

Republic of the Philippines
HOUSE OF REPRESENTATIVES
Quezon City, Metro Manila

SIXTEENTH CONGRESS
First Regular Session



HOUSE BILL NO. 732

Introduced by **CHRISTOPHER S. CO** and **RODEL M. BATOCABE**

EXPLANATORY NOTE

This bill seeks to strengthen, rationalize and professionalize the practice of stem cell therapy. It seeks to create the Professional Regulatory Board of Stem Cell Therapy and the Philippine Society of Stem Cell Medicine as integrative and professionalizing units to improve stem cell therapy practice in the Philippines.

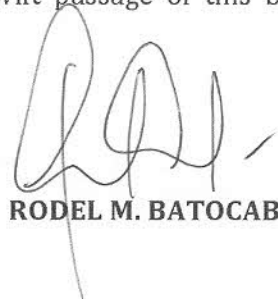
Countries like the United States, South Africa and Singapore have discovered the potential in health and medical research to find solutions to diseases such as cancer, heart attacks and other cardiovascular anomalies, Parkinson's and different birth defects.

With the increasing number of Filipinos suffering from terminal and extreme diseases, finding a medical breakthrough for their cure should be prioritized. The establishment of a stem cell research and storage center is the first step towards addressing this concern. It restores the hopes of Filipino patients who may have lost the chance to live a normal life again.

At the same time, because this is a young and novel practice, there is a need for government regulation to protect the public from abusive and unlearned practice of stem cell therapy. There have been many cases of unauthorized practice of stem cell therapy in the Philippines and abroad which have deceived hopeful patients into letting go of hard-earned money. Such unauthorized practices may also lead to deleterious effects to the health and welfare of patients.

In light of all these circumstances, the swift passage of this bill is earnestly sought.


CHRISTOPHER S. CO


RODEL M. BATOCABE

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HOUSE BILL NO. _____

Introduced by **RODEL M. BATOCABE** and **CHRISTOPHER S. CO**

AN ACT
STRENGTHENING, RATIONALIZING AND PROFESSIONALIZING THE PRACTICE OF
STEM CELL THERAPY AND CREATING FOR THIS PURPOSE A PROFESSIONAL
REGULATORY BOARD OF STEM CELL THERAPY, UPGRADING STEM CELL AND
CELL-BASED THERAPY EDUCATION, INTEGRATION OF PRACTITIONERS, AND FOR
OTHER PURPOSES

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

ARTICLE I
TITLE, DECLARATION OF POLICY, DEFINITION OF TERMS

Section 1. **Short Title.** – This Act shall be known as the “Stem Cell Therapy Professionalization Act of 2013.”

Section 2. **Declaration of Policy.** The State recognizes the essential role of stem cell or cell-based therapy as a profession in safeguarding and enhancing the health and general physical well-being of the citizenry. Such services shall therefore be promoted as a regular component of the primary health care system.

Section 3. **Definition of Terms.** – For the purpose of this Act, the following terms shall refer to and/or mean as hereunder defined:

- (a) **“Stem Cell”** is the primary cell in the human body from which all other cells with specialized functions are generated.
- (b) **“Stem Cell Therapy”** is an intervention strategy that introduces new adult stem cells into damaged tissue in order to treat disease or injury. It is done through the collection of specimen from the patient or any other human or non-human source, such as but not limited to, adipose tissue, bone marrow and umbilical cord, the processing of the stem cells in a laboratory, and injected intravenously, intramuscularly or subcutaneously to the patient, and thereafter the injected stem cells follow inflammatory signals from damaged tissues to repair the said areas.
- (c) **“Certificate of registration”** refers to a document signed by the Chair of the PRC and by all members of the Board of Stem Cell Therapy and bearing its seal, issued to an applicant who has satisfied the requirements for the

practice of stem cell therapy. It shall serve as proof that the registrant is qualified to practice the respective profession in the Philippines.

