S. No. 2990
H. No. 5973

Republic of the Philippines

Congress of the Philippines

Metro Manila

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[REPUBLIC ACT NO. 10747]

AN ACT PROMULGATING A COMPREHENSIVE POLICY IN ADDRESSING THE NEEDS OF PERSONS WITH RARE DISEASE

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

ARTICLE I

GENERAL PROVISIONS

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

SEC. 2. *Declaration of Policy.* – It is the policy of the State to protect and promote the right to health of the people, including the right of persons suffering from rare diseases to

survival and full and healthy development as individuals through access to timely health information and adequate medical care. In pursuit of such policy, the State shall institutionalize a system that is comprehensive, integrative and sustainable and will facilitate collaboration among government and nongovernment agencies and organizations at the national and local levels, private sector, professional health organizations, academic institutions, communities and families towards the provision of early and sustainable care of persons afflicted with rare disease. The State recognizes the crucial role of research in defining health programs and activities to address the needs of patients with rare disease. The State also recognizes that an effective public education program is vital in helping ensure the early diagnosis and treatment of rare disorders and in preventing those afflicted with them from being the subject of ridicule and stigmatization.

SEC. 3. *Objectives.* – The objectives of this Act are as follows:

(a) Improve the access of patients diagnosed to have a rare disease or patients highly suspected of having a rare disease to comprehensive medical care, including drugs and other healthcare products to treat or otherwise, as well as timely health information to help them cope with their condition by:

(1) Establishing a comprehensive and sustainable healthcare system integrated within the public healthcare delivery system for early and sustainable care for patients suffering from rare diseases;

(2) Establishing and maintaining the Rare Disease Registry which shall include data on rare diseases in the Philippines, patients afflicted with rare diseases, and orphan drugs and orphan products. This data shall be utilized in formulating policies, identifying program interventions and designing researches to address the needs of patients with rare disease;

(3) Integrating public educational and information campaigns in the current programs of the Department of

Health (DOH) to identify persons afflicted with rare disease and help the public understand the special needs of such persons; and

(4) Facilitating the regular collaborative activities among stakeholders regarding the realization of the objectives of this Act.

(b) Provide regulatory and fiscal incentives to support research and development studies on rare diseases and to facilitate the manufacture and importation of affordable orphan drugs and orphan products.

ARTICLE II

DEFINITION OF TERMS

SEC. 4. *Definitions.* – For the purpose of this Act, the following terms shall be defined as follows:

(a) *Commercial use* refers to the selling of orphan drugs at profit.

(b) *Healthcare Practitioner* refers to any doctor of medicine, dentist, nurse, midwife, allied health professional and other healthcare professional duly licensed by the Professional Regulatory Commission.

(c) *Healthcare institutions* refer to hospitals, health infirmaries, health centers, lying-in centers or puericulture centers, whether public or private.

(d) *Medical care* refers to a comprehensive and professional care that encompasses correct diagnosis, treatment and prevention of rare diseases.

(e) *Medical food* refers to special milk formula devoid of offending amino acids, organic acids or fatty acids, amino acid supplements, essential amino acid mixtures, amino acid gels or juices, and low protein food products that are part of the regimen for the medical treatment of patients with inherited metabolic diseases.

(f) *Medical specialist* refers to a pediatrician for patients zero to eighteen (0-18) years old or adult physician for above eighteen (18) years old adequately trained by experts in the field of inherited metabolic diseases to diagnose and treat patients with rare diseases.

(g) *National Comprehensive Newborn Screening System* refers to the Newborn Screening (NBS) system established in Republic Act No. 9288 that includes, but is not limited to: (i) education of relevant stakeholders; (ii) collection, transport, biochemical screening, and reporting on result of blood samples taken from newborns; (iii) tracking and confirmatory testing to ensure the accuracy of screening results; (iv) clinical evaluation and biochemistry/medical confirmation of follow-up results; (v) administration of drugs and/or medical and surgical management and/or dietary supplementation to counter adverse effects of the heritable conditions; and (vi) monitoring and evaluation of the National Comprehensive Newborn Screening System.

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

(i) *Orphan drug* refers to any drug or medicine used to treat or alleviate the symptoms of persons afflicted with a rare disease and declared as such by the DOH upon recommendation of the National Institutes of Health (NIH).

(j) *Orphan product* refers to any healthcare or nutritional product, other than a drug or medicine, including, but not limited to, diagnostic kits, medical devices and biological products, used to prevent, diagnose, or treat rare diseases and declared as such by the DOH upon recommendation of the NIH.

(k) *Rare disease* refers to disorders such as inherited metabolic disorders and other diseases with similar rare occurrence as recognized by the DOH upon recommendation

of the NIH but excluding catastrophic (i.e., life threatening, seriously debilitating, or serious and chronic) forms of more frequently occurring diseases.

(l) *Rare Disease Management Program* refers to a comprehensive management program encompassing the diagnosis, clinical management, genetic counseling and drug research development for people with rare diseases.

