FOURTEENTH CONGRESS OF THE)
REPUBLIC OF THE PHILIPPINES)
First Regular Session)

SENATE

SB No. 1530

Introduced by Senator Loren Legarda

EXPLANATORY NOTE

This bill seeks to fix the maximum retail price of certain medicines and increase access to cheaper medicines in the country to lower the prices of medicines and improve the health condition of our people.

According to a World Health Organization study in 2004, in developed countries, pharmaceuticals constitutes 13 percent of total health expenditures, with two-thirds of drugs being publicly financed while in developing countries pharmaceutical expenditures consist of 30-50 percent of total health expenditures, with two-thirds of these drugs privately financed or paid mainly out-of-pocket. This reflects a highly inequitable situation where those who are in greater need to medicine find it difficult to have access to essential drugs.

In a study made by the Ateneo de Manila's Institute of Philippine Culture in 2006 entitled "The Prices People Have to Pay for Medicines in the Philippines", it was found out that of the 21 medicines found in public procurement, 17 were innovator brands and only 4 were generics.

Moreover, public sector patient prices are many times higher than international reference prices (15 and 6 times higher for innovator brands and lowest priced generics respectively), and patients are paying nearly three times more to purchase innovator brands as compared to generics. Similarly, private sector patient prices are many times higher than international reference prices (17 and 6 times higher for innovator brands and lowest price generics, respectively), and patients are paying nearly three times more to purchase innovator brands as compared to generics.

Furthermore, some standard treatments are very unaffordable to the lowest paid government worker. In the private sector, a month's treatment of depression with innovator brand Fluoxetine costs the lowest paid government worker 49 days wages, the treatment of a peptic ulcer costs 8.5 days wages when innovator brands are prescribed or dispensed, and still costs 3 days' wages if generics are used. Likewise, wholesale and retail mark-ups can reach 65% and 50%, respectively.

In another study, the following were cited as reasons for the high prices of medicines in the country (Lim 1997):

1. Brand loyalty of consumers (and physicians) resulting in a sort of a "monopolistic competition" that allows drug firms to set prices above the pure competitive level, partly due to the "asymmetry of information" where the consumers know very little about the nature of the product and the variety of choices and options, while the drug manufacturers and intermediaries particularly the physicians and pharmacists know much more;

2. Prescribing patterns of physicians who tend to indicate their preferred brands while patients simply follow the brand name prescribed without trying to find out the range of differently-priced options available in the market;

3. Intensive marketing strategies on the part of pharmaceutical companies resulting in high expenditures on promotions and advertising, targeted mainly towards physicians and pharmacists; competent, fair, honest, effective regulation through a strengthened Bureau of Food and Drugs; stronger government role in procurement, production and distribution of drugs and pharmaceuticals; wider dissemination of adequate and accurate information on drugs and medicines to both physicians and the public; and coordination of investment and trade policies to achieve self-sufficiency in good quality and affordable pharmaceuticals.

Unfortunately, the burden of disease is heaviest on the poor. In 2003, 24.7% of Filipino families or 30.4% of Filipinos are considered poor. And poverty is essentially a rural phenomenon - 3 out of 4 poor Filipinos or 75% reside in the rural areas. Based on 2006 prevailing prices, at the national level, a family of five needed PhP 204 daily to buy their minimum basic food and non-food needs.

Clearly, the government's intervention is needed to address the intricate web that surrounds the pricing of medicines, which prejudice the very people that are in dire need of them, our poor. This bill aims to address such urgent concern thru timely legislation.

Under this proposed measure, a List of Regulated Drugs is hereby established, which are subject to a maximum retail price as fixed by the Drug Prices Regulation Board, likewise created under this bill. The regulated drugs include:

(1) all formulations indicated for treatment of chronic illnesses and life-threatening conditions such as, but not limited to:
   a. endocrine disorders, e.g., diabetis mellitus;
   b. gastrointestinal disorders, e.g., peptic ulcer;
   c. urologic disorders, e.g. PTB, asthma;
   d. autoimmune diseases, e.g., SLE;
   e. skin diseases, e.g., Psoriasis;
   f. neuro-psychiatric disorders
   g. other infectious diseases, e.g., HIV, AIDS; and
   h. other conditions such as organ transplants and neoplasms
(2) formulations indicated for prevention of diseases, e.g., vaccines, immunoglobulins, anti-sera;
(3) anesthetic agents, and
(4) intravenous fluids.