- (d) **"Professional license"** refers to a renewable card issued by the PRC to a stem cell therapy practitioner indicating that s/he is competent and authorized to practice stem cell or cell-based therapy in the Philippines. Until the loss of its validity or its expiration, such license shall serve as evidence that its bearer is a stem cell therapy practitioner in good standing.
- (e) **"Code of Professional Ethics"** refers to a set of standards relating to the conduct, integrity and moral duties of practitioners, as prescribed by the Philippine Society of Stem Cell Medicine as the duly integrated and accredited national organization of stem cell therapy practitioners, and adopted and promulgated by the Board of Stem Cell Therapy upon approval by the PRC.

ARTICLE II

THE PRACTICE OF STEM CELL THERAPY

SECTION 4. Acts Constituting the Practice of Stem-Cell Therapy. Any of the following acts constitute the practice of stem cell therapy:

- (a) The intravenous, intramuscular or subcutaneous injection of stem cells into a patient, whether for a valuable consideration or not, for the purpose of regeneration or repairing damaged tissues in the body;
- (b) The collection of specimen stem cells from any person or non-human source to process in a laboratory for the purpose of injecting it to a human patient to regenerate and/or repair damaged tissues in the body;
- (c) The selection, prescribing and dispensing medicine and treatments in addition to or related to stem cell therapy;
- (d) The counseling of patients regarding their diagnoses and recommending stem cell therapy as treatment for their health complications;
- (e) The use of specific instruments, tools, equipment, implements, aids, apparatuses, machines, exercises and related devices, for the purpose of determining the condition of a patient for the purpose of ascertaining whether stem cell therapy is a possible alternative treatment;
- (f) The establishment of offices, clinics, and similar places where stem cell therapy services are offered;
- (g) The collection of professional fees for the performance of any of the acts mentioned in the preceding paragraphs of this section.

This provision shall not apply to students of stem cell therapy undergoing practical training in a legally constituted school or college under the direction or supervision of a member of the faculty who is duly licensed to practice stem cell therapy in the Philippines.

SECTION 5. Prohibition Against the Unauthorized Practice of Stem Cell Therapy. No person shall practice stem cell therapy as defined in Section 4 of this Act nor perform any of the acts constituting the practice of stem cell therapy as set forth in Section 4

prohibition shall not apply to regularly licensed and duly registered physicians who have received post-graduate training in stem cell therapy.

SECTION 6. Disclosure of Authority to Practice. A stem cell therapy practitioner shall be required to indicate his or her professional license number and the date of its expiration in the documents he/she issues or signs in connection with the practice of his/her profession. S/he shall also display his/her certificate of registration in a conspicuous area of his/her clinic or office.

ARTICLE III THE PROFESSIONAL REGULATORY BOARD OF STEM CELL THERAPY

SECTION 7. The Professional Regulatory Board of Stem Cell Therapy. There is hereby created a Professional Regulatory Board of Stem Cell Therapy, hereinafter referred to as the Board, composed of five (5) members who shall be appointed by the President of the Philippines, upon the recommendation of the PRC, from a list of ten (10) nominees submitted by the duly integrated and accredited national organization of stem cell therapy practitioners, the Philippine Society of Stem Cell Medicine.

SECTION 8. Minimum Qualifications of Board Members. Only persons possessed with the following qualifications may be nominated and appointed to the Board:

- (a) A natural-born citizen of the Philippines;
- (b) A medical doctor and a duly-registered stem cell therapy practitioner in good standing holding a valid Certificate of Registration; provided, that in the case of the first members of the Board, they shall be issued Certificates of Registration as stem cell therapy practitioners without prior examination;
- (c) At least thirty-five (35) years of age at the time of his or her appointment;
- (d) Of good moral character; and
- (e) In active practice of the profession for at least ten (10) years prior to his or her appointment; provided, that for purposes of creating the initial Board, active practice of the profession for at least five (5) years prior to his or her appointment will suffice; provided, further, that a person who is a member of the faculty, whether full time, part time or lecturer of any school, college or university where a regular course in stem cell therapy is taught, or who has any pecuniary interest, directly or indirectly, in such an institution must forego his or her membership in said faculty or relinquish his or her interests in said institution before or upon taking his or her oath as a member of the Board; provided, further, that an incumbent officer of the Philippine Society of Stem Cell Medicine or any stem cell therapy association is disqualified from concurrently being appointed to or serving in the Board.

