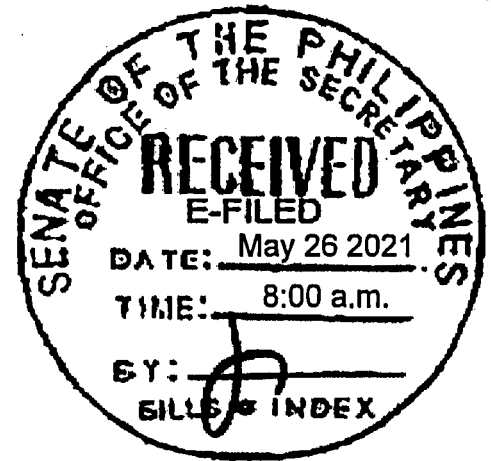


EIGHTEENTH CONGRESS OF THE )  
REPUBLIC OF THE PHILIPPINES )  
*Second Regular Session* )

SENATE

S.B. No. 2238



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Introduced by SENATOR RICHARD J. GORDON

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**AN ACT CREATING THE PHILIPPINE VACCINE AUTHORITY FOR THE DEVELOPMENT OF LOCAL VACCINE MANUFACTURING CAPABILITY, TO SUPPORT LOCALLY MANUFACTURED VACCINES, AND PROVIDING FOR A VACCINE DEVELOPMENT FUND AND FOR OTHER PURPOSES**

**EXPLANATORY NOTE**

Article II, Section 15 of the Philippine Constitution provides that, "The State shall protect and promote the right to health of the people and instill health consciousness among them."

The onslaught of the novel coronavirus, or severe acute respiratory syndrome coronavirus (COVID-19), highlighted the unpreparedness of the country in containing a highly contagious virus and in effectively protecting the public from the novelty and danger presented by this viral disease. As of February 8, 2021, there have been 105,805,951 confirmed cases, including 2,312,278 deaths worldwide, that had been reported to the World Health Organization (WHO).<sup>1</sup> Of these, 538,995 are confirmed cases and 11,231 deaths were recorded in the Philippines.<sup>2</sup>

WHO confirmed that a pandemic can be successfully curbed with vaccines. For instance, smallpox, which killed 300 million people in the 20th century alone, had been eradicated due to an intense global smallpox vaccination campaign joint with broader public health measures.<sup>3</sup> Vaccine is therefore important in stopping the spread of COVID-19 and helping revive the nation as when the population is vaccinated, workers can go back to work, students can go back to school, and ultimately revitalizing the society and bringing normalcy back to every Filipino.

Given the high demand for COVID-19 vaccine, where rich countries have already bought 80% of the supply, 2% was bought by the COVAX facility, leaving the

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<sup>1</sup> <https://covid19.who.int>

<sup>2</sup> <https://doh.gov.ph/2019-nCoV>

<sup>3</sup> <https://www.who.int/news/item/13-12-2019-who-commemorates-the-40th-anniversary-of-smallpox-eradication>

low to middle income countries like the Philippines at the tail end of the supply chain as we fight for the remaining 18% of the remaining supply.

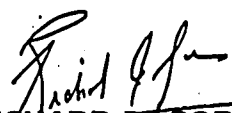
Importation of vaccines may be cheaper and a relatively easier route in protecting public health. However, the long-term and more efficient policy framework, specially in cases when there is a pandemic, is to revitalize the country's local vaccine capability.

The first Philippine vaccine laboratory was established in the 19th century and it initially produced smallpox vaccine. The laboratory was later expanded and became a major contributor to the promotion of Philippine public health program during the American occupation. In fact, in 1939, the Philippines was even able to donate vaccines to China through the Philippine Red Cross. These vaccines were produced in the serum and vaccine laboratory in Alabang, which was operated by the University of the Philippines Institute of Hygiene. The art deco building where the vaccines were manufactured has been repurposed today as part of Festival Mall in Alabang.<sup>4</sup> In the 1950's, through the UNICEF's assistance, the biologicals and vaccines produced in the Philippines included BCG, Tetanus Toxoid, Human and Animal Rabies vaccines, PPD, and biologicals like the Plasma-Derived Snake anti-venom.

