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

SENATE

S. B. No. 1420

Introduced by Senator JUAN MIGUEL F. ZUBIRI

EXPLANATORY NOTE

This bill seeks to impose price regulation on drugs and medicines in the Philippines and amend certain provisions of R.A. 8293, otherwise known as the Intellectual Property Code of the Philippines, in order to bring down the presently anomalous costing of medicines to reasonable and affordable levels and save the lives of millions of Filipinos in our generation and beyond.

There is no doubt that millions of Filipinos are grieving and literally bleeding their hearts out by each passing day as they unavoidably contend with the astronomic cost of medicines in this country.

As outrageous and scandalous enough the prices of medicines are, what is even worse is that government is helpless amid, pardon the pun, the killing by our drug manufacturing firms and pharmaceutical importers in the uncontrolled, unhampered prices of their products.

Is it not shocking that the level of prices of medicines in the Philippines is comparatively the highest in Asia?

Is it not insulting to the Filipino people that some medicines that are being sold in the market today are five times costlier compared to other Asian countries?

It is interesting to note that competition as we know it in the Philippine pharmaceutical industry does not necessarily translate to cheaper products for the Filipinos. There are more than 300 pharmaceutical firms in the Philippines that either manufacture or import some 40,000 registered drugs. Yet the level of prices of medicines in our country persistently remains to be one of the highest in the world.

It is simply because the drug manufacturers and importers are having a field day jacking up their prices as much as they wanted – in the absence of government intervention.

Nowadays, overpricing of medicines is the name of the game in the Philippines to the shock and horror of foreigners and the suppressed wrath and anger of a severely-abused and helpless nation.

Hence, approval of this bill is urgently requested.

JUAN MIGUEL F. ZUBIRI

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AN ACT

PROVIDING FOR CHEAPER MEDICINES AND FOR OTHER PURPOSES

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 "Cheaper Medicines Act of 2007".

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

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; and

(3) Director, Bureau of Food and Drugs as member.

(b) The Board shall have as many members as may be recommended by the Secretary of Trade and Industry and appointed by the President of the Philippines: *Provided,* That consumers; national and multinational pharmaceutical companies, pharmacists; physicians; hospitals and drugstores shall be duly represented from among reputable associations nationwide: *Provided, further,* That the total membership of the Board shall not exceed ten (10).

SECTION 4. ***Powers of the 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. -

(1) Upon application or *motu propio* when the public interest so requires, the Board shall have the power to regulate the retail

prices of formulations included in the List of Regulated Drugs, including their dosage form and packing, and, in order that they shall be made publicly available at affordable retail price from the different manufacturers, importers, distributors, wholesalers or retailers and after a proper determination as the Board may deem fit, fix from time to time, by publication the maximum retail price at which such formulations shall be sold;

(2) 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 retail price thereof shall be the price which prevailed immediately before the effectivity of this Act and no manufacturer, importer, distributor, wholesaler or retailer of such formulation shall sell the *same at a retail price exceeding the price prevailing immediately* before the effectivity of the Act; and

For purposes hereof, 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 Include Formulations in the List of Regulated Drugs. – *Upon* application or *motu proprio* when the public interest so requires and after proper determination, the Board may order the inclusion in the List of Regulated Drugs of any formulation excluded therefrom.

SECTION 5. ***The List of Regulated Drugs.*** The List of Regulated Drugs shall include (1) all formulations indicated for treatment of chronic illnesses and life-threatening conditions such as, but not limited to, Endocrine Disorders, e.g., Diabetis Mellitus; Gastrointestinal Disorders, e.g., Peptic Ulcer; Urologic Disorders, e.g., BPH; Cardiovascular Diseases, e.g., Hypertension; Pulmonary Diseases, e.g., PTB, Asthma; Autoimmune Diseases, e.g., SLE; Skin Diseases, e.g., Psoriasis; Neuro-Psychiatric Disorders; Other Infectious Diseases, e.g., HIV-AIDS; and Other Conditions such as Organ Transplants and Neoplasms (2) formulations indicated for prevention of diseases, e.g., Vaccines, Immnunoglobulins, Anti-sera (3) formulations indicated for prevention of pregnancy, e.g., oral contraceptives, (4) Anesthetic Agents , and (5.) Intravenous Fluids.

SECTION 6. ***Display of Prices Fixed by the Board for Formulations Included in the List of Regulated Drugs.*** – (a) Within a reasonable period as may be determined by the Board, and provided that it conforms to existing drug product labeling requirements, every manufacturer, importer, distributor, wholesaler or retailer of a formulation intended for sale shall display the retail

price of a formulation included in the List of Regulated Drugs which shall not exceed the maximum retail price fixed by the Board. The maximum retail price shall be printed on the label of the immediate container of the formulation and the minimum pack thereof offered for retail sale with the words **"retail price not to exceed"** preceding it, and **"Under Drug Price Regulation "** on a red strip provided that, in the case of a container consisting of smaller saleable packs, the retail price of such smaller pack shall also be displayed on the label of each smaller pack and such price shall not be more than the *pro-rata* retail price of the main pack rounded off to the nearest centavo.

