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H. No. 5973

BY REPRESENTATIVES ARROYO, MACAPAGAL-ARROYO, ARAGONES, ARENAS, VARGAS, TING, TAMBUNTING, VILLAR, QUISUMBING, VILLARICA, BELMONTE (J.), ERIGUEL, TAN (A.), AMATONG (I.), SANTIAGO, SUANSING, TEJADA, OCAMPO, UNGAB, NAVA (J.), ANGPING, ACHARON, ALEJANO, BATAOIL, DELOSO-MONTALLA, ESCUDERO, GUTIERREZ, KATOH, LANETE, PAEZ AND QUIMBO, PER COMMITTEE REPORT NO. 813

AN ACT PROMULGATING A COMPREHENSIVE POLICY ON NEEDS OF PERSONS AFFLICTED WITH RARE DISORDERS

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

ARTICLE 1

GENERAL PROVISIONS

SECTION 1. *Short Title.* – This Act shall be known as the "Rare Diseases Act".

SEC. 2. *Declaration of Policy.* – It is the policy of the State to protect and promote the right to health of the people, including persons suffering from rare diseases, and to provide the people with access to timely health information and adequate medical care. Towards this end, the State shall institutionalize a system that promotes research and development studies on the early diagnosis, proper care and treatment of rare diseases, educates and informs the public on the nature of these diseases, and ensures the availability

of drugs and other resources to address the needs of persons afflicted with rare diseases. It shall likewise establish and maintain a national registry of persons with rare diseases.

SEC. 3. *Objectives.* – This Act shall pursue the following objectives:

(a) Ensure that every patient diagnosed to have a rare disease has access to timely health information and adequate medical care, including drugs and other healthcare products to alleviate their health conditions;

(b) Ensure the development of medical protocols with which to alleviate if not cure the conditions associated with rare diseases, including drugs, through research and development studies and by facilitating the importation or manufacture of affordable orphan drugs or orphan products; and

(c) Provide reliable information on rare diseases to be used for policymaking by the establishment of a National Rare Disease Registry.

SEC. 4. *Definition of Terms.* – As used in this Act:

(a) *Healthcare practitioner* refers to a doctor of medicine, dentist, nurse, midwife, and other allied healthcare professional duly licensed by the Professional Regulation Commission (PRC);

(b) *Healthcare institutions* refer to public or private hospitals, health infirmaries, health centers, lying-in centers or puericulture centers;

(c) *Medical care* refers to any method used by a healthcare practitioner to prevent, diagnose, and eradicate the symptoms and cause of a disease;

(d) *National Comprehensive Newborn Screening System* refers to the existing network of medical specialists, nurses, laboratories and hospitals that screen and treat genetic diseases, many of which are also rare disorders, as established by Republic Act No. 9288, otherwise known as the "Newborn Screening Act of 2004";

(e) *Newborn Screening Continuity Clinic (NSCC)* refers to an ambulatory clinic based in a secondary or tertiary hospital identified by the Department of Health (DOH), to be part of the National Comprehensive Newborn Screening System Treatment Network. It is equipped to facilitate continuity care of patients confirmed with conditions included in the expanded newborn screening in its area of coverage;

(f) *Orphan drug* refers to any drug or medicine classified as such by the DOH, upon recommendation of the National Institutes of Health (NIH), and is used to treat or alleviate the symptoms of persons afflicted with rare diseases;

(g) *Orphan product* refers to any healthcare or nutritional product, other than a drug or medicine, that includes diagnostic kits, medical devices and biological products, and approved by the DOH to be used to prevent, diagnose, or treat rare diseases;

(h) *Rare disease* refers to disorders such as Gaucher Disease, Maple Syrup Urine Disease, Pompe Disease, Galactosemia, Phenylketonuria, Methylmalonic Acidemia, Urea Cycle Defects, Hurler Syndrome, Hunter Syndrome, Prader-Willi Syndrome, Lubag, and other diseases classified as such by the DOH, upon the recommendation of the NIH, but does not include catastrophic (i.e., life threatening, seriously debilitating, or serious and chronic) forms of more frequently occurring diseases;

(i) *Rare Disease Registry* refers to the national health information system maintained by the NIH that includes data on the types of rare diseases, persons afflicted with the disease, and orphan drugs and products available in the market;

(j) *Rare Diseases Technical Working Group (RDTWG)* refers to a DOH-designated pool of experts that is tasked to identify rare diseases, orphan drugs and products; and

(k) *Telegenetics Referral System* refers to an established system utilizing electronic communications (i.e. video conferencing, emails, and other electronic communications) which aims to make genetics services accessible to all patients with genetic conditions.

