


SENATE

9 MAY 19 P5:49

S. No. 3263

RECEIVED BY: 

Introduced by Senator Manuel "Lito" M. Lapid

EXPLANATORY NOTE

Article 13, Section 12 of the 1987 Constitution provides that the State shall establish to undertake appropriate health manpower development and research, responsive to the country's health needs and problems.

Orphan, or rare, diseases are disorders or diseases which affect small patient populations. They do not attract very much public attention, research, or funding, typically because they are extremely rare or poorly publicized. Thousands of such diseases can be found worldwide, ranging from extremely rare genetic disorders like Fatal Familial Insomnia to tuberculosis, which do not attract attention in industrialized nations due to the low incidence of reported cases. Diseases which are common in the developing world but rare or unusual in the industrialized world are also called orphan diseases, because they fail to attract attention from major pharmaceutical companies.

Many orphan diseases are genetic in nature, which can make them very challenging to study, let alone treat. Others take the form of extremely rare viruses, unusual bacteria, or peculiar allergies, and they may take time to diagnose, so they slip through the cracks for months or years until someone begins to connect multiple incidences of the same condition. Researchers such as epidemiologists are often more in touch with emerging diseases than others, but they cannot attract enough attention to extremely rare diseases to make the general public aware of the issue.

For decades, many Filipinos suffering from a number of orphan diseases and disorders were denied access to effective medicines because pharmaceutical companies make little financial incentives to produce and market new medications to treat or prevent the same. Even with the pressing health need for these medications, they came to be known as 'orphan drugs' because no companies would commercialize them.

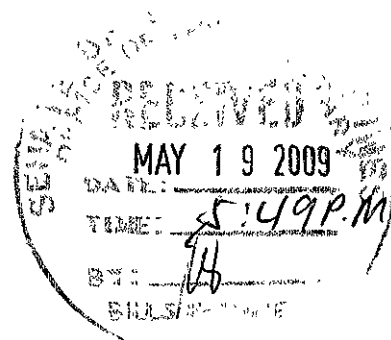
This proposed measure seeks to provide a comprehensive program for health research on orphan diseases in the country and provide a national comprehensive information and education drive to inform the general public of the nature and mode of infection of orphan diseases.

In view of the foregoing, early passage of this bill is earnestly sought


MANUEL "LITO" M. LAPID
Senator

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

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

SECTION 1. Short Title. - This Act shall be known as the "**Orphan Diseases Act of 2009.**"

SEC. 2. Declaration of Policy. – It is hereby declared the policy of the State to protect and promote the right to health of the people to full, healthy and holistic development and the right to self-determination. As such, the State shall promote an environment conducive to the development of all its citizens to become, to the best of their potentials, independent, self-reliant and productive members of society.

Towards this end, the State commits itself to the establishment of institutional mechanisms to provide quantitative and qualitative research on orphan (or rare) diseases that are responsive to the country's health needs.

SEC. 3. Definition of Terms. - For purposes of this Act, the following terms shall be defined as follows:

(a) "**Committee**" refers to the Committee on Orphan Diseases Research.

(b) "**Orphan Diseases**" are disorders or diseases which affect small patient populations, do not attract very much public attention, research, or funding, typically because they are extremely rare or poorly publicized and do not attract attention in industrialized nations due to the low incidence of reported cases.

- (c) “*Secretary*” shall refer to the Secretary of the Department of Health;

SEC. 4. Comprehensive Research on Orphan Diseases. - The Secretary of the Department of Health (DOH) is hereby mandated to conduct a comprehensive research and information drive on the incidence and prevalence of orphan diseases in the country. The Department is also mandated to support medical and epidemiological research activities to expand the knowledge and understanding of orphan diseases in the country.

The DOH is mandated to strengthen its research focus concerning orphan diseases, including a renewed investment into basic and clinical research, expanded research into the link between environmental factors and the diseases, and continued investigations into causation, diagnosis, and treatment. Such factors that will be studied shall also include, among others, infection and immune function, hormones and reproductive factors, genetic factors, gastro-intestinal factors, socio-demographic factors, and others.