(m) *Rare Disease Registry* refers to the secure health information system, including the electronic database system, relating to data on rare diseases, persons with rare disease, and orphan drugs and orphan products.

(n) *Rare Diseases Technical Working Group (RDTWG)* refers to the DOH designated pool of experts on rare diseases, which shall include experts from the NIH, tasked with identifying rare diseases, orphan drugs and orphan products.

(o) *Telegenetics Referral System* refers to telehealth using a computer network system that provides remote genetic clinical consultations to physicians in the provinces for their patients.

ARTICLE III

IDENTIFICATION, REFERRAL, MANAGEMENT AND REGISTRATION OF PERSONS WITH RARE DISEASE

SEC. 5. *Identification of Persons with Rare Disease.* – The DOH, in coordination with the NIH, shall create a Rare Disease Registry. It shall endeavor to comply with set global standards, if applicable. All patients diagnosed with rare disease shall be included in this registry.

SEC. 6. *Referral of Patients with Rare Disease.* – Patients highly suspected of, or diagnosed with, rare disease shall be referred to a newborn screening continuity clinic identified by the DOH as referral centers for treatment of rare diseases under the National Comprehensive Newborn Screening System. For patients from remote areas, the Telegenetics Referral System will be utilized.

SEC. 7. *Availability of Specialist for the Management of Persons with Rare Disease.* – The DOH, with the assistance of the NIH, shall develop a system to train a sufficient number of medical specialists to diagnose and manage persons with rare disease.

SEC. 8. *Management of Persons with Rare Disease.* – The DOH, with the assistance of the NIH, shall provide persons with rare disease better access to a support system through the creation of a Rare Disease Management Program under the National Center for Disease Prevention and Control of the DOH.

SEC. 9. *Registration of Persons with Rare Disease.* – All healthcare practitioners and health institutions shall be required to report to the Rare Disease Registry diagnosed cases of rare disease and provide reports on the status of patients: *Provided,* That such reports shall be subject to guidelines issued by the NIH to protect the privacy of patients with rare disease.

ARTICLE IV

PERSONS WITH RARE DISEASE AS PERSONS WITH DISABILITIES (PWDs)

SEC. 10. *Designation of Persons with Rare Disease as Persons with Disabilities (PWDs).* – Persons with rare disease shall be considered as persons with disabilities (PWDs), in accordance with Republic Act No. 7277, as amended, or the Magna Carta for Disabled Persons.

SEC. 11. *Rights and Privileges of Persons with Rare Disease.* – The appropriate national government agency shall ensure that they are accorded the same rights and privileges as PWDs, to wit:

(a) The Department of Social Welfare and Development (DSWD) shall provide assistance to persons with rare disease to ensure that their social welfare and benefits provided under Republic Act No. 7277, as amended, or the Magna Carta for Disabled Persons, are granted; and

(b) The Department of Labor and Employment (DOLE) shall adopt programs that promote the availability of opportunities for work and employment of able-persons with rare disease.

ARTICLE V

DESIGNATION OF RARE DISEASE, ORPHAN DRUG, AND ORPHAN PRODUCT STATUS

SEC. 12. *The Rare Disease Technical Working Group (RDTWG).* – The DOH shall convene the RDTWG which shall have the following roles and responsibilities:

(a) Determine what disorder or disease shall be considered as a rare disease, and what are the orphan drugs and orphan products, and update the list periodically;

(b) Formulate policies that shall regulate the approval and certification of orphan drugs and orphan products; and

(c) Establish a system to ensure the regular updating of information, diagnosis and treatment of rare diseases in order to provide for the comprehensive healthcare of these patients.

SEC. 13. *Designation of Rare Disease.* – The DOH, upon recommendation of the RDTWG, shall have the authority to designate any disease that is recognized to rarely afflict the population of the country as a rare disease.

SEC. 14. *Designation of Orphan Drug.* – The DOH, *motu proprio* or upon application by any interested person, and with the recommendation of the RDTWG, may designate any drug or medicine indicated for use by patients afflicted with any of the rare diseases as an orphan drug. Within one hundred twenty (120) days from the effectivity of this Act, the DOH shall publish a list of orphan drugs for these rare diseases.

SEC. 15. *Designation of Orphan Product.* – The DOH, *motu proprio* or upon application by any interested person, and with the recommendation of the RDTWG, may designate any healthcare or nutritional product, other than a drug or medicine, including, but not limited to, diagnostic kits, medical

devices and biological products, used primarily to prevent, diagnose, or alleviate the symptoms of rare diseases as an orphan product. Within one hundred twenty (120) days from the effectivity of this Act, the DOH shall publish a list of orphan products for these rare diseases.

SEC. 16. *Permit for Restricted Use of an Orphan Drug/Orphan Product.* – Any person may import any orphan drug/orphan product for compassionate use: *Provided,* That they secure a compassionate special permit from the Food and Drug Administration (FDA) in accordance with DOH Administrative Order No. 4, series of 1992, and any future guidelines that may be issued on the same.