ARTICLE 2

IDENTIFICATION, REFERRAL AND MANAGEMENT OF PERSONS WITH RARE DISORDERS

SEC. 5. *Obligation of a Healthcare Practitioner.* – A healthcare practitioner who attends to a person with a rare disorder is required to perform the following:

(a) Provide the patient and their family substantial information about the significance of diagnosis and management of rare disorder;

(b) Ensure that an afflicted person is referred to a regional NSCC identified by the DOH as referral clinic for treating rare diseases; and

(c) Report the cases of rare disease affliction to the NIH for entry into the Rare Disease Registry.

SEC. 6. *Referral of Patients With Rare Disease.* – Patients suspected to be afflicted with or diagnosed with a rare disease shall be referred to a regional NSCC identified by the DOH so the afflicted person receives adequate medical care and together with family is referred to a geneticist or genetic counselor for counseling.

In the absence of a specialist in the area, the NSCC shall coordinate with the NIH through the Center for Health Development (CHD)-DOH for comanagement of the patient.

The NSCC shall establish a system, in collaboration with the local unit and agencies, that will ensure that the afflicted person receives sustainable medical management of the disease. The NIH shall report all cases of rare disease affliction for inclusion in the Rare Disease Registry.

SEC. 7. *Designation of Persons With Rare Disorders as Persons With Disabilities.* – Individuals with rare disease shall be considered as persons with disabilities (PWDs) and shall enjoy the same rights and benefits as mandated under Republic Act No. 9442, otherwise known as the "Magna Carta for Disabled Persons".

The Department of Labor and Employment (DOLE) shall ensure that able persons with rare diseases are given the opportunity to work and become productive members of the society.

The Department of Social Welfare and Development (DSWD) shall provide assistance to persons with rare diseases to ensure that their social welfare and benefits as mandated under Republic Act No. 9442 are provided.

SEC. 8. *Continuing Education and Training of Health Personnel.* – The DOH and the NIH together with the health professional societies and academic health institutions shall:

(a) Conduct continuing education, information and training programs for health personnel on the identification and referral of persons with rare disorders for medical management; and

(b) Educate health personnel on the importance of reporting cases of rare disorders in the Rare Disease Registry.

SEC. 9. *Public Information on Rare Disorders.* – The DOH, with the assistance of the NIH and other government agencies, professional societies and nongovernment organizations, shall conduct culturally sensitive public education and information campaigns which include topics on the nature and management of rare diseases, and the behavior and needs of persons afflicted with the disease to spare them from being the subject of discrimination.

SEC. 10. *Availability of a Specialist for the Management of Afflicted Persons With Rare Disorders.* – The DOH, with the assistance of the NIH,

shall ensure the availability of a specialist for the management of persons afflicted with rare diseases.

ARTICLE 3

DESIGNATION OF RARE DISEASE, ORPHAN DRUG, AND ORPHAN PRODUCT

SEC. 11. *The Rare Diseases Technical Working Group.* – The DOH shall create a Rare Diseases Technical Working Group (RDTWG) which shall have the following roles and responsibilities:

(a) Designate rare diseases;

(b) Designate orphan drugs and products corresponding to a type of rare disease; and

(c) Formulate policies that will regulate the approval and certification of orphan drugs and products.

SEC. 12. *Designation of Rare Disease.* – The DOH, upon the recommendation of the NIH and the RDTWG, is hereby authorized to designate any disease as rare, in addition to those identified in Section 4(h) of this Act.

SEC. 13. *Designation of Orphan Drug.* – The DOH, *motu proprio,* or upon application by any interested person, may designate any drug or medicine for the use of patients afflicted with any of the rare diseases, as an orphan drug: *Provided,* That there is no existing drug or medicine in the Philippines that can provide the same or superior results, as certified by the Food and Drug Administration (FDA).

SEC. 14. *Designation of Orphan Product.* – The DOH, *motu proprio,* or upon application by any interested person, may designate any healthcare or nutritional product, other than a drug or medicine, including diagnostic kits, medical devices and biological products, used primarily to prevent, diagnose, or alleviate the symptoms of rare diseases, as an orphan product: *Provided,*

That there is no existing product in the Philippines that can provide the same or superior results, as certified by the FDA.

Health practitioners and health institutions shall inform patients afflicted with rare diseases of the relevant orphan drugs and products listed in the Rare Disease Registry.

The DOH shall publish a list of orphan drugs and products within one hundred twenty (120) days from the effectivity of this Act.

