FOURTEENTH CONGRESS OF THE)
REPUBLIC OF THE PHILIPPINES)
FIRST REGULAR SESSION)

SENATE
S.B. No. 268

Introduced by Senator Loren Legarda

EXPLANATORY NOTE

This bill seeks to amend Republic Act No. 6675 also known as the "Generic Act of 1988" to further ensure the use of generic names in the manufacture, prescription and distribution of drugs all over the country.

Republic Act No. 6675 mandated the usage of generic terminology in the importation, manufacture, distribution, marketing, advertising, promotion, prescription and dispensing of drugs. Said law further guaranteed the sufficient supply of generic drugs in affordable prices, which will be made available for free to impoverished Filipinos. In a study done by the World Health Organization (WHO) in 1997, the prescription of generic medication was higher in government hospitals and became more prevalent during the period of advocacy and when sanctions against violators were implemented.

However, the practice declined over time. The study observed the erratic pattern of prescribing generic antibiotics, which treat diseases like Acute Respiratory Infections and Urinary Tract Infections. WHO's study cited a previous survey that claimed the irrational use of drugs (i.e. antibiotics and multivitamins). Furthermore, there have been reports that doctors are enticed to prescribe branded medicines in exchange for incentives from the drug company. Clearly, the law have not been effectively implemented.

This bill addresses these concerns through the creation of a Generic Drugs Board, which will oversee the reviewing, monitoring and implementation of the "Generic Act of 1988". The Secretary of Health shall serve as an ex-officio chairman while the members of the Board will comprise of representatives from a medical practitioners association, the consumer sector, drug manufacturers and distributors, to be appointed by the chairman of the board. Among of the functions and duties of the Board are to investigate breaches of the Act and recommend penalties for the violators.

Finally, the bill increases the violation penalties, monetary and imprisonment. This measure will ensure the decrease, if not the eradication, of the violations against the Act.

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

LOREN LEGARDA
Senator

FOURTEENTH CONGRESS OF THE)
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AN ACT
FURTHER ENSURING THE USE OF GENERIC NAMES IN THE MANUFACTURE, PRESCRIPTION, AND DISTRIBUTION OF DRUGS AND MEDICINES AMENDING FOR THE PURPOSE CERTAIN SECTIONS OF REPUBLIC ACT NUMBERED 6675, OTHERWISE KNOWN AS THE "GENERICS ACT OF 1988", AND FOR OTHER PURPOSES

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

SECTION 1. Section 9 of Republic Act No. 6675, otherwise known as the "Generics Act of 1998" is hereby amended to read as follows:

"SECTION 9. [Rules and Regulation] **IMPLEMENTATION.** - The implementation of the provisions of this Act shall be in accordance with the rules and regulations to be promulgated by the Department of Health. Rules and regulations with penal sanctions shall be promulgated within one hundred eighty (180) days after the approval if this Act, and shall take effect fifteen (15) days after the publication in the Official Gazette or in two (2) newspapers of general circulation. **TO REVIEW, MONITOR AND SUPERVISE THE IMPLEMENTATION OF THIS ACT, THERE IS HEREBY CREATED A "GENERIC DRUG BOARD", HEREINAFTER REFERRED TO AS THE BOARD SHALL BE COMPOSED OF THE FOLLOWING:**

(A) THE SECRETARY OF HEALTH, AS EX-OFFICIO CHAIRMAN;

(B) A REPRESENTATIVE FROM THE MEDICAL PRACTITIONERS ASSOCIATION, AS MEMBER;

(C) A REPRESENTATIVE FROM THE CONSUMER SECTOR, AS MEMBER;

(D) A REPRESENTATIVE FROM THE DRUG MANUFACTURERS, AS MEMBER;

(E) A REPRESENTATIVE FROM DRUG DISTRIBUTORS, AS MEMBER, PROVIDED, THAT MEMBERS APPOINTED TO THE BOARD SHALL BE OF RECOGNIZED STANDING IN THEIR RESPECTIVE FIELD OR GROUP AND MUST POSSESS GOOD AND MORAL CHARACTER."

SECTION 2. Section 10 of the same Act is hereby renumbered to Section 11 and *the new provisions of Section 10 shall read as follows:*

"SECTION 10. APPOINTMENT; POWERS AND DUTIES. - THE MEMBERS OF THE BOARD SHALL BE APPOINTED BY THE SECRETARY OF HEALTH FROM A LIST OF NOMINEES TO BE SUBMITTED BY MEDICAL PRACTITIONERS, CONSUMERS, DRUG MANUFACTURERS AND DRUG DISTRIBUTORS.

