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Congress of the Philippines)
First Regular Session)

SENATE OF THE PHILIPPINES
OFFICE OF THE SECRETARY
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DATE: MAY 3 1988
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S E N A T E

COMMITTEE REPORT NO. 191

Submitted by the Committee on Health on March 3, 1988.

Re: Senate Bill No. 453

Recommending its approval in substitution of S. No. 197 and 301 and pursuant to S. Res. No. 10 and P. S. Res. No. 67

Sponsors: Senators Mercado, Pimentel, Ziga, Romulo and Angara

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MR. PRESIDENT:

Your Committee on Health respectfully submits this consolidated report of the two (2) bills and two (2) resolutions, addressing similar concerns, which were referred to it.

I N T R O D U C T I O N

The Committee started its investigation on the basis of Senate Resolution No. 10, introduced by Senator Ziga, entitled:

> "RESOLUTION DIRECTING THE COMMITTEE ON HEALTH TO CONDUCT AN INQUIRY IN AID OF LEGISLATION INTO THE MATTER OF THE RAPID AND UNCONTROLLED INCREASE OF THE PRICES OF DRUGS AND MEDICINES IN THE COUNTRY TODAY, TO PROTECT THE PEOPLE DURING THESE DIFFICULT TIMES AND TO RECOMMEND SUCH REMEDIAL MEASURES AS MAY BE NECESSARY UNDER THE CIRCUMSTANCES."

Senate Resolution No. 67, introduced by Senators Romulo and Angara, entitled:

> "RESOLUTION DIRECTING THE COMMITTEE ON HEALTH AND THE COMMITTEE ON SOCIAL JUSTICE, WELFARE AND DEVELOPMENT, IN AID OF LEGISLATION, TO LOOK INTO THE POSSIBILITY OF USING MORE EXTENSIVELY GENERIC DRUGS AND FOR OTHER PURPOSES."

and Senate Bill No. 197, introduced by Senator Mercado, entitled:

> "AN ACT REQUIRING DRUGS AND PHARMACEUTICAL COMPANIES TO PRINT ABOVE THE BRAND NAME, THE DRUG'S CORRESPONDING GENERIC NAME AND DIRECTING MEDICAL PRACTITIONERS IN PRESCRIBING MEDICINES, TO INDICATE THE DRUG'S GENERIC NAME, AND FOR OTHER PURPOSES."

Thereafter, Senate Bill No. 301, introduced by Senator Pimentel, entitled:

"AN ACT TO ENCOURAGE THE USE OF GENERIC DRUGS IN THE COUNTRY."

was referred to Your Committee. These bills and resolutions, which focused on the high cost of drugs and prayed for a legislative solution to the problem, are the subject of this report.

THE COMMITTEE HEARINGS

Your Committee scheduled hearings on dates hereunder indicated and invited the following persons, among others, to share their views and comments on the proposed measures and initiatives:

1.	**November 27, 1987**	Hon. Alran R. Bengzon Secretary of Health Hon. Rhais Gamboa Undersecretary of Health Mr. Rey M. Fuentes American Chamber of Commerce Mr. Rodolfo M. De Gracia ASTRA (Phils.) Dean Amorita Castillo University of the Phils. Prof. Ernie M. Angeles Consumers Union of the Phils. Dr. Noel Lawas UPCPH Col. Jose Cardenas Drug Assoc. of the Phils. Dr. M. Claudio Dr. Aurora A. Parong Phil. Drug Action Network
2.	**February 23, 1988**	Dr. Fernando Sanchez Phil. Drug Action Network Mr. Rod Salazar Drug Assoc. of the Phils. Mr. Alberto Romualdez, Jr. Department of Health

Mr. Antonio R. De Joya
Drug Assoc. of the Phils.

Mr. Reiner Gloor
Drug Assoc. of the Phils.

Col. Jose Cardenas
Drug Assoc. of the Phils.

