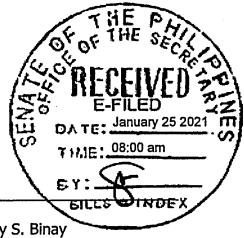
EIGHTEENTH CONGRESS OF THE REPUBLIC OF THE PHILIPPINES Second Regular Session



Introduced by Senator Maria Lourdes Nancy S. Binay

SENATE

S.B. No.

2015

AN ACT

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

EXPLANATORY NOTE

Under the Constitution, it is the duty of State to protect and promote the right to health of the people and instill health consciousness among them. It is also the duty of the State to establish and maintain an effective drug regulatory system that is responsive to the country's health needs and problems.

Consistent with these Constitutional mandates, this measure seeks to establish a system for vaccine-related injury indemnification to serve as a fair, efficient and stable mechanism for individuals to obtain compensation upon occurrence of verified vaccine-related adverse events without need to attribute fault or negligence on vaccine manufacturers or suppliers. This shall be the primary mode of compensation and an alternative to long-drawn, expensive court litigations that constrain vaccine recipients from pursuing bona fide claims for vaccine-related injuries.

Vaccine-injury compensation programmes are increasingly regarded as an important component of successful vaccination programmes. They have been used for the past 50 years to ensure that individuals who are adversely affected in the interests of protecting the whole community are adequately compensated and cared for.¹

Public confidence in the safety and effectiveness of vaccines is essential for the successful implementation of the government's vaccination programs. According to the World Health Organization, vaccine hesitancy, which is the reluctance or refusal to vaccinate despite the availability of vaccines, threatens to reverse progress made in tackling vaccine-preventable diseases. WHO identified vaccine hesitancy as one of the ten threats to global health in 2019. In the Philippines, the Dengvaxia controversy

¹ No-fault compensation following adverse events attributed to vaccination: a review of international programmes, Bulletin of the World Health Organization 2011, retrieved from: https://www.who.int/bulletin/volumes/89/5/10-081901/en/.

has contributed to the decline in vaccine confidence. Also, based on a survey conducted by Pulse Asia from November 23-December 2, 2020 regarding vaccines against COVID-19, out of 2,400 Filipinos aged 18 years old and above, almost half or 47 percent are not willing to be vaccinated. Only 32 percent are willing to get vaccinated while 21 percent are undecided. According to the survey, safety is the main reason why almost half of the respondents are not willing to get vaccinated.

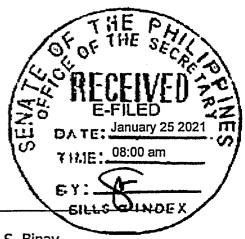
The establishment of vaccine-related injury indemnification system will help increase confidence in the government's immunization programs and ensure sustainability of vaccine supply. First, this system will help protect and compensate the most marginalized and vulnerable sectors of society from any unanticipated adverse events resulting from vaccination. Second, it will remove uncertainty of lawsuits for manufacturers and suppliers. Third, it will provide a more fair, efficient and stable approach for the injured parties.

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

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MARIA LOURDES NAMCY S. BINAY

EIGHTEENTH CONGRESS OF THE REPUBLIC OF THE PHILIPPINES Second Regular Session



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5 Be it enacted by the Senate and House of Representatives of the Philippines in 6 Congress assembled:

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8 **SECTION 1. Short Title.** - This Act shall be known as the "Vaccine 9 Indemnification Fund Act"

SEC. 2. Declaration of Policy. - It is the policy of the State to protect and promote the right to health of the people and instill health consciousness among them. Likewise, it is the State's responsibility to establish and maintain an effective drug regulatory system and undertake appropriate policies that are responsive to the country's health needs and problems.

17 Consistent with these Constitutional mandates, the State shall implement a 18 system for vaccine-related injury indemnification to serve as a fair, efficient and stable 19 mechanism for individuals to obtain compensation upon occurrence of verified 20 vaccine-related adverse events without need to attribute fault or negligence on 21 vaccine manufacturers or suppliers. This shall be the primary mode of compensation 22 and an alternative to long-drawn, expensive court litigations that constrain vaccine 23 recipients from pursuing bona fide claims for vaccine-related injuries.

