

Bill No. 136 of 2009

THE TRANSPLANTATION OF HUMAN ORGANS (AMENDMENT)
BILL, 2009

A

BILL

to amend the Transplantation of Human Organs Act, 1994.

WHEREAS it is expedient to amend the said law enacted by Parliament relating to regulation of removal, storage and transplantation of human organs for therapeutic purposes and for prevention of commercial dealings in human organs;

AND WHEREAS Parliament has no power to make or amend laws for the States with respect to any of the matters aforesaid except as provided in articles 249 and 250 of the Constitution;

AND WHEREAS in pursuance of clause (1) of article 252 of the Constitution, resolutions have been passed by all the Houses of the Legislatures of the States of Goa, Himachal Pradesh and West Bengal to the effect that the aforesaid Act should be amended by Parliament;

BE it enacted by Parliament in the Sixtieth Year of the Republic of India as follows:—

1. (1) This Act may be called the Transplantation of Human Organs (Amendment) Act, 2009.

Short title,
application
and com-
mencement.

(2) It applies, in the first instance, to the whole of the States of Goa, Himachal Pradesh and West Bengal and to all the Union territories and it shall also apply to such other State which adopts this Act by resolution passed in that behalf under clause (1) of article 252 of the Constitution.

(3) It shall come into force in the States of Goa, Himachal Pradesh and West Bengal and in all the Union territories on such date as the Central Government may, by notification, appoint and in any other State which adopts this Act under clause (1) of article 252 of the Constitution on the date of such adoption; and any reference in this Act to the commencement of this Act shall, in relation to any State or Union territory, means the date on which this Act comes into force in such State or Union territory.

Amendment
of long title.

2. In the Transplantation of Human Organs Act, 1994 (hereinafter referred to as the principal Act), in the long title, for the words "human organs for therapeutic purposes and for the prevention of commercial dealings in human organs", the words "human organs and tissues for therapeutic purposes and for the prevention of commercial dealings in human organs and tissues" shall be substituted. 42 of 1994.

Amendment
of section 1.

3. In section 1 of the principal Act, in sub-section (1), for the words "Human Organs", the words "Human Organs and Tissues" shall be substituted.

Substitution of
references to
certain
expressions by
certain other
expressions.

4. Throughout the principal Act [except clause (h) of section 2], unless otherwise expressly provided, for the words "human organ" and "human organs", wherever they occur, the words "human organ or tissue or both" and "human organs or tissues or both" shall respectively be substituted with such consequential amendments as the rules of grammar may require.

Amendment of
section 2.

5. In section 2 of the principal Act,—

(a) for clause (i), the following clause shall be substituted, namely:—

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

(b) in clause (o), the word "and" shall be omitted;

(c) after clause (o), the following clauses shall be inserted, namely:—

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

(ob) "transplant coordinator" means a person of the hospital appointed for coordinating all matters relating to removal or transplantation of human organs or tissues or both; and’.

Amendment of
section 3.

6. In section 3 of the principal Act,—

(a) after sub-section (1), the following sub-sections shall be inserted, namely:—

"(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.

(1B) 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.";

(b) in sub-section (4), the following proviso shall be inserted, namely:—

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

(c) in sub-section (6), in clause (iii),—

(i) the word "and" shall be omitted; and

(ii) the following proviso shall be inserted, namely:—

"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;"

7. In section 9 of the principal Act,—

Amendment
of section 9.

(a) after sub-section (1), the following sub-sections shall be inserted, namely:—

"(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.

(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.";

(b) after sub-section (3), the following sub-section shall be inserted, namely:—

"(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.";

(c) for sub-section (4), the following sub-section shall be substituted, namely:—

"(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."

8. After section 13 of the principal Act, the following sections shall be inserted, namely:—

"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.

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.

Insertion of new sections 13A, 13B, 13C and 13D.

Advisory Committees to advise Appropriate Authority.

Powers of Appropriate Authority.

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.

National Human Organs and Tissues Removal and Storage Network.

13D. The Central Government shall maintain a national 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."

National registry.

9. In section 14 of the principal Act, after sub-section (3), the following sub-sections shall be inserted, namely:—

Amendment of section 14.

"(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.

(5) The non-governmental organisations, registered societies, charitable trusts and such other entities engaged, either partly or exclusively, in any activity relating to the removal, storage or transplantation of any human organ and tissues for therapeutic purposes, shall immediately apply for registration in such manner as may be prescribed."

10. In section 18 of the principal Act,—

Amendment of section 18.

(a) in sub-section (1), for the words "five years and with fine which may extend to ten thousand rupees", the words "ten years and with fine which may extend to five lakh rupees" shall be substituted;

(b) in sub-section (2), for the words "two years", the words "three years" shall be substituted.

