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FOURTEENTH CONGRESS OF THE REPUBLIC OF THE PHILIPPINES First Regular Session	Ξ	7 JUN 30 P1:40	
S	SENATE	RECEIVED BY :	
Senate	Bill No. <u>90</u>		
INTRODUCED BY HON. MANNY VILLAR			

EXPLANATORY NOTE

Many of our countrymen die not because their sickness is incurable, but due to lack of medicine on account of poverty. The government cannot always remain indifferent to this reality. In this context, the bill seeks to answer the problem of high cost of medicine which is beyond the reach of many Filipinos.

The proposed legislation will amend Republic Act 8293 otherwise known as the *The Intellectual Property Code of the Philippines* in order to create competition among drug companies which will in effect lower the prices of medicine for the benefit of public health.

The constitutional provides that the State shall protect and promote the right of the people to health (Sec 15, Article II, Constitution) and shall adopt an integrated and comprehensive approach to health development with the end view of making essential health services available to all the people at affordable cost, giving priority to the needs of the underprivileged, the sick, the elderly, the disabled and the women and children.

In this light, approval of this bill is earnestly sought.

///// MANNY VILLAR

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Senate Bill No. 90

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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".

SEC. 2. *Declaration of Policy.* – It is hereby declared the policy of the State to protect and promote the right to health of the people and instill health consciousness among them. Pursuant thereto, the State shall provide cheaper medicines to the public.

SEC. 3. 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 WORKING PROVISIONS 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: PROVIDED. FURTHERMORE, THAT NOTHING HEREIN SHALL IN ANY WAY DIMINISH THE OTHER RIGHTS OF THE PATENT OWNER.

3

"(ii) 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 REQUIRED UNDER ANY LAW OF THE PHILIPPINES OR OF ANOTHER COUNTRY THAT REGULATES THE MANUFACTURE, CONSTRUCTION, USE OR SALE OF ANY PRODUCT.

"(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.

"SUBJECT TO THE CONTROL, SUPERVISION AND DETERMINATION OF THE RESPECTIVE SECRETARIES OF THE DEPARTMENT OF HEALTH AND THE DEPARTMENT OF TRADE AND INDUSTRY, THE USE OR OTHER EXPLOITATION BY THE GOVERNMENT OR ANY OF ITS **AUTHORIZED** REPRESENTATIVES OF DRUGS OR MEDICINES TO PROTECT PUBLIC HEALTH SHALL BE IMMEDIATELY EXECUTORY AND SHALL NOT BE SUBJECT TO ANY TEMPORARY RESTRAINING ORDER OR PRELIMINARY INJUNCTION OR SUCH OTHER THAT WILL PREVENT PROVISIONAL REMEDIES ITS IMPLEMENTATION. ALL CASES ARISING FROM THE IMPLEMENTATION OF THIS PROVISION SHALL BE COGNIZABLE BY COURTS WITH APPROPRIATE JURISDICTION **PROVIDED BY LAW."**

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SEC. 4. 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, [1]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 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)"

SEC. 5. *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

5

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.

SEC. 6. 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.

SEC. 7. *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.

SEC. 8. 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 Health as chairman;

(2) Secretary of Trade and Industry 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 Health and appointed by the President of the Philippines: *Provided*, That consumers; pharmaceutical companies, whether national or multinational; pharmacists; physicians; and hospitals shall be duly represented from among reputable associations nationwide: *Provided, further*, That the total membership of the Board shall not exceed ten (10).

6

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(c) The Board shall have the power to regulate prices of drugs or medicines, including life-saving ones and those indicated for chronic illnesses, in order to make them affordable to the public. For this purpose, the Board may inquire into the profit margin of drugs or medicines and is empowered to do any and all acts necessary to achieve the purposes of this Act.

SEC. 9. *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.

SEC. 10. 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.

SEC. 11. *Repealing Clause.* – All laws, decrees, executive orders, proclamations and administrative regulations or parts thereof inconsistent herewith are hereby repealed or modified accordingly.

SEC. 12. Effectivity Clause. – This Act shall take effect fifteen (15) days after its publication in at least two national newspapers of general circulation.

Approved.

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