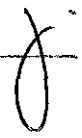


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**SENATE**

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**COMMITTEE REPORT NO. 286**

Submitted jointly by the Committees on *Health and Demography, Social Justice, Welfare and Rural Development, Ways and Means, Youth & Finance* on

OCT 07 2015

Re: S.B. No. 2990

Recommending its approval in Substitution of S.B. Nos. 1868, 2098, 2279, 2383 and 2407, and taking into consideration P.S.R. Nos. 865 and 1584, 03 September 2014 Privilege Speech of Cayetano (P) and H. No. 5973

Sponsors: Senators Pia S. Cayetano and Teofisto "TG" L. Guingona III\*

**MR. PRESIDENT:**

The Committees on *Health and Demography Social Justice, Welfare and Rural Development, Ways and Means, Youth & Finance* to which were referred

**S.B. No. 1868**, introduced by Sen. Miriam Defensor Santiago, entitled:

**"AN ACT MANDATING THE  
UNIVERSITY OF THE PHILIPPINES NATIONAL INSTITUTES OF HEALTH  
TO CONDUCT RESEARCH ON PEDIATRIC RARE DISEASES AND  
CONDITIONS"**

**S.B. No. 2098**, introduced by Sen. Pia S. Cayetano and Loren B. Legarda, entitled:

**"AN ACT PROMULGATING  
A COMPREHENSIVE POLICY AND ADDRESSING THE NEEDS  
OF PERSONS WITH RARE DISEASE"**

**S.B. No. 2279**, introduced by Sen. Cynthia A. Villar, entitled:

**“AN ACT PROMULGATING  
A COMPREHENSIVE POLICY IN ADDRESSING THE NEEDS  
OF PERSONS AFFLICTED BY RARE DISORDERS”**

S.B. No. 2383, introduced by Sen. Juan Edgardo “Sonny” Angara, entitled:

**“AN ACT PROMULGATING  
A COMPREHENSIVE POLICY IN ADDRESSING THE NEEDS  
OF PERSONS AFFLICTED BY RARE DISORDERS”**

S.B. No. 2407, introduced by Sen. Manuel “Lito” M. Lapid, entitled:

**“AN ACT ESTABLISHING  
A HOLISTIC RESEARCH AND DEVELOPMENT PROGRAM  
ON ORPHAN OR RARE DISEASES, APPROPRIATING FUNDS  
THEREFOR AND FOR OTHER PURPOSES”**

P.S.R. No. 865, introduced by Sen. Grace L. Poe, entitled:

**“RESOLUTION URGING THE DEPARTMENT OF HEALTH,  
UNIVERSITY OF THE PHILIPPINES-PHILIPPINE GENERAL HOSPITAL  
(UP-PGH) AND OTHER STATE ACADEMIC INSTITUTIONS AND  
HOSPITALS TO CREATE A STUDY GROUP ON AMYOTROPHIC  
LATERAL SCLEROSIS (ALS), A NEURODEGENERATIVE DISEASE  
THAT AFFECTS NERVE CELLS IN THE BRAIN AND THE SPINAL  
CORD LEADING TO PARALYSIS, TO DETERMINE THE EXTENT OF ITS  
AFFLICTION AND THE NUMBER OF AFFECTED FILIPINOS,  
WITH THE INTENTION OF PROVIDING SUPPORT MECHANISMS AND  
ASSISTANCE TO PATIENTS AND RAISING AWARENESS ABOUT THE  
RARE DISEASE”**

P.S.R. No. 1584, introduced by Sen. Miriam Defensor Santiago, entitled:

**“RESOLUTION DIRECTING THE PROPER SENATE COMMITTEE TO  
CONDUCT AN INQUIRY, IN AID OF LEGISLATION, ON THE REPORT THAT  
SOME 10,000 FILIPINOS ARE AFFLICTED WITH DISEASES THAT ARE  
DIFFICULT TO DIAGNOSE AND COSTLY TO TREAT”**

03 September 2014 **Privilege Speech** of Senator Cayetano (P) entitled:

**“ALS ICE BUCKET CHALLENGE AND RARE DISEASE”**

and H. No. 5973, introduced by Representatives Arroyo, Macapagal-Arroyo, Aragonés, 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, Kato, Lanete, Paez and Quimbo, entitled;

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

have considered the same and have the honor to report them back to the Senate with the recommendation that the attached S.B No. 2990, prepared by the Committees, entitled:

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

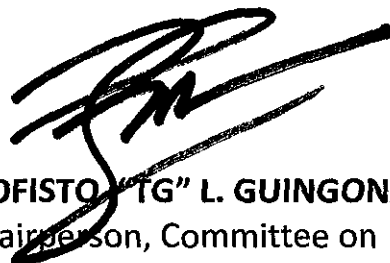
be approved in substitution of S.B. Nos. 1868, 2098, 2279, 2383 and 2407, and taking into consideration P.S.R. Nos. 865 and 1584, 03 September 2014 Privilege Speech of Cayetano (P) and H. No. 5973 with Senators Santiago, Cayetano (P), <sup>And</sup> Legarda, Villar, Angara, Lapid, Poe and Guingona as authors thereof.

