

Republic of the Philippines
HOUSE OF REPRESENTATIVES
Quezon City

EIGHTEENTH CONGRESS
Second Regular Session

House Bill No. 8816



Introduced by Representative PABLO JOHN F. GARCIA

EXPLANATORY NOTE

Article II, Section 15 of the Constitution provides that “The State shall protect and promote the right to health of the people and instill health consciousness among them.” It also states in Article XIII, Section 11 that “The State shall adopt an integrated and comprehensive approach to health development which shall endeavor to make essential goods, health and other social services available to all the people at affordable cost. [x x x]”

In 2006, then United States Health and Human Services Secretary Michael Leavitt said, “Pandemics happen. Anything we say in advance of a pandemic happening is alarmist; anything we say afterwards is inadequate.”¹ Indeed, in hindsight—after more than a year since Covid-19 started grabbing headlines and ravaging the world—we could have done more. As the government is currently all-out in addressing the present concerns brought about by this disease, we should also take stock of what we can improve upon for future pandemics so that lives and livelihoods nationwide may be saved. This is not being alarmist; it is preparing for the inevitable.

Mass vaccination is part of any sound pandemic preparedness and response policy.² It creates herd immunity for the benefit of the vulnerable aside from preventing the spread of the contagion. However, Covid-19’s novelty has made high-income nations scramble for vaccine stocks—leaving poorer nations with what little remains.³ But even rich nations such as Canada have experienced supply issues due to export restrictions and supply chain shortfalls.⁴ Local vaccine production is thus a matter of necessity especially for less capable nations such as ours.⁵

¹ Ball University, *Influenza Pandemic Operations and Response Plan*, available at <https://www.bsu.edu/about/administrativeoffices/emergency-preparedness/pandemicfluprep/operresponseplan/influpanoperrespondplan>.

² See World Health Organization, *Pandemic Influenza Preparedness and Response: A WHO Guidance Document* available at: <https://www.ncbi.nlm.nih.gov/books/NBK143067/>.

³ Megan Twohey et al., New York Times, *With First Dibs on Vaccines, Rich Countries Have ‘Cleared the Shelves’*, available at <https://www.nytimes.com/2020/12/15/us/coronavirus-vaccine-doses-reserved.html>.

⁴ Paula Newton, CNN, *Shutout by allies, Canada will produce its own vaccines by the end of 2021*, <https://edition.cnn.com/2021/02/02/americas/canada-coronavirus-vaccines/index.html>.

⁵ See notes 3 and 4.

This bill aims to incentivize the rapid partnering of local manufacturers and vaccine creators or inventors to speed up mass vaccination efforts in the event of another novel contagion. This bill empowers the Department of Health, through the Food and Drug Administration, to approve certain vaccines or drugs for emergency and/or right-to-try use, and incentivizes their local production by providing tax incentives to participating local and foreign firms.

It is hoped that this measure, in conjunction with regular vaccine procurement, importation, research and development, and other auxiliary efforts, will lead to a strong response should another pandemic spread.

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

A stylized, handwritten signature in black ink, appearing to read 'P. Garcia'.

Rep. PABLO JOHN F. GARCIA
3rd District, Province of Cebu

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AN ACT

**AUTHORIZING THE FOOD AND DRUG ADMINISTRATION TO GRANT EMERGENCY
USE AND RIGHT-TO-TRY AUTHORIZATION FOR VACCINES OR DRUGS TO ADDRESS
NOVEL PANDEMICS, PRESCRIBING CONDITIONS THEREFOR, INCENTIVIZING THEIR
LOCAL PRODUCTION, AND FOR OTHER PURPOSES**

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

Section 1. Short Title. This Act shall be known as the “*Emergency Use and Right-to-Try Authorization Act of 2021*”.