Moreover, to improve access to cheaper medicines, this bill amends certain provisions of Republic Act No. 8293 otherwise known as the Intellectual Property Code of the Philippines in order to: 1.) Remove the requirement of another patent for new uses of an existing substance (already patented) to allow drug manufacturers to immediately copy off-patent products; 2.) Permit parallel importation and international exhaustion of intellectual property rights for patents. Parallel importation refers to the importation, without the consent of the patent holder, of a patented product that is marketed in another country. International exhaustion refers to the regime where the supply and price of a product is moderated by competition; 3.) Pave the way for an 'early working doctrine' to enable generic drug companies to experiment and test generic versions of patented drugs before their patents expire. It will also allow them to produce and sell generic versions of patented drugs upon their patents' expiration; and 4.) Restructure provisions of government use by doing away with compulsory licensing to make it easier to respond to public health threats.

The government must not hesitate to take bold steps to correct the inequalities in the access to quality health care by our people, particularly the poor. The State's policy to protect and promote the right to health of our people must not be mere lip service, but a concrete action that the government must undertake.

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

LOREN LEGARDA
Senator

FOURTEENTH CONGRESS OF THE)
REPUBLIC OF THE PHILIPPINES)
First Regular Session)

SENATE

SB No. 1530

Introduced by Senator Loren Legarda

AN ACT
TO FIX THE MAXIMUM RETAIL PRICE OF MEDICINES UNDER CERTAIN CONDITIONS AND INCREASE ACCESS TO CHEAPER MEDICINES BY CREATING A DRUG PRICES REGULATION BOARD AND BY AMENDING RELEVANT PROVISIONS OF REPUBLIC ACT NO. 8293 OTHERWISE KNOWN AS THE INTELLECTUAL PROPERTY CODE OF THE PHILIPPINES, AND FOR OTHER PURPOSES

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

SECTION 1. ***Short Title.*** – This Act shall be known as the "Cheaper Medicines Act of 2007"

SECTION 2. ***Declaration of Policy.*** – It is hereby a declared policy of the State to protect and promote the right to health of the people through cheaper medicines

SECTION 3. ***Creation and Composition of the Drug Prices Regulation Board:***

(a) There is hereby created the Drug Prices Regulation Board, which shall be attached to the Department of Health and composed of the following:

1. Secretary of Trade and Industry as Chairman
2. Secretary of Health as Vice Chairman;
3. Director, Bureau of Food and Drugs as member
4. Lead Convenor of the National Anti-Poverty Commission as member
5. A Representative from each of the following sectors as members:
   - i. National pharmaceutical companies
   - ii. Hospital administrations
   - iii. Medical Profession
   - iv. Pharmacy Profession
   - v. Drugstores industry
   - vi. Drug Manufacturers
   - vii. Consumers

Associations or councils formed by and among the members of each sector shall respectively nominate three (3) nominees from each sector within six (6) months after the effectivity of the implementing rules and regulations of this Act, and every three (3) years thereafter and in case of vacancy. The President of the Philippines shall, within thirty (30) days after the submission of the list of nominees, appoint the representatives from the submitted list. Sectoral representatives shall serve for a term of three (3) years without reappointment. Appointment to any vacancy for sector representatives shall be only for the unexpired portion of the term of the predecessor.

SECTION 4. ***Powers of the Drug Prices Regulation Board.*** The Board shall have the following powers:

(a) **Power to Fix the Maximum Retail Prices of Formulations Included in the List of Regulated Drugs.** - Upon application, due notice and hearing, and after proper determination, when the public interest, in particular, national security, nutrition, public health or public safety, as determined by the appropriate agency of the government, so requires, the Board shall have the power to fix the maximum retail price of formulations included in the List of Regulated Drugs as herein defined, including dosage form and packing, at which such formulation shall be sold to the public. The retail price fixed shall be effective after fifteen days from the date the List of Regulated Drugs and the maximum retail price so fixed has been published in two newspapers of general circulation, at the expense of the Board.

No retailer shall sell a formulation at a retail price exceeding the maximum retail price fixed by the Board; *Provided that,* until the maximum retail price of a formulation is fixed by the Board, the prevailing retail price prior to the effectivity of this Act shall be controlling.

For purposes of this Act, formulations include single and multi-ingredient formulations included in the List of Regulated Drugs and sold under their generic and brand names.

(b) **Power to Identify Formulations in the List of Regulated Drugs.** -Upon application and after proper determination, when the public interest, in particular, national security, nutrition, public health or public safety, as determined by the appropriate agency of the government, so requires, the Board may order the inclusion or exclusion in the List of Regulated Drugs of any formulation. The inclusion or exclusion of a formulation from the List of Regulated Drugs shall be effective after fifteen days from the date the List has been published in two newspapers of general circulation, at the expense of the Board.

