplantation. Similarly, the National Human Organs and Tissues Removal and Storage Network seems to be a network that links organ retrieval and transplant centres to facilitate exchange information about availability of organs in case of cadaver. **The Committee, accordingly, recommends to the Department to keep a list of intended donors who have pledged their organs for donation after death as well as those who register as patients requiring organ donation. However, due process of verification may be carried out to ascertain the genuineness thereof. The same may also be put out on a dedicated website along with National Registry and National Human Organs and Tissues Removal and Storage Network.**

14. CLAUSE 9

14.1 Section 14 relates to 'Registration of hospitals engaged in removal, storage or transplantation of human organs'.

After sub-section (3), the following sub-section is proposed to be inserted:-

"(4) No hospital shall be registered under this Act, unless the Appropriate Authority is satisfied that such hospital has appointed a transplant coordinator having such qualifications and experience as may be prescribed."

14.2 Proposed new sub-section (4) seeks to make it mandatory for the hospitals to have the post of "Transplant Co-ordinator" before the Appropriate Authority gives his approval for the registration of the hospital under this Act. "Transplant Co-ordinator" recommended

by the Review Committee may be a doctor/ senior nursing staff member independent of the Transplant Team, possessing communication skills and who can liaison between the treating doctor and the potential brain-death donor.

14.3 As recommended by the Committee in previous clauses, the Transplant Co-ordinator may also be entrusted with the duties of "required request" as specified under amendment clause 6 (a). However, the Committee feels that the job of the transplant co-ordinator would be more of a counsellor who is trained in dealing with human emotions and sentiments, if he is assigned the duties of carrying out "required request" in ICU. Accordingly, it recommends that the prescribed qualification for such a post may include inter-alia qualifications required for a counsellor.

15. CLAUSES 10, 11 AND 12

15.1 Clause 10, 11 and 12 relate to Sections 18, 19 and 20 regarding 'Punishment for removal of human organ without authority', 'Punishment for commercial dealings in human organ' and 'Punishment for contravention of any other provision of this Act', respectively.

15.2 The Committee was informed that the Review Committee had recommended significant enhancements in the penalties for offences committed under the Act. The consensus that emerged in that Committee was that fines and term of imprisonment should be enhanced so as to act as deterrents for violators of law.

15.3 The Committee notes that the main objective of the Bill is to regulate the removal, storage and transplantation of human organs and also to prevent commercial dealings in human organs. Through the amendments proposed in Sections 18, 19 and 20, both fines and terms of imprisonment for different categories of violations are sought to be suitably enhanced.

15.4 Various stakeholders who appeared before the Committee or who submitted written memoranda to the Committee have welcomed the enhancement in the various penalties - both monetary as well as in the terms of imprisonment. However, it was suggested that tissues should not be placed on an equal footing with organs for the purpose of penalties and penalties in respect of them need to be relooked.

15.5 The Committee is in full agreement with the Department and appreciates its proposal of substantial hike in penalties for violation of various provisions of the Act. The Committee also welcomes the omission of discretionary power of Courts to lower the sentence which does not stand justified in the current times and with a thriving illegal transplantation network throughout India.

15.6 The Committee is also aware that with tissues being included in the Act, the Department needs to be cautious in respect of penalties for tissue removal, storage and transplantation. The Committee is, therefore, inclined to agree with the suggestion put forth by some stakeholders regarding differential penalties for tissues and organs. The Committee concludes that the removal of many of the tissues, unlike in case of human organs, do not offer any threat to human life and even some of the tissues are a discarded medical waste. Therefore, subjecting tissue transplants with the same punishment may be counterproductive and lead to unnecessary harassment of institutions engaged in the usage of tissues. The Committee, accordingly, recommends to the Department to revisit its penalties proposed in Sections 18, 19 and 20 for tissues.

16. SUGGESTIONS ON SECTIONS NOT COVERED IN THE AMENDMENT BILL

During its interactions with experts as well as the feedback received from various stakeholders, the Committee had the opportunity to have a comprehensive assessment of the

entire Act. The Committee has no other alternative but to conclude that some of the provisions of the Principal Act which were required to be amended have somehow been left unchanged. The Committee would be failing in the real accomplishment of its assigned task, if such valuable suggestions received by it are not highlighted. Following paras are an attempt in this direction.

