

Republic of the Philippines
HOUSE OF REPRESENTATIVES
Quezon City

SEVENTEENTH CONGRESS
Second Regular Session

HOUSE BILL NO. 6890



Introduced by **HON. LUIS RAYMUND "LRAY" F. VILLAFUERTE, JR.**

EXPLANATORY NOTE

In the year 1978, stem cells were discovered. Despite the controversies marring its earlier development including cloning, embryo harvesting, and fabricated research, stem cell science has become the standard of care in certain procedures that require the natural creation of new cells such as bone marrow transplants and spinal cord rehabilitation,¹ and some forms of cancer. The past decade has seen this new branch of science effective in treating stroke, autism, Parkinson's disease, disease, 3rd degree burns, spinal injuries and other ailments both common and rare. Diseases, like Parkinson's, once thought incurable, are now possible thanks to stem cell treatment. Stem cell research has become a major breakthrough in the field of biotechnology and its applications remain inexhaustible.

To date, stem cell treatment is offered only in four hospitals in the Philippines.² Moreover, the cost of the treatment is staggering. Hence, promise of stem cell treatment as a common procedure remains unknown. There is much to be learned from its benefits, how it may be applied to other "incurable diseases" as viable treatment and rehabilitation. It would need more intensive research, including clinical trials, and funding for the fledgling practice to grow. With the proper government intervention, stem cell practice may be enhanced and made accessible to the public.

However, Philippine society must also remain guarded against the rapid proliferation of clinics, and establishments falsely offering stem cell products and procedures. This can cause possible negative effects of untested and unregulated practice. There is also the question of retaining ethical integrity when practicing stem cell treatment and harvesting. Stem cells can be harvested from a variety of sources

¹ <http://www.explorestemcells.co.uk/historystemcellresearch.html>

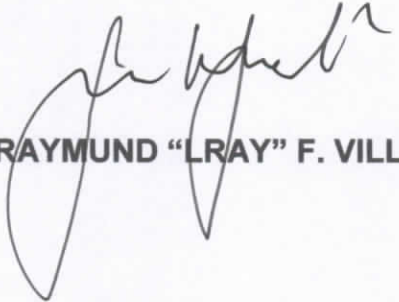
² <http://www.philstar.com/headlines/2016/01/29/1547448/4-philippine-hospitals-can-perform-stem-cell-procedures>

such as adult bone marrow, peripheral blood, umbilical cord, and, the most controversial of all, embryos.³

Stem cells harvested from embryos have the capability of transforming and multiplying into the most number of cell types known to man. The more cell types a stem cell can transform into, the more viable it is in treating various diseases. However, they are also harvested from the blastula, one of the earliest stages of human life.⁴ Because of where it is harvested from and the controversy surrounding it, embryonic stem cells are discouraged and outright banned in some countries but we do not have such regulations here. Hence, there is a need for the government to regulate stem cell research and those involved in its practice.

This bill seeks to intensify stem cell research and therapy in the Philippines. The bill intends to establish a Bioethics Advisory Board (BAB) to formulate the ethical standards that will guide the Institutional Review Committee. The Board shall be responsible for addressing contentious ethical, scientific, and legal issues in stem cell and cell-based research and therapies. Under this bill, stem cell research and therapies shall undergo IRC approval in accordance with the guidelines of the Department of Health (DOH) in the manual of Standard Operating Procedures for Hospital Ethics Review Committees.

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



LUIS RAYMUND "LRAY" F. VILLAFUERTE, JR.

³ Available URL: <http://www.cancer.ca/en/cancer-information/diagnosis-and-treatment/stem-cell-transplant/harvesting-stem-cells/?region=on>

⁴ a fertilized egg grows into a blastula (~100 cells) which only survive for a short time before it must be implanted in a womb. (<https://www.eurostemcell.org/embryonic-stem-cell-research-ethical-dilemma>)

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Introduced by HON. LUIS RAYMUND "LRAY" F. VILLAFUERTE, JR.

AN ACT
INTENSIFYING STEM CELL RESEARCH AND THERAPY IN THE PHILIPPINES
AND FOR OTHER PURPOSES

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

SECTION 1. *Short Title.* – This Act shall be known and cited as the "Stem Cell Research and Therapy Act of 2017."

