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SENATE S.B. No. <u>666</u>

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### Introduced by Senator Loren Legarda

#### **EXPLANATORY NOTE**

This bill seeks to uphold the nobility and dignity of donating human organ and tissue by establishing a unified national system of organ sharing encompassing a donor and patient registry to eliminate for-profit marketing of organ donation and to facilitate the success of organ transplants and survival of patients.

The prevalence of illicit marketing of human organs and tissues for profit in the Philippines, which has become a source of livelihood for some poor families, has drawn the attention of the world in the CNN report last November 6, 2007. Out of the 45,000 urban poor dwellers of Isla Baseco, it is projected that approximately 3,000 have donated a kidney for a price ranging from P70,000.00 to P120,000. Despite this trade being an immediate answer to their desperate need for money, the compensated organ donors may not be fully aware of the long-term health, psychosocial and economic implications of their decisions.

The lucrativeness of the illegal organ trade persists despite the existing regulations that prohibit the same. Though Republic Act No. 7170 or the Organ Donation Act of 1991 has been enacted, the law covers only cadaver donors (CAD) and the concept of brain death. Department of Health Administrative Order No. 124 clearly prohibits the sale and purchase of kidney organs by kidney donors with penalties laid down for violations. Despite these measures, kidney sale is still commonplace in depressed communities.

This bill establishes a system by which valuable human organs and tissues, which are desperately needed by waiting patients of end-stage organ failure could be readily and lawfully obtained and equitably distributed.

In view of the foregoing, the passage of this bill is earnestly sought

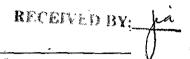
LOREN LEGARDA Senator

# SIXTEENTH CONGRESS OF THE REPUBLIC OF THE PHILIPPINES First Regular Session



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SENATE S.B. No.666



### Introduced by Senator Loren Legarda

# AN ACT TO REGULATE THE DONATION AND TRANSPLANT OF HUMAN ORGANS AND TISSUES AND FOR OTHER PURPOSES

Be it enacted by the Senate and House of Representatives of the Philippines in Congress Assembled:

| 1  |        | SECTION 1. Title This Act shall be known as the "Human Organ and                |
|----|--------|---|
| 2  | Tissue | e Donation and Transplant Act of 2013".   |
| 3  |        |   |
| 4  | . •    | SEC. 2. Declaration of Policy It is hereby declared the policy of the State to: |
| 5  | a)     | Promote public access to multiple human organs and tissues;                     |
| 6  | b)     | Address the technical and ethical issues involved in human organ and tissue     |
| 7  |        | donation and transplantation;   |
| 8  | c)     | Develop policies ensuring fair access to transplant surgery for individuals     |
| 9  | ,      | who without such surgery would be at risk of losing their lives;                |
| 10 | d)     | Devise a system by which valuable human organs and tissues which are            |
| 11 |        | desperately needed by waiting victims of end-stage organ failure could be       |
| 12 |        | readily and lawfully obtained and equitably distributed;                        |
| 13 | · e)   | Motivate the public to become human organ and tissue donors;                    |
| 14 | f)     | Encourage health professionals to identify in a timely manner prospective       |
| 15 |        | donors of human organs and tissues;   |
| 16 | g)     | Encourage and extend support to the laudable initiative and efforts of the      |
| 17 |        | voluntary non-governmental health organizations to encourage our citizens       |
| 18 |        | to become voluntary organ and tissue donors and enable those in need to         |
| 19 |        | benefit from the dramatic achievements and developments in the field of         |
| 20 |        | human organ and tissue transplantation;   |
|    |        |   |

- h) Support and direct the development of a rational and fair national health policy regarding the appropriate government and private sector roles in human organ and tissue donation and transplantation; and
  - i) Prohibit and penalize the for-profit marketing of human organs and tissues.

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#### **SEC. 3.** *Definition of Terms.* – As used in this Act, the term:

- a) "Human Organ and Tissue" refers to the kidney, liver, heart, lung, pancreas, bone marrow, cornea, eye, bone, skin, nerve, muscle tissues, and any other human organ or tissue that may be specified by the Secretary of Health by regulation;
- b) "For-profit Marketing" refers to a transaction whereby a person agrees for valuable consideration in whatever nature or form, whether given or to be given to himself or to another person to the sale or supply of any human organ or tissue from his body or from the body of another person, whether before or after his death or the death of the other person, as the case maybe;
- c) "Valuable Consideration" does not include the reasonable payments associated with the removal, transportation, implantation, processing, preservation, quality control and storage of a human organ or tissue or other hospitalization expenses or the expense of travel, housing and last wage or funeral expenses incurred by the donor of a human organ or tissue in connection with the donation of the organ or tissue. It will not also include any reasonable incentives to be given by the donee or other government or non-governmental organizations;
- d) "Transplant Center" refers to a health care facility in which transplants of organs and tissues are performed.

