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

OFFICE OF THE SECRETARY

10 JUL -1 A8:35

**SENATE**

**S.B. No. 5**

RECEIVED BY:

**Introduced by Senator Loren Legarda**

## EXPLANATORY NOTE

On June 06, 2008, Republic Act No. 9502, otherwise known as "An Act Providing for Cheaper and Quality Medicines, Amending for the Purpose Republic Act No. 8293 or the Intellectual Property Code, Republic Act No. 6675 or the Generics Act of 1988, and Republic Act No. 5921 or the Pharmacy Law, and for Other Purposes" was enacted into law. The law was purportedly passed to mitigate the suffering of the impoverished Filipinos who had to constantly deal with the ever increasing prices of basic commodities, among which are quality affordable medicines.

Unfortunately, there are serious concerns from the Filipino people that the law has failed to meet their expectations. Prices of medicines have not been effectively reduced. People from the lower bracket of society still cannot afford the prices of essential drugs despite the passage of R.A. 9502. Rather than reducing the prices of over one thousand five hundred (1,500) drug formulations, the law resulted in price reductions to merely twenty-two (22) drug formulations.

The law thus failed to serve the interests of the common man, the impoverished who continue to suffer and who should be the primary beneficiaries of a genuine Cheaper Medicine Law.

In view of the foregoing considerations, approval of this bill is earnestly sought.

**LOREN LEGARDA**
Senator

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AN ACT
AMENDING CERTAIN SECTIONS OF REPUBLIC ACT NO. 9502 OTHERWISE KNOWN AS THE "UNIVERSALLY ACCESSIBLE CHEAPER AND QUALITY MEDICINES ACT OF 2008" AND FOR OTHER PURPOSES

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

**SECTION 1.** Section 4 of Republic Act No. 9502 is hereby amended to read as follows:

"**SEC. 4.** ***Definition of Terms.*** – For purposes of this Act, the following terms are to mean as follows:

(a) **"BOARD" REFERS TO THE DRUG PRICE REGULATION BOARD.**

**(b)** [a] "Compulsory License" is a license issued by the Director General and the Director of Legal Affairs of the Intellectual Property Office to exploit a patented invention without the permission of the patent holder, either by manufacture or through parallel importation.

**(c)** [b] "Drug outlet" refers to drugstores, pharmacies, and any other business establishments, which sell drugs or medicines.

**(d) "DOHA DECLARATION" REFERS TO THE NOVEMBER 2001 DOHA DECLARATION ON THE AGREEMENT ON TRADE RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS**

**(TRIPS AGREEMENT) ADOPTED BY THE WORLD TRADE ORGANIZATION (WTO) MINISTERIAL CONFERENCE OF 2001 IN DOHA, QATAR THAT REAFFIRMED THAT THE TRIPS AGREEMENT "CAN AND SHOULD BE INTERPRETED AND IMPLEMENTED IN A MANNER SUPPORTIVE OF THE WTO MEMBERS' RIGHT TO PROTECT PUBLIC HEALTH AND, IN PARTICULAR, TO PROMOTE ACCESS TO MEDICINES FOR ALL" AND REAFFIRMS THAT THE AGREEMENT PROVIDES FLEXIBILITY FOR THIS PURPOSE, INCLUDING IDENTIFYING WAYS BY WHICH COUNTRIES WITH INSUFFICIENT OR NO PHARMACEUTICAL MANUFACTURING CAPACITIES COULD MAKE EFFECTIVE USE OF COMPULSORY LICENSING UNDER THE TRIPS AGREEMENT.**

**(e)** [c] "Drugs and medicines" refers to any chemical compound or biological substance, other than food, intended for use in the treatment, prevention or diagnosis of disease in humans or animals, including but not limited to:

(1) any article recognized in the official United States Pharmacopoeia-National Formulary (USP-NF), official Homeopathic Pharmacopoeia of the United States, Philippine Pharmacopoeia, Philippine National Drug Formulary, British Pharmacopoeia, European Pharmacopoeia, Japanese Pharmacopoeia, Indian Pharmacopoeia, any national compendium or any supplement to any of them;

(2) any article intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or animals;

(3) any article other than food intended to affect the structure or any function of the human body or animals;

(4) any article intended for use as a component of any articles specified in clauses (1), (2), and (3) not including devices or their components, parts, or accessories; and

(5) herbal and/or traditional drugs which are articles of plant or animal origin used in folk medicine which are:

(i) recognized in the Philippine National Drug Formulary;

(ii) intended for use in the treatment or cure or mitigation of disease symptoms, injury or body defects in humans;

(iii) other than food, intended to affect the structure or any function of the human body;

(iv) in finished or ready-to-use dosage form; and

(v) intended for use as a component of any of the articles specified in clauses (i), (ii), (iii), and (iv).

**(f) [**d**]** "Essential drugs list or national drug formulary" refers to a list of drugs prepared and periodically updated by the Department of Health on the basis of health conditions obtaining in the Philippines as well as on internationally accepted criteria.

**(g) [**e**]** "Importer" refers to any establishment that imports raw materials, active ingredients and finished products for its own use or for distribution to other drug establishments or outlets.

**(h) [**f**]** "Manufacture" includes any process or part of a process for making, altering, finishing, packing, labeling, breaking or otherwise treating or adapting any drug with a view to its sale and distribution, but does not include the compounding or dispensing of any drug in the ordinary course of retail business.

**(i) [**g**]** "Manufacturer" refers to any establishment engaged in the operations involved in the production of a drug with the end view of storage, distribution, or sale of the product.