SEC. 3. Sources of the Fund. - The Government Vaccine Indemnification Fund (The "Fund") shall be subsidized by pharmaceutical companies that supply government with vaccines for public immunization programs. Pharmaceutical companies participating in public tenders and are awarded government contracts for the supply of such vaccines shall reserve at least one percent (1%) of the contract price which shall form part of the Fund. The reserved amount shall be deposited with the Bureau of Treasury of the Department of Budget and Management.

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33 **SEC. 4. Use of the Fund. -** The Fund shall be earmarked exclusively to 34 compensate and indemnify identified vaccine recipients who sustain injury in connection with the use of vaccines and where adverse effects are attributable to the
vaccination.

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SEC. 5. Management of the Fund. - The Fund shall be managed by the 4 Vaccines Compensation Board (the "Board") composed of the following: 5 6 1. Secretary of Justice – Chairperson 7 2. Secretary of Health – Vice-Chairperson 8 3. Secretary of Budget and Management - Member 9 4. Secretary of Finance – Member 10 5. Sectoral representative from the healthcare industry – Member 11 6. Sectoral representative from the patient advocacy groups – Member 12 7. Sectoral representative from the medical societies – Member 13 14 The sectoral representatives shall have term of office of three (3) years. The 15 President of the Philippines shall appoint from among a list of three (3) candidates 16 upon the favorable recommendation by the organizations of their respective sectors. 17 Upon approval of this Act, the sectoral representative from the healthcare industry 18 shall have an initial term of one (1) year and the sectoral representative from patient 19 advocacy groups shall have an initial term of two (2) years. Thereafter, the three-year 20 term shall apply to all subsequent appointment. No sectoral representative who has 21 served a full term shall be eligible for reappointment to the Board. 22 23 SEC. 6. Powers and Functions of the Board. - The Board shall have the 24 following powers and functions. 25 26 (a) Provide overall strategic direction and guidance in the implementation of 27 this Act including, but not limited to the administration and utilization of the 28 Fund, eligibility requirements, rules on filing claims for injury or death and 29 the decision-making process, standard of proof required, elements of 30 compensation and litigation rights of the parties involved; 31 for (b) Exercise original and exclusive jurisdiction on verified bona fide claims 32 compensation or indemnification on vaccine-related injuries or death; 33 (c) Establish an efficient system for reporting and periodic reviews on the use 34 and management of the Fund through stringent internal controls and 35 information systems; and, 36 (d) Such other powers as may be proper and necessary to perform their duties 37 and responsibilities effectively and with full transparency taking into 38 consideration the best interests of all relevant stakeholders. 39 SEC. 7. Appropriations. - The amount needed for the initial implementation 40 of this Act shall be charged against the appropriations of the Department of Health 41 (DOH) in the current and subsequent General Appropriations Act. Thereafter, the 42 amount needed for the continued implementation of this Act shall be taken from the 43 Fund. In case the Fund, after careful assessment and projected utilization, shall be 44

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. 8 Implementing Rules and Regulations (IRR). - Within six (6) months from the approval of this Act, the Department of Justice (DOJ), the Department of Health (DOH), and 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.

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SEC. 9. Oversight Committee. - There is hereby created a Joint Congressional Oversight Committee (JCOC) to oversee, monitor and evaluate the implementation of this Act. The JCOC shall be composed of five (5) members from the Senate and five (5) members from the House of Representatives, to be appointed by the Senate President and the Speaker of the House of Representatives, respectively. It shall be jointly chaired by Chairpersons of the Senate Committee on Health and Demography and the House of Representatives Committee on Health.

SEC. 10. Separability Clause. - if any provision of this Act is held invalid or unconstitutional, the other provisions not so declared shall remain in force and effect.

22 **SEC. 11. Repealing Clause.** - All laws, rules, regulations, orders, circulars, 23 and memoranda inconsistent with any provisions of this Act are hereby repealed, 24 amended or modified accordingly.

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26 **SEC. 12. Effectivity Clause.** - Notwithstanding the non-issuance of the IRR, 27 this Act shall take effect fifteen (15) days after its publication in the Official Gazette 28 or in at least two (2) newspapers of general circulation.

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Approved,