**SEC. 4.** *For-Profit Marketing.* - The for-profit marketing of human organs and tissues is hereby declared unlawful.

SEC. 5. Human Organ and Tissue Transplantation Coordinating Network (Network). - The Secretary of Health shall encourage the establishment and maintenance of the Human Organ and Tissue Transplantation Coordinating Network in various strategic geographical areas of the country to be determined by the Task Force as hereinafter created.

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| 1   | SEC. 6. Composition The Human Organ and Tissue Transplantation                         |
| 2   | Coordinating Network shall be a non-profit entity which is engaged in activity         |
| 3   | solely related to organ and tissue donation and transplantation. It shall have a Board |
| 4   | of Directors which include representatives of organ and tissue donation and            |
| 5   | transplantation organizations.   |
| 6   |  |
| 7   | SEC. 7. Function of the Network The Network shall establish a list of                  |
| . 8 | individuals in one location who need organs or tissues, and a national system in       |
| . 9 | accordance with established medical criteria, to match organs or tissues and           |
| 10  | individuals included in the list.  |
| 11  | In addition, the Network shall:  |
| 12  | a) Maintain a twenty-four hour telephone service to facilitate matching organs         |
| 13  | or tissues with individuals included in the list;                                      |
| 14  | b) Assist local organ and tissue donation and transplantation organizations in         |
| 15  | the distribution of organs and tissues which cannot be placed within the               |
| 16  | service areas of the organizations;  |
| 17  | c) Adopt and use standards of quality for the acquisition and transportation of        |
| 18  | donated organs and tissues;  |
| 19  | d) Prepare and distribute, on a regionalized basis, samples of blood sera from         |
| 20  | individuals who are included on a list and whose immune system makes it                |
| 21  | difficult for them to receive organs or tissues, in order to facilitate matching       |
| 22  | the compatibility of such individuals with organ and tissue donors;                    |
| 23  | e) Coordinate the transportation of organs and tissues from donation                   |
| 24  | organizations to transplant including those from other countries. In case, the         |
| 25  | latter shall be facilitated in accordance with Section 14 of Republic Act No.          |
| 26  | 7170, otherwise known as the Organ Donation Act of 1991 under the                      |
| 27  | provision on International Sharing of Human Organs or Tissues;                         |
| 28  | f) Provide information to physicians and other health professionals regarding          |
| 29  | organ and tissue donations; and  |
| 30  | g) Collect, analyze and publish data concerning organ and tissue donations and         |
| `31 | transplants.   |
| 32  |  |
| ,33 | SEC. 8. Human Organ and Tissue Transplantation Coordinating Office A                   |
| 34  | human organ and tissue transplantation coordinating office may be established in       |
| 35  | strategic locations in the country subject to the approval of the Secretary of Health. |

Such organization shall:

- a) Be a non-profit entity;
- b) Have an accounting and other fiscal procedures necessary to assure the fiscal stability of the organization;
- c) Have a Board of Directors or Advisory Board, the composition of which shall be determined by the Task Force as may be hereinafter be created;
- d) Have a director and such other staff, including the human organ donation and tissues coordinators and human organ and tissue transplantation specialist necessary to effectively obtain human organs and tissues from donors in its service area.

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- SEC. 9. Functions of the Human Organ and Tissue Transplantation Coordinating Office. A human organ and tissue transplantation coordinating office shall:
  - a) Conduct and participate systematic efforts, including professional education, to acquire all useable organs and tissues from potential donors;
  - b) Arrange for the acquisition and preservation of donated human organs and tissues and provide quality standards for the acquisition of human organs and tissues which are consistent with the standards adopted by the Network;
  - c) Arrange for the appropriate tissue typing of donated human organs;
- d) Have a system to allocate donated human organs and tissues among transplant centers and patients according to medical criteria;
  - e) Participate in the Network authorized to be established under this Act; and
  - f) Make arrangements to cooperate with human organ and tissue banks for the retrieval, processing, preservation, storage and distribution of human organs and tissues as may be appropriate to assure that all useable human organs and tissues are obtained from potential donors.

