FOURTEENTH CONGRESS OF THEREPUBLIC OF THE PHILIPPINESFirst Regular Session

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SENATE S.B. No. 1958

HECLIVED BY:

Introduced by Senator Loren Legarda

EXPLANATORY NOTE

This bill seeks to uphold the nobility and dignity of donation of human organ and tissue by establishing a unified national system of organ sharing encompassing a donor and patient registry, to minimize, if not eliminate, for-profit marketing of organ and facilitate the success of organ transplantation and survival of patients.

The prevalence of illicit marketing of human organs and tissues for profit in the Philippines, which has become a livelihood source for some poor families, has drawn the attention of the world in the CNN report last November 6, 2007 on kidney sale in the country. Out of the 45,000 urban poor dwellers of Isla Baseco, it is projected that approximately 3,000 have donated one of their kidneys in exchange for a price ranging from P70,000 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.

A study conducted at Kermanshah University of Medical Sciences in Iran of 300 kidney vendors 6 to 132 months after the transplant findings show that 90% of the vendors complained of impaired physical ability and ill-health which includes palpitations, chest pains, backache, nervousness and fatigue; 65% reported that the sale of their kidney has led to negative effects on their employment; 38% representing largely uninsured manual laborers had lost their jobs as they were unable to continue working at the same job after the transplant; and 70% suffered from post-operative depression. But for a needy person, a hundred thousand pesos makes it difficult to say no and think of what is best for him in the long run. In view of this, there is an urgent call to prevent organ donations from being commercialized and protecting potential organ donors from the negative consequences of illegal organ trade.

Another problem in organ transplant is the unfair allocation of organ and tissue donations. At present, the highest bidder for an organ obtains a status of privilege because of his wealth. At least 30,000 Filipinos have diseased kidneys, but many of them cannot afford the expense of transplantation, widely regarded by the World Health Organization as the best solution to end-stage organ failure. In five leading hospitals in Manila, including the state-run National Kidney and Transplant Institute, about 250 kidney transplants are performed every year, many of them for wealthy Filipino families and foreigners. According to the New England Journal of Medicine, Americans – about 200-300 a year – go to China, the Philippines and South America for transplants. Moreover, according to Norbert Lameire of the International Society of Nephrology, the United Arab Emirates sends its kidney patients to the Philippines for transplants. From WHO estimates, the Philippines hosted up to 200 "transplant tourists" in the recent years. Of the 468 kidney transplants in the country in 2003 alone, 110 were for patients from abroad.

The lucrativeness of the illegal organ trade persists despite the existing regulations that prohibit the same. Though we already enacted Republic Act No. 7170 or the Organ Donation Act of 1991, the law covers only cadaver donors (CAD) and the concept of brain death. Department of Health Administrative Order No. 124 clearly states that the sale and purchase of kidney organs by kidney donors is prohibited. Penalties for violations are also laid down in this issuance. In spite of these measures, kidney sale still is a commonplace in depressed communities, proving that we need a strong proposal that will put an end to this.

This bill establishes a system by which valuable human organs and tissues which are desperately needed by waiting victims of end-stage organ failure could be readily and lawfully obtained and equitably distributed. Some of the salient features of this bill are the following:

- 1. The establishment and maintenance of a Human Organ and Tissue Transplantation Coordinating Network. This shall be a national system that will facilitate the locating of a possible donor of human organs and tissue to individuals who are in need of receiving life-saving organ transplantation. Further, the Network will coordinate the transportation of organs and tissues from donation organizations to transplant including those from other countries.
- 2. The formation of Human Organ and Tissue Transplantation Coordinating Office in strategic locations in the country which will 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.
- 3. The creation of a Task Force which will conduct a study on all issues and common problem areas in the human organ and tissue donation and transplantation.
- 4. The prohibition and punishment of individuals engaged in the marketing of human organs and tissues for profit.
- 5. The enhancement and promotion of programs for organ and tissue donations.

The problem of for-profit marketing and unfair distribution of organ and tissue donations will persist or even aggravate if not properly addressed with a legislation that answers the need for an effective regulation of the practice of human organ donation and tissue transplantation.

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

LOREN LEGARDA Senator

FOURTEENTH CONGRESS OF THE) REPUBLIC OF THE PHILIPPINES) First Regular Session

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HECHIVED BY :_____

SENATE S.B. No. <u>19</u>58

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:

SECTION 1. *Title. – This* Act shall be known as the "Human Organ and Tissue Donation and Transplant Act of 2007".

SEC 2. *Declaration of Policy* – It is hereby declared national policy of the State to:

- (a) Promote public access to multiple human organs and tissues;
- (b) Address the technical and ethical issues involved in human organ and tissue donation and transplantation;
- (c) Develop policies ensuring fair access to transplant surgery for individuals who without such surgery would be at risk of losing their lives;
- (d) Devise a system by which valuable human organs and tissues which are desperately needed by waiting victims of end-stage organ failure could be readily and lawfully obtained and equitably distributed;
- (e) Motivate the public to become human organ and tissue donors;
- (f) Encourage health professionals to identify in a timely manner prospective donors of human organs and tissues;
- (g) Encourage and extend support to the laudable initiative and efforts of the voluntary non-governmental health organizations to encourage our citizens to become voluntary organ and tissue donors and enable those in need to

benefit from the dramatic achievements and developments in the field of 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.