16.1 AMENDMENT IN SECTION 2 : DEFINITIONS

SUB-SECTION (k) defines the term 'payment' as follows:

"Payment means payment in money or money's worth but does not include any payment for defraying or reimbursing -

- (i) the cost of removing, transporting or preserving the human organ to be supplied; or
- (ii) any expenses or loss of earnings incurred by a person so far as reasonably and directly attributable to his supplying any human organ from his body."

16.1.1 A suggestion was put forth before the Committee to further expand the definition of the term 'payment' in the following manner:

- iii) the cost of maintaining deceased person in a state of functioning of the human organs till their removal and handing over the dead body to the person in lawful possession of it, inclusive of costs of brain death certification and of clinical and laboratory assessment required to judge suitability of the organs for therapeutic purposes and to match specific recipients.
- iv) Expenses incurred in transportation of the deceased donor between hospitals and from hospital to home and in burial or funeral as may be authorized by the State or Central government.
- v) Costs of any recognition or award or benefit accorded to the near relative of the deceased donor as authorized by the State or Central government.

16.1.2 It was argued that that failure to exclude these from the definition of "payment" was causing confusion and it was necessary and correct to incur such costs for the success of deceased donor transplantation programme. It has been stated that the US Act provides for the deferment of organ procurement costs. The Department, on being asked about their views in this regard also found it to be agreeable. It was, accordingly, suggested that the same may be included in the Rules.

16.1.3 The Committee is in full agreement with the suggestion of excluding the cost of maintaining the functional state of organs of a deceased person, transportation costs and benefits/costs of award to near relative of deceased person, from the term "payment". The Committee, however, is not in favour of placing the same in Rules. As the definition has already covered two exclusions in the Act, there is no point in moving these suggestions to the Rules. The Committee, accordingly, recommends to the Department to amend the definition of "payment" suitably in Section 2 of the Act.

16.2 AMENDMENT IN SECTION 3

Authority for removal of human organs. –

"(2) If any donor had, in writing and in the presence of two or more witnesses (at least one of whom is a near relative of such person), unequivocally authorised at any time before his death, the removal of any human organ of his body, after his death, for therapeutic purposes, the person lawfully in possession of the dead body of the donor

shall, unless he has any reason to believe that the donor had subsequently revoked the authority aforesaid, grant to a registered medical practitioner all reasonable facilities for the removal, for therapeutic purposes, of that human organ from the dead body of the donor.”

16.2.1 This clause states that if a patient, before death, has given his consent for organ removal post-death, the person who is legally in possession of his body would give all facilities to a registered medical practitioner for the removal of that human organ for therapeutic purposes from the dead body of the donor.

16.2.2 Attention of the Committee was drawn to the fact that the term ‘lawfully in possession of the dead body’ was ambiguous as the Act failed to explain the term. It was, accordingly, suggested that it may further be clarified according to the priority of relatives like – spouse, parents, children, brothers/sisters, grandparents, grandchildren etc. This would take care of an eventuality when the family member on the top of the list not being present, the decision could be taken by the next family member. Another view put forth before the Committee was that in those cases where verified donor consent was on record, the requirement to obtain the permission of a near relative for removal of the organs for transplant could be dispensed with.

16.2.3 The Department’s response was that the definition of the term ‘lawfully in possession of the dead body’ was beyond the scope of the Act as the concerned legal provisions under IPC/CrPC were dealt with by the Ministry of Home Affairs. It was also contended that permission of the near relative was taken to rule out the commercial aspect and any undue pressure to donate.

16.2.4 The Committee is aware that certain legal issues covered under various provisions of IPC and CrPC come under the domain of the Ministry of Home Affairs. However, the Committee does not find merit in keeping the term ‘lawfully in possession of the dead body’ ambiguous in the present Act. The Committee finds no harm in relevant provisions of IPC/ CrPC being referred to in the Act. The Department can easily work out an appropriate provision in consultation with the Ministry of Home Affairs so that element of ambiguity whatsoever does not remain. The Committee strongly feels that such a provision will prove effective in checking both misinterpretation of the provision as well as misuse thereof. The Committee, accordingly, recommends to the Department to move forward in this regard.