- SEC. 10. Registry of Recipients/ Report. The Secretary of Health shall require the network to develop and maintain a scientific registry of the recipients of human organ and tissue transplants. The registry shall include such information respecting patients and transplant procedures as he may deem necessary to an ongoing evaluation of the scientific and clinical status of human organ and tissue transplantation.
- The Secretary of Health shall regularly report to Congress on the analysis of information derived from registry.

**SEC. 11.** Advisory Panel or Board. - The Secretary of Health shall form an advisory panel or board in the Department of Health which shall assist him in:

- a) Supervising the private sector in the human organ and tissue donation and transplantation activities provided for in this Act;
- b) Conducting a program of public information to inform the public of the need for human organ and tissue donations;
- c) Providing technical assistance to human organ and tissue transplantation to coordinating offices established in accordance with this Act;
- d) The preparation of an annual report to be submitted to Congress on the status of human organ and tissue donation and coordination services, including an analysis of the efficiency and effectiveness of the donation and allocation of human organs and tissues, a description of problems encountered in the donation and allocation of human organs and tissues, and clinical and scientific status of human organ and tissue transplantation;

**SEC. 12.** *Task Force.* - Within two (2) months from the effectivity of this Act, the Secretary of Health shall establish a Task Force on Human Organs and Tissue Donation and Transplantation (hereinafter referred to as the Task Force).

### SEC. 13. Composition/Appointment and Business. -

- a) The Task Force shall be composed of the following:
  - (1) Five (5) physicians or scientist who are eminent in various medical and scientific specialties related to human organ and tissue transplantation;
  - (2) One (1) person who is not a physician or a scientist and who represents the field of human organ and tissue donation;
  - (3) Three (3) individuals who have expertise in the fields of law, theology, ethics, health care financing and social and behavioral sciences;
  - (4) Two (2) individuals who are not physicians or scientists and who are members of the general public.
- b) The members of the Task Force shall be appointed by the President;
- 31 c) No individual who is a full-time officer or employee of the Philippine 32 Government may be appointed to the Task Force. A vacancy in the Task 33 Force shall be filled in the manner of an original appointment, as provided for 34 in this Act;
- d) The members shall be appointed for the life of the Task Force;
  - e) The Task Force shall elect its Chairman from among its members;

- f) One -half plus one of the members of the Task Force shall constitute a quorum to do business, but may hold hearings;
  - g) The Task Force shall hold its first meeting on the date specified by the Secretary of Health which shall not be later than thirty (30) days from the establishment of the Task Force. Thereafter, the Task Force shall meet at the call of the Chairman or a majority of its members, not less than twelve (12) times during the lifetime of the Task Force.
  - h) The Secretary of Health shall provide the Task Force with administrative and support services as the Task Force may require to carry out effectively its duties.

**SEC. 14.** Honorarium. - The members of the Task Force shall receive honorarium in such amount as the President of the Philippines shall determine for each meeting actually attended by each member of the Task Force, but in no case shall the honorarium exceed the sum of Twenty-Four Thousand Pesos (P24,000.00) for each member for the whole life of the Task Force.

- **SEC. 15.** *Functions.* The Task Force shall perform the following functions:
- a) Conduct comprehensive examinations of the medical, legal, ethical, economic and social issues presented by human organ and tissue donation and transplantation;
- b) Make an assessment of immunosuppressive medications used to prevent organ and tissue rejection in transplant patients, including:
  - 1. An analysis of the safety, effectiveness, and cost (including cost savings from improved success rates of transplantation) of different modalities of treatment.
  - 2. An identification of problems that patients encounter in obtaining immunosuppressive medications;
  - 3. An analysis of the extent of insurance reimbursement for long-therapy for organ and tissue transplant patients by private insurers and the public sector;
  - 4. An analysis of the comparative advantages of grants, coverage under existing programs or other means to assure that individuals who need such medications can obtain them.