Within thirty (30) days from receipt of the requirements, the FDA shall issue a permit for restricted use of an orphan drug/orphan product which shall be effective for a period of three (3) years, renewable for a period of three (3) years thereafter: *Provided,* That the FDA shall expedite the said permit in cases of emergency.

ARTICLE VI

IMPLEMENTATION

SEC. 17. *Lead Agency.* – The DOH shall be the lead agency in the implementation of this Act. For purposes of achieving the objectives of this Act, the DOH shall:

(a) Establish the RDTWG as defined in Section 4(n);

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

(c) Coordinate with all government and nongovernment agencies that are involved in the implementation of this Act;

(d) Support the activities of the newborn screening continuity clinics and designate referral centers in strategic locations in the country for the timely and sustainable medical management of persons with rare disease;

(e) Organize a pool of medical specialists who will be responsible in the diagnosis and management of persons afflicted with rare disease and their families;

(f) With the assistance of the NIH and other government agencies, professional societies and nongovernment organizations, conduct culturally sensitive public educational and information campaigns on the nature of rare diseases, identify persons with rare disease and help the general public understand the special needs of afflicted persons and their right against ridicule and discrimination;

(g) Develop the implementing rules and regulations for the implementation of this Act within one hundred eighty (180) days from the enactment of this Act; and

(h) Allot budget for the implementation of this Act.

SEC. 18. *Other Implementing Agencies.* – The FDA, NIH, Department of the Interior and Local Government (DILG), Department of Education (DepED), DSWD, DOLE, Department of Science and Technology (DOST), and other relevant government agencies shall have the following tasks:

(a) FDA shall ensure that medical foods, orphan drugs and orphan products are permitted in the country for purposes of treating rare diseases and shall develop a system that addresses emergency cases, as they may arise;

(b) NIH shall provide technical assistance to the DOH in the implementation of this Act;

(c) DILG, DepED, DSWD and DOLE shall ensure that persons with rare disease are given the opportunity to be productive members of society and that they are given the same rights and benefits as PWDs;

(d) DOST shall provide mechanisms to further research for a better understanding of rare diseases in the country and develop low cost medical foods and orphan products for the patients; and

(e) All other relevant government agencies shall assist in the full implementation of this Act.

SEC. 19. *Obligation of Healthcare Practitioners.* – A healthcare practitioner who attends to a person with rare disease has the responsibility of informing the patient and their family of available resources and refer them to the nearest available specialist.

SEC. 20. *Continuing Education and Training of Health Personnel.* – The DOH and the NIH, together with health professional societies and academic healthcare institutions, shall:

(a) Conduct continuing education, information, and training programs for healthcare practitioners on the identification and referral of persons with rare disease for medical management; and

(b) Educate healthcare practitioners on the importance of reporting cases to the Rare Disease Registry.

ARTICLE VII

RESOURCE GENERATION AND FISCAL INCENTIVES

SEC. 21. *Financial Assistance for Persons with Rare Disease.* – A person with rare disease may avail of the following:

(a) Basic benefit package from the Philippine Health Insurance Corporation, which shall be provided in accordance with its guidelines; and

(b) Medical assistance as provided in Section 8 of Republic Act No. 10351 or the Sin Tax Reform Act of 2012.

SEC. 22. *Fiscal Incentives.* – The following shall be exempted from all taxes and customs duties, as applicable, whether national or local:

(a) Donations intended for researches on rare diseases, maintenance of the Rare Disease Registry, or for purchase of

orphan drugs or orphan products for use solely by patients with rare diseases; and

(b) Orphan drugs and orphan products for use solely by patients with rare diseases, as certified by the FDA.

ARTICLE VIII

FINAL PROVISIONS

SEC. 23. *Implementing Rules and Regulations (IRR).* – Within one hundred eighty (180) days from the effectivity of this Act, the DOH, in consultation with the NIH, shall issue the IRR of this Act.

SEC. 24. *Repealing Clause.* – All general and special laws, decrees, executive orders, proclamations and administrative regulations, or any part or parts thereof, which are inconsistent with this Act are hereby repealed or modified accordingly.

SEC. 25. *Separability Clause.* – If, for any reason or reasons, any part or provision of this Act shall be declared or held to be unconstitutional or invalid, other parts or provisions hereof which are not affected thereby shall continue to be in full force and effect.

SEC. 26. *Effectivity.* – This Act shall take effect fifteen (15) days after its publication in at least two (2) newspapers of general circulation.

Approved,

FELICIANO BELMONTE JR.
Speaker of the House of Representatives

FRANKLIN M. DRILON
President of the Senate

Senate Bill No. 2990, which was approved by the Senate on December 14, 2015, was adopted as an amendment to House Bill No. 5973 by the House of Representatives on December 15, 2015.

MARILYN B. BARUA-YAP
Secretary General
House of Representatives

OSCAR G. YABES
Secretary of the Senate

Approved: MAR 0 3 2016

BENIGNO S. AQUINO III
President of the Philippines

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