The country's vaccine manufacture slowly declined due to absence of training on updated vaccine production, non-replacement of outdated facilities, and ultimately lack of governmental support.

The right way forward to truly protect and promote the people's right to health is to science our way through by investing in research and development and technology, and increasing our expert pool, all for the purpose of institutionalizing our local vaccine capability.

Thus, we seek the passage of this bill.

  
**RICHARD J. GORDON**  
Senator

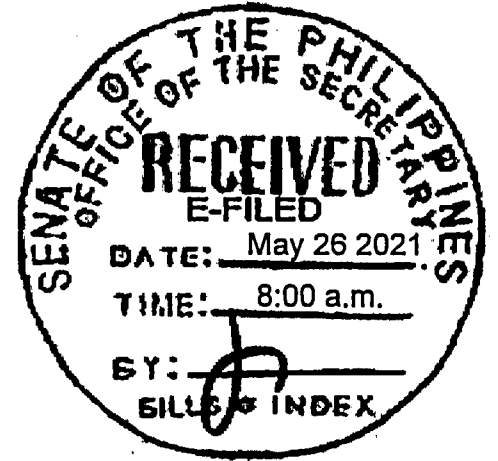
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<sup>4</sup> <https://cph.upm.edu.ph/node/2818>

EIGHTEENTH CONGRESS )  
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*Be it enacted by the Senate and House of Representatives of the Philippines in Congress assembled:*

**A. GENERAL PROVISIONS**

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Section 1. Short Title. – This Act shall be known as the Philippine Vaccine Development Act of 2021.

Section 2. Declaration of Policy. -

- a. It is hereby declared the policy of the State to improve the access to and delivery of safe, reasonably cost and effective vaccines to the Filipino people.
- b. It shall also be the policy of the State to support the creation of a local vaccine development and manufacturing ecosystem.

Section 3. Objectives. - The objectives of this Act are as follows:

- a. to support human resource development for vaccine technology and related fields;
- b. to encourage and support local research on vaccines and biologicals; and,
- c. to provide incentives to companies for the local manufacture of vaccines and biologicals.

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**B. DEFINITION OF TERMS**

Section 4. Definition of Terms. - When used in this Act:

- a. Biologics/biologicals shall refer to a substance that is produced by or extracted from a biological source and that needs for its characterisation and the determination of its quality a combination of physical-chemical-biological testing together with the production process and its control; also refers to products or preparations containing the said substance as an active ingredient;
- b. Biosafety shall refer to containment principles, technologies, and practices that are implemented to prevent unintentional exposure to pathogens and toxins or their accidental release from a laboratory or similar facility.
- c. Biosecurity shall refer to institutional and personal security measures designed to prevent the loss, theft, misuse, diversion, or intentional release of pathogens and toxins from a laboratory or similar facility.
- d. Biotechnology shall refer to any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use.
- e. Vaccine shall refer to a biological preparation that improves immunity to a particular disease that contains an agent that resembles a disease-causing microorganism, and is often made from weakened or killed forms of the microbe, its toxins, its surface proteins, or its genetic material.
- f. Vaccine Technology shall refer to any technological application to make vaccines including but not limited to genetic engineering, cell & tissue culture, chemical engineering, and packaging & materials technology.

**C. ESTABLISHMENT OF THE PHILIPPINE VACCINE AUTHORITY**

Section 5. Philippine Vaccine Authority. – The Philippine Vaccine Authority is hereby established, hereinafter referred to as the Authority, that shall oversee an ecosystem conducive for the development of the Philippine Vaccine Industry. Its principal office shall be in Metro Manila, but it may establish other branches or offices elsewhere in the Philippines as may be necessary or proper for the accomplishment of its purposes and objectives.