16.2.5 The Committee has, in preceding paras, suggested that on the lines of the National Registry and National Human Organs and Tissues Removal and Storage Network, a list of intended donors who have pledged their organ for donation as well as those who register as patients requiring organ donation should be maintained after due verification process. If that recommendation is adhered to, then it would be more than enough proof for establishing that a patient has voluntarily offered donation of his organs before his death. In that eventuality, no formal permission of the relative should be mandatory for organ removal. The Authorisation Committee can move in at this point and proceed with all relevant procedural formalities of organ removal as per the wish of the deceased donor. The Committee, accordingly, recommends to the Department to come up with suitable amendment in the provisions of the Act.

16.3 AMENDMENT IN SECTION 5

Section 5 relating to ‘Authority for removal of human organ in case of unclaimed bodies in hospital or prison’ reads as follows:

“5. (1) In the case of a dead body lying in hospital or prison and not claimed by any of the near relatives of the deceased person within forty-eight hours from the time of the

death of the concerned person, the authority for the removal of any human organ from the dead body which so remain unclaimed may be given in the prescribed form, by the person in charge, for the time being, of the management or control of the hospital or prison, or by an employee of such hospital or prison authorized in this behalf by the person in charge of the management or control thereof.

(2) No authority shall be given under sub-section (1) if the person empowered to give such authority has reason to believe that any near relative of the deceased person is likely to claim the dead body even though such near relative has not come forward to claim the body of the deceased person within the time specified in sub-section (1)."

16.3.1 Some of the experts had stated that this whole provision had no meaning for organ donation unless such body that was left unclaimed in a hospital or a body from the prison was put on a ventilator. In ordinary circumstances in 48 hours the body would be decomposed and no organs could be utilized. Accordingly, it was suggested that in such situations, presumed consent for eyes, heart valves, bones and cartilages should be allowed. The Department, however, was of the view that the same was beyond the scope of the Act as legal provisions involved therein were dealt with by the Ministry of Home Affairs. It was also pointed out that the principle of "required request" and not "presumed consent" was the basis of the Act.

16.3.2 The Committee is aware that legal issues are involved in case of unclaimed bodies and the same cannot be ignored. The Committee also notes that ordinarily a dead body is not useful for organ donation after 48 hours of death unless kept under required medical conditions. The Committee understands that chances of preservation of a dead body lying in prison may not be there. However, situation in hospitals would perhaps be far better. Therefore, keeping in view acute shortage of human organs in the country, a beginning can be made in the case of well-equipped hospitals where unclaimed dead bodies could be kept fit for organ donation. If that is not found viable, the Committee feels that at least tissues can be harvested from unclaimed dead bodies. The Committee, accordingly, recommends that this sensitive issue may be examined, taking care of all types of complexities, and a viable solution arrived at. Other legal issues, like keeping viscera or post-mortem etc. can simultaneously be taken care of as per the directions of the investigating officer and requirements of the case. The identity of the donor could be established with the help of the Authorisation Committee of the hospital where such death has occurred or the nearest hospital to the Police Station where such unclaimed body is reported. The Department needs to work closely with the Ministry of Home Affairs in this regard.

16.4 AMENDMENT IN SECTION 6

Section 6 of the Act deals with the procedure of organ removal in case of bodies sent for post-mortem examination for medico-legal or pathological purposes, as reproduced below:

"6. Where the body of a person has been sent for post-mortem examination -

- (a) for medico-legal purposes by reason of the death of such person having been caused by accident or any other unnatural cause; or
- (b) for pathological purposes,

the person competent under this Act to give authority for the removal of any human organ from such dead body may, if he has reason to believe that such human organ will not be required for the purpose for which such body has been sent for post-mortem examination, authorize the removal, for therapeutic purposes, of that human organ of the deceased person provided that he is satisfied that the deceased person had not expressed,

before his death, any objection to any of his human organs being used, for therapeutic purposes after his death or, where he had granted an authority for the use of any of his human organs for therapeutic purposes after his death, such authority had not been revoked by him before his death.”

