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Republic of the Philippines
HOUSE OF REPRESENTATIVES
Quezon City

THIRTEENTH CONGRESS
First Regular Session

HOUSE BILL NO. 499

Introduced by **Hon. Arthur "Dodo" Y. Pingoy, Jr., M.D.**

Explanatory Note

The President was emphatic and equivocal when she assured her administration's action on the runaway and inordinate prices of medicine in her first state-of-the-nation-address (SONA).

This is understandable considering that the problem concerning the high cost of medicine has constantly exacted a heavy toll on the already impoverished populace and through the years has innumerably called for an urgent and decisive response from the government.

It is no surprise, therefore, that President Macapagal-Arroyo vowed to substantially reduce the prices of medicine by half within one (1) year. It is disheartening to note, however, that prices of drugs and medicines have remained high after three years since the President's policy pronouncement.

Drug prices have gone from bad to worse starting more than ten years ago. Studies conducted by the National Drug Policy Program Group of the Department of Health (NDPP-DOH) as well as exposés and researches by the media and non-governmental organizations show that ***the prices of drugs in the Philippines are the highest now in the ASEAN Region*** which remains to be disproved by multinational companies and lobby groups who continue to discredit and campaign against exposés and government programs aimed at reducing drug prices.

Deliberations during the 11th Congress confirmed this lamentable and deplorable trend. Several bills and resolutions were filed to address this very pressing concern, clearly a record with the greatest number of measures ever filed in the country's legislative history.

All these initiatives, however, were frustrated by myriad factors ranging from the laggard pace and delays of scheduling the committee deliberations and diversionary, muddling and stonewalling strategies cleverly mounted by personalities and groups lobbying against the proposed measures, reminiscent of the time when these same bands also attempted to block the passage of the Generics Act of 1988 before Congress up to the Supreme Court. Not a single bill or resolution was approved even in the committee level.

At one point during a committee meeting, Congressman Edgar R. Lara, who filed a comprehensive bill designed to reduce drug prices, became quite exasperated with the indecisiveness of the committees involved and the snail-paced consideration of closely related bills that he exclaimed in an appeal before the committee's members: "If we will not approve these bills now, these will never see the light of day!"

He later withdrew sponsorship of the bill because of a proposed consolidated draft which he called a watered-down version that deliberately mutilated the original intent of his bill.

Then Deputy Speaker Daisy Avance_Fuentes also withdrew her sponsorship of a similar bill. Greatly irked by the consolidated draft, she claimed that her bill was drowned by the committee's substitutions. She called it "flaccid" and "toothless".

Despite these setbacks, a great reawakening was attained by the whole policy environment, as well as by the media and concerned groups, of the need to carry out policy and structural reforms in the drug industry as a whole to reduce drug prices, among other things, for the greater benefit of the people. It expanded the arena and blazed the paths for a more vigorous advocacy of needed programs and policies towards these goals.

The NDPP-DOH study have also established that drug-prices from manufacturing to distribution and retail have a high mark-up; that there is a significant difference of prices between generic drugs and branded drugs and that drugs prices are pegged to achieve maximal industry profits to the exclusion of the poor who cannot afford the high cost of medicines.

According to experts, the unreasonable pricing of pharmaceutical firms and drug outlets which has persisted through the years is due to the following factors:

1. Monopoly of patents and brand names by multinational drug companies (MNC's):

2. Heavy dependence on imports:

   Our country does not have the capability to produce the active substances or basic raw materials used in the manufacture of drug. Majority of the local players in the drug industry merely buys chemicals from abroad and reformulate, recompound and repack them into finished products. This leaves local drug firms as mere drug importers and distributing arms.

3. Transfer pricing

   Under this pratice, a multinational company inflates the cost of a raw materials and sells them to a drug company which may be a subsidiary at a higher price than that prevailing in the world market. This practice accounts for the large disparity between prices paid by subsidiaries of MNC's and those paid by the local subsidiaries.

4. Ineffective and weak implementation of the Generics Act because of the following factors, among others:

   (a) Lack of cooperation of doctors as indicated by their decreased compliance with generic prescribing especially those belonging to the Philippine Medical Association who have continued to doubt the safety and efficacy of drugs;

   (b) Lack of capability of BFAD to exact compliance with standards of safety, efficacy and good quality;

   (c) Failure of the government to import raw materials tax-free as provided for in Sec. 10 therein to develop the local drug industry and the absence of inadequate government support;

   (d) Absence of a pricing policy by the Department of Health to ensure the affordability of drugs and medicines and delimitations in the operating policy and strategy options of the DOH in implementing the National Drug Policy because of existing laws (e.g. Pharmacy Law);

   (e) Dominance of foreign multinationals in the drug industry.