c) Make an assessment of public and private efforts to obtain human organs 1 2 and tissues for transplantation and identification of factors that diminish 3 the number of human organs and tissues available for transplantation; d) Make an assessment of problems in coordinating the donation of viable 4 human organs and tissues, including skin and bone for transplantation; 5 e) Make recommendations for the education and training of health 6 7 professionals, including physicians, nurses and hospital and emergency 8 care personnel, with respect to human organ and tissue donation and 9 transplantation; f) Make recommendations for the education of the general public, health 10 workers, the clergy, law enforcement officers, members of the local fire 11 departments and other agencies and individuals that may be instrumental 12 in affecting human and tissue donation; 13 g) Make recommendations for assuring equitable access by patients to organ 14 and tissue transplantation and for assuring equitable allocation of donated 15 human organs and tissues among transplant centers and among patients 16 medically qualified for an organ and tissue transplant; 17 h) Identify the barriers to the donation of human organs and tissues to 18 patients (with special emphasis upon pediatric patients), including an 19 assessment of: 20 Barriers to the improved identification of human organ and tissue 21 donors and their families and organ and tissue recipients; 22 The number of potential human organ and tissue donors and their 23 geographical distribution; 24 3. Current health care services provided for patients who need human 25. organ and tissue transplantation and human organ and tissue donation 26 procedures, systems and programs which affect such patients; 27 Cultural factors affecting the family with respect to the donation of 28 29 human organs and tissues; and 5. Ethical and economic issues relating to human organ and tissue 30 31 needed by chronically-ill patients. 32 i) Make recommendations for the conduct and coordination of continuing research concerning all aspects of the transplantation of human organs 33 34. and tissues; Make an analysis of the factors involved in insurance reimbursement for 35

transplant procedures by private insurers and the public sector; and

k) Make an analysis of the manner in which human organ and tissue transplantation technology is diffused among and adopted by qualified medical centers, including a specification of the number and geographical distribution of qualified medical centers, of whether using such technology is sufficient and of whether the public has sufficient access to medical procedures using such technology.

**SEC. 16.** Designation of Hospitals and Medical Centers. - The Secretary of Health may, upon the recommendation of the Task Force, designate hospitals and medical centers equipped with the appropriate state-of-the-art facilities as training centers for human organ donation and transplantation.

**SEC. 17.** Reports. - The Task Force, not later than three (3) months after its establishment, shall transmit a report to the Secretary of Health and to Congress of its assessment of immune-suppressive medications to prevent organ and tissue rejection.

Not later than six (6) months after it is established, the Task Force shall transmit a final report to the Secretary of Health and the Congress, which shall include -

- a) A description of any findings and conclusions of the Task Force made pursuant to any study conducted under this Act;
- b) Such recommendations as the Task Force considers appropriate.

SEC. 18. Penalty. - Any person who shall buy or sell human organs or tissues for profit-marketing shall, upon conviction suffer the penalty of imprisonment for not less than two (2) years nor more than five (5) years and to pay a fine of not less than Ten Thousand Pesos (P10,000.00), nor more than Fifty Thousand Pesos (P50,000.00), at the discretion of the court: *Provided*, That if the offender is a public officer or belongs to the medical profession, he shall, in addition, suffer the penalty of perpetual absolute disqualification from holding a public office or forfeiture of his license to practice medicine, respectively. Provided further, that if the offender is an alien, he shall be deported after service of sentence without further proceedings.

SEC. 19. Appropriation. - The sum of Three Million Pesos (P3,000,000.00) not otherwise appropriated from the funds of the National Treasury is hereby

| 1    | appropriated to implement the provisions of this Act. Thereafter, the same shall be    |
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| 2    | included in the General Appropriations Act.  |
| `3   |  |
| 4    | SEC. 20. Rules and Regulations The Secretary of Health, after consultation             |
| 5    | with health professionals, both government and private, and non-governmental           |
| 6    | health organizations shall promulgate such rules and regulations as may be             |
| 7    | necessary for the proper implementation of this Act.                                   |
| 8    |  |
| 9    | SEC. 21. Repealing Clause All laws, decrees, ordinances, rules and                     |
| 10   | regulations, executive or administrative orders, and other presidential issuances      |
| 11   | inconsistent with the provisions of this Act are hereby repealed, amended or           |
| 12   | modified accordingly.  |
| · 13 |  |
| 14   | SEC. 22. Separability Clause If any provision of this Act should be declared           |
| 15   | invalid or unconstitutional, other provisions hereof not affected thereby shall remain |
| 16   | in full force and effect.  |
| . 17 |  |
| 18   | SEC. 23. Effectivity This Act shall take effect fifteen (15) days after its            |
| 19   | publication in at least two (2) newspapers of general circulation.                     |
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| 21   | Approved.  |
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