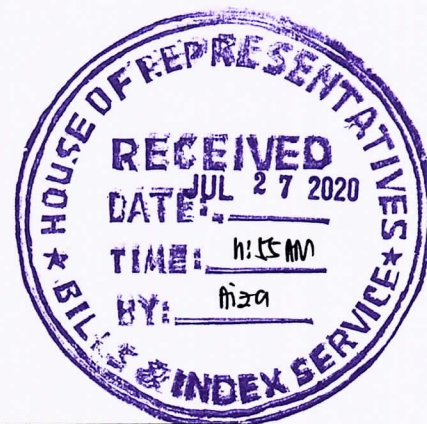


Republic of the Philippines
HOUSE OF REPRESENTATIVES
Quezon City

EIGHTEENTH CONGRESS
Second Regular Session

HOUSE BILL NO. 7185



INTRODUCED BY:
HONORABLE CHERYL P. DELOSO-MONTALLA
Representative, 2nd District, Zambales

AN ACT
PROVIDING FOR THE FRAMEWORK FOR THE ESTABLISHMENT AND
OPERATION OF PHARMACEUTICAL DEVELOPMENT CENTER OF THE
PHILIPPINES, APPROPRIATING FUNDS THEREFOR
AND FOR OTHER PURPOSES

EXPLANATORY NOTE

The country needs a comprehensive drug discovery and development program to respond to the growing health needs of the Filipinos, and to harness the potential of Philippine biodiversity. With available technical expertise and collaborations in place, limited resource may be maximized and drug discovery cost may be minimized without compromising the quality of the products developed from natural sources.¹

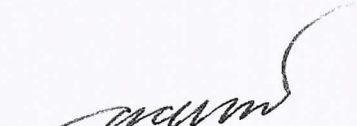
The Philippines, being one of the megadiverse countries in the world in terms of species thriving, makes it favorable for the discovery of novel compounds from indigenous/endemic terrestrial and marine species.²

However, the path through drug development is marked by detours, roadblocks and very few shortcuts. Unexpected delays can lead to missed milestones, rework and delayed timelines – all setbacks that no one wants to experience.

Fully cognizant of the problems besetting the Philippine pharmaceutical industry in addition to the pressing need to develop potent drugs to combat emerging and re-emerging infections, the Department of Science and technology has called upon Congress to enact a law providing for the creation of the Pharmaceutical Development Center that shall spearhead pharmaceutical researches to discover and develop and eventually produce therapeutic drugs for the wide array of diseases.

The vast array of underutilized pharmaceutical research in the science industry of our country is due to our limited capacity to perform these researches. This bill is a response to that.

Immediate passage of this bill is earnestly sought.


CHERYL P. DELOSO-MONTALLA
Representative
2nd District, Zambales

¹ <http://www.healthresearch.ph/index.php/about-pnhrs/downloads/category/222-technologies?download=1025:tuklas-lunas-program>

² Ibid.

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

Section 1. Short Title. – This Act shall be known as the “Pharmaceutical Development Center of the Philippines Act”

Section 2. Declaration of Policy. – It is hereby declared the mandatory policy of the State to protect and promote the right to health of every Filipino by ensuring that they are proactively protected from diseases.

Towards this end, it is also hereby declared the policy of the State to establish a reliable national pharmaceutical development and research center that shall play a critical role in discovery and development of pharmaceutical products for humans, plants and animals as well as the understanding of the therapeutic actions of these pharmaceutical products as a prerequisite for a strong public health response to diseases in order to raise the level of health of the Filipino and improve their social, economic and cultural conditions.

It is hereby further declared the policy of the State that a systematic approach to the improvement of our health system requires the establishment of an institution equipped with the necessary capacity, competency, latitude and authority to decisively and scientifically respond to the demands of public health and public health emergencies, crises and situations brought about by infectious and non-infectious diseases.