(b) Within a period as may be determined by the Board from time to time, every manufacturer or importer shall issue a price list to distributors, wholesalers, retailers and the Board, indicating the retail prices and the maximum retail price and such other information as may be required by the Board.

SECTION 7. ***Display of Prices and Price List of Formulations Excluded from the List of Regulated Drugs.*** – (a) Every manufacturer, importer, distributor, wholesaler or retailer of a formulation excluded from the List of Regulated Drugs shall display in indelible print mark on the label of the immediate container of the formulation and the minimum pack thereof offered for retail sale, the words "**Not Under Price Regulation**" on a green strip.

(b) If required by the Board, every manufacturer, importer, wholesaler, distributor, or retailer shall issue a price list of formulations excluded from the List of Regulated Drugs, indicating changes from time to time.

SECTION 8. A new chapter after Chapter VIII, Part 2 of the Law on Patents of Republic Act No. 8293 is hereby created to read as follows:

"Chapter VIII-A

"NON-PATENTABLE INVENTIONS, PARALLEL IMPORTATION, EARLY WORKINGPROVISIONS AND GOVERNMENT USE OF DRUGS AND MEDICINES"

"(A) IN THE CASE OF DRUGS OR MEDICINES, THE MERE DISCOVERY OF A NEW FORM 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 PROPERTY OR NEW USE FOR A KNOWN SUBSTANCE OR THE MERE USE OF A KNOWN PROCESS UNLESS SUCH KNOWN PROCESS RESULTS IN A NEW PRODUCT THAT EMPLOYS AT LEAST ONE NEW REACTANT SHALL NOT BE PATENTABLE.

"IN THE CASE OF DRUGS OR MEDICINES, SALTS, ESTERS, ETHERS, POLYMORPHS, METABOLITES, PURE FORM, PARTICLE SIZE, ISOMERS, MIXTURES OF ISOMERS, COMPLEXES, COMBINATIONS AND OTHER DERIVATIVES OF A KNOWN SUBSTANCE SHALL BE CONSIDERED TO BE THE SAME SUBSTANCE, UNLESS THEY DIFFER SIGNIFICANTLY IN PROPERTIES WITH REGARD TO EFFICACY.

"(B) OTHER THAN THE INSTANCES SPECIFIED IN SECTION 72, THE OWNER OF A PATENT TO DRUGS OR MEDICINES SHALL LIKEWISE BE PREVENTED FROM EXERCISING HIS RIGHTS UNDER SECTION 71, UNDER THE FOLLOWING CIRCUMSTANCES:

"(i) USING, OFFERING FOR SALE, SELLING OR IMPORTING A PATENTED PRODUCT WHEN IT HAS BEEN INTRODUCED ANYWHERE IN THE WORLD BY THE PATENT OWNER OR ANY PARTY AUTHORIZED TO USE THE INVENTION: *PROVIDED,* THAT A PATENTED PRODUCT SHALL MEAN A PATENTED ACTIVE PHARMACEUTICAL INGREDIENT (API), DRUGS OR MEDICINES: *PROVIDED, FURTHER, THAT SUCH IMPORTED PATENTED PRODUCTS* SHALL CLEARLY INDICATE ITS COUNTRY OF ORIGIN AND MANUFACTURE AND BE CLEARLY DISTINGUISHED FROM THE SAME PRODUCT MANUFACTURED WITH LICENSE IN THE PHILIPPINES.

"(ii) WHERE THE ACT CONSISTS OF MAKING OR USING EXCLUSIVELY FOR EXPERIMENTAL USE OF THE INVENTION FOR SCIENTIFIC PURPOSES OR EDUCATIONAL PURPOSES AND SUCH OTHER ACTIVITIES DIRECTLY RELATED TO SUCH SCIENTIFIC OR EDUCATIONAL EXPERIMENTAL USE.

"(iii) 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 OR OF ANOTHER COUNTRY THAT REGULATES THE MANUFACTURE, CONSTRUCTION, USE OR SALE OF ANY *PRODUCT: PROVIDED, THAT IN ORDER TO PROTECTTHE* DATA SUBMITTED BY THE ORIGINAL PATENT HOLDER FROM UNFAIR COMMERCIAL USE PROVIDED IN ARTICLE 39.3 OF THE TRIPS AGREEMENT, THE INTELLECTUAL PROPERTY OFFICE, IN CONSULTATION WITH THE APPROPRIATE GOVERNMENT AGENCIES, SHALL ISSUE THE APPROPRIATE RULES AND REGULATIONS NECESSARY THEREIN NOT LATER THAN ONE HUNDRED EIGHTY (180) DAYS AFTER ENACTMENT OF THIS LAW.