SECTION 2. *Declaration of Policy.* – It shall be the policy of the State to protect and promote the people's right to life and health. For this purpose, the State shall intensify human stem cell research on medical interventions that are evidence-based under an effective food and drug regulatory system which will undertake appropriate health manpower for research and development responsive to the country's health needs and problems essential for national development and progress. As such, priority will be given to research and development, and invention, innovation and utilization without prejudice to the human embryo.

SECTION 3. *Scope and Coverage.* – The provisions of this Act shall apply to all government and private facilities that are and will be involved in the use of human stem cell and cell-based therapies.

SECTION 4. *Definition of Terms.* – For the purpose of this Act, the following terms and phrases shall have the following definitions:

1. Adverse Event – a noxious and unintended response suspected or demonstrated to be caused by the collection or infusion of a cellular therapy product or by the product itself.
2. Allogeneic – refers to cells obtained from a donor and intended for infusion into a genetically distinct recipient.

3. Autologous – refers to cells obtained from a patient and intended for infusion into a patient.
4. Bioethics Advisory Board (BAB) – the national body to examine the scientific, ethical, legal, and social issues arising from biomedical research and development and recommends policies on stem cell and cell-based or cellular research and therapies in the Philippines.
5. Cellular Therapy – the administration of products with the intent of providing effector cells in the treatment of disease or support of other therapy.
6. Clinical Laboratory – a facility where tests are done on specimens from the human body to obtain information about the health status of a patient for the prevention, diagnosis and treatment of diseases. The tests include, but are not limited to, the following disciplines: clinical chemistry, hematology, immunohematology, molecular biology and cytogenetics. The total testing process includes pre-analytical, analytical and post-analytical procedures. Facilities that are involved in the pre-analytical processes such as collection, handling or preparation of specimens or act as a mailing or distribution center such as in a laboratory network or system are also considered to be a part of a clinical laboratory.
7. Donor – a person who is the source of cells or tissue for a cellular therapy product.
8. Expansion – refers to growth of one or more cell populations in an in vitro culture system.
9. Facility – a location where activities covered by these Standards are performed. Such activities include determination of donor eligibility suitability, product collection, processing, storage, distribution, issue and administration. A facility, under this Act may be any or all of the following:
 - a. Collection Facility – an entity providing the service of cellular therapy product collection.
 - b. Processing Facility – a location where cellular therapy product processing activities are performed in support of the Clinical Program.
 - c. Storage Area/Facility – an entity holding a cellular therapy product for future processing, distribution or administration.
10. Genetic Manipulation – refers to an ex vivo procedure(s) that genetically alters cell populations. A significant stem cell manipulation involves any process that alters the biological and/or physiological characteristics of cells or tissues including introduction of viral genes and other genetic processes that incorporate exogenous genetic material into the genome of the recipient cells.

12. Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps) – articles containing or consisting of human cells or tissues that are intended for implantation, transplantation, infusion or transfer into a human recipient.
13. Institutional Reviews Committee (IRC) – a Committee established by an institution in accordance with the regulations of the relevant governmental agency to review biomedical and behavioral research that involves human subjects and is conducted at or supported by that institution.
14. Philippine Food and Drug Administration (Phil. FDA) – the agency of DOH in the Philippines charged with the regulation of stem cell and cell-based or cellular products.
15. Prohibited – refers to procedures, preparations or products that shall not be allowed or permitted for development or commercial use without exemption. These are banned or forbidden by law.
16. Restricted – refers to procedures, preparations or products that shall not be allowed unless a prior regulatory approval is obtained. These are controlled by law or rules and limited to authorized activities. These are stem cell products that have genetic manipulation.
17. Registered and Permitted – refers to procedures, preparations and products allowed to be in trade by the Phil.FDA, and in facilities with prior DOH accreditation. These are certified officially and legally by the government office for specific activities. These are stem cell products that do not have a genetic manipulation.
18. Standard Operating Procedures (SOP) – refers to a compilation of written policies and detailed instructions required to perform the defined activities of the accredited facilities.
19. Stem Cell – undifferentiated cells from multicellular organisms that have the capacity to divide and differentiate into different types of cells found in the body.

SECTION 5. *Bioethics Advisory Board.* – Health facilities engaged in stem cell and cell-based or cellular therapies shall comply with the guidelines set by BAB.