Section 3. Objectives. – This Act seeks to establish a pharmaceutical development center that shall pursue drug discovery and development by leveraging on the country's very own biodiversity. It shall focus on the following key development areas for pharmaceutical development and research and their technological, medical and biological applications:

- a. Harness the potential of the country's own resources under two tracks: the herbal and drug tracks with the end in view of maximizing the effect of discovered drugs, minimizing their adverse effects and promoting safety of prescription;
- b. Discovery of new drugs from local natural sources for development up to the pre-clinical stage;
- c. Development of standardized herbal drugs;

- d. Identification and characterization of high-value purified active compounds derived from marine and terrestrial sources for specific therapeutic indications;
- e. Development and/or validation of standard processes and protocols for various stages of drug discovery and development S
- f. Strengthen the capacities of both researchers and the local industry in drug discovery and development, generate optimum data for use of drugs and promote usage of evidence-based medicine;
- g. Provide scientific understanding to support the establishment of design space, specifications and manufacturing controls of developed pharmaceuticals;
- h. Operate of pharmaceutical research and reference laboratory to focus on the discovery and development of drugs for medical, zoological and botanical disease prevention and control;

Section 4. Definition of Terms. – As used in this Act, the following terms shall mean:

- a. *Animal pharmacology* deals with the different properties of drugs in animals and plants. Drugs are given to the animals and all parameters (their behavior, activities, vital signs, etc.) are recorded. Any change is noted down. If found to be useful in animals, then the drug is tested on humans.
- b. *Chemotherapy* refers to the treatment of diseases by chemicals that kill the cells, particularly those of microorganisms and neoplastic or malignant cells. It is classified into two divisions: antibiotics and antineoplastic or anti-cancer drugs;
- c. *Clinical pharmacology* refers to the scientific study of drugs in man. It includes pharmacokinetic and pharmacodynamic investigations in healthy or diseased individuals. It also includes the comparison with placebos, drugs in the market and surveillance programs;
- d. *Comparative pharmacology* deals with the comparison of one drug to another belonging to the same or another group;
- e. *Design space* refers to the multidimensional combination and interaction of input variables (e.g., material attributes) and process parameters that have been demonstrated to provide assurance of quality. Working within the design space is not considered as a change. Movement out of the design space is considered to be a change and would normally initiate a regulatory post approval change process. Design space is proposed by the applicant and is subject to regulatory assessment and approval.
- f. *Pharmacodynamics* refers to the mechanism of action of drug and the relation between the drug concentration and physical and chemical effects on the body, parasites and microorganisms;
- g. *Pharmacoeconomics* deals with the cost of a drug in comparison to another which can provide a similar desired effect on the individual using it;
- h. *Pharmacoepidemiology* deals with the effects of drugs on a large population. These include different phases:
 - 1. Human pharmacology (20 to 50 subjects), pharmacokinetics and pharmacodynamics of the drug are observed;

3. Therapeutic confirmation (250 to 1000 subjects), safety, efficacy of drugs is compared with the drugs already present; and
4. Therapeutic use (2000 to 10000 subjects), the opinion of physicians prescribing the drugs is collected regarding dosage and efficacy. Surveillance programmes are lengthy when conducted outside hospitals.
 - i. *Pharmacogenetics* deals with the genetic variations that cause difference in drug response among individuals or population;
 - j. *Pharmacogenomics* refers to the broader application of genomic technologies to new drug discovery and further characterization of older drugs;
 - k. *Pharmacognosy* deals with the drugs in crude or unprepared form and study of properties of drugs from natural sources or identification of new drugs obtained from natural sources;
 - l. *Pharmacokinetics* refers to the absorption, distribution, metabolism and excretion of drugs and their relationship with the onset, duration and intensity of the drug effect;
 - m. *Pharmacy* refers to the art and science of compounding by dispensing drugs, preparing suitable dosage form for administration to man and animals;
 - n. *Posology* deals with the dosage of drugs to achieve a desired effect;
 - o. *Therapeutics* refers to the art and science of treatment of disease. It is the application of pharmacological information together with the knowledge of disease, for the prevention and cure of the disease;
 - p. *Toxicology* refers to the study of adverse effects of drugs on the body particularly on the symptoms, mechanisms, treatment and detection of poisoning caused by different chemical substances;

Section 5. Creation of the Pharmaceutical Development Center of the Philippines. – To carry out the provisions of this Act, there is hereby created a research and development institute under the Department of Science and Technology to be called the Pharmaceutical Development Center of the Philippines (PDCP).