**(j)** [h] "Multisource pharmaceutical products" refers to pharmaceutically equivalent or pharmaceutically alternative products that may or may not be therapeutically equivalent. Multisource pharmaceutical products that are therapeutically equivalent are interchangeable;

**(k) "PARALLEL IMPORTS" REFERS TO PRODUCTS IMPORTED INTO A COUNTRY WITHOUT THE AUTHORIZATION OF THE RIGHT HOLDER IN THAT COUNTRY, WHICH HAVE BEEN PUT ON THE MARKET IN ANOTHER COUNTRY BY THAT PERSON OR WITH HIS CONSENT OR BY ANY PARTY AUTHORIZED TO USE THE PATENTED PRODUCT.**

**(l)** [i] "Retailer" refers to a licensed establishment carrying on the retail business of sale of drugs or medicines to customers.

**(m)** [j] "Trader" refers to any licensed establishment, which is a registered owner of a drug product that procures the materials and packaging components, and provides the production monographs, quality control standards and procedures, but subcontracts the manufacture of such products to a licensed manufacturer.

**(n)** [k] "TRIPS Agreement" or Agreement on Trade-Related Aspects of Intellectual Property Rights refers to the international agreement administered by the WTO that sets down minimum standards for many forms of intellectual property regulation.

**(o)** [l]"Wholesaler" refers to a licensed establishment or drug outlet who acts as merchant, broker or agent, who sells or distributes for resale or wholesale drugs or medicines."

**SECTION 2.** Section 6 of Republic Act No. 9502 is hereby repealed.

**SECTION 3.** Section 7 of Republic Act No. 9502 is hereby renumbered as Sec. 6, and the succeeding sections are renumbered accordingly.

**SECTION 4.** Section 9 of Republic Act No. 9502 is hereby amended to read as follows:

"**SEC. 9.** Section 76.1 of Republic Act No. 8293, otherwise known as the Intellectual Property Code of the Philippines, is hereby amended to read as follows:

'SEC. 76. Civil Action for Infringement. – 76.1. The making, using, offering for sale, selling, or importing a patented product or a product obtained directly or indirectly from a patented process, or the use of a patented process without the authorization of the patentee constitutes patent infringement: *Provided,* That, this shall not apply to instances covered by Section 72.1 and 72.4 (Limitations of Patent Rights); **SUBSECTIONS C, D, AND E OF** Section 74 (Use of Invention by Government); Section 93.6 (Compulsory Licensing); and Section 93-A (**IMPLEMENTATION OF PARAGRAPH 6 OF THE DOHA DECLARATION**) of this Code."

**SECTION 5.** Section 11 of Republic Act No. 9502 is hereby amended to read as follows:

"**SEC. 11.** A new Section 93-A is hereby inserted after Section 93 of Republic Act No. 8293, otherwise known as the Intellectual Property Code of the Philippines, to read as follows:

'Sec. 93-A. [Procedures on Issuance of a Special Compulsory License under the TRIPS Agreement.] **IMPLEMENTATION OF PARAGRAPH 6 OF THE DOHA DECLARATION ON THE TRIPS AGREEMENT AND PUBLIC HEALTH WHICH RECOGNIZES THAT WORLD TRADE ORGANIZATION (WTO) MEMBERS WITH INSUFFICIENT OR NO MANUFACTURING CAPACITIES IN THE PHARMACEUTICAL SECTOR COULD FACE DIFFICULTIES AND MAKING EFFECTIVE USE OF COMPULSORY LICENSING UNDER THE TRIPS AGREEMENT AND THE 30 AUGUST 2003 DECISION OF THE WTO GENERAL COUNCIL**

**WHICH IMPLEMENTS PARAGRAPH 6 OF THE DOHA DECLARATION.** – 93-A.1. The Director General of the Intellectual Property Office, upon the written recommendation of the Secretary of Health, shall, upon filing of a petition, grant a compulsory license for the importation of patented drugs and medicines [.] **PURSUANT TO THE IMPLEMENTATION OF PARAGRAPH 6 OF THE DOHA DECLARATION ON THE TRIPS AGREEMENT AND PUBLIC HEALTH AND THE 30 AUGUST 2003 DECISION OF THE WORLD TRADE ORGANIZATION (WTO) GENERAL COUNCIL.** [The special compulsory license for the importation contemplated under this provision shall be an additional special alternative procedure to ensure access to quality affordable medicines and shall be primarily for domestic consumption: Provided, That adequate remuneration shall be paid to the patent owner either by the exporting or importing country. The compulsory license shall also contain a provision directing the grantee the license to exercise reasonable measures to prevent the re-exportation of the products imported under this provision.]

'The grant of a compulsory license shall be an exception to Sections 100.4 and 100.6 of Republic Act No. 8293 and shall be immediately executory.

'No court, except the Supreme Court of the Philippines shall issue any temporary restraining order or preliminary injunction or such other provisional remedies that will prevent the grant of the special compulsory license.

"93-A.2. A compulsory license shall also be available for the manufacture and export of drugs or medicines to any country having insufficient or no manufacturing capacity in the pharmaceutical sector to address public health problems: *Provided,* That, compulsory license has been granted by such country or such country has, by notification or otherwise, allowed importation of the patented drugs and medicines from the Philippines in compliance with the TRIPS Agreement."