Mr. Mario Fadullon
Drug Assoc. of the Phils.

Mr. Ramon Y. Gonzales
Drug Assoc. of the Phils.

Mr. Aubrey C. Bout
Drug Assoc. of the Phils.

Mr. Noel A. Laman
Drug Assoc. of the Phils.

Mr. Fred Baltazar
Drug Assoc. of the Phils.

Mr. Ignacio Sapano
Bureau of Patents

Mr. S. Q. Samson
Drug Assoc. of the Phils.

Mr. U.T. Adams
Drug Assoc. of the Phils.

Ms. Julie Amargo
Kapisanan ng Mamimiling Pil.

3. **March 2, 1988**

Hon. Rhais Gamboa
Undersecretary of Health

Hon. Alberto Romualdez, Jr.
Assistant Secretary of Health

Mr. George Olivar
Department of Health

Ms. Cora Rivera
Department of Health

Likewise, various interest groups have submitted to Your Committee their position papers, statistical datas and tables, and other documents germane to the subject of this inquiry. All these documents were carefully reviewed, analyzed and properly evaluated by Your Committee.

SCOPE OF THE INVESTIGATION/PUBLIC HEARINGS

In the public hearings, Your Committee undertook

(a) To inquire into the reasons for the alarming and

unabated increase in the price of common and life-saving drugs and medicines; and

(b) To determine and formulate the proper remedial and legislative measures which must be enacted to immediately address the problem on hand.

Worthy of mention, however, is the fact that the Department of Health and the various interest groups which monitor the health and drug policies of the government called for a broad-based and comprehensive approach in the formulation of a national drug policy.

On the other hand, the Drug Association of the Philippines proposed that:

(a) The drug industry should be provided relief from the taxes and duties to reduce drug prices.

(b) Legislation should be passed imposing a special tax on cetain non-essential or deleterious products and activities as source of funding for the purchase by the Department of Health of generic drugs.

(c) Legislation should be enacted to make purchases by bulk tender mandatory.

(d) Legislation should be passed to impose stronger penalties for sale of fake and harmful drug to protect consumers.

(e) Government should take a lead in the development of herbal madicines to serve the rural folk and those who cannot afford western-type medicines.

Measures emanating from this august chamber may, in the near future, respond to call of these sectors.

FINDINGS

During the various hearings conducted by Your Committee, the following observations were made on the state of the pharmaceutical industry.

Market Profile

As of 1986, there are 9,838 registered drugs in the Philippines, 7,167 of which carry brand names. Yet, a great portion of our population cannot lay their hands on drugs essential to comply with prescribed medical regimens.

In studying the patterns in the purchase of drugs, one must bear in mind the basic distinction between proprietary (or over-the-counter) drugs and ethicals (or prescription drugs).

The nature of demand for proprietary drugs (or over-the-counter drugs) is similar to other consumer items, such as softdrinks, cosmetics, toileteries, etc. The consumer diagnoses his ailments and then shops around for remedy that will meet his needs.

The nature of demand for prescription drugs (ethicals) is different, at least from the vantage point of the consumer. The physician determines for the consumer which specific product to use.

In 1985, the composition of the drug market in (by channel and by region) was:

TABLE I
Size and Composition of Market for Pharmaceuticals

	VALUE (in million pesos)	
TOTAL MARKET		**P 6,348**
Sales through drugstores		**5,683**
---Ethicals	P 4,712	
---Proprietary (OTCs)	971	
Sales through hospital pharmacies		**665**
---Private Hospitals	487.5	
---Government Hospitals	177.5	

PERCENTAGE BREAKDOWN OF DRUGSTORE SALES (%), By region

Greater Manila Area	48.8
Rest of Luzon	26.6
Visayas	14.2
Mindanao	10.4

Source: IMS, Philippines.

This distinction in the decision-making process in the purchase of drugs must be borne in mind in evolving a system for the rationalization of the procurement, prescription and use of drugs.