SECTION 5. ***The List of Regulated Drugs.*** - The List of Regulated Drugs shall include:

(5) all formulations indicated for treatment of chronic illnesses and life-threatening conditions such as, but not limited to:

a. endocrine disorders, e.g., diabetis mellitus;
b. gastrointestinal disorders, e.g., peptic ulcer;
c. urologic disorders, e.g. PTB, asthma;
d. autoimmune diseases, e.g., SLE;
e. skin diseases, e.g., Psoriasis;
f. neuro-psychiatric disorders
g. other infectious diseases, e.g., HIV, AIDS; and
h. *other conditions such as organ transplants and neoplasms*

(6) formulations indicated for prevention of diseases, e.g., vaccines, immunoglobulins, anti-sera;

(7) anesthetic agents, and

(8) intravenous fluids.

SECTION 6. ***Display of Prices Fixed by the Board for Formulations.*** - a) All government health agencies and their personnel as well as other government agencies, aside from using generic terminology or generic names in all transactions related to purchasing, prescribing, dispensing and administering of drugs and medicines shall, pursuant to Republic Act No. 6675 or the Generics Act of 1998, indicate whether the formulation prescribed is included in the List of Regulated Drugs;

(b) All medical, dental and veterinary practitioners, including private practitioners, shall indicate in their prescriptions that the formulation is included in the List of of Regulated Drugs if it is so included;

(c) Drug outlets, including drugstores, hospital and non-hospital pharmacies and non-traditional outlets such as supermarkets and stores, shall post in conspicuous places in their establishments the List of Regulated Drugs and their corresponding maximum retail price; and

(d) Within fifteen (15) days after the publication of the List of Regulated Drugs and their corresponding maximum retail price, every manufacturer or importer shall issue a price list consistent with the maximum retail price set by the Board, to distributors, wholesalers and retailers.

SECTION 7. Section 26 of Republic Act No. 8293 is hereby amended to read as follows:

"Sec. 26. **Inventive Step. - 26.1.** An invention involves an inventive step if, having regard to prior art, it is not obvious to a person skilled in the art at the time of the filing date or priority date of the application claiming the invention.

"26.2. THERE IS NO INVENTIVE STEP IF THE INVENTION RESULTS FROM THE MERE DISCOVERY OF A NEW FORM OR NEW PROPERTY OF A KNOWN SUBSTANCE WHICH DOES NOT RESULT IN THE ENHANCEMENT OF THE KNOWN EFFICACY OF THAT SUBSTANCE, OR, THE MERE DISCOVERY OF ANY NEW USE FOR A KNOWN SUBSTANCE OR A KNOWN PROCESS UNLESS

SUCH KNOWN PROCESS RESULTS IN A NEW PRODUCT THAT EMPLOYS AT LEAST ONE NEW REACTANT."

SECTION 8. . Section 72 of Republic Act No. 8293 is hereby amended to read as follows:

"Sec. 72. Limitations of Patent Rights. - The owner of a patent has no right to prevent third parties from performing, without his authorization, the acts referred to in section 71 hereof in the following circumstances:

"72.1. Using a patented product which has been put on the market in the Philippines by the owner of the product, or with his express consent, insofar as such use is performed after that product has been so put on the said market: *PROVIDED,* **THAT, WITH REGARD TO DRUGS OR MEDICINES, THE LIMITATION ON PATENT RIGHTS TO THE USE, SALE, OFFERING FOR SALE OR IMPORTATION OF THE PRODUCT SHALL APPLY AFTER A DRUG OR MEDICINE HAS BEEN INTRODUCED ANYWHERE IN THE WORLD BY THE PATENT OWNER, OR BY ANY PARTY AUTHORIZED TO USE THE INVENTION.**

"72.2. Where the act is done privately and on a non-commercial scale or for a non-commercial purpose: *provided,* that it does not significantly prejudice the economic interests of the owner of the patent;

"72.3. Where the act consists of making or using exclusively for [the purpose of experiments that relate to the subject matter of the patented invention;] **EXPERIMENTAL USE OF THE INVENTION FOR SCIENTIFIC PURPOSES OR EDUCATIONAL PURPOSES AND SUCH OTHER ACTIVITIES DIRECTLY RELATED TO SUCH SCIENTIFIC OR EDUCATIONAL EXPERIMENTAL USE;**