"93-A.3. [The right to grant a special compulsory license under this section shall not limit or prejudice the rights, obligations and flexibilities provided under the TRIPS Agreement and under Philippine laws, particularly Section 72.1 and Section 74 of the Intellectual Property Code, as amended under this Act. It is also without prejudice to the extent to which drugs and medicines produced under a compulsory license can be exported as allowed in the TRIPS Agreement and applicable laws.] **THE INTELLECTUAL PROPERTY OFFICE SHALL PROMULGATE THE RULES AND REGULATIONS FOR THE EFFECTIVE IMPLEMENTATION OF THIS SECTION, TAKING INTO ACCOUNT THE GUIDELINES FOR THE IMPLEMENTATION OF PARAGRAPH 6 OF THE DOHA DECLARATION ON THE TRIPS AGREEMENT AND PUBLIC HEALTH AND THE 30 AUGUST 2003 DECISION OF THE TRIPS GENERAL COUNCIL."**

**SECTION 6.** Section 15 of Republic Act No. 9502 is hereby repealed.

**SECTION 7.** Section 16 of Republic Act No is hereby renumbered as Sec. 15, and amended to read as follows:

"SEC. **15** [16]. [Implementing] Rules and Regulations [on Amendments to Republic Act No. 8293, otherwise known as the Intellectual Property Code of the Philippines]. - [Unless otherwise provided herein,] T[he] Intellectual Property Office of the Philippines [in coordination with the Department of Health and the Bureau of Food and Drugs,] shall issue and promulgate, within one hundred twenty (120) days after the enactment of this Act, the implementing rules and regulations to effectively implement the provisions of this Act that relate to Republic Act No. 8293, otherwise known as the Intellectual Property Code of the Philippines."

**SECTION 8.** *Chapter 3 of Republic Act No. 9502 is hereby amended to read* as **"CREATION AND POWERS OF THE DRUG PRICE REGULATION BOARD."**

**SECTION 9.** Section 17 of Republic Act No. 9502 is hereby repealed.

**SECTION 10.** Section 18 of Republic Act No. 9502 is hereby renumbered as Sec. 16, and amended to read as follows:

"SEC. **16** [18]. *CREATION AND COMPOSITION OF THE DRUG PRICE REGULATION BOARD.* - **(A) THERE IS HEREBY CREATED THE DRUG PRICE REGULATION BOARD, WHICH SHALL BE ATTACHED TO THE DEPARTMENT OF HEALTH, AND COMPOSED OF SEVEN (7) MEMBERS AS FOLLOWS:**

**(1) SECRETARY OF HEALTH OR HIS DULY DESIGNATED REPRESENTATIVE WHO SHALL HAVE THE RANK OF AN UNDERSECRETARY AS CHAIRPERSON;**

**(2) SECRETARY OF TRADE AND INDUSTRY OR HIS DULY DESIGNATED UNDERSECRETARY AS VICE-CHAIRPERSON;**

**(3) DIRECTOR, BUREAU OF FOOD AND DRUGS AS MEMBER;**

**(4) PRESIDENT, PHILIPPINE HEALTH INSURANCE CORPORATION AS MEMBER;**

**(5) ONE (1) FACULTY FROM THE HEALTH SCIENCES SCHOOL AS MEMBER; AND**

**(6) TWO (2) REPRESENTATIVES FROM THE CONSUMERS' SECTOR AS MEMBERS.**

**(B) THE MEMBERS OF THE BOARD REPRESENTING THE ACADEME AND THE CONSUMERS' SECTOR SHALL BE APPOINTED BY THE PRESIDENT OF THE PHILIPPINES UPON THE RECOMMENDATION OF THE SECRETARY OF HEALTH AND SHALL SERVE FOR A TERM OF TWO (2) YEARS:** *PROVIDED,* **THAT, THE REPRESENTATIVES FROM THE**

**CONSUMERS' SECTOR SHALL NOT SERVE FOR MORE THAN TWO (2) TERMS.**

**(C) THE BOARD SHALL BE CONSTITUTED WITHIN THIRTY (30) DAYS AFTER THE EFFECTIVITY OF THIS ACT AND SHALL BE ASSISTED BY A SECRETARIAT FROM THE EXISTING ORGANIZATIONAL STRUCTURE OF THE DEPARTMENT OF HEALTH (DOH). THE SECRETARIAT SHALL BE HEADED BY AN EXECUTIVE DIRECTOR FROM AMONG THE UNDERSECRETARIES OR ASSISTANT SECRETARIES OF THE DOH SERVING IN AN *EX OFFICIO* CAPACITY.**

**IN THE IMPLEMENTATION OF THIS ACT, THE ORGANIZATIONAL STRUCTURE PROVIDED UNDER REPUBLIC ACT NO. 7581, OTHERWISE KNOWN AS THE PRICE ACT, SHALL BE UTILIZED."**

**SECTION 11.** Section 19 of Republic Act No. 9502 is hereby renumbered as Sec. 17, and amended to read as follows:

"SEC. 17 [19]. *POWERS OF THE BOARD.* - **THE BOARD SHALL HAVE THE FOLLOWING POWERS:**

**(A) POWER TO DETERMINE THE MAXIMUM RETAIL PRICE OF DRUGS OR MEDICINES SUBJECT TO PRICE REGULATION - (1) UPON APPLICATION OR *MOTU PROPRIO* WHEN THE PUBLIC INTEREST SO REQUIRES, THE BOARD SHALL HAVE THE POWER TO REGULATE THE RETAIL PRICE OF DRUGS OR MEDICINES LISTED UNDER SECTION 20 HEREOF, AND, IN ORDER THAT THEY SHALL BE MADE WIDELY AVAILABLE TO THE PUBLIC AT AFFORDABLE RETAIL PRICE FROM THE DIFFERENT MANUFACTURERS, IMPORTERS, TRADERS, 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 DRUGS OR MEDICINES SHALL BE SOLD.