Table I likewise demonstrates that the farther away the region is from Metro Manila, the smaller is its market share.

A characteristic of the drug market worthy of particular attention is the extent of foreign-domination. One source estimates the market distribution of sales as follows:

TABLE 2
Percentage Distribution of Sales through Drugstores, by Nationality of Ownership, 1985

		Market Share
Filipino Owned Firms		**39.86%**
United Laboratories	21.28%	
Foreign-Owned Firms		**60.14**
American	39.35	
German	7.95	
Swiss	5.89	
British	2.79	
Swedish	2.38	
Dutch	.63	
French	.52	
Italian	.46	
Japanese	.17	

Source: IMS, Philippines.

The Secretary of Health, on the other hand, estimates that foreign-owned companies account for some sixty-seven (67%) percent to seventy (70%) percent of the ten billion pesos (P 10B) drug market for 1986 (Public Hearing, November 20, 1987, Minutes, p. 2), while United Laboratories, the leading corporate group controlled twenty-two (22%) percent of the market (ibid.).

Pricing of Drugs

Drug companies have come under fire for prices which are reputed to be one of the highest, if not the highest in Asia (Bulletin Today, June 4, 1987).

The data from the National Census and Statistical Office reveals that drug prices grew at an average of 14.3% per year over the period 1978 to 1985. This rate, however, is comparatively lower than that posted by other consumer items as shown in Table 3.

TABLE 3
Comparative Movements of
Consumer Prices and Drug Prices, 1978-1985

	Average percentage increase
All items	20.4%
Food, Beverage & Tobacco	19.5
Clothing	22.2
Housing & Repairs	19.0
Fuel, Light & Water	28.1
Services	20.8
Miscellaneous	20.2
Drugs	**14.3**

Source: NCSO, Pollard Index.

Be that as it may, the relatively lower rate of price increase registered by drugs should not be interpreted to mean as the absence of cause for concern. Every effort exerted by the Government at easing the cost of living of its citizens is always a step in the right direction.

An estimate of the cost structure of the industry is given, thus:

TABLE 4
Estimates of Pharmaceutical Industry Cost Structure

	as percentage of total sales
Cost of Goods Manufactured & Sold	50.0 - 60.0
Manufacturing Cost	35.0 - 45.0
Direct Materials	30.0 - 34.0
Direct Labor	1.0 - 2.5
Manufacturing Overhead	4.5 - 10.5
Cost of Finished Goods	15.0 - 19.0

Inventory Cost	0.5 - 1.5
Operating & Selling Expenses	**31.5 - 36.5**
General Management Costs	4.3 - 12.4
Selling Costs	15.0 - 18.5
Promotion and Advertising	4.5 - 9.2
R & D and Royalties	0.5 - 2.5
Interest & Bank Charges	0.3 - 6.0
Returns	**8.0 - 13.0**

Source: Nicanor Gabunda, Jr. "Drug Prices: Are they Reasonable?" Staff Memos 13. Center for Research and Communication, July 1985.

The same study reveals that pharmaceutical companies with manufacturing facilities spend 24% of total sales for advertising promotion. The costs are broken into: 17% for cost of marketing personnel and 7% for promotion.

Advertising and promotion is handled in several ways. For ethical products it comes in the form of advertisement in medical journals and direct mails to medical professionals. For proprietary products, companies advertise in radio, television, and print.

To promote their products to doctors, companies hire professional medical representatives. They also sponsor film showings of technical and scientific subjects, scientific seminars and conferences.

Indeed, the advertising and promotion efforts of drug companies are rather costly. For the proponents of generic drugs, this is one area where costs may be reduced or eliminated to reduce price. Indeed, the 32-36% which goes to operations, advertising, marketing, etc. assumes an unconscionable allocation of costs in view of the economic circumstance in which majority of our people find themselves in.

