

Republic of the Philippines
HOUSE OF REPRESENTATIVES
Quezon City

SIXTEENTH CONGRESS
First Regular Session

HOUSE BILL NO. 212



Introduced by HON. EUFRANIO C. ERIGUEL, M.D.

EXPLANATORY NOTE

This Bill, which was previously filed in the 15th Congress, seeks to intensify stem cell research and therapy in the Philippines.

Stem cell science has been in existence for almost half a century and is already the standard of care in certain procedures such as bone marrow transplants. The past decade has seen this new and innovative science reach new heights and has been proven to be effective in treating diseases such as stroke, autism, Parkinson's, diabetes, spinal cord injury and a host of other ailments, both common and rare. Diseases once considered as incurable are responding well to stem cell treatment and are restoring hope to patients who thought they had lost their lives forever.

As of now, the full promise of stem cell treatment remains unknown. There is much to be learned from its benefits and application in the cure of some of the most devastating diseases and conditions, hence more intensive research, including clinical trials, needs to be done to further discover its uses and to develop novel techniques and more promising procedures. Though the benefits of stem cell treatment are a major breakthrough in the field of biotechnology, the cost far outweighs its benefits. It is very expensive and only a few physicians are trained to do stem cell procedures here in the Philippines. With the proper government intervention, stem cell practice may be enhanced and be made accessible to the public while also regulating the people and institutions involved in its practice.

On the other hand, the layman also needs to be guarded against the rapid proliferation of clinics and establishments claiming to offer stem cell products and procedures for the possible negative effects of untested and unregulated practice. Hence there is an urgent necessity for the proper government agencies to govern the accreditation or licensing of health facilities and practitioners to ensure access to safe and reliable stem cell therapies.

In response, this Bill seeks to intensify stem cell research and therapy in the Philippines by conducting research and trials under established standards of open scientific exchange, peer review, and public oversight. Aside from this, it seeks to promote research and human clinical trials using stem cells that are ethically obtained and show evidence of providing clinical benefit for human patients; promote the derivation of stem cell lines without the creation of human embryos for research purposes nor the destruction of, discarding of, or risk of injury to, an existing human embryo.

Such an act will make the country a haven for open scientific inquiry and technological innovation, and will promote investment and generate jobs. Further on, the Philippines may become known as a hub for medical tourism, with the surging increase of foreigners to come in for stem cell therapy that some hospitals in the country may offer at a much cheaper cost but with highest quality.

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



EUFRANIO "FRANNY" C. ERIGUEL, M.D.

Second District, La Union

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Introduced by **HON. EUFRANIO C. ERIGUEL, M.D.**

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 2013.”

SEC. 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.

SEC. 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 or cellular therapies.

SEC. 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 that 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. Department of Health (DOH)
8. Donor - a person who is the source of cells or tissue for a cellular therapy product.
9. Expansion - refers to growth of one or more cell populations in an in vitro culture system.
10. 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.
11. 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 Review 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 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.

SEC. 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.

SEC. 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 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.

SEC. 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 preparations 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 (HCT/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.
4. Human organ-specific cells.

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

SEC. 9. *Appropriations.* – There is hereby appropriated the amount of Ten Million Pesos (P 10,000,000.00) out of any appropriated funds in the National Treasury for such initial requirements for the implementation of this Act.

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

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

Approved,