- a. The Board Shall be comprised of, but not limited to, the following:
 1. Chairperson – Secretary of Health / National Transplant Ethics Committee (NTEC)
 2. Vice-chairperson – Director of Phil.FDA
 3. Members:
 - a. Representative from a government health facility or organization;
 - b. Representative from a private health facility or organization;
 - c. Academicians, researchers, local and international experts.

- b. The Board shall be responsible in formulating the ethical standards which shall guide the IRC that shall be created in hospitals and other health facilities using human stem cell and cell-based or cellular therapies.
- c. The Board shall be responsible in addressing contentious ethical, scientific and legal issues in stem cell and cell-based or cellular research and therapies.

SECTION 6. *Institutional Review Committee (IRC).* – Stem cell and cell-based or cellular research and therapies shall undergo IRC approval in accordance with the current guidelines set by DOH in the manual of “Standard Operating Procedures for Hospital Ethics Review Committees”. The Committee shall be responsible for reviewing and verifying the following:

- a. Ethical aspect of the research and therapy;
- b. Scientific rationale, design and data collection on safety and efficacy of stem cell and cell-based or cellular therapy programs;
- c. Assurance and certification that the institution or clinical laboratory does not carry out activities or programs involving the Prohibited Stem Cells specified in Section 7 (a) of this Act;
- d. Documentation and reporting of adverse events observed in patients receiving stem cell and cell-based or cellular treatments.

SECTION 7. *Prohibited Restricted and Permitted Activities for Stem Cell Preparation and Therapy.* –

- a. *Prohibited* – The following stem cell preparations and therapies shall be prohibited from creation, importation, promotion, marketing and use.
 - 1. Creation of human embryos for research purposes;
 - 2. Human embryonic stem cells and their derivatives for human treatment and research;
 - 3. Aborted human fetal stem cells and their derivatives for human treatment and research;
 - 4. Plant parts labeled as stem cells.
- b. *Restricted* – The following stem cell preparation and therapies shall not be allowed for importation, promotion, marketing and use in humans without prior regulatory application and approval from Phil.FDA.:
 - 1. Genetically altered human adult stem cells for human treatment;
 - 2. Genetically altered human umbilical cord stem cells for human treatment;
 - 3. Adipose (Fat) derived human stem cell;
 - 4. Any human cells, tissues, and cellular and tissue-based products (HTC/PS) that are subjected to genetic manipulation, as defined in Section 4 of this Act;
 - 5. Live animal (xenobiotic) embryonic, fetal or adult stem cells in parenteral form for human administration.

c. *Registered and Permitted* – the following stem cell preparations and therapies may be performed only in health facilities accredited by DOH:

1. Adult Human stem cells (autologous) – extracted from the same patient. It may undergo basic processing (including separation, fractionation, primary culture, expansion) but without genetic modification.
2. Adult human stem cells (allogeneic) – extracted from a human donor. It may be followed by basic processing including separation, fractionation, primary culture, expansion) but without genetic modification. It requires Human Leukocyte Antigen (HLA) compatibility testing and infectious screening as is used with organ transplants or blood transfusions.
3. Human umbilical cord stem cells – includes stem cells derived from umbilical cord blood and other stem cells derived from umbilical cord, placenta and placental membrane extracted at time of birth. It may be followed by basic processing (including separation, fractionation, primary culture, expansion) but without genetic modification. It requires HLA compatibility testing, if used allogeneically, and infectious screening as is used with organ transplants or blood transfusions.

SECTION 8. *Implementing Rules and Regulations.* – Within ninety (90) days from effectivity of this Act, the Department of Health shall formulate the Implementing Rules and Regulations.

SECTION 9. *Appropriations.* – There is hereby appropriated the amount of Ten Million Pesos (PhP10,000,000.00) out of any appropriated funds in the National Treasury for such initial requirements for the implementation of this Act.

SECTION 10. *Repealing Clause.* – All laws, decrees, orders, rules and regulations and other issuances, or parts thereof, which is inconsistent with the provisions of this Act are hereby repealed or amended accordingly.

SECTION 11. *Effectivity.* – This Act shall take effect fifteen (15) days following its publications in two (2) newspapers of general circulation.

Approved,