Budgetary Allocations

Congressional concern for health has been manifested by allocating to the Department of Health 5.76% of the 1988 budget, with Three Hundred million pesos (P 300 M) for the purchase of drugs and medicines. This concern must be complemented by

measures which would make such drugs and medicines affordable to ensure optimal utilization of the funds.

Use of Generics: An immediate response to the Problem on High Prices of Drugs

A State policy encouraging the extensive use of generic drugs presents itself as an immediate and promising solution to the problem of high prices of drugs. While it is not totally comprehensive, it is no mere pallative.

The policy would effectively lower drug prices by reducing and/or eliminating advertising and promotional expenses as well as packaging costs. Moreover, it would place some rationality in the procurement, purchase and use of drugs by making efficacy and potency the primary criteria and not product awareness or positioning.

RECOMMENDATIONS

In view of the foregoing, Your Committee most respectfully recommends the approval of Senate Bill No. 453, entitled:

"AN ACT TO ESTABLISH THE EXTENSIVE USE OF GENERIC DRUGS IN THE COUNTRY AND FOR OTHER PURPOSES."

with Senators Angara, Mercado, Pimentel, Romulo and Ziga as sponsors be approved in substitution of S. No. 197 and 301.

Respectfully submitted,

EDGARDO J. ANGARA
Chairman

JOHN H. OSMEÑA
Vice-Chairman

JOSEPH EJERCITO ESTRADA
Vice-Chairman

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Majority Floor Leader

JUAN PONCE ENRILE
Minority Floor Leader

TEOFISTO T. GUINGONA
President Pro-Tempore

Congress of the Philippines)
First Regular Session)

S E N A T E

S. No. 453

Introduced by Senators Mercado, Pimentel, Ziga, Romulo and Angara

E X P L A N A T O R Y N O T E

The Constitution mandates the State to protect and promote the right to health of the people (Article II, section 15); to adopt an integrated and comprehensive approach to health development to make essential goods and health, inter alia, available to all the people at affordable cost (Article XIII, section 11); and to maintain an effective food and drug regulatory system responsive to the country's basic health needs and problems (Article XIII, section 12).

Given the present situation, where the majority of the Filipinos continually suffer from the disease of poverty and the dwindling purchasing power of the peso, the alarming and unabated increase in the prices of the drugs and medicines calls for an immediate compliance with the constitutional mandate.

This bill, without any pretense of being integrated and comprehensive in either approach or scope, proposes a modest step toward the protection of the people's basic right to health by encouraging the extensive use of generic drugs in the country. It seeks to make good health and quality drugs available to all people at affordable cost and to inject some sense of rationality in the procurement, prescription and use of drugs.

The existing situation is such that Filipinos are not able to afford essential drugs, an ironic situation because the local market is in fact awash with thousands of medical preparations, albeit many of which are irrational or of doubtful safety and

efficacy and often used inappropriately. Medical indigents, therefore, spend their meager budgets for such irrational products, while not being able to afford life-saving drugs. An ominous sign that science is losing to commerce everyday.

The situation is further exaccerbated by the excessive pharmaceutical propaganda upon the consumers and the medical practitioners. On the average, packaging, advertising and promotion costs account for about thirty-two to thirty-six percent (32-36%) of the cost. These items, which are totally unrelated to a drug's quality and efficacy, tend to push prices upward.

These concerns are at the very heart of the bill. The use of generic names hopes to cut down prices and lessen the number of brands being sold, without compromising the quality and efficacy of the drugs and medicines sold in the country.

It must be emphasize, though, that the bill does not prohibit the manufacture, importation and distribution of brand-name drugs.

With a listing of the generic drugs, the bill mandates Government Health agencies and workers to prescribe, dispense, administer and use generic drugs upon their patients. This is in recognition of the urgent need for the Government, which has health centers all over the country, to put some rationality in their procurement and distribution of drugs for optimal utilization of their budget of P 300 M for such purposes.