11. In section 19 of the principal Act,—

Amendment of section 19.

(a) after clause (f), the following clause shall be inserted, namely:—

"(g) abets in the preparation or submission of false documents including giving false affidavits to establish that the donor is making the donation of the human organs or tissues or both, as a near relative or by reason of affection or attachment towards the recipient.";

(b) for the words "two years but which may extend to seven years and shall be liable to fine which shall not be less than ten thousand rupees but may extend to twenty thousand rupees", the words "five years but which may extend to ten years and shall be liable to fine which shall not be less than five lakh rupees but may extend to twenty lakh rupees" shall be substituted;

(c) the proviso shall be omitted.

12. In section 20 of the principal Act, for the words "three years or with fine which may extend to five thousand rupees", the words "five years or with fine which may extend to five lakh rupees" shall be substituted.

Amendment of section 20.

13. In section 24 of the principal Act, in sub-section (2),—

Amendment of section 24.

(a) after clause (a), the following clauses shall be inserted, namely:—

"(aa) the human organs or tissues or both under sub-section (1A) and the manner of informing to the Human Organ Removal Centre under clause (iii) of sub-section (1A) of section 3 and the date from which duties mentioned in clauses (i) to (iii) of sub-section (1A) are to apply to a registered medical practitioner working in a Intensive Care Unit of a hospital which is not registered under this Act under sub-section (1B) of that section;

(*ab*) the qualifications and experience of a technician under the proviso to sub-section (4) of section 3;"

(*b*) after clause (*b*), the following clause shall be inserted, namely:—

"(*ba*) the conditions for nomination of a surgeon or a physician and an anaesthetist or intensivist to be included in the Board of medical experts under the proviso to clause (*iii*) of sub-section (6) of section 3;"

(*c*) after clause (*e*), the following clauses shall be inserted, namely:—

"(*ea*) the manner of removal of human organs or tissues or both from the body of a minor before his death for transplantation under sub-section (1B) of section 9;

(*eb*) the composition of the Authorisation Committees under sub-section (4) of section 9;"

(*d*) after clause (*i*), the following clauses shall be inserted, namely:—

"(*ia*) the qualifications of medical experts and the terms and conditions for appointment to Advisory Committee under sub-sections (2) and (3) of section 13A;

(*ib*) the power of the Appropriate Authority in any other matter under clause (*d*) of section 13B;

(*ic*) the manner of establishment of a National Human Organs and Tissues Removal and Storage Network and Regional Network and functions to be performed by them under section 13C;

(*id*) the information in the national registry of the donors and recipients of human organs and tissues and all information under section 13D;"

(*e*) after clause (*k*), the following clauses shall be inserted, namely:—

"(*ka*) the qualifications and experience of a transplant coordinator under sub-section (4) of section 14;

(*kb*) the manner of registration of the non-governmental organisations, registered societies, charitable trusts and such other entities under sub-section (5) of section 14;"

STATEMENT OF OBJECTS AND REASONS

The Transplantation of Human Organs Act, 1994 came into force on the 4th day of February, 1995 in the States of Goa, Himachal Pradesh and Maharashtra and all the Union territories. Thereafter, it has been adopted by all the States except the States of Jammu and Kashmir and Andhra Pradesh which have enacted their own legislation to regulate transplantation of human organs. The main purpose of the Act is to regulate the removal, storage and transplantation of human organs for therapeutic purposes and to prevent commercial dealings in human organs.

2. It has been observed that despite having put into place a regulatory mechanism for transplantation of human organs, there has been a spate of reports in the print and electronic media about thriving human organ trade in India and the consequential exploitation of economically weaker sections of the society. There has, therefore, been an increasing perception in civil society that the said Act has not been effective in curbing commercial transactions in organ transplant and thwarted genuine cases due to the complicated and long drawn process of organ donation.

3. On the above issue, Hon'ble High Court of Delhi in its judgment dated 6-9-2004 in W.P. No. 813 of 2004 Balbir Singh v.s. Union of India and Others constituted a committee to examine the lacunae in implementation of the said Act. The recommendations of the said Committee were examined along with the recommendations of the Rajiv Gandhi Foundation. The draft guiding principles of the organ transplantation prepared by the World Health Organisation were also taken into consideration and after wide consultation, the administrative Ministry proposes to amend the said Act.