SECTION 9. Term of Office. The members of the Board shall hold office for a non-renewable term of five (5) years, starting on the date of appointment and until their successors shall have been appointed; provided, however, that the first appointees to

the Board shall hold office as follows: the chairperson for five (5) years and the four (4) other members for fixed terms of four (4), three (3), two (2), and one (1) year/s, such that the term of one member shall be due to expire every year. Thereafter, one member shall be appointed for the full term every year and such member, in the last year of his or her term, shall automatically become the chairperson of the Board. Vacancies brought about by reasons other than expiration of term shall be filled for the unexpired portion of the term only.

SECTION 10. Removal or Suspension of Board Members. Any member of the Board, after having been given the opportunity to defend himself or herself in a proper administrative investigation conducted by the PRC, may be removed by the President of the Philippines for neglect of duty, incompetence, malpractice, or unprofessional, unethical, immoral or dishonorable conduct. During the process of investigation, the President of the Philippines may suspend such member under investigation for a period of not more than sixty (60) days and appoint a temporary member in his place.

SECTION 11. Compensation of Board Members. The members of the Board shall each receive compensation in accordance with the rules and regulations of the Professional Regulatory Commission.

SECTION 12. Functions and Powers of the Board. The Board is hereby vested with authority to:

- (a) Promulgate the rules and regulations for the practice of stem cell therapy, subject to the approval of the PRC and in accordance with the provisions of this Act;
- (b) Administer and enforce the rules and regulations specified in the preceding sections;
- (c) Determine, prepare, adopt, issue or amend the syllabi and contents of, and questions for licensure examinations, adopt measures to ensure the integrity thereof, correct and rate the examination papers and submit the results thereof to the PRC;
- (d) Formulate and oversee, in consultation and coordination with the PRC, guidelines for the proper conduct of licensure examinations and the registration of stem cell therapy practitioners;
- (e) Issue, suspend, revoke and reissue certificates of registration of qualified stem cell therapy practitioners and renew their professional licenses;
- (f) Impose reasonable requirements and conditions, such as attendance in continuing education activities and programs for the renewal of a practitioner's license to practice and for the purpose of upgrading the professional competence of stem cell therapy practitioners;
- (g) Maintain a registry of practitioners in good standing;
- (h) Adopt, promulgate and disseminate the Code of Ethics for the practice of stem cell therapy in the Philippines;
- (i) Administer oaths in connection with the implementation of this Act;
- (j) Conduct hearings and investigations to resolve complaints against practitioners of stem cell therapy for malpractice, unethical and unprofessional conduct, and violations of this Act or its implementing rules

and regulations, and in connection therewith, issue subpoena ad testificandum and subpoena duces tecum and punish with contempt persons obstructing, impeding and/or otherwise interfering with the conduct of such proceedings;

- (k) Conduct ocular inspections of establishments and/or premises where stem cell therapy services are offered to ascertain that professional standards are complied with;
- (l) Upon application, to issue an order enjoining or abating the illegal practice of stem cell therapy by unqualified persons;
- (m) Impose fines and penalties, after due process and in accordance with the provisions of this Act, for causes provided for by law or by the rules and regulations promulgated therefor;
- (n) Evaluate periodically the status of stem cell research and education and recommend and/or adopt measures to upgrade and maintain its high standards; and
- (o) Study the conditions affecting the practice of stem cell therapy in all parts of the Philippines, and, whenever necessary, adopt such measures as may be deemed proper for the maintenance of good ethics and high professional standards of the practice.

SECTION 13. Quorum in Board Meetings. The attendance of three (3) members shall constitute a quorum for the Board to officially transact business.