THE MEMBERS OF THE BOARD SHALL HOLD OFFICE FOR TERM OF TWO (2) YEARS. PROVIDED, THAT THE MEMBERS OF THE BOARD FIRST APPOINTED SHALL HOLD OFFICE FOR THE FOLLOWING TERMS: TWO (2) MEMBERS FOR TWO (2) YEARS AND THE OTHER TWO (2) MEMBERS FOR ONE (1) YEAR.

THE BOARD SHALL HAVE THE FOLLOWING POWERS AND DUTIES:

(A) INVESTIGATE ANY VIOLATIONS OF THIS ACT AND RECOMMEND PROSECUTION THEREFOR IN THE PROPER AGENCIES;

(B) RECOMMEND SUSPENSION OR REVOCATION OF LICENSES OF MEDICAL PRACTITIONERS AFTER PROPER INVESTIGATION FOR VIOLATIONS OF THIS ACT;

(C) RECOMMEND SUSPENSION OR REVOCATION OF LICENSE TO OPERATE ISSUED TO DRUG ESTABLISHMENTS OR DRUG OUTLETS AFTER INVESTIGATION;

(D) PERIODOCALLY RECOMMEND TO CONGRESS MEASURES UPDATING THE LAW TO CONFORM WITH THE PREVAILING SITUATION; AND

(E) PROMULGATION RULES AND REGULATIONS AS MAY BE DEEMED NECESSARY TO CARRY OUT THE PROVISIONS OF THIS ACT."

SECTION 3. The subsequent Sections shall be numbered accordingly.

SECTION 4. Section 1, now renumbered as Section 13, of the same Act is hereby amended to read as follows:

"Sec. [(12)] 13. Penalty. - A) Any person who shall violate Sec. 6 (a) or 6 (b) of R.A. No. 6675 shall suffer the penalty graduated hereunder, viz:

(a) for the first conviction, he shall suffer the penalty of reprimand which shall be officially recorded in the appropriate books of the Professional Regulatory Commission.

(b) for the second conviction, the penalty of fine in the amount of not less than [Two Thousand Pesos (P2,000.00)] **TEN THOUSAND PESOS (P10,000.00)** nut not exceeding [Five Thousand Pesos (P5,0000)] **TWENTY THOUSAND PESOS (P20,000.00)** at the discretion of the court.

(c) for the third conviction, the penalty of fine in the amount of not less than [Five Thousand Pesos (P5,000)] **TWENTY THOUSAND PESOS (P20,000.00)** but not exceeding [Ten Thousand Pesos (P10,000.00)] **FIFTY THOUSAND PESOS (P50,000.00)** and suspension of his license to practice his profession for [thirty (30) days] **SIXTY DAYS** at the discretion of the court.

(d) *for the fourth and subsequent convictions, the penalty of fine of not* less than [Ten Thousand Pesos (P10,000.00)] **FIFTY THOUSAND PESOS (P50,000.00)** and suspension of his license to practice his profession for [One (1)] **TWO YEARS** or longer at the discretion of the court.

B) Any juridical person who violates Section 6 [c], 6 [d], 7 and 8 shall suffer the penalty of a fine not less than [Five Thousand Pesos (P5,000.00) **TWENTY THOUSAND PESOS (P20,000.00)** nor more than [Ten Thousand Pesos (P10,000.00) **FIFTY THOUSAND PESOS (P50,000.00)** and suspension or revocation of license to operate such drug establishment or drug outlet at the discretion of the court. Provided, That its officers directly responsible for the violation shall suffer the penalty of fine and suspension or license to practice the profession, if applicable, and by imprisonment of not less than [six (6) months nor more than] **ONE YEAR** or both fine and imprisonment at the discretion of the court: and Provided, further, That if the guilty party is an alien, he shall ipso facto be deported after service of sentence without need of further proceedings.

C) The Secretary of Health shall have the authority to impose administrative sanctions such as suspension or cancellation if license to practice the profession to the Profession Regulatory Commission as the case maybe for the violation of this Act.

SECTION 5. Annual Report. – The Board shall submit to the Office of the President and to Congress an annual report detailing its activities towards the implementation of the Act.

SECTION 6. Separability Clause. - If any of this Act is declared invalid, the remainder or any provision hereof not affected thereby shall remain in full force and effect.

SECTION 7. Repealing Clause. - The provisions of any law, executive order, presidential decree or other issuances inconsistent with this Act are herby repealed or modified accordingly.

SECTION 8. Effectivity. This Act shall take effect fifteen (15) days after its publication in the Official Gazette or in two (2) newspapers of general circulation.

Approved,