Respectfully submitted:



**PIA S. CAYETANO**


\*Chairperson Designate,  
Sub-Committee and Vice-Chair,  
Committee on Health and Demography



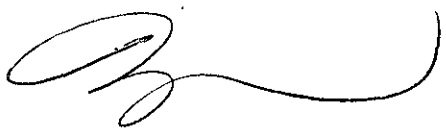
**TEOFISTO "TG" L. GUINGONA III**  
Chairperson, Committee on  
Health and Demography & Vice  
Chair, Committee on Finance



**LOREN B. LEGARDA**  
Chairperson  
Committee on Finance



**MARIA LOURDES NANCY S. BINAY**  
Chairperson, Committee on Social  
Justice, Welfare & Rural  
Development

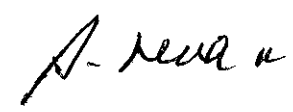


**SONNY ANGARA**  
Chairperson  
Committee on Ways and Means  
Vice Chair, Committee on Finance



**PAOLO BENIGNO "BAM" AQUINO**  
Chairperson  
Committee on Youth  
Vice Chair, Committee on Finance

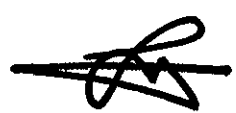
**MIRIAM DEFENSOR SANTIAGO**  
Vice Chairperson  
Committee on Ways and Means



**SERGIO R. OSMEÑA III**  
Vice Chairperson  
Committee on Finance

**CYNTHIA A. VILLAR**  
Vice Chairperson  
Committee on Finance

**MEMBERS:**

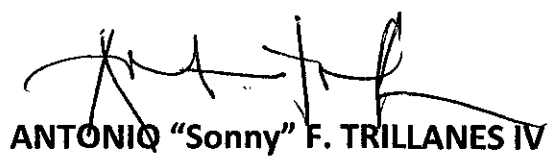


**FRANCIS "Chiz" G. ESCUDERO**

**FERDINAND R. MARCOS, JR.**



**GRACE POE**



**ANTONIO "Sonny" F. TRILLANES IV**

**RAMON BONG REVILLA, JR.**



**AQUILINO "Koko" PIMENTEL III**



JOSEPH VICTOR G. EJERCITO

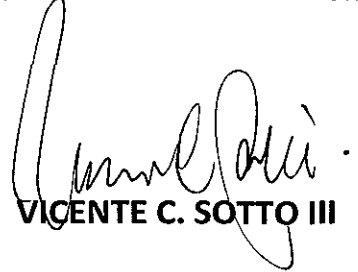


MANUEL "Lito" M. LAPID



GREGORIO B. HONASAN II

JINGGOY EJERCITO ESTRADA



VICENTE C. SOTTO III

Ex-Officio Members:



RALPH G. RECTO  
President Pro-Tempore



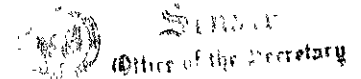
JUAN PONCE ENRILE  
Minority Leader



ALAN PETER "Compañero" S. CAYETANO  
Majority Leader

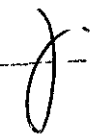
HON. FRANKLIN M. DRILON  
*Senate President*  
Senate of the Philippines  
Pasay City

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



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SENATE  
S. B. No. 2990

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PREPARED JOINTLY BY THE COMMITTEES ON HEALTH AND DEMOGRAPHY,  
SOCIAL JUSTICE, WELFARE AND RURAL DEVELOPMENT, WAYS AND MEANS,  
YOUTH AND FINANCE WITH SENATORS SANTIAGO, (P.) CAYETANO, LEGARDA,  
VILLAR, ANGARA, LAPID, POE, AND GUINGONA AS AUTHORS THEREOF

---

**“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**

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

3           **SEC. 2. Declaration of Policy** - It is the policy of the State to protect and  
4 promote the right to health of the people, including the right of persons suffering from  
5 rare diseases to survival and full and healthy development as individuals through  
6 access to timely health information and adequate Medical Care. In pursuit of such  
7 policy, the State shall institutionalize a system that is comprehensive, integrative and  
8 sustainable and will facilitate collaboration among government and non-government  
9 agencies and organizations at the national and local levels, private sector, professional  
10 health organizations, academic institutions, communities and families towards the  
11 provision of early and sustainable care of persons afflicted with rare disease. The State  
12 recognizes the crucial role of research in defining health programs and activities to  
13 address the needs of patients with rare disease. The State also recognizes that an  
14 effective public education program is vital in helping ensure the early diagnosis and  
15 treatment of rare disorders and in preventing those afflicted with them from being the  
16 subject of ridicule and stigmatization.