"(C) OTHER THAN THE INSTANCES MENTIONED IN SECTION 74, A GOVERNMENT AGENCY OR THIRD PERSON AUTHORIZED BY THE GOVERNMENT MAY EXPLOIT THE INVENTION OF A DRUG OR MEDICINE IN CASES OF NATIONAL EMERGENCY OR OTHER CIRCUMSTANCES OF EXTREME URGENCY; OR WHERE THERE IS PUBLIC NON-COMMERCIAL USE OF THE PATENT BY THE PATENTEE, WITHOUT SATISFACTORY REASON.

UNLESS OTHERWISE PROVIDED HEREIN, THE USE BY THE GOVERNMENT OR THIRD PERSON AUTHORIZED BY THE GOVERNMENT SHALL BE SUBJECT TO THE FOLLOWING PROVISIONS:

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

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

"(iii) SUCH USE SHALL BE NON-EXCLUSIVE;

"(iv) THE RIGHT HOLDER SHALL BE PAID ADEQUATE REMUNERATION IN THE CIRCUMSTANCES OF EACH CASE, TAKING INTO ACCOUNT THE ECONOMIC VALUE OF THE AUTHORIZATION.

"THE USE OREXPLOITATION BY THE PRESIDENT OR THIRD PERSON AUTHORIZED BY THE PRESIDENT OR 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 (OTHER PROVISIONAL REMEDIES / PRELIMINARY MANDATORY INJUNCTION) THAT WILL PREVENT ITS IMMEDIATE EXECUTION. THE OFFICE OF THE PRESIDENT, IN CONSULTATION WITH 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.

" (D) THERE SHALL BE NO INFRINGEMENT OF TRADEMARKS OR TRADENAMESOF SOLD, PATENT OR OFF-PATENT DRUGS OR MEDICINES ALLOWED UNDER SECTION B OF CHAPTER VIII-A OF THIS ACT: 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 9. Section 147 of Republic Act No. 8293 is hereby amended to read as follows:

"SEC. 147. *Rights Conferred.* – 147.1. **EXCEPT IN CASES OF IMPORTATION OF DRUGS OR MEDICINES ALLOWED UNDER CHAPTER VIII-A AND OF OFF-PATENT DRUGS OR MEDICINES,** [T]The owner of a registered mark shall have the exclusive right to prevent all third parties not having the owner's consent from using in the course of trade identical or similar signs or containers for goods or services which are

identical or similar to those in respect of which the trademark is registered where such use would result in a likelihood of confusion. In case of the use of an identical sign for for goods or services which are identical or similar to those in respect of which the trademark is registered where such use would result in a likelihood of confusion. In case of the use of an identical sign for identical goods or services, a likelihood of confusion shall be presumed.

"147.2. The exclusive right of the owner of a well-known mark defined in Subsection 123.1(e) which is registered in the Philippines, shall extend to goods and services which are not similar to those in respect of which the mark is registered: *Provided,* That use of that mark in relation to those goods or services would indicate a connection between those goods or services and the owner of the registered mark: *Provided, further,* That the interests of the owner of the registered mark are likely to be damaged by such use. (n)"

SECTION 10. ***Non-Discriminatory Clause.*** – It shall be unlawful for any retail drug outlet to refuse to carry and/or offer for sale imported drugs or medicines which had been previously approved for distribution or sale by the Bureau of Food and Drugs (BFAD). For this purpose, the said products shall be displayed with equal prominence as all other products sold in the establishment.

Any person who shall refuse to carry or sell drugs or medicines as provided herein shall be punished with a fine of not less than One hundred thousand pesos (Php100,000.00) but not more than Five hundred thousand pesos (Php500,000.00) at the discretion of the court. For the succeeding offense, the penalty shall not be less than Five hundred thousand pesos (Php500,000.00) but not more than One million pesos (Php1,000,000.00) at the discretion of the court plus the cancellation of the license to operate by the BFAD.

SECTION 11. ***Oversight Committee.*** – For the effective implementation of this Act, there shall be created an Oversight Committee to be composed of five Members from the Senate and five Members from the House of Representatives. There shall be proportionate representation of both the Majority and Minority Members of both Houses, with the Minority being assured of membership thereat.

The Oversight Committee shall oversee full implementation of the provisions of this Act.

SECTION 12. ***Appropriations.*** – For the initial implementation of this Act, the amount of Twenty-five million pesos (Php25,000,000.00) 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. ***Rules and Regulations***. – The Department of Health shall, within sixty (60) days from the approval of this Act, promulgate and issue the rules and regulations as may be necessary for the effective implementation of this Act.

SECTION 14. ***Separability Clause.*** – Any portion or provision of this Act that may be declared unconstitutional or invalid shall not have the effect of nullifying other portions and provisions hereof as long as such remaining portion or provision can still subsist and be given effect in their entirety.

SECTION 15. ***Repealing Clause***. – All laws, decrees, executive orders, proclamations and administrative regulations or parts thereof inconsistent herewith are hereby repealed or modified accordingly.

SECTION 16. ***Effectivity Clause***. – This Act shall take effect fifteen (15) days after its publication in at least two national newspapers of general circulation.

Approved,