(2) IN DETERMINING THE MAXIMUM RETAIL PRICE, THE BOARD SHALL CONSIDER THE FOLLOWING FACTORS:

(A) RETAIL PRICES OF THE SAME OR SIMILAR DRUGS AND MEDICINES IN OTHER COUNTRIES;

(B) THE SUPPLY AVAILABLE IN THE MARKET;

(C) THE COST TO THE MANUFACTURER, IMPORTER, TRADER, DISTRIBUTOR, WHOLESALER OR RETAILER OF THE FOLLOWING BUT NOT LIMITED TO:

(I) THE EXCHANGE RATE OF THE PESO TO THE FOREIGN CURRENCY WITH WHICH THE DRUG OR MEDICINE OR ANY COMPONENT, INGREDIENT OR RAW MATERIAL THEREOF WAS PAID FOR;

(II) ANY CHANGE IN THE AMORTIZATION COST OF MACHINERY BROUGHT ABOUT BY ANY CHANGE IN THE EXCHANGE RATE OF THE PESO TO THE FOREIGN CURRENCY WITH WHICH THE MACHINERY WAS BOUGHT THROUGH CREDIT FACILITIES;

(III) ANY CHANGE IN THE COST OF LABOR BROUGHT ABOUT BY A CHANGE IN THE MINIMUM WAGE; OR

(IV) ANY CHANGE IN THE COST OF TRANSPORTING OR DISTRIBUTING THE DRUGS OR MEDICINES TO THE AREA OF DESTINATION.

(D) SUCH OTHER FACTORS OR CONDITIONS, WHICH WILL AID IN ARRIVING AT A JUST AND REASONABLE MAXIMUM PRICE.

(3) NO RETAILER SHALL SELL DRUGS OR MEDICINES AT A RETAIL PRICE EXCEEDING THE MAXIMUM RETAIL PRICE FIXED BY THE BOARD: *PROVIDED,* THAT, UNTIL THE MAXIMUM RETAIL PRICE OF DRUGS OR MEDICINES SUBJECT TO PRICE REGULATION IS FIXED BY THE BOARD, NO MANUFACTURER, IMPORTER, TRADER, DISTRIBUTOR, WHOLESALER, OR RETAILER OF SUCH DRUG OR MEDICINE SHALL SELL THE SAME AT A RETAIL PRICE EXCEEDING THE PRICE PREVAILING IMMEDIATELY BEFORE THE EFFECTIVITY OF THIS ACT: *PROVIDED, FURTHER,* THAT, IMMEDIATELY AFTER THE DRUG PRICE REGULATION BOARD IS CONSTITUTED, THE BOARD SHALL UNDERTAKE A STUDY ON THE PREVAILING PRICES OF DRUGS OR MEDICINES *SUBJECT TO PRICE REGULATION AND IMMEDIATELY AFTER* THE EFFECTIVITY OF ITS POWERS, PROVIDE AN INITIAL LIST OF DRUGS OR MEDICINES WHOSE NEW MAXIMUM RETAIL PRICES SHALL BE FIXED BY THE BOARD.

(B) POWER TO INCLUDE OTHER DRUGS OR MEDICINES IN THE LIST SUBJECT TO PRICE REGULATION - UPON APPLICATION OR *MOTU PROPRIO* WHEN THE PUBLIC INTEREST SO REQUIRES AND AFTER PROPER DETERMINATION, THE BOARD MAY ORDER THE INCLUSION OF DRUGS OR MEDICINES TO THE LIST SUBJECT TO PRICE REGULATION UNDER SECTION 19 HEREOF.

(C) POWER TO IMPLEMENT COST-CONTAINMENT AND OTHER MEASURES - (1) THE BOARD SHALL HAVE THE POWER TO DETERMINE THE FAIR PRICE OF DRUGS OR MEDICINES FOR PURPOSES OF PUBLIC HEALTH INSURANCE AND GOVERNMENT PROCUREMENT; AND

(2) THE BOARD SHALL HAVE THE POWER TO IMPLEMENT ANY OTHER MEASURES THAT THE GOVERNMENT MAY AVAIL OF TO EFFECTIVELY REDUCE THE COST OF DRUGS OR MEDICINES THAT SHALL INCLUDE, BUT NOT BE LIMITED TO, COMPETITIVE BIDDING, PRICE-VOLUME NEGOTIATIONS, AND OTHER APPROPRIATE MECHANISMS THAT INFLUENCE SUPPLY, DEMAND, AND EXPENDITURES ON DRUGS OR MEDICINES.

(D) POWER TO IMPOSE ADMINISTRATIVE FINES AND PENALTIES – AFTER DUE NOTICE AND HEARING, THE BOARD SHALL HAVE THE POWER TO IMPOSE ADMINISTRATIVE FINES AGAINST ANY PERSON, MANUFACTURER, IMPORTER, TRADER, DISTRIBUTOR, WHOLESALER, RETAILER OR ANY OTHER ENTITY, IN SUCH AMOUNT AS IT MAY DEEM REASONABLE, WHICH SHALL IN NO CASE BE LESS THAN FIFTY THOUSAND PESOS (P50,000.00) NOR MORE THAN FIVE MILLION PESOS (P5,000,000.00) FOR VIOLATIONS OF THE MAXIMUM RETAIL PRICE FIXED PURSUANT TO THIS SECTION.