The thrust of the bill in providing the public with considerable guidance in the purchase and use of drugs is buttressed by the provisions which requires private physicians and dentists to indicate, in their prescriptions, the brand's generic name and for drugstores to make available the list of generic drugs and brand-name drugs with their corresponding generic names. Furthermore, manufacturers, importers, repackers, and distributors of brand-name drugs are directed to

place the generic name of said drugs on the packages and labels.

This bill earnestly requests approval.

EDGARDO J. ANGARA
Senator

ORLANDO S. MERCADO
Senator

AQUILINO Q. PIMENTEL
Senator

ALBERTO G. ROMULO
Senator

VICTOR S. ZIGA
Senator

Congress of the Philippines)
First Regular Session)

S E N A T E

S. No. 453

Introduced by Senators Mercado, Pimentel, Ziga, Romulo and Angara

AN ACT
TO ESTABLISH THE EXTENSIVE USE OF GENERIC DRUGS IN THE COUNTRY AND FOR OTHER PURPOSES

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

SECTION 1. Title. - This Act shall be known as the Generic Drugs Act of 1988.

SECTION 2. Statement of Policy. It is hereby declared the policy of the State:

(1) To make quality drugs and good health available to all people at affordable cost;

(2) To evolve a rational system in the procurement, prescription and use of drugs by encouraging the extensive use of generic drugs.

SECTION 3. Generic Drugs, defined. For purposes of this Act, generic drugs are non-proprietary or unbranded medicines, identified by their scientifically recognized active ingredients of chemical compositions instead of a registered trademark or brandname. Drugs, as used herein, shall include medicines.

SECTION 4. Listing of Generic Drugs. - The Department of Health and the Bureau of Food and Drug Administration shall, within six (6) months from the approval of this Act and annually threafter, draw up:

(a) a list of duly certified generic drugs which are affordable, accessible, safe and of good quality.

(b) a list of all brand name drugs which must be manufactured and/or distributed not only with their brand names

but also their corresponding generic name.

The Department of Health shall publish in at least two (2) newspapers of general circulation in the Philippines the aforementioned lists.

SECTION 5. Government Health Agencies to Use and Make Available Generic Drugs. - All government physicians, nurses, nursing aides, dentists, and persons employed in the field of public health services shall prescribe, dispense, administer and use generic drugs found in the certified list referred to in section 4(a), whenever appropriate, in ministering to needs of patients in public hospitals, clinics, health centers and other health delivery outlets.

SECTION 6. Private Medical and Dental Practitioners. - Private physicians and dentists, in giving out prescriptions, must indicate the brand's generic name.

SECTION 7. Drug Manufacturers, Importers, Repackers and Distributors. - No manufacturer, importer, repacker or distributor of brand name drugs listed in the certified list referred to section 4 (b) shall sell such drugs unless the generic name in bold letters is placed above the brand name.

SECTION 8. Drugstores. Drugstores shall include generic drugs in their product mix and shall make them regularly available to the public: Provided, That drugstores shall post in conspicuous places in their business establishments the lists referred to in section 4(a) and (b).

SECTION 9. Education Drive. - The Department of Health shall conduct a continuous information campaign to make the public, particularly the poor, aware of generic drugs as a low-cost alternative to the more expensive brand name drugs.

SECTION 10. Rules and Regulations. - The Department of Health shall promulgate rules and regulations to implement the objectives of this Act with special emphasis on monitoring effectively its strict compliance.

SECTION 11. Penalty. - Any person who violates the provision of this Act or any regulation issued by the Secretary of Health to carry out the purposes of this Act shall be punished by imprisonment of not less than thirty (30) days but not more than six (6) months or by a fine of not less than P 5,000.00 but not more than P 15,000,00, or both such fine and imprisonment at the discretion of the court: Provided, That in case of corporations or juridical persons, the President or the Manager thereof shall suffer the above-mentioned penalties.