The PDCP shall serve as the premier research and development institute in the field of pharmacology, pharmaceutical development and its application. It shall act as a venue for scientists, both here and abroad, to work collaboratively to study drug and drug development and their industrial, clinical, and environmental importance.

The PDCP shall establish strategic partnerships with the world's leading scientists, pharmaceutical research centers, and institutes and conduct innovative and pioneering researches that will advance the frontiers of pharmacology and pharmaceutical development and application in the country.

Section 6. Mandate. – The PDCP shall implement policies, plans, programs, and projects for the development of biomedical, therapeutic drugs in the country and the promotion of scientific and technological activities for both the public and private sectors, and ensure that the results of these activities are properly applied towards self-reliance and utilized to accelerate economic and social development towards the protection of the citizens and its resources.

Section 7. Powers, Functions, and Duties. – To accomplish its mandate, the PDCP shall

- a. Serve as the lead convener of the pharmaceutical development research agenda as part of the National Unified Health Research Agenda (NUHRA);
- b. Undertake scientific and technological research and development (R&D) in the field of pharmacology and pharmaceutical development as part of the Harmonized National Unified Health Research and Development Agenda (HNRDA);
- c. Conduct product research and development in the areas of drug discovery and development with focus on drug pharmacokinetics, pharmacodynamics, chemotherapy and therapeutics, toxicology, clinical pharmacology, pharmacy and pharmacognosy, pharmacogenetics, pharmacogenomics, pharmacoeconomics, pharmacoepidemiology, comparative pharmacology, animal pharmacology and posology;
- d. Promote and undertake the transfer of the results of scientific research and development to concerned government agencies, industry, and academe;
- e. Develop and maintain an information system on biomedical and industrial pharmacology for use by both the public and private sectors;
- f. Develop and implement, together with other entities concerned, programs for strengthening scientific and technological capabilities in pharmacology and relevant disciplines through human resource development, infrastructure, and institution building;
- g. Undertake policy research, technology assessment, and other related researches in pharmacology;
- h. Provide laboratory and technical services in pharmacology and pharmaceutical development;
- i. Promote and advocate the national programs on biomedical and industrial pharmacology; and
- j. Establish linkages with local and international partners.

Section 8. *Organizational Structure.* – The PDCP shall be an attached agency of the Department of Science and Technology (DOST) for purposes of policy and program coordination, and to ensure alignment in national policies and priorities. It shall be headed by a Director and two (2) Deputy Directors, one (1) for Research and Development, and another one (1) for Support, Policy, and Linkages.

The PDCP shall be composed of the Office of the Director, Office of the Deputy Director for Research and Development, Office of the Deputy Director or Support, Policy, and Linkages and the following divisions:

- a) Pharmacological Discovery and Development Studies;
- b) Clinical Pharmacology and Therapeutics Research;
- c) Toxicology and Chemotherapy Research;
- d) Technical Services and Training;
- e) Policy, Planning, and Linkages; and
- f) Finance and Administration.

The Deputy Director for Research and Development shall head the first three (3) divisions while the Deputy Director for Support, Policy, and Linkages shall head the next three (3) divisions.

Subject to the approval of the Department of Budget and Management (DBM), the PDCP

necessary and shall appoint officers and employees of the PDCP following the civil service laws, rules, and regulations.

For this purpose, the PDCP shall draw up the necessary position qualifications and standards for its personnel following the Civil Service Law, rules and regulations, in consultation with the DBM.

Section 9. *The Governing Board.* – The Governing Board shall be the principal policy-making body for scientific and technological activities of the Institute. It shall be composed of the following:

- a. Chair, Secretary of DOST;
- b. Co-chair, Undersecretary for R&D, DOST;
- c. Members:
 - i. Director General of the Food and Drug Administration (FDA);
 - ii. Executive Director of Philippine Council for Health Research & Development (PCHRD);
 - iii. Executive Director of Philippine Council for Agriculture, Aquatic, and Natural Resources Research and Development (PCAARRD);
 - iv. Executive Director of Philippine Council for Industry, Energy and Emerging Technology Research & Development (PCIEERD);
 - v. Director of Pharmaceutical Development Center of the Philippines (PDCP);
 - vi. Director of University of the Philippines-National Institutes of Health (UP-NIH); and
 - vii. Three (3) representatives from the Private Sector elected by the ex-officio Board Members.