(E) POWER TO DEPUTIZE GOVERNMENT ENTITIES – THE BOARD SHALL HAVE THE POWER TO CALL UPON AND DEPUTIZE ANY OFFICIAL, AGENT, EMPLOYEE, AGENCY, OR INSTRUMENTALITY OF THE NATIONAL OR LOCAL GOVERNMENT FOR ANY ASSISTANCE THAT IT MAY DEEM NECESSARY TO CARRY OUT THE PURPOSES OF THIS ACT.

(F) OTHER POWERS NECESSARY TO IMPLEMENT PROVISIONS OF THIS ACT – THE BOARD SHALL EXERCISE SUCH POWERS AND FUNCTIONS AS MAY BE NECESSARY TO IMPLEMENT AND ENFORCE THE PROVISIONS OF THIS CHAPTER OF THE ACT SUCH AS, BUT NOT LIMITED TO, THE POWER TO ISSUE *SUBPOENA DUCES TECUM* AND *SUBPOENA AD TESTIFICANDUM*, AND TO REQUIRE THE PRODUCTION AND SUBMISSION OF RECORDS, DOCUMENTS, BOOKS OF

**ACCOUNT, BILLS OF LADING, INPUT DOCUMENTS, RECORDS OF PURCHASE AND SALE, FINANCIAL STATEMENTS, AND SUCH OTHER DOCUMENTS, INFORMATION AND PAPERS AS MAY BE NECESSARY TO ENABLE THE BOARD TO CARRY OUT ITS FUNCTIONS, DUTIES AND RESPONSIBILITIES."**

**SECTION 12.** Section 20 of Republic Act No. 9520 is hereby renumbered as Sec. 18, and amended to read as follows:

"SEC. **18** [20]. *BOARD Procedures* [*for Inquiries, Studies, Hearings, Investigations, and Proceedings*]. — All inquiries, studies, hearings, investigations and proceedings conducted by the [Secretary of the Department of Health] **BOARD** shall be governed by rules adopted by [him/her] **THE BOARD**, and in the conduct thereof **THE BOARD** shall not be bound by the technical rules of evidence.

**IN ACCORDANCE WITH ITS POWER TO INVESTIGATE ANY MATTER BEFORE IT, THE BOARD SHALL HAVE THE POWER TO DEPOSE WITNESSES RESIDING WITHIN OR WITHOUT THE PHILIPPINES ACCORDING TO ITS RULES AND REGULATIONS."**

**SECTION 13.** Section 21 of Republic Act No. 9502 is hereby renumbered as Sec. 19, and amended to read as follows:

"SEC. **19** [21]. *Effectivity of the BOARD'S Decisions or Orders* [*of the Secretary of the Department of Health*]. — All decisions or orders of the **BOARD** [Secretary of the Department of Health] pursuant to Section **17** [19], Paragraphs **(A) POWER TO DETERMINE THE MAXIMUM RETAIL PRICE OF DRUGS OR MEDICINES SUBJECT TO PRICE REGULATION, (B) POWER TO INCLUDE OTHER DRUGS OR MEDICINES IN THE LIST SUBJECT TO PRICE REGULATION, (C) POWER TO IMPLEMENT COST-CONTAINMENT AND OTHER MEASURES, (D) POWER TO IMPOSE ADMINISTRATIVE FINES AND PENALTIES, (E) POWER TO DEPUTIZE GOVERNMENT ENTITIES, OR (F) OTHER POWERS NECESSARY TO**

**IMPLEMENT PROVISIONS OF THIS ACT** [A) Power to Recommend the Maximum Retail Price of Drugs and Medicines Subject to Price Regulation, (B) Power to Include Other Drugs and Medicines in the List Subject to Price Regulation, (C) Power to Implement Cost-Containment and Other Measures, (D) Power to Impose Administrative Fines and Penalties, (E) Power to Deputize Government Entities, or (F) Other Powers Necessary to Implement Provisions of this Chapter], shall be immediately operative, **UNLESS OTHERWISE PROVIDED BY THE BOARD**."

**SECTION 14.** Section 22 of Republic Act No. 9502 is hereby renumbered as Sec. 20, and amended to read as follows:

"SEC. **20** [22]. *Review of the **BOARD'S** Decisions or Orders* [*of the Secretary of the Department of Health*]. — A party adversely affected by a decision, order or ruling of the **BOARD** [Secretary of the Department of Health] may, within thirty (30) days from notice of such decision, order or ruling, or in case of a denial of a motion for reconsideration thereof, within fifteen (15) days after notice of such denial, file an appeal with the Court of Appeals, which shall have jurisdiction to review such decision, order or ruling **AND TO MODIFY OR SET ASIDE THE SAME WHEN IT CLEARLY APPEARS THAT THERE WAS NO EVIDENCE BEFORE THE BOARD TO SUPPORT REASONABLY SUCH DECISION, ORDER OR RULING, OR THAT THE SAME IS CONTRARY TO LAW, OR THAT IT WAS WITHOUT THE JURISDICTION OF THE BOARD. THE EVIDENCE PRESENTED TO THE BOARD, TOGETHER WITH THE RECORD OF THE PROCEEDINGS BEFORE THE BOARD, SHALL BE CERTIFIED BY THE BOARD TO THE COURT OF APPEALS. SAID APPEAL SHALL BE PLACED ON FILE IN THE OFFICE OF THE CLERK OF THE COURT OF APPEALS WHO SHALL FURNISH COPIES THEREOF TO THE BOARD AND OTHER PARTIES INTERESTED.**

**ANY DECISION, ORDER OR RULING OF THE BOARD MAY LIKEWISE BE REVIEWED BY THE SUPREME COURT UPON A**

**WRIT OF CERTIORARI IN APPROPRIATE CASES. THE PROCEDURE FOR REVIEW, EXCEPT AS HEREIN PROVIDED, SHALL BE IN ACCORDANCE WITH THE RULES PRESCRIBED BY THE SUPREME COURT.**

The filing of a petition for a writ of certiorari or other special remedies in the Supreme Court shall in no case supersede or stay any decision, order or ruling of the Board, unless the Supreme Court shall so direct, and the petitioner may be required by the Supreme Court to give bond in such form and of such amount as may be deemed proper."

