SIXTEENTH CONGRESS OF THE REPUBLIC)
OF THE PHILIPPINES)
Second Regular Session)

Senate
Office of the Secretary

'14 AUG 27 P3 :46

RECEIVED BY:

SENATE
S. No. **2382**

Introduced by Senator Miriam Defensor Santiago

AN ACT
TO LAUNCH A NATIONAL STRATEGY TO SUPPORT REGENERATIVE MEDICINE THROUGH FUNDING FOR RESEARCH AND COMMERCIAL DEVELOPMENT OF REGENERATIVE MEDICINE PRODUCTS AND DEVELOPMENT OF A REGULATORY ENVIRONMENT THAT ENABLES RAPID APPROVAL OF SAFE AND EFFECTIVE PRODUCTS

EXPLANATORY NOTE

The Constitution, Article 2, Section 15 provides:

> SEC. 15. The State shall protect and promote the right to health of the people and instill health consciousness among them.

According to the U.S. Department of Health and Human Services, the potential benefits of regenerative medicine in improved health care and economic savings are enormous. Regenerative medicine products reportedly have been effective in the treatment of numerous diseases such as diabetes, spinal cord injury, heart disease, stroke, and various forms of cancer.

The Alliance for Regenerative Medicine in the U.S. said "Regenerative medicine represents the single most promising new approach to mitigating the human and economic costs of disease, and changing the course of human health."

Hence, this bill seeks to establish a national strategy to support regenerative medicines and a Regenerative Medicine Coordinating Council within the Department of Health, Office of the Secretary.[1]

MIRIAM DEFENSOR SANTIAGO

[1] This bill was originally filed by Ms. Degette and Mr. Paulsen in the U.S. House of Representatives (H.R. 4494; 113th Congress, Second Session).

SIXTEENTH CONGRESS OF THE REPUBLIC)
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SENATE
S. No. 2382

RECEIVED BY:

Introduced by Senator Miriam Defensor Santiago

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

AN ACT
LAUNCHING A NATIONAL STRATEGY TO SUPPORT REGENERATIVE MEDICINE THROUGH FUNDING FOR RESEARCH AND COMMERCIAL DEVELOPMENT OF REGENERATIVE MEDICINE PRODUCTS AND DEVELOPMENT OF A REGULATORY ENVIRONMENT THAT ENABLES RAPID APPROVAL OF SAFE AND EFFECTIVE PRODUCTS

SECTION 1. *Short Title.* – This Act shall be known as the "Regenerative Medicine Promotion Act."

SECTION 2. *Report on Ongoing Government Programs and Activities Regarding Regenerative Medicine.* – Not later than six months after the date of effectivity of this Act, the Secretary of Health (referred to as the "Secretary") shall provide for the completion, and submission to the Congress, of a report identifying all ongoing government programs and activities regarding regenerative medicine.

SECTION 3. *Establishment of Regenerative Medicine Coordinating Council.* –

(a) *Establishment.* – The Secretary shall establish, within six months of the enactment of this Act, in the Office of the Secretary, a Regenerative Medicine Coordinating Council (referred to as the "Council").

(b) *Composition.* – The Council shall be composed of the following:

(1) The Secretary of Trade and Industry

(2) The Secretary of Defense.

(3) The Secretary of Health.

(4) The Secretary of Budget and Management.

(5) The Administrator of Philippine Veterans Affairs Office

(6) The Administrator of Food and Drugs.

(7) The Director of the National Institutes of Health.

(8) The members appointed by the Secretary under subsection (d).

(c) *Chair.* – The Secretary of Health shall be the Chair of the Council.

(d) *Members Appointed by Secretary.* – The Secretary shall appoint at least five persons to serve as members of the Council under paragraph (b)(8). The members of the Council appointed shall include persons with expertise in third-party payment, regenerative medicine researchers from academic institutions, patient advocates, persons with expertise in drug discovery, persons with expertise in drug development, persons with expertise in basic research, persons with expertise in translational research, persons with expertise in medical device development, persons with expertise in biomaterials, clinicians, and persons with expertise in clinical research.

