Republic of the Philippines
HOUSE OF REPRESENTATIVES
Quezon City, Metro Manila

EIGHTEENTH CONGRESS
Second Regular Session

House Bill No. **9261**

Introduced by REP. JOEY SARTE SALCEDA

AN ACT
TO EDUCATE HEALTH CARE PROVIDERS AND THE PUBLIC ON BIOSIMILAR BIOLOGICAL PRODUCTS AND MEDICAL SUPPLIES, AND FOR OTHER PURPOSES

EXPLANATORY NOTE

As the Philippines moves towards Universal Health Care (UHC), ensuring that our health care system uses the most cost-effective medical supplies is crucial. In the meantime, while the health care system remains primarily market-driven, with much of the healthcare costs being out-of-pocket, it is also lifesaving to help patients and healthcare providers find cheaper alternatives to necessary medical supplies.

Cheaper alternatives are especially vital to the poor. According to the Family Income and Expenditure Survey for 2015, the richest half of the population account for 65% of all expenditures on healthcare, while those under poverty line spend only 10% of health expenditures. While the poor tend to be exposed to greater health risks, they are also unable to afford the medical interventions needed to mitigate those risks. Affordable medical options, then, are a matter of social equity and justice.

The role of biosimilars in giving the poor access to cheaper medicine is not yet fully appreciated in the country's healthcare system. Biosimilars are competitors' versions of originator drugs. They usually enter the market at a discount, which offers patients and the healthcare system the potential for savings.

Increased education on biosimilars, and publicly available material that compares the costs of biosimilars, will allow patients and healthcare providers to make better informed choices on their healthcare preferences. Education will also improve price competition among pharmaceutical providers, as uncompetitive practices in pricing of biological products comes in part from the inability of patients to compare the prices of such products.

To expand the range of choices for patients and healthcare providers, the bill includes the following provisions:

1. Mandates the Secretary of Health to ensure the availability of educational resources for health care providers, patients, and caregivers, regarding the meaning of the terms, and the

standards for review and licensing of, biological products, including biosimilar biological products and interchangeable biosimilar biological products;
2. Allows the Secretary to offer such materials in a wide range of formats;
3. Requires the Secretary to maintain a list of biosimilar products with their prevailing prices, in a manner that will easily allow its readers to compare such prices; and
4. Mandates the Secretary to advance education and awareness among health care providers regarding biological products.

Recent incidents of fake cures and unproven claims on therapeutics for COVID-19 show the public's desperation for cheaper healthcare options. This desperation has long persisted for other diseases. It is time we offer the public most cost-effective choices that allow them to take greater financial control over their healthcare.

In view of the foregoing, the approval of this bill is urgently sought.

JOEY SARTE SALCEDA

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

SECTION 1. *Short Title.* **–** This Act shall be known as the "Informed Choices for Patients and Health Care Workers Act"

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. Towards this end, the State shall ensure that all Filipinos have access to information that would encourage the use of affordable and cost-effective healthcare options and reduce anti-competitive practices in the pricing of healthcare products.

SEC. 3. *Definition of Terms*. – For purposes of this Act:

(a) The term "*biological product*" means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein, or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings.
(b) The term "*biosimilar*" or "*biosimilarity*", in reference to a biological product means-
    1) that the biological product is highly similar to the reference product notwithstanding minor differences in clinically inactive components; and
    2) there are no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity, and potency of the product.
(c) The term "*interchangeable*" or "*interchangeability*", in reference to a biological product that is shown to meet the standards prescribed by the Food and Drug Administration (FDA), means that the biological product may be substituted for the reference product without the intervention of the health care provider who prescribed the reference product.

SEC. 4. *Education on Biological Products*. **–** The Secretary of Health shall ensure the availability of educational resources for health care providers, patients, and caregivers, regarding the meaning of the terms, and the standards for review and licensing of, biological products, including biosimilar biological products and interchangeable biosimilar biological products, with

a view towards expanding the range of options for patients to include cheaper and more effective alternatives to prevailing biological products.

SEC. 5. *Educational materials.* – Educational materials provided may include:

(a) explanations of key statutory and regulatory terms, including 'biosimilar' and 'interchangeable', and clarification regarding the use of interchangeable biosimilar biological products;
(b) information related to development programs for biological products, including biosimilar biological products and interchangeable biosimilar biological products and relevant clinical considerations for prescribers, which may include, as appropriate and applicable, information related to the comparability of such biological products;
(c) an explanation of the process for reporting adverse events for biological products, including biosimilar biological products and interchangeable biosimilar biological products; and
(d) an explanation of the relationship between biosimilar biological products and interchangeable biosimilar biological products licensed under Republic Act No. 3720, or the Food and Drug Act, as amended.

The educational materials provided may be in formats such as webinars, continuing education modules, videos, fact sheets, infographics, stakeholder toolkits, or other formats as appropriate and applicable; and tailored for the unique needs of health care providers, patients, caregivers, and other audiences, as the Secretary determines appropriate.

In addition, and notwithstanding any laws to the contrary, the Secretary may publish any information deemed necessary to help health care providers, patients, and caregivers make informed decisions about biosimilar drugs.

SEC. 6. *Biosimilar Products Price List.* **–** The Secretary of Health shall publish, as regularly as possible but at least once every ninety (90) days, a list of biosimilar products with their prevailing prices, in a manner that will easily allow its readers to compare such prices. The Secretary shall ensure the availability and use of the list as a guide in the procurement process of public health institutions.

SEC. 7. *Continuing Education*. **–** The Secretary shall advance education and awareness among health care providers regarding biological products, including biosimilar biological products and interchangeable biosimilar biological products, as appropriate, including by developing or improving continuing education programs that advance the education of such providers on the prescribing of, and relevant clinical considerations with respect to, biological products, including biosimilar biological products and interchangeable biosimilar biological products.

SEC. 8. *Separability Clause.* **–** If any provision or part hereof is held unconstitutional or invalid, the remainder of the law, or the provisions not otherwise affected shall remain valid and subsisting.

SEC. 9. *Repealing Clause*. **–** Any provisions of Presidential Decree No. 1467, as amended, and all other laws, inconsistent herewith is hereby repealed or modified accordingly.

SEC. 10. *Effectivity*. **–** This Act shall take effect fifteen (15) days after its complete publication in at least two (2) newspaper of general circulation.

Approved,