**SECTION 15.** Sec. 23 of Republic Act No. 9502 is hereby renumbered as Sec. 21 deleting subparagraph (c) thereof with succeeding subparagraphs renumbered successively, and amended to read as follows:

"SEC. **21 [23].** *List of Drugs and Medicines that are Subject to Price Regulation.* - The list of drugs and medicines that are subject to price regulation shall include, inter alia:

(a) All drugs and medicines indicated for treatment of chronic illnesses and life threatening conditions, such as, but not limited to, endocrine disorders, e.g., diabetes mellitus; gastrointestinal disorders, e.g., peptic ulcer; urologic disorders, e.g., benign prostatic hyperplasia (BPH); cardiovascular diseases, e.g., hypertension; pulmonary diseases, e.g., pulmonary tuberculosis (PTB), asthma; auto-immune diseases, e.g., systemic lupus erythematosus (SLE); skin diseases, e.g., psoriasis; neuro-psychiatric disorders; other infectious diseases, e.g., human immunodeficiency virus-acquired immune deficiency syndrome (HIV-AIDS); and other conditions such as organ transplants and neoplasm;

(b) Drugs and medicines indicated for prevention of diseases, e.g., vaccines, immunoglobulin, anti-sera;

[(c) Drugs and medicines indicated for prevention of pregnancy, e.g., oral contraceptives;]

**(c)** [(d)] Anesthetic agents;

**(d)** [(e)] Intravenous fluids;

**(e)** [(f)] Drugs and medicines that are included in the Philippine National Drug Formulary (PNDF) Essential Drug List; and

**(f)** [(g) All other drugs and medicines which, from time to time, the Secretary of the Department of Health determines to be in need of price regulation.

**SECTION 16.** Section 24 of Republic Act No. 9502 is hereby renumbered as Sec. 22, and the succeeding section renumbered accordingly. ]

**SECTION 17.** Section 26 of Republic Act No. 9502 is hereby renumbered as Sec. 24 and amended to read as follows:

"SEC. **24** [26]. *Display of [Maximum Retail] Price Fixed [and Approved by Order of the President of the Philippines] **BY THE BOARD** for Drugs and Medicines Subject to Price Regulation.* – (a) Within a reasonable period as may be determined by the [Secretary of the Department of Health] **BOARD**, and: Provided, That it conforms to existing drug product labeling requirements, every manufacturer, importer, distributor, wholesaler, trader, or retailer of a drug or medicine intended for sale shall display the retail price which shall not exceed the maximum retail price [approved by order of the President of the Philippines] **FIXED BY THE BOARD**. The maximum retail price shall be printed on the label of the immediate container of the drug or medicine 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 *PRORATA* RETAIL PRICE OF THE MAIN PACK ROUNDED OFF TO THE NEAREST CENTAVO.**

(b) Within a period as may be determined by the [Secretary of the Department of Health] **BOARD** from time to time, every manufacturer, importer, or trader shall issue a price list to wholesalers, distributors, retailers and the Board, indicating the retail price, the maximum retail price, and such other information as may be required by the [Secretary of the Department of Health] **BOARD**."

**SECTION 18.** Section 27 of Republic Act No. 9502 is hereby renumbered as Sec. 25 with a new provision and sub-section to read as follows:

"SEC. **25** [27]. *DISPLAY OF PRICE AND PRICE LIST OF DRUGS OR MEDICINES EXCLUDED FROM THE LIST SUBJECT TO PRICE REGULATION.* - **(A) EVERY MANUFACTURER, IMPORTER, TRADER, DISTRIBUTOR, WHOLESALER, OR RETAILER OF A DRUG OR MEDICINE EXCLUDED FROM THE LIST SUBJECT TO PRICE REGULATION UNDER SECTION 21 HEREOF SHALL DISPLAY IN INDELIBLE PRINT MARK ON THE LABEL OF THE IMMEDIATE CONTAINER OF THE DRUG OR MEDICINE 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, TRADER, WHOLESALER, DISTRIBUTOR, OR RETAILER SHALL ISSUE A PRICE LIST OF DRUGS OR *MEDICINES EXCLUDED FROM THE LIST SUBJECT TO PRICE* REGULATION, INDICATING CHANGES FROM TIME TO TIME.**

**(C) EVERY MANUFACTURER, IMPORTER, TRADER, *DISTRIBUTOR, WHOLESALER, OR RETAILER SHALL SUBMIT* PERIODICALLY THEIR PRICES AND INVENTORY OF ALL THE DRUGS OR MEDICINES THEY CARRY TO THE BOARD.**

**SEC. 25.1.** - *Reports from Local Government Units (LGUs) and the Department of Trade and Industry (DTI).* - All local government units **(LGUs)** [and the Department of Trade and Industry] shall help ensure

the implementation of pricing policies provided under this Chapter by submitting quarterly price monitoring reports to the [Secretary of the Department of Health] BOARD of drugs or medicines identified by the latter, and any and all necessary information that the [Secretary of the Department of Health] **BOARD** may require."