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

18           1. Improve the access of patients diagnosed to have a rare disease or patients  
19 highly suspected of having a rare disease to comprehensive Medical Care,  
20 including drugs and other healthcare products to treat or otherwise, as well as  
21 timely health information to help them cope with their condition by:

22           a. Establishing a comprehensive and sustainable health care system  
23 integrated within the public health care delivery system for early and  
24 sustainable care for patients suffering from rare diseases;



1 supplementation to counter adverse effects of the heritable conditions; and f)  
2 monitoring and evaluation of the National Comprehensive Newborn Screening  
3 System.

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

9 i) *Orphan Drug* refers to any drug or medicine used to treat or alleviate the  
10 symptoms of persons afflicted with a rare disease and declared as such by the  
11 DOH upon recommendation of the National Institutes of Health (NIH).  
12

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

17 k) *Rare Disease* refers to disorders such as inherited metabolic disorders and  
18 other diseases with similar rare occurrence as recognized by the DOH upon  
19 recommendation of the NIH but excluding catastrophic (i.e., life threatening,  
20 seriously debilitating, or serious and chronic) forms of more frequently occurring  
21 diseases.

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

25 m) *Rare Disease Registry* refers to the secure health information system,  
26 including the electronic database system, relating to data on rare diseases,  
27 persons with rare disease, and Orphan Drugs and Orphan Products.

28 n) *Rare Diseases Technical Working Group (RDTWG)* refers to the DOH  
29 designated pool of experts on rare diseases, which shall include experts from the  
30 National Institutes of Health, tasked with identifying rare diseases, Orphan Drugs  
31 and Orphan Products.

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

35 **ARTICLE III**  
36 **IDENTIFICATION, REFERRAL, MANAGEMENT AND REGISTRATION OF**  
37 **PERSONS WITH RARE DISEASE**  
38

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

43 **SEC. 6. Referral of Patients with Rare Disease** – Patients highly suspected of,  
44 or diagnosed with, rare disease shall be referred to a Newborn Screening Continuity  
45 Clinic identified by the DOH as referral centers for treatment of rare diseases under the



1 National Comprehensive Newborn Screening System. For patients from remote areas,  
2 the Telegenetics Referral System will be utilized.

3 **SEC. 7. Availability of Specialist for the Management of Persons with Rare**  
4 **Disease** -The DOH, with the assistance of NIH, shall develop a system to train a  
5 sufficient number of Medical Specialists to diagnose and manage persons with rare  
6 disease.

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

11 **SEC. 9. Registration of Persons with Rare Disease.** All Healthcare  
12 Practitioners and Health Institutions shall be required to report to the Rare Disease  
13 Registry diagnosed cases of Rare Disease and provide reports on the status of patients;  
14 *Provided*, That such reports shall be subject to guidelines issued by the NIH to protect  
15 the privacy of patients with rare disease.

16 **ARTICLE IV**  
17 **PERSONS WITH RARE DISEASE AS PERSONS WITH DISABILITIES (PWDs)**

18 **SEC. 10. Designation of Persons with Rare Disease as Persons with**  
19 **Disabilities (PWDs)** – Persons with Rare Disease shall be considered as persons with  
20 disabilities (PWDs), in accordance with Republic Act 7277, as amended, or the Magna  
21 Carta for Disabled Persons.

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

- 25 a) The Department of Social Welfare and Development (DSWD) shall provide  
26 assistance to persons with Rare Disease to ensure that their social welfare  
27 and benefits are provided under Republic Act 7277, as amended, or the  
28 Magna Carta for Disabled Persons, are granted; and
- 29 b) The Department of Labor and Employment (DOLE) shall adopt programs that  
30 promote the availability of opportunities for work and employment of able-  
31 persons with Rare Disease.