16.4.1 The Committee has received some valid suggestions in regard to the applicability of this provision at the ground level. Some of the experts were of the view that usually in accidents or other cases where post-mortem was to be held mandatorily, the family members often turn down the request or backtrack from the consent later on for organ donation due to long drawn procedural formalities resulting in undue delay in performing the last rites of the deceased. It was also pointed out that organ retrieval after the post-mortem required cutting the body again. Moreover, sometimes the body was required to be taken to a different place having facilities for organ retrieval. It was contended that the undue delay in handing over the body to the families of the deceased was a crucial factor for deceased organ donation success rate. Accordingly, it was suggested that the process of post-mortem could be clubbed with retrieval of organs.

16.4.2 The Committee fully shares the reasoning that our social set up and the intrinsic values and emotions attached with such a sensitive issue like death of a relative and the subsequent last rites, many a time, results in turning down or withholding the request of organ donation. The Committee also understands that there is a need to cut down the time taken between the post-mortem, organ retrieval, and the subsequent handing over of the body to the relatives for the last rites. The Committee opines that a workable via media of conducting the post-mortem and organ retrieval simultaneously can perhaps be put into place. However, the Committee is aware that to give effect to such a solution, legal provisions might require an amendment. Accordingly, in the best interest of the civil society, the Committee recommends to the Department to approach the Ministry of Home Affairs so as to come out with a proposition where the post-mortem could simultaneously be carried out with the retrieval of the organs so as to minimise the delay in handing over body of the deceased to his relatives.

16.5 AMENDMENT IN SECTION 10

Section 10 which relates to ‘Regulation of hospitals conducting the removal, storage or transplantation of human organs’ reads as follows:-

“10. (1) On and from the commencement of this Act, -

(a) no hospital, unless registered under this Act, shall conduct, or associate with, or help in, the removal, storage or transplantation of any human organ;

(b) no medical practitioner or any other person shall conduct, or cause to be conducted, or aid in conducting by himself or through any other person, any activity relating to the removal, storage or transplantation of any human organ at a place other than a place registered under this Act; and

(c) no place including a hospital registered under sub-section (1) of section 15 shall be used or cause to be used by any person for the removal, storage or transplantation of any human organ except for therapeutic purposes.

(2) Notwithstanding anything contained in sub-section (1), the eyes or the ears may be removed at any place from the dead body of any donor, for therapeutic purposes, by a registered medical practitioner.

Explanation- For the purposes of this sub-section, “ears” includes ear drums and ear bones.”

16.5.1 The Section prohibits a hospital from the removal, storage or transplantation of any human organ or association with, or helping in such activities, unless it is registered under this Act.

16.5.2 Some of the experts submitted that removing organs from a cadaver did not require elaborate facilities and infrastructure. Further, if the death occurred in a hospital other than the registered one, then in such a scenario inspite of the relatives being willing to donate the organs, potential donation opportunity was lost if the relatives were told to take the body to nearest registered hospital for this purpose. Similarly, experts in the field of tissue harvesting stated that many of the tissues did not require specialised procedures/technicians for removal. Therefore, it was suggested that due protection needed to be given to tissues in this regard.

16.5.3 The Committee is of the opinion that the whole idea of promotion of cadaveric organ donation would remain on paper if the condition of retrieval of organs only at the registered hospitals is enforced. The fact that the relatives would be hesitant to move the body to a registered hospital due to unnecessary delay, would be a major stumbling block in success of cadaveric donation inspite of willing relatives or pledge of the deceased. The Committee, accordingly, is in full agreement with the argument that unregistered hospitals where the death takes place may be allowed for organ retrieval. However, the organ retrieval should be allowed to be carried out only by the team from a registered hospital after following due process in order to ensure that no irregularities occur leading to illegal activities. For this, registered hospitals for the purpose can be made co-ordinating units in the area with jurisdiction over other small and unregistered hospitals and nursing homes for the purpose of organ retrieval. This can easily be done once the Clinical Establishments (Registration and Regulation) Act is enforced by suitably inserting a provision in this regard. The Committee, therefore, recommends to the Department to make appropriate amendment in this Section in this regard.