Section 2. Declaration of Policy. - It is the policy of the State to protect and promote the right to health of the Filipino people. Furthermore, the State shall adopt an integrated and comprehensive approach to health development which shall endeavor to make essential goods, health and other social services available at affordable cost. Finally, it is the policy of the State to exert all measures possible such as the authorization of the emergency and right-to-try use of drugs and vaccines and the incentivization of their local manufacture, to save the lives and livelihoods of Filipinos from novel pandemics.

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

(a) A **drug or vaccine** shall mean a pharmaceutical product, whether registered with the Food and Drug Administration (FDA) or given emergency use or right-to-try authorization, and which pertains to chemical compounds or biological substances, other than food, intended for use in the diagnosis, treatment, or prevention of a disease involved in a novel pandemic; and

(b) A **novel pandemic** is a new life-threatening infectious disease that has not been previously identified in humans and which is quickly spreading across countries or continents.

(c) **Foreign entity** shall mean the foreign patent-holders or creators of a novel pandemic drug or vaccine;

(d) **Recognition** shall refer to the acceptance of the regulatory decision of another trusted institution concerning a drug or vaccine. It shall be based on evidence of conformity that the requirements of the reference regulatory authority are sufficient to meet the regulatory requirements of the FDA as provided for in this Act.

(e) **Reliance** shall refer to the act whereby the national regulatory authority (NRA) in one jurisdiction may take into account and give significant weight to assessments performed by another NRA or trusted institution, or to any other authoritative information in reaching its own decision.

Section 4. Emergency Use Authorization for drugs and vaccines for novel pandemics. - The Director General of the FDA is hereby authorized to issue an Emergency Use Authorization (EUA) for drugs and/or vaccines for use against novel pandemics subject to the conditions in the succeeding Section.

Outside clinical trials and except in cases where a right-to-try authorization is issued, no unregistered novel pandemic drug or vaccine may be manufactured, sold, imported, exported, distributed or transferred without an EUA.

Section 5. Conditions for the Issuance of Emergency Use Authorization. - An EUA on a drug or vaccine for a novel pandemic shall be issued and remain valid only when all of the following circumstances are present:

(a) Based on the totality of evidence available, including data from adequate and well-known controlled trials, it is reasonable to believe that the drug or vaccine may be effective to prevent, diagnose or treat the novel pandemic;

(b) The known and potential benefits of the drug or vaccine when used to diagnose, prevent or treat the novel pandemic disease outweigh the known and potential risks of the drug or vaccine, if any; and

(c) There is no adequate, approved and available alternative to the drug or vaccine for diagnosing, preventing or treating the novel pandemic disease.

Section 6. Applications for Emergency Use Authorization. - An application for the issuance of an EUA shall be submitted by the local or foreign drug or vaccine manufacturer, the drug or vaccine creator, or government agency concerned, such as the national procurer or the public health program implementer.

The application should demonstrate compliance with current good manufacturing practices, as may be determined in the implementing rules and regulations consistent with the objectives and policies of this Act, and be accompanied by an undertaking by the manufacturer to complete the development of the drug and vaccine, among others.

Section 7. *Reliance and Recognition.* - In evaluating applications for EUA, the FDA Director General shall have the power to implement reliance and recognition processes for emergency use of novel pandemic drugs and vaccines. For this purpose, the FDA Director General may accept the regulatory decisions of institutions such as the World Health Organization, the Centers for Disease Control and Prevention of the United States, or other internationally recognized and established regulatory authorities.

Section 8. *Expert Panel.* - The FDA shall convene a panel composed of experts on drug and vaccine development, which shall conduct a review of available data on the safety and effectiveness of a novel pandemic drug or vaccine applied for an EUA. After review, the panel shall submit to the FDA Director General its report and recommendations.

Section 9. *Validity of the Emergency Use Authorization.* - An EUA issued pursuant to this Act shall be valid only within the duration of the declared public health emergency due to the novel pandemic, without prejudice to the discretion of the FDA Director General to revisit or revoke the same, as may be appropriate, to protect the general public health and safety.