Section 6. Powers and Functions. – In furtherance of its purposes and objectives, the Authority shall have the following powers and functions:

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- a. to create a long term Philippine Vaccine Development Plan and update it accordingly;
- b. to create a research agenda for vaccines and biologicals;
- c. to develop and prescribe policies and standards for vaccines and biologicals research and manufacturing including, but not limited to, biosecurity and biosafety, for recommendation to appropriate government implementing agencies;
- d. to coordinate and facilitate technology transfer from technology owners and research institutions to local institutions and manufacturers;
- e. to enter into, make and execute contracts and agreements of any kind or nature related to the implementation of this Act;
- f. to acquire or obtain from any governmental authority whether national or local, foreign or domestic, or from any person, corporation, partnership, association or other entity, such charters, franchises, licenses, rights, privileges, assistance, financial or otherwise, and concessions as are conducive to, and necessary or proper for the attainment of its purposes and objectives;
- g. to outsource services, activities, projects, and programs, to capable third party providers; and,
- h. to exercise all the powers necessary to attain the purposes of this Act.

Section 7. Board of Administrators. – The powers of the Authority shall be exercised, and all its activities and properties shall be controlled by a Board of Administrators, hereinafter referred to as the Board.

- a. Composition. – The Board shall be composed of the following:
  - i. Secretary of the Department of Health as ex-officio Chairman;
  - ii. Secretaries of the Department of Science and Technology, Department of Trade and Industry, and Department of National Defense as permanent members;
  - iii. Private sector representatives: one (1) from the academe or research institution engaged in vaccine technology, virology, or related fields; one (1) licensed clinician providing vaccination services; and one (1) from the pharmaceutical industry belonging to Filipino companies as appointive members, to be appointed by the President of the Philippines for a non-extendible term of three (3) years; provided that the Department of Health shall promulgate the rules on the qualifications

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and process in the selection of the appointive members from the relevant sectors.

b. Meetings and quorum. – The Board shall meet regularly at least once a month or more often as the exigencies of the service demand. The presence of at least four (4) members shall constitute a quorum, and the majority vote of the members present, there being a quorum, shall be necessary for the adoption of any resolution, decision, or any other act of the Board. Virtual meetings may be held in lieu of face-to-face meetings.

c. Allowances and per diems. – The members of the Board shall receive a per diem for every meeting actually attended subject to the pertinent budgetary laws, rules and regulations on compensation, honoraria and allowances.

**Section 8. Powers and Functions of the Board. – The Board shall exercise the following powers and functions:**

a. define and approve the policies, plans, strategies, programs, procedures and guidelines for the Authority in accordance with its purposes and objectives, and to control the management, operation and administration of the Authority;

b. approve the Authority's organizational structure, staffing pattern, operating and capital expenditure, and financial budgets in accordance with pertinent laws;

c. appoint, transfer, promote, suspend, remove or otherwise discipline any subordinate officer or employee of the Authority, upon recommendation of the Director General;

d. create such committee or committees and appoint the members thereof, as may be necessary or proper for the management of the Authority or the attainment of its purposes and objectives;

e. determine the research priorities of the Authority consistent with the framework of its purposes and objectives and in coordination with other government agencies; and,

f. exercise such other powers and functions and perform such other acts as may be necessary or proper for the attainment of the purposes and objectives of the Institute.

**Section 9. Director General and Other Officers. – The Authority shall be headed by a Director General who shall be appointed by the President of the Philippines upon recommendation of the Secretary of Health. The Director General shall have a term of six (6) years, unless sooner removed by the President.**

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The Director General shall be assisted by such Deputy Director General(s) and program managers/coordinators as the Board may determine to carry out the purposes and objectives of this Act.

**Section 10. Powers, Functions and Duties of the Director General. – The Director General shall have the following powers, functions and duties:**

- a. supervise and direct the management, operation and administration of the Authority;
- b. execute contracts, including the deeds that may incur obligations, acquire and dispose of assets and deliver documents on behalf of the Authority;
- c. implement and enforce policies, decisions, orders, rules and regulations adopted by the Board;
- d. recommend to the Board the Authority's organizational structure, staffing pattern, operating and capital expenditure in accordance with pertinent laws;
- e. submit to the Board a quarterly report of the Authority;
- f. submit to the Board an annual budget and such supplemental budget as may be necessary for its consideration and approval; and,
- g. exercise such other powers and functions and perform such other acts as may be necessary or proper for the attainment of the purposes and objectives of the Authority, or as may be delegated by the President of the Philippines.

