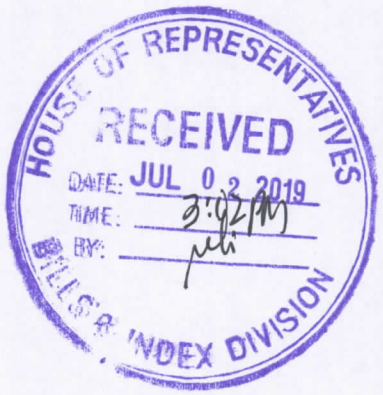


Republic of the Philippines
**HOUSE OF REPRESENTATIVES**
Quezon City

**18TH CONGRESS**
First Regular Session

HOUSE BILL NO. 994

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**Introduced by Representative MICHAEL L. ROMERO**

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# EXPLANATORY NOTE

A **counterfeit drug** is a pharmaceutically manufactured product which is produced and sold with the intent to deceivingly represent its origin, authenticity or effectiveness. It may contain unsuitable quantities of active ingredients, or none, may be improperly processed within the body, may contain ingredients that are not on the label *(which may or may not be harmful)*, or may be supplied with inaccurate or fake packaging and labeling.

Counterfeit drugs are related to pharmaceutical fraud. Drug manufacturers and distributors are increasingly investing in countermeasures, such as traceability and authentication technologies, to try to minimize the impact of counterfeit drugs. Antibiotics with insufficient quantities of an active ingredient add to the problem of antibiotic resistance.

If legitimate, correctly labeled, low-cost generic drugs are not considered as counterfeit or fake, but can be caught up in anti-counterfeiting enforcement measures. In that respect, a debate is raging as to whether counterfeit products are first and foremost a threat to human health and safety or whether provoking anxiety is just a clever way for wealthy nations to create sympathy for increased protection of their intellectual property rights.

This House Bill seeks to safeguard, protect and promote the right to health of the people and instill health consciousness among them, most especially against counterfeit drugs.

Thus, the early passage of this bill is earnestly requested.

**MICHAEL L. ROMERO Ph.D.**

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AN ACT

AMENDING **REPUBLIC ACT 8203,** OTHERWISE KNOWN AS THE **"SPECIAL LAW ON COUNTERFEIT DRUGS"** TO FOSTER THE IMPOSITION OF ALL EXISTING POLICIES AND GUIDELINES, PROVIDING STIFFER PENALTIES AND SANCTIONS, AND FOR OTHER PURPOSES

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

**SECTION 1.**

Section 7 of Republic Act No. 8203 is hereby amended to read:

**SECTION 7. *Administrative Sanctions*** – Upon finding that the drugs examined are counterfeit and the determination of the parties liable thereof, the Bureau shall impose any or all of the following sanctions:

a) permanent closure of the establishment concerned and the revocation of its license to business;
b) a fine of not less than Three hundred thousand pesos **(P300,000.00)** but not more than One million pesos **(P1,000,000.00)**;
c) upon order of the Court, forfeiture, confiscation, and destruction of products found to be counterfeited and the

equipment, instruments, and other articles used in violation of this Act;

d) filing of an appropriate proceedings against the registered pharmacist with the Professional Regulations Commission for cancellation of professional license;

e) filing of criminal charges against the violator (s), which can be instituted independently from the administrative case: Provided, That the dismissal of the criminal case shall not lift the closure order, except when it is a dismissal on the merits or for lack of basis: Provided, further, That the withdrawal of the private criminal complaint shall not be a ground for the dismissal of the administrative proceedings; and

f) permanent disqualification of the person concerned, whether natural or juridical, from owning or operating an establishment engaged in any business activity under the supervision of the Bureau.

**SECTION 2.**

Section 8 of Republic Act No. 8203 is hereby amended to read:

**SECTION 8. *Penalties*.** – The commission of any of the acts prohibited under Sections 4 and 6 of this Act shall be punished by:

a) imprisonment of not less than one **(1)** year and one (1) day; but not more than six (6) years for more possession of counterfeit drugs as provided for in Section 4(b) hereof; or

b) imprisonment of not less than six **(6)** years and one (1) day, but not more than ten (10) years or a fine of not less than Three hundred thousand pesos **(P300,000.00)** but not more than One million pesos **(P1,000,000.00)** or both such imprisonment and fine at the discretion of the court in any other case mentioned in Section 4 hereof; or

c) imprisonment of not less than one **(1)** year and one (1) day, but not more than four **(4)** years and four (4) months if the counterfeit drug is intended for animals; or

d) imprisonment of not less than six (6) years and one (1) day but not more than ten (10) years for any manufacturer, seller or distributor who shall conceal, substitute, dispose or destroy any drug as may have been segregated and sealed by the Bureau or who shall break, alter or tamper any mark or seal used by the

Bureau to identify those segregated drugs as provided for under Section 6(a) of this Act. Any other person who breaks, alters or tampers any mark or seal used by the Bureau to identify the segregated drugs shall suffer the penalty of not less than one **(1)** year and one (1) day, but not more than six (6) years imprisonment; or

e) if, as a result of the use of the drug found to be counterfeit, the illness sought to be cured is aggravated or physical injury or suffering results therefore, a punishment of imprisonment from twelve (12 years to fifteen (15) years and a fine ranging from Three hundred thousand pesos **(P300,000.00)** to One million pesos **(P1,000,000.00)** shall be meted out; or

f) should a counterfeit drug be the proximate cause of death of a victim, who unknowingly purchased and took a counterfeit drug, the penalty of life imprisonment and a fine of not less than One million pesos **(P1,000,000.00)** to Five million pesos (P5,000,000.00) shall be imposed.

In case any act prohibited in Section 4 hereof is also punishable under other laws, the offender shall, if warranted by the evidence, be prosecuted under the law prescribing the highest penalty.

**SECTION 3. TRANSITORY PROVISION** – Existing industries, businesses and offices affected by the implementation of this Act shall be given six **(6)** months transitory period from the effectivity of the IRR or such other period as may be determined, to comply with the requirements of this Act.

**SECTION 4. IMPLEMENTING RULES AND REGULATIONS** – The departments and agencies charged, to be led by the Department of Health **(DOH)** with carrying out the provisions of this Act, shall within sixty **(60)** days after the effectivity of this Act, formulate the necessary rules and regulations for its effective implementation.

**SECTION 5. REPEALING CLAUSE** – All laws, decrees, executive orders, rules and regulations, or parts thereof inconsistent with the provisions of this Act are hereby repealed or modified accordingly.

**SECTION 6. SEPARABILITY CLAUSE** – If, for any reason, any section or provision of this Act is held unconstitutional or invalid, the other sections or provisions hereof shall not be affected thereby.

**SECTION 7. EFFECTIVITY CLAUSE** – This Act shall take effect after fifteen (15) days from its publication in the Official Gazette or in at least two (2) national newspapers of general circulation whichever comes earlier.

Approved,