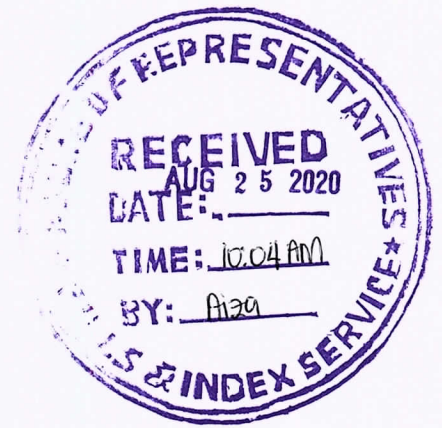


EIGHTEENTH CONGRESS OF THE
REPUBLIC OF THE PHILIPPINES
Third Regular Session

HOUSE OF REPRESENTATIVES

House Bill No. 7480



Introduced by **BHW Partylist Rep. Angelica Natasha Co**

**AN ACT
ESTABLISHING THE GOVERNMENT VACCINE INDEMNIFICATION
PROGRAM, PROVIDING FUNDS THEREFOR, AND FOR OTHER
PURPOSES**

EXPLANATORY NOTE

No less than the Constitution states that it is the policy of the State to protect and promote the right to health of the people and instill health consciousness among them.¹ Further in Articles XIII, Section 12, on Social Justice and Human Rights on Health, declares that it is the responsibility of the State to “establish and maintain an effective food and drug regulatory system and undertake appropriate health, manpower development, and research, responsive to the country's health needs and problems”.

With these Constitutional mandate in mind, this measure proposes to institutionalize a government vaccine-related injury indemnification program to balance the need for social justice while recognizing the government’s obligation to ensure a sustainable supply of safe and cost-effective vaccines within a predictable regulatory environment.

¹ 1987 Constitution. Article 2, Section 15.

The State shall protect and promote the right to health of the people and instill health consciousness among them.

This scheme is not without precedence. Prior to the US Congress' enactment of the National Childhood Vaccine Injury Act of 1986² that established the National Vaccine Injury Compensation Program, claimants for vaccines-related injuries' only course of action was through the court system. Without a clear and predictable system of indemnification, vaccine manufacturers are constantly in a difficult predicament with ever-present potential exposure to lawsuits. Accordingly, the market had to contend with high prices, shortages and reduced investment in vaccine research. Furthermore, several small vaccine manufacturers left the market.³

In view of the societal benefits of having in place such a vaccine compensation scheme, several countries have implemented a variety of approaches as to the administration and funding, eligibility, process and decision-making, standard of proof, elements of compensation and litigation rights to this scheme. These countries include China, Japan, Taiwan and South Korea, as well as those in the European Union, notably Austria, Denmark, Sweden. Italy, Hungary, Iceland and Slovenia.⁴

To ensure the effective implementation of this Act, the bill proposes to create the Vaccines Compensation Board whose composition shall come from both the government and key players in the private healthcare sector. This is in recognition of the Constitutional principle of promoting greater public-private collaboration by encouraging the participation of non-governmental, community-based, or sectoral organizations that promote the welfare of the nation.⁵

The warnings and lessons from the current pandemic must be heeded. Putting in place a vaccine-related injury indemnification system that will be embedded in the public immunization program will help protect and compensate the most

² Cf. <https://www.federalregister.gov/documents/2020/07/20/2020-15673/national-vaccine-injury-compensation-program-revisions-to-the-vaccine-injury-table>

³ Cf. *Damage Payments Unit* [Internet site] http://www.direct.gov.uk/en/MoneyTaxAndBenefits/BenefitsTaxCreditsAndOtherSupport/Disabledpeople/DG_10018714

⁴ Cf. <https://www.who.int/bulletin/volumes/89/5/10-081901/en/>

⁵ 1987 Constitution. Article 2, Section 23.

The State shall encourage non-governmental, community-based, or sectoral organizations that promote the welfare of the nation.

marginalized and vulnerable sectors of society from any unanticipated adverse events resulting from vaccination. Such a system will build mutual trust and foster closer collaboration among the relevant stakeholders within the healthcare ecosystem.

Finally, having this vaccine-injury compensation scheme will remove apprehension and reluctance on the part of manufacturers and suppliers of ensuring adequate supply of vaccines over threats of possible court cases for liability and the associated negative media coverage. On the other hand, this system will provide a fair, efficient and predictable remedy for the injured parties.

With the prospects of the availability and the eventual supply of essential vaccines in the country in response to the current pandemic by various pharmaceutical companies and the likely occurrence of similar public health crises in the future, there is an urgent necessity for government to anticipate valid concerns over the introduction and use of new vaccines. We must be prepared now.

Hence, approval of this proposed measure is earnestly sought.