16.5.4 The Committee also agrees that surgical tissue residues that are routinely discarded may be stored at a tissue bank for subsequent transplantation. A surgery may take place in any nursing home or hospital which is not engaged in organ transplantation and hence may not be registered under the present Act. In order to utilise such tissues, and other forms of tissues which do not require specialised infrastructure, some kind of exemption is required on the lines of eyes and ears in sub-section (2) above. The Committee, accordingly, recommends suitable exemption of tissues in sub-section (2) of this section. However, details of the exempted tissues may be given in the Rules as it may not be practical to exempt all tissues from the purview on account of their specialised procedures of retrieval.

16.6 AMENDMENT IN SECTION 14

Section 14 which relates to 'Registration of hospitals engaged in removal, storage or transportation of human organs' reads as follows:-

"(1) No hospital shall commence any activity relating to the removal, storage or transplantation of any human organ for therapeutic purposes after the commencement of this Act unless such hospital is duly registered under this Act:

Provided that every hospital engaged, either partly or exclusively, in any activity relating to the removal, storage or transplantation of any human organ for therapeutic purposes immediately before the commencement of this Act, shall apply for registration within sixty days from the date of such commencement:

Provided further that every hospital engaged in any activity relating to the removal, storage or transplantation of any human organ shall cease to engage in any such activity on the expiry of three months from the date of commencement of this Act unless such hospital has applied for registration and is so registered or till such application is disposed of, whichever is earlier.

(2) Every application for registration under sub-section (1) shall be made to the Appropriate Authority in such form and in such manner and shall be accompanied by such fees as may be prescribed.

(3) No hospital shall be registered under this Act unless the Appropriate Authority is satisfied that such hospital is in a position to provide such specialised services and facilities, possess such skilled manpower and equipments and maintain such standards as may be prescribed."

16.6.1 The Section provides for the need of compulsory registration of hospitals engaged in removal, storage or transportation of human organs. With the addition of "tissues" after the present amendment Bill is passed, even hospitals engaged in the removal, storage and transplantation of tissues would be required to be registered under the Act.

16.6.2 During the course of the deliberations, representatives of a prominent Tissue Bank put forth a view that Section 14 (1) needs to be amended in view of the introduction of tissues in the Act. They were of the view that it is necessary to separate the processes of removal, storage and transplantation in case of tissues. It was argued that the tissues removed from living donors as surgical waste in any hospital or nursing home may be donated to tissue banks, where they are stored. In the case of deceased donors any death, even one occurring at home is an occasion for potential donation. Tissues (cornea or skin) can be recovered at home or a funeral home. Similarly, with regard to transplantation, it was stated that tissues could be transplanted even in a clinic (e.g. dental clinic) as an outpatient procedure. These clinics/ nursing homes cannot be required to register under the Act. It was accordingly suggested that procurement organizations may be registered and not the hospitals or facilities donating tissues. Further, in Section 14, "hospital" could be replaced by "hospital or tissue bank".

16.6.3 These suggestions were also found agreeable by the Department, which stated that the same may be included in the Rules.

16.6.4 The Committee is inclined to agree with the arguments put forth before it regarding giving a special treatment/status to tissues here as they differ from the organ, in removal, manner and time of storage and transplantation. However, as the proposed amendments are putting the word "tissues" in the Act itself, the Committee does not find any reason why they should be covered just in Rules as stated by the Department. The Committee also finds merit in the logic that in case of tissues, only Tissue Banks need to be registered. The Committee, accordingly, recommends to the Department to specify broadly the extent of waiver for registration of institutions engaged in tissues removal, storage and transplantation. However, specific tissues which need specific procedures for removal etc. need to be treated differently and status with regard to them can be taken care of in Rules.

17. MISCELLANEOUS

17.1 The Transplantation of Human Organs Act, 1994 was enacted with the objective of regulation of removal, storage and transplantation of human organs for therapeutic purposes and also for the prevention of commercial dealings in human organs. The proposed amendments have been brought forward against the backdrop of the Act not being effective

enough in curbing commercial transactions in organ transplantation complicated and long drawn process of organ donation.

