Republic of the Philippines HOUSE OF REPRESENTATIVES Quezon City

SEVENTEENTH CONGRESS First Regular Session

House Bill No. 3393



Introduced by Representative GLORIA MACAPAGAL ARROYO

AN ACT TO REQUIRE MANUFACTURERS OR LABELERS OF PRESCRIPTION DRUGS TO REPORT THEIR ANNUAL MARKETING COSTS

EXPLANATORY NOTE

The Constitution in Article 2, Section 5 provides that:

Section 5. The maintenance of peace and order, the protection of life, liberty, and property, and promotion of the general welfare are essential for the enjoyment by all the people of the blessings of democracy.

Article 2, Section 15, also provides that:

Section 15. The State shall protect and promote the right to health of the people and instill health consciousness among them.

The cost of medicines in the Philippines is among the highest in the world. A study shows that it would take a full six days of wages for an average worker to purchase basic medicines in the country. There are more than 17,000 registered drugs in the local market, but a majority of the population can barely afford these expensive essential drugs.

In a US study, two significant factors contributing to the increase in drug costs are the large annual profits of drug companies and the costs in promotional spending by pharmaceutical manufacturers. Drug companies, however, argue that prices are high due to the high cost of Research and Development. However, according to the Kaiser Family Foundation, since 1996, promotional spending by drug manufacturers includes paying for television commercials, giving free drug samples to physicians, and taking physicians and their staffs on expensive trips.

The situation in the Philippines is no different. Drug manufacturers spend millions of pesos in marketing expenses. In order to create policy decisions relative to the problem of high medicine costs, lawmakers should be informed of the current level of marketing costs in relation to total production cost of drug manufacturers. This bill aims to require drug manufacturers to submit annual reports of their marketing expenses to the Secretary of Health in order to fill in the information gap in the minds of our lawmakers.

I therefore urge my colleagues to ensure the immediate approval of this proposed measure.

GLORIA MACAPAGAL ARROYO

2nd District, Pampanga

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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 "Annual Marketing Expenses Report for Drug Manufacturers Act of 2016."

SECTION 2. Declaration of Principles. – The maintenance of peace and order, the protection of life, liberty, and property, and promotion of the general welfare are essential for the enjoyment by all the people of the blessings of democracy. In order to protect the general welfare of the population as regards access to cheap medicines, it is the policy of the state to inquire into the reasonability of marketing expenses of drug firms.

SECTION 3. Definition of Terms. – As used in this Act, unless the context clearly indicates otherwise, the following terms shall have the following meanings:

- (a) "Labeler" means any person or entity that receives a prescription drug from the manufacturer or a wholesaler of such drug, and repackages such drug to be dispensed in this country.
- (b) "Manufacturer" means a manufacturer of prescription drugs dispensed in this country, and shall include the subsidiary or affiliate of such manufacturer.
- (c) "Marketing" means advertising and promotional activities for prescription drugs dispensed in this country including, but not limited to, those activities described in this Act.

SECTION 4. Reportorial Requirement. – The Secretary of Health is authorized and directed to require manufacturers or labelers of prescription drugs, which dispense such drugs in this country and which employ, direct or utilize marketing representatives, to report the marketing costs of each of its prescription drugs dispensed in this country.

SECTION 5. Manner of Reporting. - On or before February 1 of each year every manufacturer and labeler shall file a report with the Department of Health on its

marketing activities conducted in the country. Such report shall be submitted in such form and manner, and include the payment of such a fee as shall be determined by the Secretary of Health. Each such report shall include the value, nature, purpose and recipient of marketing expenses including, but not limited to:

- (a) all expenses associated with advertising, marketing and direct promotion of prescription drugs through radio, television, magazines, newspapers, direct mail and telephone communications as they pertain to residents of e country;
- (b) all expenses associated with educational or informational programs, materials and seminars, and remuneration for promoting or participating in educational or informational sessions, regardless of whether the manufacturer or labeler provides the educational or informational sessions or materials;
- (c) all expenses associated with food, entertainment and gifts valued at more that One Thousand Pesos (Php 1,000.00) and anything provided to a health care professional for less than market value;
- (d) all expenses associated with trips and travel for marketing purposes;
- (e) all expenses associated with product samples, except for samples that will be distributed free of charge to patients; and
- (f) the aggregate cost of all employees and contractors of the manufacturer or labeler who directly or indirectly engage in the advertising or promotional activities, including all forms of payment to such employees and contractors.

The cost reported pursuant to this Act shall reflect only that portion of payment to employees and contractors that pertains to activities within the country or to recipients of the advertising or promotional activities who are residents of or are employed in this country.

- SECTION 6. Exceptions. The following marketing expenses shall not be subject to the reporting requirements of this subdivision:
 - (a) expenses of One Thousand Pesos or less;
 - (b) Reasonable compensation and reimbursement for expenses in connection with a bona fide clinical trial of a new vaccine, therapy or treatment; and
 - (c) scholarships and reimbursement of expenses for attending a significant educational, scientific or policy-making conference or seminar of a national, regional or specialty medical or other professional association if the recipient of the scholarship is chosen by the association sponsoring the conference or seminar.

SECTION 7. Department Reports. – Annually on or before November 30, the Department of Health shall submit a report, providing information in aggregate form, on prescription drug marketing expenses to both Houses of Congress. One year after the passage of this Act and every two years thereafter, the Department of Health shall provide a report to both Houses of Congress, providing information in aggregate form, containing an analysis of the data submitted to the Department of Health, including the scope of prescription drug marketing activities and expenses and their effect on the cost, utilization and delivery of health care services and any recommendations with regard to marketing activities of prescription drug manufacturers and labelers.

SECTION 8. Violations. - Any person who violates any provision of this Act shall be punished with a penalty of Five Hundred Thousand Pesos (Php500,000.00).

Subsequent violations shall be cause for the revocation of the manufacturer's or labeler's permit to do business in the country.

SECTION 9. Implementing Rules and Regulations. – Six (6) months after the passage of this Act, the Secretary of Health shall promulgate the rules and regulations necessary to implement the provisions of this Act.

SECTION 10. Separability Clause. – If any provision or part of this Act is held invalid, the remainder of this Act shall not be affected thereby.

SECTION 11. Repealing Clause. – All laws, decrees, executive order or rules and regulations inconsistent with this Act are hereby repealed or modified accordingly.

SECTION 12. Effectivity Clause. - This Act shall take effect fifteen (15) days after its publication in the Official Gazette or two (2) newspapers of general circulation.

Approved,