   It is estimated that only Filipino-owned and controlled companies manufacturing and distributing mainly off-patent, generic drugs and medicines comprise a mere 12% to 15% of the total market.

   In a DOH budget briefing on 03 September 2001, Secretary Manuel M. Dayrit estimated the hold of multinationals in the P50-60 billion a year drug industry to be 75%.

   (f) Devolution of health services to the local government units;

   (g) Lack and weakness of technical and managerial and other components of the administrative machinery of the DOH as well as in the local government level in the implementation of the Generics Act;

(h) Low level of awareness of the public concerning generic products arising from the absence of alternative information other than those given by the drug manufacturers whose expansive and vigorous advertising and promotion activities strongly influence the Filipino behavior on drug use.

Furthermore, according to study made by the Department of Trade and Industry (DTI), the cost of drugs may be broken down as follows: 1) 45%-60% goes to importation of raw materials; 2) 18%-25% goes to marketing; 3) 10%-15% to labor and 4) 0.4%-3% to licensing. The Department of Health and the local drug players, however, estimate that expenses incurred by pharmaceutical firms in marketing and other promotional activities which includes the giving of gifts, rewards, fellowships, junkets and other incentives to medical practitioners is a high as 40% to 60% of the total cost of medicine.

Faced with the growing challenges of poverty, worsening health conditions of the populace inadequacy of social services in many areas of the country made worse by a diminished purchasing power of the peso, high unemployment rate and continuous price increases in fuel and basic commodities, the exorbitant and inordinate pricing of life-saving drugs and other pharmaceuticals currently sold in the country certainly calls for a more vigorous, complete and effective compliance with the constitutional mandate of protecting and promoting the health of the people. Needless to state, that for all times, the price of medicine need not hinder the person's right to basic health care.

Moreover, the good health and well-being of the public should no longer be continuously sacrificed in our excessive obeisance to the tenets of globalization, liberalization and deregulation. The interests of the sovereign state especially its people should ever remain supreme. We must no longer continuously expand the already bloated coffers and extensive protection enjoyed by the multinationals at the expense of our people.

The present situation, thus, requires the strengthening of the mandate and administrative machinery of the Department of Health and existing laws concerning drugs and pharmaceuticals notably the Generics Act of 1988 and the National Drug Policy and Program.

To achieve this, this bill seeks, among others, to introduce vital amendments to existing laws concerning drugs and pharmaceuticals not only to pave the way for: (1) a greater state intervention through a more active and efficient regulatory system in the drug industry complemented by more vigorous and intrusive participation of the DOH in the purchase and distribution of drugs as to effectively influence the prevailing price schemes in the market but also (2) in extending the support long clamored by local drug firms.

This bill will also help ensure the prosecution of erring pharmaceutical firms who do not manufacture generic products and other stakeholders in the drug industry like medical practitioners, health care providers, hospitals and drug outlets who all collude with the multinationals in fleecing the Filipinos with the highest drug prices in the ASEAN Region.

The author firmly believes that with this two-thronged approach, a more effective and decisive implementation of the Generics Act and other related laws will be achieved which will finally result to lower, more affordable and reasonable prices of medicine.

Again, may it be stressed that with the current trends of drug pricing in the country and also because of a continuously deteriorating state of public health, more drastic measures and interventions not only by Congress but also by the DOH and the BFAD who are at the forefront in addressing this great social malady are not only timely and essential but also of paramount interest.

Arthur "Dodo" Y. Pingoy, Jr., M.D.

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HOUSE BILL NO. 499

Introduced by Hon. Arthur "Dodo" Y. Pingoy, Jr., M.D.

AN ACT
STRENGTHENING THE REGULATORY POWER OF THE STATE AND THE POSITION AND COMPETITIVENESS OF LOCAL DRUG FIRMS IN THE IMPORTATION, MANUFACTURE, PACKAGING, SALE AND DISTRIBUTION OF PHARMACEUTICAL DRUGS IN THE PHILIPPINES, AND INSTITUTING FURTHER MEASURES TO LOWER THE COST OF MEDICINES, AND FOR OTHER PURPOSES

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

ARTICLE I
General Provisions

Section 1. This Act shall be known as the "Drugs Act of 2004."