17.2 During the course of the Committee's extensive deliberations with the stakeholders as well as the representation of the Ministry, one disturbing trend which was raised again and again was wide disparity between the demand and availability of human organs in the country. The Committee was given to understand that organ donation rate was only 0.08 per million in our country. Against a requirement of around 1,00,000 eyes donation, availability was only of 38,000. Similarly, only 4,000 kidneys against 1,50,000, only 10 livers against demand of 50,000 and just 43 hearts against a requirement of around 5,000 was being reported. The black marketing or trafficking in organs was mainly attributable to this gap in demand and supply. A viable solution in this regard repeatedly emphasized by experts was that a cadaver could be a source of many organs and tissues that could be retrieved and transplanted in many recipients. It has been stated that even countries like Greece, Poland and Turkey could manage to have 4-6 per million donation rate. It was pointed out that India had 1,00,000 brain death cases in fatal accidents. If the donation rate was increased to 1 per million rate, there would be 1,100 organ donors donating 2,200 kidneys, 1,000 hearts, 1,100 livers and 2,200 eyes.

17.3 Keeping in view the ground realities in the country, the Committee is of the view that it is high time that the Department gives some attention to cadaveric donations, also. The Committee has received some very good suggestions to promote organ donation, particularly cadaveric and accordingly it would like to recommend to the Department to incorporate them while coming up with a revised Bill so as to achieve the larger goals of the Act. Some of the viable suggestions are indicated below:

(1) One of the foremost suggestions that came from across the spectrum of stakeholders was creating opportunities for the public at large to exercise the option of donation of organs through various means. **The Committee finds the idea very healthy and sound as otherwise it is not feasible and practical to enforce "presumed consent" in our multi-cultural society. Taking into account various suggestions, the Committee recommends to the Department to make it mandatory for the citizens of the country to exercise this option during the ongoing exercise of preparing Biometric National ID Card and data registry. This way, it would help in making available a secure data as regards to consent of the donor which can easily be used in case of death. With the passage of time, the Committee hopes that the lost opportunity of potential cadaver donation due to 48 hour mandatory period in case of unclaimed bodies can also be taken care of.**

Another viable option can be exercising the option of organ donation while applying for driving license. The Committee is of the view that this initiative can easily be taken in coordination with the concerned Ministries.

Similarly, all persons while filing their annual income tax returns and paying their property tax can indicate their option for organ donation. Again, the Department would need to coordinate with the concerned Ministries in this regard.

Similar initiative can be taken with regard to CGHS and other medical facility cards.

All the data so collected by the above sources can be utilised to update the proposed donor list, as recommended by the Committee on the lines of National Registry, on regular basis.

(2) The Committee also takes note of the fact that the Department in co-ordination with many State Governments is in the process of setting up of trauma centres on highways across the country. These trauma centres, which receive large number of brain

dead accident victims, may easily be utilised as centres of organ retrieval after following the due process under the Act.

(3) The Committee notes that organ donation is directly related to IEC campaigns. The Committee finds that the citizens of the country lack basic knowledge about organ donation and even educated people do not know how they can donate their organs. Therefore, the Committee recommends to the Department to undertake an intensive publicity drive through IEC activities like pamphlets, advertisements in mass media, small documentaries on TV channels and radio etc in close co-ordination with the State Governments.

(4) In order to promote organ donation, the children and youth of the nation need to be made aware about the issues related with it from the beginning. Therefore, the Department in consultation with the Ministry of Human Resource Development can start compulsory educational material in the curriculum of schools and universities.

(5) In order to promote organ donation, families of cadaveric donors need to be given due recognition. Therefore, all the State Governments may be advised to organise such programmes to facilitate the families of organ donors. Similarly all live donors need to be facilitated by respective State Governments.

(6) The Department should frame a policy to provide free medical facilities to all live donors who donate their organs to unrelated patients.

(7) The Department should try to provide necessary infrastructure so as to ensure that there is at least one registered hospital for the purpose of retrieval, storage and transplantation within say 50-75 Kms. radius in the country.

(8) A National Organ Donation Day may be declared. This would help in generating awareness among people about organ donation. Special functions and camps may be organised to celebrate the day.

(9) In order to generate awareness about organ donation and solve queries of general public in this regard, the Department can also start a national toll free telephone helpline on the pattern of other help lines already functioning like for children and women harassment.