SEC. 5. Committee on Orphan Diseases Research. - To assist the Secretary in receiving accurate and complete information on orphan diseases, its symptoms, origins, classifications, preventions and treatment, there is hereby established a Committee, to be known as the Committee on Orphan Diseases, to ensure the strategic management, communication, and oversight of the policy formation, research, and activities of the government regarding these diseases.

The Committee on Orphan Diseases Research shall endeavor to:

- a) promote public awareness, education and information on issues concerning orphan diseases;
- b) establish sustainable networks of support group for families of afflicted persons;
- c) provide referral services to patients with orphan diseases and identify the appropriate educational and medical expertise and facilities suited to the needs of the patients;
- d) combat the spectrum of medical problems related to orphan diseases through education, prompt referrals for treatment and services;
- e) undertake research and/or collaborate with other entities on research activities regarding the prevalence of the orphan diseases in the Philippines;

- f) receive donations and grants from international donor institutions, foundations, and multilateral and bilateral foreign donor agencies involved in research, prevention, cure and rehabilitation of persons with orphan diseases;
- g) provide the avenue for exchange of information, exchange programs and sharing of best practices on issues relating to prevention, cure, treatment and rehabilitation of afflicted patients; and
- h) ensure that materials concerning the disease are available, up to date, and responsive to reports of problems with orphan diseases, and that timely aggregate data concerning such reports shall be made available to the public upon request and consistent with existing confidentiality standards.

SEC. 6. Composition. - The Committee on Orphan Diseases Research shall be composed of the following members:

- (a) One (1) representative from the Department of Health (DOH);
- (b) One (1) representative from the National Institute of Health (NIH);
- (c) One (1) representative from duly accredited association of drug and vaccine manufacturers and distributors;
- (d) One (1) representative from the duly accredited association of hospitals in the Philippines;
- (e) One (1) representative from the duly accredited association of medical doctors in the Philippines; and
- (f) One (1) representative from non-governmental organizations (NGOs) involved in the advocacy for the prevention, cure and rehabilitation of persons with orphan disease.

The Secretary shall be the Chairperson of the Committee.

SEC. 7. Meetings. - The Committee shall meet at least once a month upon three-day notice signed by the two (2) Chairpersons or as often as necessary upon the written request signed by two-thirds (2/3) of its members.

The presence of a majority of the members of the Committee shall constitute a quorum in order for it to conduct its business.

The meetings of the Committee shall be open to the public and public witnesses shall be given the opportunity to speak and make presentations at such meetings.

Each member shall make a presentation to the full Committee at each meeting concerning the activities conducted by such member.

SEC. 8. *Intervention for Persons with Orphan Diseases.* – The DOH is hereby mandated to establish a program for identification and detection of persons with orphan disease.

SEC. 9. *Prevention of Conflict of Interest in the Research Process.* - Within six (6) month from the date of effectivity of this Act, the DOH shall issue the necessary standards, guidelines and regulations in order to ensure that there is no conflict of interest between the research agenda of the researchers and the drug manufacturers or government agencies promoting the widespread usage of a particular vaccine or medicine for the treatment and rehabilitation of persons with orphan disease.

The DOH shall ensure the timely publication and dissemination of information of these guidelines and regulations in order to ensure that the various health providers and stakeholders all over the country are adequately informed.

SEC. 10. *Appropriations.* - To carry out the provisions of this Act, the funds necessary to implement the provisions of this Act shall be incorporated in the annual general appropriations of the Department of Health.

SEC. 11. *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.

SEC. 12 *Repealing Clause* - Any law, presidential decree or issuance, executive order, letter of instruction, administrative order, rule or regulation contrary to or inconsistent with the provision of this act is hereby repealed, modified or amended accordingly.

SEC. 13. *Effectivity Clause.* - This Act shall take effect fifteen (15) days from the date of its complete publication in the Official Gazette or in at least two (2) newspapers of general circulation.

Approved,