(e) *Functions.* – The Council shall consult with, and provide information to, the Secretary of Health for purposes of implementing any recommendations in the report required by Section 2;

(1) consult with, and provide information to, the Secretary of Health for purposes of implementing any recommendations in the report required by Section 2;

(2) prepare, and keep up-to-date, a national strategy to support research into regenerative medicine and the development of drugs, biological products, medical devices, and biomaterials for use in regenerative medicine;

(3) prepare a plan specifying priorities for research into regenerative medicine;

(4) not later than one year after the date of effectivity of this Act, establish priorities for the award of grants under Sections 4 and 5 (relating to grants for basic or preclinical research into regenerative medicine and for development of drugs, biological products, medical devices, and biomaterials for use in regenerative medicine, respectively);

(5) identify sources of funding for research into regenerative medicine;

(6) identify areas where such funding is inadequate;

(7) make recommendations regarding policies that will support development and marketing of regenerative medicine products;

(8) facilitate development of consensus standards regarding scientific issues critical to regulatory approval of regenerative medicine products; and

(9) determine the need for establishing centers of excellence or consortia to further advance regenerative medicine.

(f) *Transparency; Reporting Requirements.* –

(1) *Transparency.* – The Council shall adopt procedures to ensure the receipt of public input, such as holding public stakeholder meetings or creating advisory boards.

(2) *Annual Reports.* – The Council shall submit an annual report on its activities to the Congress, the Director of the National Institutes of Health, and the Administrator of Food and Drugs. Each such report shall:

(A) provide details on progress in meeting goals identified by the Council for regenerative medicine;

(B) make recommendations regarding funding, regulatory, or other policies to achieve regenerative medicine goals identified by the Council;

(C) identify all regenerative medicine products currently on the market and those in development;

(D) identify regenerative medicine research and technological advances and discoveries that occurred in the previous year; and

(E) assess the impact of regenerative medicine on the country's economy, including with respect to:

(i) the number of people employed in companies or research institutions working in regenerative medicine;

(ii) the number of companies pursuing regenerative medicine products;

(iii) increases in tax revenues; and

(iv) the impact on national health spending.

SECTION 4. *Grants for Basic or Preclinical Research into Regenerative Medicine.* –

(a) *Grants For Basic or Preclinical Research.* – The Secretary may make grants to eligible entities for the purpose of funding basic or preclinical research into regenerative medicine.

(b) *Conditions.* – The Secretary may make a grant under this section for research only if:

(1) the research is carried out directly by the grant recipient;

(2) the research is partly funded by one or more private entities; and

(3) the amount of the grant does not exceed the total amount provided for the research by private entities (other than the grant recipient itself).

(c) *Terms and Conditions.* – A grant may be made on such terms and conditions as the Secretary determines appropriate.

(d) *Priority.* – In awarding grants, the Secretary shall take into consideration the priorities established by the Regenerative Medicine Coordinating Council under Section 3(e).

SECTION 5. *Grants for Development of Drugs, Biological Products, Medical Devices, and Biomaterials for Use in Regenerative Medicine.* –

(a) *Grants For Drug Development.* – The Secretary may make grants to eligible entities for the purpose of funding projects that have as their aim –

(1) the research and development of drugs, biological products, medical devices, and biomaterials for use in regenerative medicine; and

(2) the making of an investigational new drug application with respect to such drugs or biological products, or the making of an investigational device exemption application with respect to such devices, by not later than the end of the 4-year period beginning on the date on which such grant is made.

"Eligible entity" means a collaborative partnership including a qualified non-profit entity or an institution of higher education; and a for-profit entity.

(b) *Terms and Conditions.* – A grant under this Section may be made on such terms and conditions as the Secretary determines appropriate.

(c) *Priority.* – In awarding grants under this Section, the Secretary shall take into consideration the priorities established by the Regenerative Medicine Coordinating Council under Section 3(e).

SECTION 6. *Authorization of Appropriations.* – To carry out the provisions of this Act, there are authorized to be appropriated such sums as may be necessary for each fiscal year.

SECTION 7. *Separability Clause.* – If any provision or part hereof, is held invalid or unconstitutional, the remainder of the law or the provision not otherwise affected shall remain valid and subsisting.

SECTION 8. *Repealing Clause.* – Any law, presidential decree or issuance, executive order, letter of instruction, administrative order, rule or regulation contrary to

or is inconsistent with the provision of this Act is hereby repealed, modified, or amended accordingly.

SECTION 9. *Effectivity Clause*. – This Act shall take effect fifteen (15) days after its publication in at least two (2) newspapers of general circulation.

Approved,

/fldp20aug2014