Rep. Angelica Natasha Co
BHW Partylist

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

1 **Sec. 1. Short Title.** – This Act shall be known as the “Vaccine Indemnification
2 Fund Act of 2020”.

3 **Sec. 2. Declaration of Policy.** – It is the policy of the State to protect and
4 promote the right to health of the people and instill health consciousness among them.
5 Likewise, it is the State’s responsibility to establish and maintain an effective drug
6 regulatory system and undertake appropriate policies that are responsive to the
7 country’s health needs and problems.

8 Consistent with this Constitutional mandate, the State shall implement a
9 system for vaccine-related injury indemnification to serve as a fair, efficient and stable
10 mechanism for individuals to obtain compensation upon the occurrence of verified
11 vaccine-related adverse events without need to attribute fault or negligence on vaccine
12 manufacturers or supplier. This shall be the primary mode of compensation and as an
13 alternative to long-drawn, expensive court litigations that constrain vaccine recipients
14 from pursuing bona fide claims for vaccine-related injuries.

15 **Sec. 3. Sources of the Fund** – The Government Vaccine Indemnification
16 Fund (the “Fund”) shall be subsidized by pharmaceutical companies that supply

1 government with vaccines for public immunization programs. Pharmaceutical
2 companies participating in public tenders and are awarded government contracts for
3 the supply of such vaccines shall reserve least one percent (1%) of the contract price
4 which shall form part of the Fund. The reserved amount shall be deposited with the
5 Bureau of the Treasury of the Department of Budget and Management.

6 **Sec. 4. Use of the Fund.** – The Fund shall be earmarked exclusively to
7 compensate and indemnify identified vaccine recipients who sustain injury in
8 connection with the use of the vaccines and where the adverse effects are attributable
9 to the vaccination.

10 **Sec. 5. Management of the Fund.** – The Fund shall be managed by the
11 Vaccines Compensation Board (the “Board”) composed of the following:

- 12 1. Secretary of Justice – Chairperson
- 13 2. Secretary of Health – Vice-Chairperson
- 14 3. Secretary of Budget and Management – Member
- 15 4. Secretary of Finance – Member
- 16 5. Sectoral representative from the healthcare industry - Member
- 17 6. Sectoral representative from the patient advocacy groups – Member
- 18 7. Sectoral representative from the medical societies - Member

19 The sectoral representatives shall have a term of office of three (3) years. The
20 President of the Philippines shall appoint from among a list of three (3) candidates
21 upon the favorable recommendation by the organizations of their respective sectors.
22 Upon approval of this Act, the sectoral representative from the healthcare industry
23 shall have an initial term of one (1) year and the sectoral representative from patient
24 advocacy groups shall have an initial term of two (2) years. Thereafter, the three-year
25 term shall apply to all subsequent appointments. No sectoral representative who has
26 served a full term shall be eligible for reappointment to the Board.

27 **Sec. 6. Powers and Functions of the Board.** – The Board shall have the
28 following powers and functions:

- 29 (a) Provide overall strategic direction and guidance in the implementation of
30 this Act including but not limited to the administration and utilization of
31 the Fund, eligibility requirements, rules on filing claims for injury or death

and the decision-making process, standard of proof required, elements of compensation and litigation rights of the parties involved;

(b) Exercise original and exclusive jurisdiction on verified bona fide claims for compensation or indemnification on vaccine-related injuries or death;

(c) Establish an efficient system for reporting and periodic reviews on the use and management of the Fund through stringent internal controls and information systems; and,

(d) Such other powers as may be proper and necessary to perform their duties and responsibilities effectively and with full transparency taking into consideration the best interests of all relevant stakeholders.

Sec. 7. Appropriations. – The amount needed for the initial implementation of this Act shall be charged against the appropriations of the Department of Health (DOH) in the current and subsequent General Appropriations Act. Thereafter, the amount needed for the continued implementation of this Act shall be taken from the Fund. In case the Fund, after careful assessment and projected utilization, shall be insufficient to answer for potential claims, the DOH shall subsidize such amount in the supplemental budget to be included in the annual General Appropriations.

Sec. 5. Implementing Rules and Regulations. – Within six (6) months from the approval of this Act, the Department of Justice (DOJ), the Department of Health (DOH), the Department of Budget and Management (DBM) and the Department of Finance (DOF) in coordination with other implementing agencies, shall formulate rules and guidelines as may be necessary for the proper implementation and enforcement of this Act.

Sec. 6. Repealing Clause. – All laws, decrees, letters of instruction, resolutions, orders or parts thereof which are inconsistent with the provisions of this Act are hereby repealed, modified or amended accordingly.

Sec. 7. Effectivity Clause. – This Act shall take effect fifteen (15) days after its publication in the Official Gazette or in two (2) newspapers of general circulation.

Approved,