SEC. 15. *The Rare Disease Registry.* – All healthcare practitioners and health institutions shall be required to report all diagnosed cases and the status of patients treated with rare diseases in the Rare Disease Registry maintained by the NIH: *Provided,* That such reports shall be treated with confidentiality and subject to the guidelines issued by the NIH.

ARTICLE 4

ROLE DELINEATION OF IMPLEMENTING AGENCIES

SEC. 16. *Lead Agency.* – The DOH, as the lead agency in the implementation of this Act, shall perform the following tasks:

(a) Establish the Rare Diseases Technical Working Group;

(b) Formulate the implementing rules and regulations of this Act within one hundred eighty (180) days after its approval;

(c) Coordinate with the NIH for technical assistance in the implementation of this Act;

(d) Coordinate with all government and nongovernment agencies that will be involved in the implementation of this Act;

(e) Designate referral clinics in strategic locations in the country for the timely and sustainable medical management of persons afflicted with rare disorders;

(f) Organize a pool of medical specialists who will be responsible for the management of persons afflicted with rare disorders and their families;

(g) Establish a system to qualify persons afflicted with rare diseases as beneficiaries of its health program to ensure sustainable compliance to the medical management of the disease; and

(h) Provide the necessary funding for the implementation of this Act.

SEC. 17. *Specific Responsibilities of the Philippine Council for Health Research and Development-Department of Science and Technology (PCHRD-DOST), FDA, NIH, DSWD, and DOLE.* – The aforementioned government agencies shall perform the following responsibilities:

(a) The Philippine Council for Health Research and Development (PCHRD) under the Department of Science and Technology (DOST) shall be the lead coordinating agency for health research as mandated by Republic Act No. 10532, otherwise known as the "Philippine National Health Research System Act of 2013";

(b) The FDA shall facilitate the entry of orphan drugs and products in the country for the treatment of rare diseases;

(c) The NIH shall provide technical assistance to the DOH and conduct research studies on rare diseases in coordination with the PCHRD; and

(d) The DSWD and the DOLE shall ensure that persons with rare diseases are given the opportunity to be productive members of society and that they are given the same rights and benefits as PWD.

ARTICLE 5

RESOURCE GENERATON AND INCENTIVES FOR RARE DISEASES

SEC. 18. *Source of Funds for Maintaining Medical Management of Persons Afflicted With Rare Disorder.* –

(a) The Philippine Health Insurance Corporation (PhilHealth) shall include the treatment and medicines for rare diseases as part of the health package for catastrophic illnesses; and

(b) A portion of the revenues from sin taxes earmarked for health programs and projects shall be allotted to cover the cost of care for patients with rare diseases.

SEC. 19. *Tax Exemptions.* – All grants, bequests, endowments, donations and contributions to the RDTWG of the DOH and the NIH for its actual, direct and exclusive use including research and maintenance of Rare Disease Registry of patients afflicted with rare diseases as certified by the FDA shall be exempt from donor's tax and the same shall be allowed as deductions from the gross income of the donor for purposes of computing the taxable income of the donor in accordance with the provisions of the National Internal Revenue Code of 1997, as amended.

Imported orphan drugs and products that are solely meant to be donated to patients afflicted with rare diseases, as certified by the NIH, shall be exempt from payments of customs duties subject to the evaluation and documentation requirements for clearance by the FDA for medicines, and the National Economic and Development Authority (NEDA), for certain equipment, in accordance with the Tariff and Customs Code of the Philippines, as amended.

ARTICLE 6

FINAL PROVISIONS

SEC. 20. *Appropriations.* – The initial amount necessary to implement the provisions of this Act shall be charged against the current year's appropriation of the DOH. Thereafter, such sums as may be necessary for the continued implementation of this Act shall be included in the annual General Appropriations Act.

SEC. 21. *Implementing Rules and Regulations.* – The Secretary of the DOH, in consultation with the Secretaries of the DSWD, DOLE, and the Executive Directors of the PCHRD-DOST and NIH, shall issue the implementing rules and regulations within one hundred twenty (120) days after the approval of this Act.

SEC. 22. *Separability Clause.* – If any provision or part of this Act is declared unconstitutional or invalid, the remaining parts or provisions not affected shall remain in full force or effect.

SEC. 23. *Repealing Clause.* – All laws, decrees, orders, rules and regulations, and other issuances or parts thereof which are inconsistent with this Act are hereby repealed, amended or modified accordingly.

SEC. 24. *Effectivity.* – This Act shall take effect fifteen (15) days after its publication in the *Official Gazette* or in a newspaper of general circulation.

Approved,

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