**Section 11. Government Agency Support and Coordination. – The Authority may, for the purpose of its research and development activities, obtain and secure the services of scholars, scientists and technical personnel of any unit of the Department of Health and other agencies of the Philippine Government. Such personnel may be paid honoraria as may be fixed and authorized by the Board following the usual government rules and regulations governing honoraria and allowances.**

The Authority shall also assist, cooperate and coordinate with other government agencies, such as but not limited to the Food and Drug Administration and the Research Institute for Tropical Medicine of the Department of Health, the Philippine Council for Health Research and Development of the Department of Science and Technology, the State Universities and Colleges, the National Institutes of Health, and the Philippine Genome Center for the implementation of the purposes and objectives of this Act.

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2 **D. SUPPORT FOR THE CREATION OF A VACCINE MANUFACTURING**  
3 **ECOSYSTEM**  
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5 Section 12. Human Resource Development. - The Authority, in pursuit of its objectives,  
6 shall endeavor:  
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8 a. to provide for human resource development in the following fields:  
9 vaccine technology and related areas including but not limited to molecular  
10 biology, microbiology, virology, chemistry, biosecurity & biosafety, and  
11 biotechnology;  
12

13 b. to provide funds for scholarships, study grants, training programs and  
14 short courses, both local and foreign in accordance with Republic Act No. 7687,  
15 or the "Science and Technology Scholarship Act of 1994", Republic Act No.  
16 8439, or the "Magna Carta for Scientists, Engineers, Researchers and other S  
17 & T Personnel in the Government", Republic Act No. 10931 or the "Universal  
18 Access to Quality Tertiary Education Act", and other related laws,  
19 governmental rules and policies;  
20

21 c. to support annual conventions & conferences of professionals in the field  
22 of vaccine technology and related areas;  
23

24 d. to engage Balik Scientists and foreign experts following the terms of  
25 reference and compensation structure of the Balik Scientist Program pursuant  
26 to Republic Act No. 11035, or the "Balik Scientist Act" ; and,  
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28 e. to provide for qualified employees of the Authority and its attached units  
29 the benefits of Republic Act No. 8439, "Magna Carta for Scientists, Engineers,  
30 Researchers and Other Science and Technology Personnel in Government" or  
31 the Republic Act No. 7305, "The Magna Carta of Public Health Workers",  
32 whichever is applicable.  
33

34 Section 13. Vaccines & Biologicals Research and Development. - The Authority, in  
35 pursuit of its objectives, shall endeavor:  
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37 a. to provide funding for a spectrum of researches, from basic to clinical,  
38 towards the development of safe & effective vaccines & biological products;  
39

40 b. to support research institutions, facilities, laboratories, in the private or  
41 government sector in terms of funding for operations, maintenance, research,  
42 capacity building, acquisition of equipments, buildings and other capital  
43 assets; and,  
44



1 c. to support venues for publication and dissemination of research output  
2 in the field of vaccine technology and related areas.

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4 Section 14. Designating Biotechnology Industrial Parks - In coordination with PEZA,  
5 there shall be a designated biotechnology industrial parks with applicable economic  
6 zone privileges and with infrastructure adequate for biosafety and biosecurity global  
7 standards.

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9 Section 15. Support for Filipino Vaccine Manufacturers. -

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11 a. Financial Incentives - In coordination with the DTI-Board of Investments  
12 and the Department of Finance, there shall be provided a tax holiday for the  
13 first FIVE (5) years to Filipino vaccine manufacturers covering the following:

- 14  
15 i. income;  
16 ii. import duties on equipment and modular units including  
17 bioreactors, related materials including APIs, reagents, excipients,  
18 preservatives, and vials, containers and other packaging materials; and,  
19 iii. export sales of locally-manufactured vaccines & biologicals whether  
20 in bulk or in finished form.