"72.4. WHERE THE ACT INCLUDES TESTING, USING, MAKING OR SELLING THE INVENTION INCLUDING ANY DATA RELATED THERETO, SOLELY FOR PURPOSES REASONABLY RELATED TO THE DEVELOPMENT AND SUBMISSION OF INFORMATION AND ISSUANCE OF APPROVALS BY GOVERNMENT REGULATORY AGENCIES REQUIRED UNDER ANY LAW OF THE PHILIPPINES THAT REGULATES THE MANUFACTURE, CONSTRUCTION, USE OR SALE OF ANY PRODUCT *PROVIDED,* THAT IN ORDER TO PROTECT THE DATA SUBMITTED BY THE ORIGINAL PATENT HOLDER FROM UNFAIR COMMERCIAL USE PROVIDED IN ARTICLE 39.3 OF THE TRIPS AGREEMENT, THE INTELLECTUAL PROPERTY OFFICE (IPO), IN CONSULTATION WITH THE APPROPRIATE GOVERNMENT AGENCIES, SHALL ISSUE THE APPROPRIATE RULES AND REGULATIONS NECESSARY THEREIN NOT LATER THAN ONE HUNDRED TWENTY (120) DAYS AFTER ENACTMENT OF THIS LAW;

"[72.4] **72.5.** *Where the act consists of the preparation for individual* cases, in a pharmacy or by a medical professional, of a medicine in

accordance with a medical prescription or acts concerning the medicine so prepared;

"[72.5] **72.6.** Where the invention is used in any ship, vessel, aircraft, or land vehicle of any other country entering the territory of the Philippines temporarily or accidentally: *Provided,* That such invention is used exclusively for the needs of the ship, vessel, aircraft, or land vehicle and not used for the manufacturing of anything to be sold within the Philippines. (Secs. 38 and 39, R.A. No. 165a)"

SECTION 9. Section 74 of Republic Act no. 8293 is hereby amended to read as follows:

"Sec. 74. Use of Invention by Government. - 74.1. a government agency or third person authorized by the government may exploit the invention even without agreement of the patent owner where:

(a) the public interest, in particular, national security, nutrition, health or the development of other sectors, as determined by the appropriate agency of the government, so requires; or

(b) a judicial or administrative body has determined that the manner of exploitation, by the owner of the patent or his license, is anti-competitive; or

(C) THERE IS PUBLIC NON-COMMERCIAL USE OF THE PATENT BY THE PATENTEE, WITHOUT SATISFACTORY REASON.

"74.2. **UNLESS OTHERWISE PROVIDED HEREIN,** [T] the use by the government, or third person authorized by the government shall be subject, [*mutatis mutandis,* to the conditions set forth in sections 95 to 97 and *100* to 102. (Sec. 41, R.A. no. 165a)] **TO THE FOLLOWING PROVISIONS:**

(A) IN SITUATIONS OF NATIONAL EMERGENCY OR OTHER CIRCUMSTANCES OF EXTREME URGENCY, THE RIGHT HOLDER SHALL BE NOTIFIED AS SOON AS REASONABLY PRACTICABLE;

(B) IN THE CASE OF PUBLIC NON-COMMERCIAL USE, WHERE THE GOVERNMENT OR CONTRACTOR, WITHOUT MAKING A PATENT SEARCH, KNOWS OR HAS DEMONSTRABLE GROUNDS TO KNOW THAT A VALID PATENT IS OR WILL BE USED BY OR FOR THE GOVERNMENT, THE RIGHT HOLDER SHALL BE INFORMED PROMPTLY;

(C) THE SCOPE AND DURATION OF SUCH USE SHALL BE LIMITED TO THE PURPOSE FOR WHICH IT WAS AUTHORIZED, AND IN THE CASE OF SEMI-CONDUCTOR TECHNOLOGY, SHALL ONLY BE FOR PUBLIC NONCOMMERCIAL USE OR TO REMEDY A PRACTICE

DETERMINED AFTER JUDICIAL OR ADMINISTRATIVE PROCESS TO BE ANTI-COMPETITIVE;

(D) THE RIGHT HOLDER SHALL BE PAID ADEQUATE REMUNERATION IN THE CIRCUMSTANCES OF EACH CASE, TAKING INTO ACCOUNT THE ECONOMIC VALUE OF THE AUTHORIZATION; THE LEGAL VALIDITY OF ANY DECISION RELATING TO THE AUTHORIZATION OF SUCH USE SHALL BE SUBJECT TO JUDICIAL REVIEW AND SUCH USE SHALL BE NON-EXCLUSIVE;