Section 10. *Transfer of offices and units.* – All offices and units under the DOST system that are handling matters related to pharmaceutical development and research shall be transferred to the PDCP.

The transfer of an office or unit shall include the functions, appropriations, funds, records, equipment, facilities, choses in action, rights, other assets, and liabilities, if any, of the transferred office or unit as well as the personnel thereof, as may be necessary.

Section 11. *Engagement of Balik Scientists and Foreign Experts.* – The institute may engage *Balik Scientists* and foreign experts following the terms of reference and compensation structure of the *Balik Scientist* Program.

Section 12. *International Cooperation.* – The PDCP may enter into a memorandum of agreement or memorandum of understanding with international partners, upon the approval of its Governing Board.

Section 13. *Interagency contribution of the PDCP.* – The findings of the PDCP shall be integrated in other plans relating to disease control and prevention.

Section 14. *Official Site of PDCP.* – A lot with an area equivalent to at least five (5) hectares under the administration of the Bases Conversion and Development Authority (BCDA) within the New Clark Economic Zone in Tarlac shall be allocated exclusively for the PDCP, its research facilities, and laboratories. The biosafety infrastructure shall be designed based on internationally-accepted standards for pharmaceutical researches.

Section 15. *Entitlement to Magna Carta Benefits.* – Qualified employees of PDCP and its attached units shall be covered by Republic Act No. 8439, otherwise known as “Magna Carta for

Section 16. *Annual Report.* – The PDCP shall submit its annual report to the President and the Committee on Science and Technology in both Chambers of the Congress not later than the 30th of March of every year following the effectivity of this Act. The report shall provide a detailed account of the status of the implementation of this Act and recommended legislation, where applicable and necessary.

Section 17. *Pharmaceutical Development Research Fund.* – There is hereby created a pharmaceutical Development Research Fund to be used exclusively for the implementation of the Pharmaceutical Development Strategic Plan, which shall be administered by the PDCP following, existing government budgeting, accounting, and auditing rules and regulations. The Fund shall be sourced from the following:

a. The initial amount of Two Billion pesos (P 2,000,000,000.00) to be taken from the current fiscal year's appropriation, in case the General Appropriation Act (GAA) was approved before this law is enacted;

b. The income produced from its operations, technology transfer, and licensing agreements; and

c. Loans, contributions, grants, bequests, gifts, and donations whether from local or foreign sources. *Provided*, that acceptance of grants, bequests, contributions, and donations from foreign governments shall be subject to the approval of the President upon the recommendation of the Secretary of the DOST and Secretary of the Department of Foreign Affairs (DFA). The Secretary of DOST, with the approval of the NEDA and subsequently, the Department of Finance (DOF), is hereby granted the authority to enter into loan agreements with foreign financial institutions.

Section 18. *Use of Income.* – The PDCP shall be authorized to use all of the income generated from its operations, as well as donations, bequests, grants for the upgrading of its physical and human resources, and for the augmentation of its budget, in case of a shortfall.

Section 19. *Appropriations.* – The sum of Two Billion Pesos (Php 2,000,000,000.00) is hereby appropriated as an initial operating fund for the operation of the PDCP, taken from the current fiscal year's appropriation. Thereafter, the amount needed for its operation shall be included in the General Appropriation Act.

Section 20. *Implementing Rules and Regulations.* – Within one hundred twenty (120) days from the effectivity of this Act, the DOST in coordination with DBM, Civil Service Commission, and other relevant government agencies, shall promulgate the necessary rules and regulations for the effective implementation of this Act.

Section 21. *Separability Clause.* – Any portion or provision of this Act that may be declared unconstitutional or invalid shall not have the effect of nullifying the other portions or provisions hereof as long as such remaining portion or provision can still subsist and be given effect in their entirety.

Section 22. *Repealing Clause.* – All laws, decrees, orders, rules, and regulations or other issuances or parts thereof inconsistent with the provisions of this Act are hereby repealed or modified accordingly.

Section 23. *Effectivity.* – This Act shall take effect fifteen (15) days after its publication in the Official Gazette or any two (2) newspapers of general circulation in the Philippines.

Approved,