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 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

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various strategic geographical areas of the country to be determined by the Task Force as hereinafter created.

SEC 6. *Composition.* The Human Organ and Tissue Transplantation Coordinating Network shall be a non-profit entity which is not engaged in any activity not related to organ and tissue donation and transplantation, and shall have a Board of directors which include representatives of organ and tissue donation and transplantation organizations.

SEC 7. *Function of the Network.* - The Network shall establish a list of individuals in one location who needs organs or tissues, and a national system in accordance with established medical criteria, to match organs or tissues and individuals included in the list especially individuals whose immune system makes it difficult for them to readily or successfully receive organs or tissues.

In addition, the Network shall:

- (a) Maintain a twenty-four hour telephone service to facilitate matching organs or tissues with individuals included in the list;
- (b) Assist local organ and tissue donation and transplantation organizations in the distribution of organs and tissues which cannot be placed within the service areas of the organizations;
- (c) Adopt and use standards of quality for the acquisition and transportation of donated organs and tissues;
- (d) Prepare and distribute, on a regionalized basis, samples of blood sera from individuals who are included on a list and whose immune system makes it difficult for them to receive organs or tissues, in order to facilitate matching the compatibility of such individuals with organ and tissue donors;
- (e) Coordinate the transportation of organs and tissues from donation organizations to transplant including those from other countries. In case, the latter shall be facilitated in accordance with Section 14 of Republic Act No. 7170, otherwise known as the Organ Donation Act of 1991 under the provision on International Sharing of Human Organs or Tissues;
- (f) Provide information to physicians and other health professionals regarding organ and tissue donations; and

(g) Collect, analyze and publish data concerning organ and tissue donations and transplants.

SEC 8. Human Organ and Tissue Transplantation Coordinating Office. - A human organ and tissue transplantation coordinating office may be established in 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.

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 on-going 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 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:

- 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 represent the field of human organ and tissue donation;

- (3) Three (3) individuals who are not physicians and who as a group 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 which need not be submitted for confirmation by the Commission on Appointments;
- (c) No individual who is a full-time officer or employee of the Philippine Government may be appointed by the Task Force. A vacancy in the Task Force shall be filled in the manner of an original appointment, as provided for 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 but shall meet at least 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 -

- 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 and tissues for transplantation and identification of factors that diminish the number of human organs and tissues available for transplantation;
- (d) Make an assessment of problems in coordinating the donation of viable human organs and tissues, including skin and bone for transplantation;
- (e) Make recommendations for the education and training of health professionals, including physicians, nurses and hospital and emergency care personnel, with respect to human organ and tissue donation and transplantation;
- (f) Make recommendations for the education of the general public, health workers, the clergy, law enforcement officers, members of the local fire departments and other agencies and individuals that may be instrumental in affecting human and tissue donation;
- (g) Make recommendations for assuring equitable access by patients to organ and tissue transplantation and for assuring equitable allocation of donated human organs and tissues among transplant centers and among patients medically qualified for an organ and tissue transplant;
- (h) Identify the barriers to the donation of human organs and tissues to patients (with special emphasis upon pediatric patients), including an assessment of:
 - 1. Barriers to the improved identification of human organ and tissue donors and their families and organ and tissue recipients;
 - 2. The number of potential human organ and tissue donors and their geographical distribution;

- 3. Current health care services provided for patients who need human organ and tissue transplantation and human organ and tissue donation procedures, systems and programs which affect such patients;
- 4. Cultural factors affecting the family with respect to the donation of human organs and tissues; and
- 5. Ethical and economic issues relating to human organ and tissue needed by chronically-ill patients.
- (i) Make recommendations for the conduct and coordination of continuing research concerning all aspects of the transplantation of human organs and tissues;
- (j) Make an analysis of the factors involved in insurance reimbursement for 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.* - Not later than three (3) months after the Task Force is established, shall transmit a report to the Secretary of Health and to Congress its assessments of immune-suppressive medications to prevent organ and tissue rejection.

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

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

SEC 18. *Penalty.* - Any person who shall buy and 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, he shall, in addition, suffer the penalty of perpetual absolute disqualification from holding a public office. Provided further, that if the offender is an alien, he shall be deported 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 appropriated to implement the provisions of this Act. Thereafter, the same shall be included in the General Appropriations Act.

SEC 20. *Rules and Regulations.* - The Secretary of Health, after consultation with health professionals, both government and private and nongovernmental health organizations shall promulgate such rules and regulations as may be necessary for the proper implementation of this Act.

SEC 21. *Repealing Clause.* - All laws, decrees, ordinances, rules and regulations, executive or administrative orders, and other presidential issuances inconsistent with the provisions of this Act are hereby repealed, amended or modified accordingly.

SEC 22. *Separability Clause.* - The provisions of this Act are hereby deemed separable. If any provision hereof should be declared invalid or unconstitutional, the remaining provisions shall remain in full force and effect.

SEC 23. *Effectivity.* - This Act shall take effect after fifteen (15) days following its publication in at least two (2) newspapers of general circulation.

Approved.