(E) THE USE OR OTHER EXPLOITATION BY THE GOVERNMENT OR THIRD PERSON AUTHORIZED BY THE GOVERNMENT OF DRUGS OR MEDICINES UNDER THIS SECTION SHALL BE SUBJECT TO THE EXCLUSIVE DETERMINATION OF THE PRESIDENT OF THE REPUBLIC OF THE PHILIPPINES AND SHALL BE IMMEDIATELY EXECUTORY: *PROVIDED,* THAT NO COURT, EXCEPT THE SUPREME COURT OF THE PHILIPPINES, SHALL ISSUE ANY TEMPORARY RESTRAINING ORDER OR PRELIMINARY INJUNCTION OR PRELIMINARY MANDATORY INJUNCTION THAT WILL PREVENT ITS IMMEDIATE EXECUTION. THE OFFICE OF THE PRESIDENT, IN CONSULTATION WITH THE APPROPRIATE GOVERNMENT AGENCIES, SHALL ISSUE THE APPROPRIATE IMPLEMENTING RULES AND REGULATIONS FOR THE EXERCISE OF THIS AUTHORITY WITHIN ONE HUNDRED TWENTY (120) DAYS AFTER ENACTMENT OF THIS LAW. ALL CASES ARISING FROM THE IMPLEMENTATION OF THIS PROVISION SHALL BE COGNIZABLE BY COURTS WITH APPROPRIATE JURISDICTION PROVIDED BY LAW."

SECTION 10. Section 159 of Republic Act no. 8293 is hereby amended to read as follows:

"Sec. 159. Limitations to Actions for Infringement. - Notwithstanding any other provision of this Act, the remedies given to the owner of a right infringed under this Act shall be limited as follows:
"159.1. x x x
"159.2. x x x
"159.3. x x x

"159.4 THERE SHALL BE NO INFRINGEMENT OF TRADEMARKS OR TRADE NAMES OF IMPORTED OR SOLD DRUGS OR MEDICINES ALLOWED UNDER SECTION 72.1: PROVIDED, THAT SAID DRUGS OR MEDICINES BEAR THE REGISTERED MARKS THAT HAVE NOT BEEN TAMPERED, MODIFIED, OR INFRINGED UPON AS DEFINED UNDER SECTION 155 OF THIS CODE."

SECTION 11. **Prohibited Acts.** Any person who shall violate Section 6 of this Act shall suffer the penalty graduated hereunder, viz:

a. for the first conviction, the penalty of reprimand which shall be officially recorded in the appropriate books of the Professional Regulation Commission shall be imposed

b. for the second conviction, the penalty of fine in the amount of not less than ten thousand pesos (P10,000.00) but not exceeding fifty thousand pesos (P50,000.00) at the discretion of the court

c. for the third conviction, the penalty of fine in the amount of not less than fifty thousand pesos (P50,000.00) but not exceeding one hundred thousand pesos (P100,000.00) and suspension of his license to practice his profession for thirty (30) days at the discretion of the court

d. for the fourth and subsequent convictions, the penalty of fine of not less than one hundred thousand pesos (P100,000.00) and suspension of his license to practice his profession for one year or longer at the discretion of the court.

Any juridical person who violates Section 4(a), 6(c), or 6(d) shall suffer the penalty of a fine of not less than fifty thousand pesos (P50,000.00) nor more than one hundred thousand pesos (P100,000.00) 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 revocation of license to practice profession, if applicable, and by imprisonment of not less than six (6) months nor more than one (1) 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 be *ipso facto* deported after service of sentence without need of further proceedings.

The Secretary of Health shall have the authority to impose administrative sanctions such as suspension or cancellation of license to operate or recommend suspension of license to practice profession to the Professional Regulation Commission as the case may be for the violation of this Act.

SECTION 12. ***Appropriations.*** - For the initial implementation of this Act, the amount of Twenty-five million pesos (P25,000,000.00) shall be taken from the current General Appropriations Act. Thereafter, such sum as may be necessary for its continued implementation shall be included in the annual General Appropriations Act.

SECTION 13. ***Implementing Rules and Regulations.*** The Department of Trade and Industry, in consultation with the Department of Health and Intellectual Property Office, shall promulgate the implementing rules and regulations within ninety (90) days from the effectivity of this Act.

SECTION. 14. ***Separability Clause.*** - If any part of this Act shall be held to be unconstitutional or invalid, other parts or provisions hereof which are not affected thereby shall continue to be in full force and effect.

SECTION 15. *Repealing Clause.* - All laws, presidential decrees, executive orders, rules and regulations which are contrary to the provision of this Act are hereby repealed, amended and modified accordingly.

SECTION 16. *Effectivity.* - This Act shall take effect fifteen (15) days after its publication in at least two (2) newspapers of general circulation, whichever comes first.

Approved,