SECTION 12. Separability Clause. If any provision of this Act is declared invalid, the remainder of this Act or any provision not affected thereby shall remain in force and effect.

SECTION 13. Repealing Clause. The provisions of any law, executive order, presidential decrees, or other issuances inconsistent with this Act are hereby repealed or modified accordingly.

SECTION 14. Effectivity. - This Act shall take effect fifteen (15) days after its complete publication in the Official Gazette or two (2) newspapers of general circulation in the Philippines.

Approved,

(3)

Congress of the Philippines)
First Regular Session)

CORRECTED COPY
(Amended as of May 26, 1988)

S E N A T E

S. NO. 453

(Substitute bill prepared by the Committee)

Introduced by Senators Mercado, Pimentel, Jr., Ziga, Romulo and Angara

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AN ACT
[TO ESTABLISH THE EXTENSIVE USE OF GENERIC DRUGS IN THE COUNTRY AND FOR OTHER PURPOSES]

TO PROMOTE AND ENSURE THE PRODUCTION OF AN ADEQUATE SUPPLY, DISTRIBUTION AND PUBLIC USE AND ACCEPTANCE OF DRUGS AND MEDICINES IDENTIFIED BY THEIR GENERIC NAMES

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

SECTION 1. Title. - This Act shall be known as the Generic Drugs Act of 1988.

SEC. 2. Statement of Policy. - It is hereby declared the policy of the State:

(1) To promote the use of generic terminology (names) in the importation, manufacture, distribution, marketing and promotion, prescription and dispensing of drugs;

(2) To ensure the adequate supply of quality drugs with generic names and endeavor to make them available for free to paupers and at the lowest possible cost to non-paupers; and

(3) To encourage the extensive use of drugs with generic names through a rational system of procurement and prescription.

SEC. 3. Generic Terminology Defined. - For purposes of this Act, generic terminology is the identification of drugs by their scientifically recognized active ingredients in their chemical composition or by their international non-proprietary name (INN) in contrast with their proprietary brand names. For this purpose, generic terminology includes

generic name. Drugs, as used herein, shall include medicines. The term "generic drugs", as used in this Act, refers to drugs identified by generic terminology.

SEC. 4. Use of Generic Terminology/Name for Essential Drugs. - The Department of Health shall, within sixty (60) days from the approval of this Act and quarterly or as often thereafter as the Department of Health may deem appropriate and with the assistance of an expert committee which it shall constitute pursuant to the objectives of this Act, draw up a list of essential drugs, using generic terminology and in accordance with internationally established criteria as well as, considering prevalent health problems in the country, a list of generic drugs in the manufacture of which the raw materials are derived completely from indigenous sources, and a list of manufacturers of generic drugs duly recognized and certified by the Department of Health as authorized to manufacture and sell generic drugs.

The Department of Health shall publish in at least two (2) newspapers of general circulation in the Philippines the aforementioned lists.

SEC. 5. Incentives. - The use of generic terminology/name in the importation, manufacture, distribution, prescription, dispensing and sales of drugs in the said lists shall be promoted through such a system of incentives as the Department of Health or other government agencies shall promulgate in accordance with existing provisions of law.

SEC. 6. Government Health Agencies to Use and Make Available Generic Drugs. - All government physicians and dentists shall purchase, prescribe, dispense, administer and use, and all pharmacists, nurses, nursing aides, and other persons employed in the field of public health services shall dispense, administer and use generic drugs found in the certified lists referred to in Section 4 hereof, whenever appropriate, in ministering to needs of patients in public hospitals, clinics, health centers and other health delivery outlets.

SEC. 7. Government Purchases of Drugs with Generic Names. - All purchases of medicines by the Department of Health and/or any other government entity shall be in the form of generic drugs, whenever and wherever available.

