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

s. b. no. 2056

'21 FEB 16 P1:44

Introduced by SENATOR VICENTE C. SOTTO III

AN ACT

AUTHORIZING THE PRESIDENT OF THE PHILIPPINES TO ASSUME LIABILITIES WHICH MAY ARISE FROM THE ADMINISTRATION OF APPROVED VACCINES, ESTABLISHING A VACCINE INDEMNIFICATION FUND, AND FOR OTHER PURPOSES

EXPLANATORY NOTE

Participation in the immunization program of the government carries with it a heightened fear of possible serious adverse events, such as death, requires hospitalization or prolongation of existing hospitalization, or results in persistent or significant disability/incapacity, among others. Ensuring that Filipinos will be willing to partake in the immunization program is only half the problem. Equally important is to meet the one of the requirements of vaccine manufacturers that is to hold them free and harmless from any and all liabilities which may arise from the administration of their respective vaccines.

This bill seeks to enact in one law the grant of authority to the President of the Philippines to assume, for and in behalf of the National Government, such liabilities which may arise from the administration of vaccine, the establishment of a vaccine indemnification fund and the designation of the manager thereof, and for other purposes.

Through this bill, the Executive Branch may efficiently facilitate the immunization program of the government while warranting security on the part of the Filipinos and the vaccine manufacturers a compensation mechanism who may have suffered a vaccine-related injury.

In view of the foregoing, the prompt enactment of the bill is earnestly sought.

CENTE C SOTTO III

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

SECTION 1. Short Title. – This Act shall be known as the "COVID-19 Vaccine Indemnification Fund."

- SEC. 2. Declaration of Policy. It is the policy of the State to protect and promote the right to health of all Filipinos and instill health consciousness among them. To this end, the State shall adopt a comprehensive approach to ensure that each and every Filipino will have an equal access to a safe and effective Covid-19 vaccine. The State shall likewise adopt an action plan against Covid-19 that fosters a whole-of-system, whole-of-government, and whole-of-society approach in the development, implementation, monitoring and evaluation of the policies and programs to curb Covid-19.
- SEC 3. Grant of Authority. In compliance with the requirements of vaccine manufacturers and suppliers and in order to meet the urgent need of Filipinos for vaccines against Covid-19, the President of the Philippines, for and in behalf of the National Government, is hereby authorized to assume any and all liabilities which will be incurred by vaccine manufacturers and their suppliers in relation to the administration of their respective products, except if the damage or injury is due to any of the following:
 - (i) Breach of Good Manufacturing Practice (as applied at the time of manufacture) before certification of batch-release of the vaccine for export, leading to a Quality Defect in the vaccine; or
 - (ii) Willful Misconduct of the manufacturer relating to the development, manufacture, use or administration of the Vaccine.

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- For purposes of this section, "quality defect" shall mean a product quality defect resulting in an adverse impact on human health where the vaccine no longer possesses the quality attributes for it to be considered fit for its intended medical use, according to the product quality specifications and requirements of the marketing authorisation or the terms of the WHO pre-qualification procedure, having particular regard to the main principles described in the WHO guidelines on good manufacturing practices for pharmaceutical products.
 - **SEC. 4.** *Period of Filing the Claim.* The claim for indemnification for serious adverse event directly arising from the administration of COVID-19 vaccine must be filed within one (1) year from the day of the inoculation.

An adverse event will be considered serious, if it:

a) Results in death,

- b) Is life-threatening,
- c) Requires in-patient hospitalization or prolongation of existing hospitalization
- d) Results in persistent or significant disability/incapacity,
- e) Requires intervention to prevent permanent impairment or damage.
- **SEC. 5.** Coverage of the Indemnification. Upon the proper determination of the appropriate court of the causal connection between the COVID-19 vaccine and the serious adverse event as supported by compelling, reliable, valid, medical and scientific evidence, a vaccinee who suffered serious adverse event as a direct result of the administration of any COVID-19 vaccine shall be paid of his or her medical expenses and lost wages, if any.
- **SEC. 6.** Establishment of an Indemnification Fund. There is hereby established a fund to be known as the Vaccine Indemnification Fund which shall be used in the payment of allowed claims filed by vaccinees, who suffered a serious adverse event upon the administration of an approved vaccine, against vaccine manufacturers or any of their suppliers.
- SEC. 7. Sources of the Indemnification Fund. The amount necessary to carry out the initial implementation of this Act shall be sourced from both the current budget of the Department of Health (DOH) and the Philippine Health Insurance Corporation (PhilHealth) each of the agencies equally sharing in the fund. Thereafter, such sum as may be necessary for the continued implementation of this Act shall be in the annual General Appropriations Act (GAA).
- SEC. 8. Indemnification Fund Manager. The account for the Vaccine Indemnification Fund shall be separate from any other fund. The Department of Finance, as the steward of sound fiscal policy and management, shall manage the Vaccine Indemnity Fund. All disbursements from the account shall be made by the Secretary of the Department of Finance upon presentation of appropriate documents.

- SEC. 9. Implementing Rules and Regulations. Within three (3) months from the approval of this Act, the Department of Finance shall, in coordination with the Department of Health, the Department of Justice the Department of Budget and Management, and the National Task Force Against Covid-19, formulate the rules and regulations necessary for the effective implementation of this Act.
- **SEC. 10.** Separability Clause. Should any provision of this Act or any part thereof be declared invalid, the other provisions, insofar as they are separable from the invalid ones, shall remain in full force and effect.
- **SEC. 11.** Repealing Clause. All laws, orders, issuances, rules and regulations inconsistent with this Act are hereby repealed or modified accordingly.
- **SEC. 12.** Effectivity. This Act shall take effect fifteen (15) days after its complete publication in at least two (2) newspapers of general circulation.

Approved,