SECTION 14. Votes Required in Administrative Cases. To render a decision in an administrative case for unethical practice, malpractice, immorality, dishonesty, and related charges affecting the professional fitness and integrity of a practitioner, the vote of three (3) members must be obtained; provided, that in case members are disqualified to vote by virtue of their relation to or interest in any of the parties or voluntarily inhibits themselves from participating in the proceedings, the Board shall designate, with the approval of the Commission, a practitioner in good standing who is respected in the community for their probity and integrity to sit in the Board, participate in the proceedings and vote on the case.

SECTION 15. Supervision of the Board and Custody of its Records. The members of the Board shall be under the general supervision of the Professional Regulation Commission (PRC). All records, including examination papers, examination results, minutes of deliberations, records of administrative cases and investigation of the Board shall be kept by the said Commission.

SECTION 16. Annual Report. The Board shall, at the end of each calendar year, submit to the PRC an annual report of its activities and proceedings during the year. Other information or data may be requested by the Commission as often as may be necessary and practicable.

ARTICLE IV

THE STEM CELL THERAPY BOARD EXAMINATIONS

SECTION 17. Licensure Examination. Every applicant seeking to be registered as a practitioner shall undergo an examination as provided in this Act. Examination for the practice of stem cell therapy or limited practice

SECTION 18. Scope of Examination. The Board of Stem Cell Therapy shall prescribe the scope and prepare the contents of the licensure examinations. In the discharge of this function, the Board shall take into account recent developments in stem cell research as well as the academic standards imposed by the Commission on Higher Education on educational institutions which offer a course in stem cell therapy.

SECTION 19. Requirements for Examination of Applicants. To be eligible to take the licensure examination in stem cell therapy, the applicant must be:

- (a) A Filipino citizen;
- (b) A duly registered medical doctor
- (c) Of good moral character;

SECTION 20. Minimum Passing Level. In order that the candidate may be considered to have successfully passed the examination, he or she must have obtained a general average of at least seventy-five percent (75%) in all subjects, with no rating below fifty percent (50%) in any subject.

SECTION 21. Report of the Result of the Examination. The Board shall report the ratings obtained by each candidate to the PRC within sixty (60) days after the last examination day, unless extended by the Commission. The PRC shall cause the publication of the names of successful candidates in alphabetical order, without the ratings obtained by each, within sixty (60) days of the date the Commission receives the aforementioned report from the Board.

SECTION 22. Additional Requirement for Reexamination. Any applicant who, for the third time, fails to pass the board examination shall not be allowed to take the next succeeding examination without submitting to the Board proof that he or she has taken a refresher course in a duly accredited institute.

ARTICLE V

REGISTRATION AND LICENSURE OF STEM CELL THERAPY PRACTITIONERS

SECTION 23. Oath of Stem Cell Therapy Practitioners. All successful examinees shall be required to take their oath before the Board or before any person authorized to administer oaths prior to the issuance of the certificate of registration, provided, however, that the applicant is not disqualified under any of the provisions of Section 24 hereof.

SECTION 24. Disqualification. The following applicants shall not be allowed to take their oath as stem cell therapy practitioners nor issued certificates of registration:

- (a) Those who do not possess the qualifications set forth in Section 19 of this Act;
- (b) Those who fail to pass the Stem Cell Therapy Board licensure examination;

- (c) Those who have been convicted by final judgment of any crime involving moral turpitude by any court;
- (d) Those who have been found guilty by the Board of immoral or dishonorable conduct; and
- (e) Those who have been declared to be of unsound mind.

Such fact of disqualification shall be communicated by the Board to the applicant by written statement, which statement shall form part of the records of the Board.

SECTION 25. Registration. The PRC shall register successful examinees who have taken their oath and thereafter grant them professional licenses to practice stem cell therapy. The certificate of registration shall be considered as evidence that the registrant is qualified to practice stem cell therapy in the Philippines.

SECTION 26. Registration without taking Licensure Examination. A person who possesses the pertinent qualifications listed below pursuant to the provisions of this act may be registered without examination:

- (a) Was a PRC-duly registered Doctor of Medicine in the Philippines with at least five (5) years clinical experience in the practice of stem cell therapy in the Philippines;
- (b) Had at least seven (7) years of clinical experience in stem cell therapy.