SEC. 8. Authority to Import. - Within three (3) years from the effectivity of this Act, extendible by the President for another two (2) years, and during periods of critical shortages and absolute necessity, the Department of Health is hereby authorized to import tax and duty-free raw materials in short supply for the use of local Filipino manufacturers of drugs to be marketed and sold exclusively under generic nomenclature. The Secretary of Health shall ensure that the imported raw materials are allocated fairly and efficiently among the local Filipino manufacturers. He shall submit to the Office of the Presdident a quarterly report on the volume, quantity, kind and value of the raw materials imported.

SEC. 9. Private Medical and Dental Practitioners. - Private physicians and dentists, in giving out prescriptions, must indicate the generic name of the drug: Provided, That for Medicare patients preferably generic drugs shall be prescribed whenever appropriate and available.

SEC. 10. Drug Manufacturers, Importers, Repackers and Distributors. - No manufacturer, importer, repacker, distributor or outlet of brand name drugs included in the lists referred to in Section 4 hereof, shall sell and/or advertise such drugs unless the generic name in bold letters is placed prominently above the brand name.

SEC. 11. Name of Manufacturer . - The name of the manufacturer of every generic drug shall be clearly indicated in the label.

SEC. 12. Drugstores. - Subject to the rules and regulations promulgated by the Department of Health, drugstores shall, within one year from the approval of this Act, include generic drugs in their product mix and shall make them regularly available to the public: Provided, That drugstores shall post in conspicuous places in their business establishments the lists referred to in Section 4 hereof, and which lists shall include the selling prices of such drugs both generic and branded.

SEC. 13. Required Production. - Subject to the rules and regulations promulgated by the Department of Health, every drug manufacturing company operating in the Philippines shall distribute and make available to the general public each type of medicine it produces in the form of generic drugs.

SEC. 14. Education Drive. - The Department of Health shall conduct a continuous information campaign to make the public, particularly the poor, aware of generic drugs as a low-cost alternative to the more expensive brand name drugs. Such educational campaign shall include information on the illnesses or symptoms which each generic drugs is supposed to cure or alleviate, as well as it's contraindications. The Department of Health shall establish a feedback and evaluation mechanism that shall monitor the progress of the education drive, and shall submit regular reports to Congress.

SEC. 15. Rules and Regulations. - The Department of Health shall, within six (6) months from the effectivity of this Act, promulgate rules and regulations to implement the objectives of this Act with special emphasis on monitoring effectively its strict compliance. The rules and regulations may include the prohibition of use in any drug marketed in the Philippines of ingredients whose use has been banned, withdrawn or restricted in other countries. Rules and regulations with penal sanctions shall take effect fifteen (15) days after completion of its publication in the Official Gazette or in two (2) newspapers of general circulation.

SEC. 16. Penalty. - Any person who violates the provision of this Act or any regulation issued by the Secretary of Health to carry out the purposes of this Act shall be required to render community service in health or sanitation for a period not less thirty (30) days but not more than six (6) months in areas, whether rural or urban, to

be designated by the Secretary of Health or by a fine of not less than five thousand pesos (P5,000) but not more than fifteen thousand pesos (P15, 000), or both such fine and community service at the discretion of the court: Provided, That in case of corporations or juridical persons, the president or the manager thereof shall render the community service required and the fine shall be paid by the corporation or the juridical person: Provided, further, That a failure of the manufacturer, importer, repacker or distributor to comply with the requirements contained in Section 10 hereof, will cause the suspension or forfeiture of its license to do business in addition to the penalties imposed in this section.

SEC. 17. Separability Clause. - If any provision of this Act is declared invalid, the remainder of this Act or any provision not affected thereby shall remain in force and effect.

SEC. 18. Repealing Clause. - The provisions of any law, executive order, presidential decree, or other issuances inconsistent with this Act are hereby repealed or modified accordingly.

SEC. 19. Effectivity. - This Act shall take effect fifteen (15) days after its complete publication in the Official Gazette or two (2) newspapers of general circulation in the Philippines.

Approved,