4. The amendments proposed, *inter alia*, are as follows:—

(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) amendment of section 3 with a view 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) amendment of section 9 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) insertion of a new section 13A to constitute the Advisory Committees to advise the Appropriate Authorities;

(vi) insertion of a new section 13B to empower the Appropriate Authorities to summon persons, seek production of documents, issue search warrants, etc.;

(vii) insertion of new section 13C 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) amendment of section 14 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) amendment of sections 18, 19 and 20 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.

5. The Bill seeks to achieve the above objectives.

NEW DELHI;

The 17th November, 2009.

GHULAM NABI AZAD

PRESIDENT'S RECOMMENDATION UNDER ARTICLE 117 OF THE CONSTITUTION
OF INDIA

[Copy of letter No. S.12011/13/2007—MS dated the 30th November, 2009 from Shri Ghulam Nabi Azad, Minister of Health and Family Welfare to the Secretary-General, Lok Sabha]

The President, having been informed of the subject matter of the proposed Transplantation of Human Organs (Amendment) Bill, 2009 recommends to the House the consideration of the Bill under article 117(3) of the Constitution.

FINANCIAL MEMORANDUM

Clause 8 of the Bill, *inter alia*, seeks to insert section 13C which empowers the Central Government to establish a National Human Organs and Tissues Removal and Storage Network that links organ retrieval and transplant centres to facilitate exchange of information about availability of organs and data base of recipients which holds the key to the success of any transplant programme. A similar role was expected of Organ Retrieval and Banking Organisation (ORBO). However, experience indicates that ORBO has got confined to the All India Institute of Medical Sciences, Delhi only. Therefore, the need has been felt for the establishment of a nationwide network to maintain a waiting list of patients awaiting transplantation through computerised network and data base. The expenditure on account of procurement and maintenance of electronic equipments and setting up of network with the State Government will have to be borne by the Central Government. The Bill, if enacted, would involve expenditure from the Consolidated Fund of India which may be of both recurring and non-recurring in nature. The estimated total expenditure per annum will be to the tune of rupees five crore.

MEMORANDUM REGARDING DELEGATED LEGISLATION

Sub-clause (a) of clause 6 of the Bill seeks to insert a new sub-section (1A) in section 3 which empowers the Central Government to prescribe human organs or tissues or both for the purpose of their removal, storage or transplantation, the manner in which the hospitals will be required 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 and also the date from which duties mentioned in clauses (i) to (iii) of sub-section (1A) are to apply in the case of a registered medical practitioner working in a Intensive Care Unit of a hospital which is not registered under this Act.

Sub-clause (b) of clause 6 of the Bill seeks to insert a proviso to sub-section(4) of section 3 which empower the Central Government to prescribe qualifications and experience of the technicians to be authorised to remove corneas.

Sub-clause (c) of clause 6 of the Bill seeks to insert proviso after clause (iii) to sub-section (6) of section 3 to prescribe the conditions for the nomination by a registered medical practitioner of a surgeon or a physician and an anaesthetist or intensivist to be included in the Board of medical experts to certify brain-stem death of a person for the purpose of removal of human organs or tissues or both.

Sub-clause (a) of clause 7 of the Bill seeks to insert sub-section (1B) in section 9 which empowers the Central Government to prescribe the manner of removal of organs or tissues or both from the body of a minor before his death for the purpose of transplantation.

Sub-clause (c) of clause 7 of the Bill seeks to amend sub-section (4) of section 9 which empowers the Central Government to prescribe the composition of Authorisation Committee and empowers the State Governments and the Union territories to notify the constitution and terms and conditions of the Authorisation Committees.

Clause 8 of the Bill seeks to insert a new section 13A to the Act which empowers the Central Government and the State Governments to notify the constitution of the Advisory Committee and the Central Government to prescribe the terms and conditions, for appointment to the Advisory Committee to aid and advise the Appropriate Authority in the discharge of its functions.

Clause 8 of the Bill seeks to insert a new section 13B to the Act which empowers the Central Government to prescribe other matters where the Appropriate Authorities can exercise the powers of a civil court.

Clause 8 of the Bill seeks to insert a new section 13C to the Act which empowers the Central Government to notify the establishment of National Human Organs and Tissues Removal and Storage Network and to prescribe the manner of establishment thereof and the functions to be performed by such a Network.

Clause 8 of the Bill seeks to insert a new section 13D to the Act which empowers the Central Government to maintain a national registry of donors and recipients of human organs and tissues and to prescribe information for such registry for an ongoing evaluation of the scientific and clinical status of human organs and tissues.

Clause 9 of the Bill seeks to insert sub-sections (4) and (5) in section 14 which empowers the Central Government to prescribe the qualifications and experience required of the person for his appointment as a transplant coordinator; and to prescribe the manner for registration of non-governmental organisations, registered societies, charitable trusts and such other entities that are engaged in transplantation of human organs and tissues for thereapeutic purposes.