Provided, that the applicant files with the Board within three (3) years after its creation, an application for registration, issuance of a Certificate of Registration and Professional Identification Card by submitting credentials showing that the applicant was a member of good standing in the Philippine Society of Stem Cell Medicine for three (3) years before the effectivity of this Act.

SECTION 27. Revocation of Certificates and Suspension of Professional Licenses. The Board may, after giving proper notice and hearing to the party concerned, revoke a practitioner's certificate of registration or suspend his or her license to practice for any unprofessional or unethical conduct, malpractice, or violation of any of the provisions of this Act, or its rules and regulations, or upon the conviction of the practitioner of a crime involving moral turpitude.

SECTION 28. Appeals. The revocation of a certificate or suspension of a professional license by the Board shall become final unless appealed to the PRC within fifteen (15) days from the receipt of its decision.

SECTION 29. Reinstatement, Reissuance or Replacement of Certificates. The Board may, upon application and for reasons deemed proper and sufficient, reinstate any suspended certificate of registration or accreditation, or issue another certificate in lieu of one previously revoked, and in so doing it may, in its discretion, exempt the applicant from taking another examination.

A new certificate to replace any certificate lost, destroyed or mutilated may be issued subject to the rules that may be implemented by the Board.

SECTION 30. Renewal. All licenses shall be renewable every three (3) years and shall be renewed only upon satisfying the requirements imposed by the Board, such as attendance in continuing education programs and payment of the corresponding fees as may be fixed by the Board in accordance with the schedule of fees fixed by the PRC.

ARTICLE VI PROHIBITED ACTS

SECTION 31. Prohibited Acts. The following acts are prohibited:

- (a) Giving false or forged evidence of any kind to the Board or to any member thereof for the purpose of obtaining a certification of registration or a professional license;
- (b) Assumption, use or advertisement by a person, not holding a valid professional license in accordance with this Act, of a description, in connection with his name or title, tending to convey the impression that he or she is a duly registered stem cell therapy practitioner;
- (c) Any form of advertisement in media outlets giving information and impression to the public that the particular practitioner is better than the others, is collecting lower professional fees or offering cheaper medicinal treatments;
- (d) Engaging in unauthorized practice of stem cell therapy as defined in this Act; and
- (e) Violation by any person, whether natural or juridical, of any of the provisions of this Act and the rules and regulations promulgated for its effective implementation.

SECTION 32. Penal Provisions. The commission of any of the prohibited acts listed in the immediately preceding section shall be punished with imprisonment of not less than one (1) year but not more than eight (8) years, or a fine of not less than Fifty thousand pesos (P50,000) but not more than One hundred thousand pesos (P100,000) or both, at the discretion of the court.

In addition, the administrative penalties specified in Section 27 hereof shall be imposed whenever applicable.

If the violation is committed by an association, partnership, corporation or any other institution, the managing officers and other persons responsible for its commission shall be liable for the penalties provided for in this Act.

ARTICLE VII PROFESSIONAL AND ETHICAL STANDARDS

SECTION 33. Foreign Reciprocity. No foreigner shall be admitted to the board examinations unless he or she proves in the manner prescribes by the Rules of Court that by specific provision of law, the country of which he or she is a citizen, subject or national, either admits Filipino citizens to the practice of stem cell therapy without restriction or allows them to practice stem cell therapy after an examination on terms of strict and absolute equality with citizens, subjects or nationals of said country, including the unconditional recognition of prerequisite degrees prescribed by the Commission on Higher Education, provided, however, that the Board, upon approval by the PRC, may grant a special permit to a foreign practitioner to practice the profession in this country whether or not reciprocity exists between his or her country and the Philippines and under such conditions as may be determined by the Board, if such foreigner is intentionally known to be an outstanding expert in the profession or a well-known

specialist in any of its branches, and that his or her services will promote the advancement of the profession in the Philippines. The Board is also hereby authorized to prescribe, upon approval by the PRC, additional requirements or grant certain privileges to foreigners, seeking registration in the Philippines if the same privileges are granted to or some additional requirements are required of citizens of the Philippines in acquiring the same certificate in his country.