Section 10. *Post-Authorization Monitoring.* - The FDA, together with other concerned offices of the DOH, shall conduct post-authorization monitoring to track product deployment, additional relevant information, and the status from the manufacturer concerning the full life-cycle of the product drug or vaccine. The holder of an EUA shall be required to complete specific pharmacovigilance obligations, with a view to providing comprehensive data confirming a positive benefit-risk balance.

Section 11. *Right-to-Try Authorization.* - Eligible patients may be permitted by the FDA to have access to eligible investigational drugs or vaccines for novel pandemics.

An eligible patient is a patient who has:

- (a) Been diagnosed with a life-threatening disease due to a novel pandemic;
- (b) Exhausted approved treatment options and is unable to participate in a clinical trial involving the eligible investigational drug or vaccine, the fact of which must be certified by a licensed physician in good standing; and
- (c) Has provided, or their legally authorized representative has provided, written informed consent regarding the eligible investigational drug or vaccine.

An eligible investigational drug or vaccine is an investigational drug or vaccine:

- (a) For which a Phase 1 clinical trial has been completed;
- (b) That has not been approved or licensed by the FDA for any use;
- (c) For which an application has been filed with the FDA, or is eligible under a reliance and recognition process as described herein, or is under investigation in a

clinical trial that is intended to form the primary basis of a claim of effectiveness in support of FDA approval and is the subject of an active investigational new drug application submitted to the FDA; and

(d) Whose active development or production is ongoing, and that has not been discontinued by the manufacturer or placed on clinical hold by the FDA.

The FDA shall act on Right-to-Try Authorization applications within three (3) days from date of application.

Section 12. *Tax Incentives for the Local Manufacture of Drugs and Vaccines.* - Local manufacturers and foreign entities, which have entered into agreements for the production of drugs or vaccines, whether registered with the Food and Drug Administration (FDA) or given emergency use or right-to-try authorization, to expedite mass treatment and immunization efforts following a novel pandemic, shall both enjoy the following tax benefits, when applicable:

(a) Full tax exemption, whether from income tax, sales tax, excise tax, transfer tax, value-added tax, percentage tax, or otherwise, for any revenue, income, profit, and the like concerning the agreement, manufacturing, and subsequent sale of the novel pandemic drug or vaccine;

(b) Exemption from all kinds of local taxes, fees, or charges imposed by a local government unit on the agreement, manufacturing, and subsequent sale of the novel pandemic drug or vaccine, including real property taxes for two (2) years after on the machineries and equipment directly used for the manufacturing process; and

(c) Tax- and customs duty-free importation of equipment, supplies, ingredients, components, raw materials, and the like used solely for the local manufacture of the drug or vaccine and which are not locally available.

Section 13. *Intellectual Property Protection.* - Nothing in this Act shall be construed to mean a diminution or elimination of any Intellectual Property Rights enjoyed by any person, natural or juridical, by virtue of any law, rule, regulation, treaty, and/or international agreement.

Section 14. *Revenue Issuances.* - The Department of Finance, through the Bureau of Internal Revenue and the Bureau of Customs, shall issue the corresponding Revenue Regulations and/or Revenue Memorandum Circulars related to the grant of the incentives mentioned in the preceding section within thirty (30) days from the effectivity of this Act.

Section 15. *Implementing Rules and Regulations.* - The Department of Health shall issue within ninety (90) days from the effectivity of this Act the necessary rules and regulations for the effective implementation of this Act.

Section 16. *Repealing Clause.* - All laws, executive orders, proclamations, rules, regulations and other issuances or parts thereof which are inconsistent with the provisions of this Act are hereby repealed, amended, or modified accordingly.

Section 17. *Separability Clause.* - If any part or provision of this Act is held unconstitutional or invalid, other parts or provisions thereof which are not affected shall continue to remain in full force and effect.

Section 18. *Effectivity.* - This Act shall take effect fifteen (15) days following completion of its publication in at least two (2) newspapers of general circulation.

Approved,