**SECTION 19.** Section 28 of Republic Act No. 9502 is hereby renumbered as Sec. 26 and amended to read as follows:

"SEC. **26** [28]. *Role of the Department of Health (DOH) and the Department of Trade and Industry (DTI).* - The Department of Health and the Department of Trade and Industry shall **JOINTLY** conduct independent periodic surveys and studies of the selling prices of all drugs and medicines referred to in Section [23] **21** of this Act all over the country as well as their share or effect on the family income of the different economic groups in the country for purposes of serving as data base for government efforts to promote access to more affordable medicines, as well as evaluating the effectivity of the measures undertaken to promote access to more affordable medicines. [The DTI shall always officially provide the Secretary of the Department of Health copies of these independent reports.]"

**SECTION 20.** Section 29 of Republic Act No. 9502 is hereby renumbered as Sec. 27 and amended to read as follows:

"SEC. **27** [29]. *Rules and Regulations.* - The [Secretary of the Department of Health] **BOARD**, in consultation with the **DOH AND** the Department of Trade and Industry, the Congressional Oversight Committee and other appropriate government agencies, shall, within one hundred twenty (120) days from the effectivity of this Act, promulgate the rules and regulations necessary to effectively implement the provisions of this chapter."

**SECTION 21.** Section 30 of Republic Act No. 9502 is hereby renumbered as Sec. 28 and amended to read as follows:

"SEC. 28 [30]. **ANNUAL REPORT. - WITHIN THIRTY (30) DAYS FROM THE EFFECTIVITY OF THIS ACT AND EVERY DECEMBER 31ST OF EVERY YEAR THEREAFTER, EVERY MANUFACTURER, IMPORTER, TRADER, DISTRIBUTOR, WHOLESALER, AND RETAILER OF A DRUG OR MEDICINE WHETHER INCLUDED IN OR EXCLUDED FROM THE LIST OF DRUGS OR MEDICINES THAT ARE SUBJECT TO PRICE REGULATION SHALL FURNISH THE BOARD A LIST OF ALL DRUGS OR MEDICINES IT MANUFACTURES, IMPORTS, TRADES, DISTRIBUTES, WHOLESALES, OR RETAILS, DATA PERTAINING TO THE FACTORS ENUMERATED UNDER SECTION 17(A)(2), AND ANY AND ALL NECESSARY INFORMATION THAT THE BOARD MAY REQUIRE.**"

**SECTION 22.** Sections 31 and 32 of Republic Act No. 9502 are hereby repealed.

**SECTION 23.** Section 33 of Republic Act No. 9502 is renumbered as Sec. 29, and hereby amended to read as follows:

"SEC. **29** [33]. *Non-Discriminatory Clause.* - It shall be unlawful for any retail drug outlet to refuse to carry either by sale or by consignment, or offer for sale drugs or medicines brought into the country **[**, as allowed under Section 7 of this Act which amends Section 72.1 of the Intellectual Property Code of the Philippines or Republic Act No. 8293,**]** **THROUGH PARALLEL IMPORTATION** by the government or **[**authorized**]** third party **AUTHORIZED BY THE GOVERNMENT AND** which have been previously approved for distribution or sale by the Bureau of Food and Drugs. For this purpose, the said products shall be displayed with equal prominence as all other products sold in the establishment."

**SECTION 24.** Section 34 of Republic Act No. 9502 is hereby renumbered as Sec. 30, and the succeeding sections are renumbered accordingly.

**SECTION 25.** Section 38 of Republic Act No. 9502 is hereby renumbered as Sec. 34 and amended to read as follows:

"SEC. **34** [38]. Section 6 of Republic Act No. 6675 is hereby amended to read as follows:

"SEC. 6. *Who Shall Use Generic Terminology.* - "(a) All government health agencies and their personnel as well as other government agencies shall use generic terminology or generic names in all transactions related to purchasing, prescribing, dispensing and administering of drugs and medicines.

"(b) All medical, dental and veterinary practitioners, including private practitioners, shall write prescriptions using the generic name **OF THE DRUG OR MEDICINE ONLY AND ITS BRAND NAME SHALL NOT APPEAR ON ANY PART OF THE PRESCRIPTION**. [The brand name may be included if so desired.]

"(c) Any organization or company involved in the manufacture, importation, repacking, marketing and/or distribution of drugs and medicines shall indicate prominently the generic name of the product. In the case of brand name products, the generic name shall appear prominently and immediately above the brand name in all product labels as well as in advertising and other promotional materials.

"(d) Drug outlets, including drugstores, hospital and non-hospital pharmacies and nontraditional outlets such as supermarkets and stores, shall inform any buyer about any and all other drug products having the same generic name, together with their corresponding prices so that the buyer may adequately exercise his option. Within one (1) year after approval of this Act, the drug outlets referred to herein shall post in conspicuous places in their establishments a list of drug products with the same generic name and their corresponding prices.

"(e) There shall appear prominently on the label of a generic drug the following statement: **THIS PRODUCT HAS THE SAME THERAPEUTIC EFFICACY AS ANY OTHER GENERIC PRODUCT OF THE SAME NAME. SIGNED: BFAD.** "

**SECTION 26.** Section 39 of Republic Act No. 9502 is hereby renumbered as Sec. 35, and the succeeding sections are renumbered accordingly.