The matters in respect of which notifications may be issued or rules to be made under the aforesaid provisions pertain to procedure or administrative detail and it is not practicable to provide for them in the Bill itself, the delegation of legislative power is therefore of a normal character.

The rules made under the said provisions shall be laid before each House of Parliament.

ANNEXURE

EXTRACTS FROM THE TRANSPLANTATION OF HUMAN ORGANS ACT, 1994

(42 OF 1994)

An Act to provide for the regulation of removal, storage and transplantation of human organs for therapeutic purposes and for the prevention of commercial dealings in human organs and for matters connected therewith or incidental thereto.

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CHAPTER I

PRELIMINARY

Short title,
application
and com-
mencement.

1. (1) This Act may be called the Transplantation of Human Organs Act, 1994.

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Definitions.

2. In this Act, unless the context otherwise requires,—

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(i) "near relative" means spouse, son, daughter, father, mother, brother or sister;

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(o) "therapeutic purposes" means systematic treatment of any disease or the measures to improve health according to any particular method or modality; and

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CHAPTER II

AUTHORITY FOR THE REMOVAL OF HUMAN ORGANS

Authority for
removal of
human organs.

3. (1)

* * * * *

(4) The authority given under sub-section (1) or sub-section (2) or, as the case may be, sub-section (3) shall be sufficient warrant for the removal, for therapeutic purposes, of the human organ; but no such removal shall be made by any person other than the registered medical practitioner.

* * * * *

(6) Where any human organ is to be removed from the body of a person in the event of his brain-stem death, no such removal shall be undertaken unless such death is certified, in such form and in such manner and on satisfaction of such conditions and requirements as may be prescribed, by a Board of medical experts consisting of the following, namely:—

* * * * *

(iii) a neurologist or a neurosurgeon to be nominated by the registered medical practitioner specified in clause (i), from the panel of names approved by the Appropriate Authority; and

* * * * *

Restrictions
on removal
and transplan-
tation of
human organs.

9. (1)

* * * * *

(4) (a) The Central Government shall constitute, by notification, one or more Authorisation Committees consisting of such members as may be nominated by the Central Government on such terms and conditions as may be specified in the notification for each of the Union territories for the purposes of this section.

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

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CHAPTER VI

OFFENCES AND PENALTIES

18. (1) Any person who renders his services to or at any hospital and who, for purposes of transplantation, conducts, associates with, or helps in any manner in, the removal of any human organ without authority, shall be punishable with imprisonment for a term which may extend to five years and with fine which may extend to ten thousand rupees.

Punishment for removal of human organ without authority.

(2) Where any person convicted under sub-section (1) is a registered medical practitioner, his name shall be reported by the Appropriate Authority to the respective State Medical Council for taking necessary action including the removal of his name from the register of the Council for a period of two years for the first offence and permanently for the subsequent offence.

19. Whoever—

Punishment for commercial dealings in human organs.

(a) makes or receives any payment for the supply of, or for an offer to supply, any human organ;

(b) seeks to find a person willing to supply for payment any human organ;

(c) offers to supply any human organ for payment;

(d) initiates or negotiates any arrangement involving the making of any payment for the supply of, or for an offer to supply, any human organ;

(e) takes part in the management or control of a body of persons, whether a society, firm or company, whose activities consist of or include the initiation or negotiation of any arrangement referred to in clause (d); or

(f) publishes or distributes or causes to be published or distributed any advertisement,—

(a) inviting persons to supply for payment of any human organ;

(b) offering to supply any human organ for payment; or

(c) indicating that the advertiser is willing to initiate or negotiate any arrangement referred to in clause (d),

shall be punishable with imprisonment for a term which shall not be less than two years but which may extend to seven years and shall be liable to fine which shall not be less than ten thousand rupees but may extend to twenty thousand rupees:

Provided that the court may, for any adequate and special reason to be mentioned in the judgment, impose a sentence of imprisonment for a term of less than two years and a fine less than ten thousand rupees.

20. Whoever contravenes any provision of this Act or any rule made, or any condition of the registration granted, thereunder for which no punishment is separately provided in this Act, shall be punishable with imprisonment for a term which may extend to three years or with fine which may extend to five thousand rupees.

Punishment for contravention of any other provision of this Act.

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24. (1) * * * * *

Power to make rules.

(2) In particular, and without prejudice to the generality of the foregoing power, such rules may provide for all or any of the following matters, namely:—

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LOK SABHA

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BILL

to amend the Transplantation of Human Organs Act, 1994.

(Shri Ghulam Nabi Azad, M.P.)