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22 b. Guaranteed Purchase (Filipino First) - The DOH and Local Government  
23 Units, together with its health facilities, offices, and hospitals, will  
24 preferentially purchase first from Filipino manufacturers ALL the vaccines  
25 required for its immunization programs. Should forecasted demand exceed the  
26 capacity of local production by Filipino manufacturers, the balance may be  
27 purchased by DoH and LGUs from foreign producers.

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29 c. Multi-year Supply Agreement - The DOH and Local Government Units,  
30 together with its health facilities, offices, and hospitals, may procure vaccines  
31 through negotiated multi-year supply agreements with Filipino manufacturers.

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33 Section 16. Vaccination Statistics Database - In coordination with the Department of  
34 Health, the Authority shall endeavor:

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36 a. to regularly collect and publish domestic vaccination information  
37 including but not limited to prevalence of vaccination, volume of vaccines  
38 purchased and sold, volume of imported and exported vaccines;

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40 b. to establish and regularly update a registry of vaccine research  
41 institutions, vaccine manufacturers, and biotechnology industrial parks in the  
42 country, including production capacity and current status; and,  
43

1 c. to establish and regularly update a registry individuals trained in vaccine  
2 technology and related fields including but not limited to molecular biology,  
3 microbiology, virology, chemistry, biosecurity & biosafety, and biotechnology.  
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5 Section 17. International Cooperation. The Authority may enter into a memorandum  
6 of agreement or memorandum of understanding with international partners, upon the  
7 approval of its Governing Board.  
8

9 Section 18. Vaccine Development Fund - There is hereby created a Vaccine  
10 Development Fund to be used exclusively for the purposes of this Act, which shall be  
11 administered by the Authority following existing government budgeting, accounting,  
12 and auditing rules and regulations. The Fund shall be sourced from the following:  
13

14 a. The initial amount of Two Billion pesos (P 2,000,000,000.00) to be taken  
15 from the current Department of Health's fiscal year's appropriation, in case  
16 the General Appropriation Act (GAA) was approved before this Act is enacted,  
17 otherwise the initial amount of Two Billion pesos (P 2,000,000,000.00) shall  
18 be accordingly appropriated for the establishment of the Authority and initial  
19 implementation of the objectives under this Act;  
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21 b. Grants, bequests, gifts, and donations consisting of such properties, real  
22 or personal, including funds and valuable effects or things, as may be useful,  
23 whether from local or foreign sources. Provided, that acceptance of grants,  
24 bequests, and donations from foreign governments shall be subject to the  
25 approval of the Office of the President upon the recommendation of the  
26 Secretary of the DOH.  
27

28 Thereafter, such amount as may be necessary to fund the continued implementation  
29 of this Act shall be included in the annual GAA.  
30

31 Section 19. Appointment of Board Members. – Within thirty (30) days from the date  
32 of effectivity of this Act, the President of the Philippines shall appoint the members of  
33 the Board as well as the Director General and Deputy Director General(s).  
34

35 Section 20. Oversight Function. – The Authority shall submit to Congress an annual  
36 accomplishment report which shall include the status of its priority researches and  
37 operation. In the exercise of its oversight functions, Congress may inquire into the  
38 programs of the Authority.  
39

40 Section 21. Implementing Rules and Regulations. – Within thirty (30) days from the  
41 completion of their appointments, the Board shall convene and formulate the rules  
42 and regulations necessary for the implementation of this Act. Said rules and  
43 regulations shall be issued within sixty (60) days from the date of the Board's initial  
44 meeting and shall take effect upon publication in a newspaper of general circulation.  
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1 Section 22. Repealing Clause. – All laws, decrees, executive orders, and other laws  
2 including their implementing rules and regulations inconsistent with the provisions of  
3 this Act are hereby amended, repealed or modified accordingly.

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5 Section 23. Separability Clause. – If any provision of this Act is declared  
6 unconstitutional or invalid, other provisions thereof which are not affected thereby  
7 shall continue in full force and effect.

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9 Section 24. Effectivity. – This Act shall take effect fifteen (15) days following its  
10 publication in the Official Gazette or in at least two (2) newspapers of general  
11 circulation.

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13 **Approved,**