SECTION 34. Rules and Regulations. The Board shall set professional standards for the practice of stem cell therapy in the Philippines and adopt such rules and regulations as may be necessary to carry out the provisions of this Act, subject to the approval of the PRC. Such standards, rules and regulations shall take effect thirty (30) days after its publication in the Official Gazette or any newspaper of general circulation.

SECTION 35. Philippine Society of Stem Cell Medicine. In order for every practitioner to contribute to his or her profession and to bear his or her share of professional responsibilities, all stem cell therapy practitioners shall be encouraged to join and be integrated into one national organization, the Philippine Society of Stem Cell Medicine, which shall be recognized by the Board and the PRC. Every practitioner, upon registration with the Board, may become a member of the integrated national organization. Those who have been registered with the Board before the effectivity of this Act may register as members of the integrated organization within three (3) years after said effectivity.

SECTION 36. Purposes. The Society shall promulgate the Code of Ethics or the practice of the profession, define the professional responsibilities of its members, ensure adherence to said professional ethics and responsibilities, improve the standards of the profession and enable all practitioners to discharge their public responsibility more effectively.

SECTION 37. Membership Fees and Dues. All members shall be subject to the payment of reasonable fees and dues for the effective discharge of the purposes of the Society. A practitioner shall receive the benefits and privileges appurtenant to his or her membership only upon payment of the required membership fees and dues.

SECTION 38. Other Organizations. The integration of stem cell therapy practitioners into one national organization shall not prohibit the creation of other associations of stem cell therapy practitioners organized by individual practitioners themselves.

SECTION 39. Code of Professional Ethics. The Board shall adopt the Professional Code of Ethics promulgated by the Society, provided that such Code provides that it is the duty of the stem cell therapy practitioner to:

- (a) Consider as his or her primary responsibility the welfare of his or her patients and the public in general;
- (b) Promote the best possible standards of professional care;
- (c) Enhance continuously his or her theoretical and practical proficiency;
- (d) Render his or her services with equal diligence to all, regardless of race, creed or status;
- (e) Respect the confidential nature of information concerning those he or she serves; and
- (f) Refer for medical or other professional attention where the need is indicated.

The Board shall also distribute the Code of Ethics of the Stem Cell Therapy Profession in the Philippines to all new stem cell therapy practitioners during their oath-taking.

Any act or omission which violates this Code shall be considered as unethical conduct and shall be suspended or prohibited from the practice of stem cell therapy, in accordance with Section 27 of this Act.

ARTICLE VIII MISCELLANEOUS PROVISIONS

SECTION 40. Funding Provisions. The Chairperson of this Commission shall include in the Commission's Programs the implementation of this Act, the funding of which shall be included in the General Appropriations Act.

SECTION 41. Assistance of Law Enforcement Agency. Any law enforcement agency shall, upon call or request of the Commission or the Board, render assistance in enforcing this Act, including all the rules and regulations promulgated thereunder by prosecuting the violators thereof in accordance with law and the Rules of Court.

SECTION 42. Implementing Rules and Regulations. Within sixty (60) days after the effectivity of this Act,

Subject to the approval of the Commission, the Board shall promulgate the necessary rules and regulations, in coordination with the Society, to implement the provisions of this Act, which shall be effective after fifteen (15) days following its publication in the Official Gazette or two Philippine newspapers of general circulation.

SECTION 43. Separability Clause. If any provision of this Act is declared invalid or unconstitutional, the other provisions not affected thereby shall continue to be in full force and effect.

SECTION 44. Repealing Clause. All laws, decrees, executive orders or rules and regulations contrary to or inconsistent with the provisions of this Act are hereby repealed or modified accordingly.

SECTION 45. Effectivity Clause. This Act shall take effect fifteen (15) days from its publication in the Official Gazette or in at least two (2) newspapers of general circulation.

Approved.