**SECTION 27.** There shall be incorporated after Section 44 of Republic Act No. 9502 a new section to read as follows:

"Sec. 40.1. *QUALITY ASSURANCE OF DRUGS.* - **THE BUREAU OF FOOD AND DRUGS SHALL TAKE THE NECESSARY STEPS TO ENSURE THE SAFETY AND QUALITY OF DRUGS, WHETHER LOCALLY PRODUCED OR IMPORTED AS PROVIDED HEREIN. BIO-EQUIVALENCE TESTING SHALL BE MADE ON THE *DRUGS LISTED IN THE ESSENTIAL DRUG LIST.*"**

**SECTION 28.** Section 45 of Republic Act No. 9502 is renumbered as Sec. 41 and amended to read as follows:

"SEC. **41** [45]. *Congressional Oversight Committee.* - **TO OVERSEE THE IMPLEMENTATION OF THIS ACT, THERE SHALL BE CREATED A CONGRESSIONAL OVERSIGHT COMMITTEE (COC) TO BE COMPOSED OF THE CHAIRS OF THE SENATE COMMITTEES ON TRADE AND COMMERCE, HEALTH AND DEMOGRAPHY, AND FINANCE, AND THE HOUSE OF REPRESENTATIVES COMMITTEES ON TRADE AND INDUSTRY, HEALTH, AND APPROPRIATIONS, AND TWO (2) MEMBERS EACH FROM THE SENATE AND HOUSE OF REPRESENTATIVES WHO SHALL BE DESIGNATED BY THE SENATE PRESIDENT AND THE SPEAKER OF THE HOUSE OF REPRESENTATIVES: *PROVIDED,* THAT ONE (1) OF THE TWO (2) SENATORS AND ONE (1) OF THE TWO (2) HOUSE MEMBERS SHALL BE NOMINATED BY THE RESPECTIVE MINORITY LEADERS OF THE SENATE AND THE HOUSE OF REPRESENTATIVES.**

**THE SECRETARIAT OF THE COC SHALL BE DRAWN FROM THE EXISTING SECRETARIAT PERSONNEL OF THE SENATE AND THE HOUSE OF REPRESENTATIVES COMMITTEES COMPRISING THE COC."**

**SECTION 29.** Section 46 of Republic Act No. 9502 is hereby renumbered as Sec. 42 and amended to read as follows:

"SEC. **42** [46]. *Appropriations* ***FOR THE DRUG PRICE REGULATION BOARD.*** **– THE AMOUNT NECESSARY FOR THE INITIAL IMPLEMENTATION OF CHAPTER 3 OF THIS ACT SHALL BE CHARGED AGAINST THE CURRENT YEAR'S APPROPRIATIONS OF THE DOH AND THE DTI. THEREAFTER, SUCH AMOUNTS AS MAY BE NECESSARY FOR ITS CONTINUED IMPLEMENTATION SHALL BE INCLUDED IN THE ANNUAL GENERAL APPROPRIATIONS ACT."**

**SECTION 30.** Section 48 of Republic Act No. 9502 is hereby renumbered as Sec. 44 and amended to read as follows:

"SEC. **44** [48]. *Repealing Clause.* **– SECTIONS 22, 61, 71, 72, 74, 76, 93, 94, 95, AND 147 OF REPUBLIC ACT NO. 8293, OTHERWISE KNOWN AS THE INTELLECTUAL PROPERTY CODE OF THE PHILIPPINES; SECTIONS 5, 6, 8, 11, AND 12 OF REPUBLIC ACT NO. 6675, OTHERWISE KNOWN AS THE GENERICS ACT OF 1988; AND SECTION 25 OF REPUBLIC ACT NO. 5921, AS AMENDED, OTHERWISE KNOWN AS THE PHARMACY LAW, ARE HEREBY AMENDED.**

All laws, decrees, executive orders, proclamations and administrative regulations or parts thereof inconsistent herewith are hereby repealed or modified accordingly."

**SECTION 31.** There shall be incorporated after Section 48 of Republic Act No. 9502 a new section to read as follows:

**"SEC. 45. *EFFECTIVITY OF SECTION 33 OF THIS ACT.* - THE AMENDMENT TO SECTION 6(B) OF REPUBLIC ACT NO. 6675 REFERRED TO IN SECTION 33 WHICH MANDATES THE MEDICAL, DENTAL AND VETERINARY PRACTITIONERS, INCLUDING PRIVATE PRACTITIONERS, TO WRITE PRESCRIPTIONS IN GENERIC NAME ONLY SHALL TAKE EFFECT AFTER A PERIOD OF TWELVE (12) MONTHS FROM THE EFFECTIVITY OF THIS ACT: *PROVIDED*, THAT, WITHIN THIS TWELVE (12)-MONTH PERIOD, NO PRESCRIPTION SHALL CARRY THE WORDS "NO SUBSTITUTION" OR A SIMILAR PHRASE."**

**SECTION 32.** ***Implementing Rules and Regulations.*** - The Department of Health (DOH) and the Department of Trade and Industry (DTI), in consultation with the appropriate government agencies shall, within sixty (60) days from the effectivity of this Act, promulgate the necessary rules and regulations for the effective implementation of the provisions of this Act.

**SECTION 33.** ***Separability Clause.*** - If any provision of this Act is declared unconstitutional or invalid, the provisions not affected thereby shall continue to be in full force and effect.

**SECTION 34.** ***Repealing Clause.*** - All laws, including Republic Act No. 9502, decrees, orders, rules and regulations or other issuances inconsistent with the provisions of this Act are hereby repealed, amended or modified accordingly.

**SECTION 35.** ***Effectivity Clause.*** - This Act shall take effect fifteen (15) days after its publication in two (2) national newspapers of general circulation.

Approved,