32 **ARTICLE V**  
33 **DESIGNATION OF RARE DISEASE, ORPHAN DRUG, AND**  
34 **ORPHAN PRODUCT STATUS**

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

- 37 a) Determine what disorder or disease shall be considered as a Rare Disease,  
38 and what are the Orphan Drugs and Products, and update the list periodically;
- 39 b) Formulate policies that shall regulate the approval and certification of Orphan  
40 Drugs and Products; and

- 1 c) Establish a system to ensure the regular updating of information, diagnosis  
2 and treatment of Rare Diseases in order to provide for the comprehensive  
3 health care of these patients.

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

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

13 **SEC. 15. Designation of Orphan Product** - The DOH, *motu proprio* or upon  
14 application by any interested person, and with the recommendation of the RDTWG, may  
15 designate any healthcare or nutritional product, other than a drug or medicine, including  
16 but not limited to diagnostic kits, medical devices and biological products, used primarily  
17 to prevent, diagnose, or alleviate the symptoms of Rare Diseases as an Orphan  
18 Product. Within one hundred twenty (120) days from the effectivity of this Act, the DOH  
19 shall publish a list of Orphan Products for these Rare Diseases.

20 **SEC. 16. Permit for Restricted Use of an Orphan Drug/Orphan Product** - Any  
21 person may import any Orphan Drug or Orphan Product for compassionate use,  
22 *Provided*, That they secure a compassionate special permit from the FDA in accordance  
23 with DOH Administrative Order No. 4, series of 1992, and any future guidelines that  
24 may be issued on the same.

25  
26 Within thirty (30) days from receipt of the requirements, the FDA shall issue a  
27 permit for restricted use of an Orphan Drug/Orphan Product which shall be effective for  
28 a period of three (3) years, renewable for period of three (3) years thereafter: *Provided*,  
29 That the FDA shall expedite the said permit in cases of emergency.

30 **ARTICLE VI**  
31 **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:

- 32 a) Establish the RDTWG as defined in Sec. 4(n);
- 33 b) Coordinate with the NIH for the technical assistance in the implementation of  
34 this Act;
- 35 c) Coordinate with all government and non-government agencies that are  
36 involved in the implementation of this Act;
- 37 d) Support the activities of the Newborn Screening Continuity Clinics and  
38 designate referral centers in strategic locations in the country for the timely  
39 and sustainable medical management of persons with Rare Disease;  
40
- 41 e) Organize a pool of Medical Specialists who will be responsible in the  
42 diagnosis and management of persons afflicted with Rare Disease and their  
43 families;

- 1 f) With the assistance of the NIH and other government agencies, professional  
2 societies and non-government organizations, conduct culturally sensitive  
3 public educational and information campaigns on the nature of Rare  
4 Diseases, identify persons with Rare Disease and help the general public  
5 understand the special needs of afflicted persons and their right against  
6 ridicule and discrimination;  
7  
8 g) Develop the implementing rules and regulations for the implementation of this  
9 Act within one hundred eighty (180) days from the enactment of this Act; and  
10  
11 h) Allot budget for the implementation of this Act.

11 **SEC. 18. *Other implementing agencies*** - The FDA, NIH, Department of Interior  
12 and Local Government (DILG), Department of Education (DepEd), DSWD, DOLE,  
13 Department of Science and Technology (DOST), and other relevant government  
14 agencies shall have the following tasks:

- 15 a) FDA shall ensure that Medical Foods, Orphan Drugs and Products are  
16 permitted in the country for purposes of treating Rare Diseases and shall  
17 develop a system that addresses emergency cases, as they may arise;  
18  
19 b) NIH shall provide technical assistance to the DOH in the implementation  
20 of this Act;  
21  
22 c) DILG, DepEd, DSWD and DOLE shall ensure that persons with Rare  
23 Disease are given the opportunity to be productive members of society  
24 and that they are given the same rights and benefits as PWDs;  
25  
26 d) DOST shall provide mechanisms to further research for a better  
27 understanding of Rare Diseases in the country and develop low cost  
28 Medical Foods and Orphan Products for the patients; and  
29  
30 e) All other relevant government agencies shall assist in the full  
31 implementation of this Act.

32 **SEC. 19. *Obligation of Healthcare Practitioners*** – A Healthcare Practitioner  
33 who attends to a person with Rare Disease has the responsibility of informing the  
34 patients and their families of available resources and refer them to the nearest available  
35 specialist.  
36

37 **SEC. 20. *Continuing Education and Training of Health Personnel.*** – The DOH  
38 and the NIH, together with health professional societies and academic Healthcare  
39 Institutions, shall:  
40

- 41 a) Conduct continuing education, information, and training programs for  
42 Healthcare Practitioners on the identification and referral of persons with  
Rare Disease for medical management; and  
43  
44 b) Educate Healthcare Practitioners on the importance of reporting cases to  
the Rare Disease Registry.