Section 2. Declaration of Policy. --It is hereby declared the policy of the State to:

(a) Establish and maintain an effective drug regulatory system responsive to the country's health needs and problems;

(b) Ensure the full implementation of the Generics Law particularly the compliance of key players in the pharmaceutical industry and in the health delivery system of the country;

(c) Make drugs and pharmaceutical products available and affordable at all times;

(d) Strengthen the local drug industry through the institutionalization of new policies in the drug and pharmaceutical industry and adequate government support;

(e) Empower the Department of Health (DOH) to adopt and implement alternative policies that shall forestall any unreasonable and unconscionable pricing schemes of drug manufacturers and distributors;

(f) Institute effective measures to further promote drug safety, efficacy and rationality of use;

(g) Ensure than in the implementation of international agreements, humanitarian and societal interests will be paramount over all considerations that may include trade and economic concerns;

Section 3. Definition of Terms. For purposes of this Act, the term:

(a) Pharmaceutical drug means any pharmaceutical or biological product containing active ingredients responsible for its desired effect intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease or to affect the structure or function of the body of man or animal or substances intended for use as a component of the same;

(b) Essential drugs mean selected drugs and medicines listed in the Essential Drugs List or National Drug Formulary prepared and periodically updated by the Department of Health on a basis of health conditions obtaining in the Philippines, as well as an internationally accepted criteria.

(c) Brand name refers to the proprietary/trade name assigned to the product by the drug establishment;

(d) Generic name refers to the identification of drugs and medicines by their scientifically and internationally recognized active ingredient as determined by the Bureau of Food and Drugs (BFAD);

(e) Generic Drugs are drugs not covered by patent protection and which are labeled solely by their international nonproprietary or generic name.

(f) Drug establishment means any organization or company involved in the manufacture, importation, repacking and/or distribution of drugs or medicines. The different types are the following:

f.1) Drug manufacturer means any establishment engaged in the production of a drug, including propagation, processing, compounding, finishing, filling, packing, repacking, altering, ornamenting and labeling with the end in view of storage, distribution or sale of the product;

f.2) Drug trader means any establishment which is a registered owner of the drug product, procures the materials and packing components and provides the production monographs, quality control standards and procedures, but sub-contracts the manufacture of such product to a licensed manufacturer. In addition, a trader may also engage in distribution and/or marketing of its products.

f.3) Drug distributor/importer means any establishment that imports raw materials, active ingredients and/or finished products for its own use or for wholesale distribution to other drug establishments or outlets.

f.4) Drug distributor/exporter means any drug establishment that exports raw materials, active ingredients and/or finished products to another country.

f.5) Drug distributor/wholesaler means any drug establishment that procures raw materials, active ingredients and/or finished products from local establishments for local distribution on wholesome basis.

(g) Drug outlets:

g.1) Drugstore, pharmacy or botica, including hospital pharmacy/dispensary means a drug outlet where registered drugs, chemical products, active principles, proprietary medicines or pharmaceutical specialties and dental medicines, galenical or veterinary preparations are compounded and/or dispensed.

g.2) Retail outlet for non-prescription drugs including non-traditional outlets such as supermarkets and stores, means a drug outlet where registered non-prescription or over-the-counter drugs (OTC) are sold in their original packages, bottles or containers or in smaller quantities not in their original containers.

(h) Philippine National Drug Formulary or Essential Drugs List is a list of drugs prepared and periodically updated by the DOH on the basis of health conditions obtaining in the Philippines as well as on an internationally accepted criteria. It shall consist of:

h.1) Core list is a list of drugs that meets the health care needs of the majority of the population;

h.2) Complementary list is a list of alternative drugs used when there is no response to the core essential drug or when there is a hypersensitivity reaction to the core essential drug or when, for one reason or another, the core essential drug cannot be given.

(i) Tax credit shall mean any other credits against taxes and/or duties equal to those actually paid or would have been paid to evidence which tax credit certificate shall be issued by the Secretary of Finance or his representative, or the Board of Investments, if so delegated by the Secretary of Finance.

Such certificate shall be used to pay taxes, duties, charges and fees due to the National Government but shall be valid only for a period of ten (10) years from date of issuance.

(j) Proprietary drug or medicine is an "over-the counter" drug or medicine dispensed without the physician's prescription. It may be advertised by print, radio, television, outdoor advertisement or other medium for the purpose of inducing or which is likely to induce directly or indirectly the purchase of a drug or medicine.

(k) Ethical drug or medicine is a prescription drug or medicine that is not allowed to be advertised by print, radio, television, outdoor advertisement or other medium for the purpose of inducing or which is likely to induce directly or indirectly the purchase of a drug or medicine. An ethical drug or medicine may be promoted only through the endorsement of a sales representative, a physician or through a scientific journal.

(l) Price Ceiling means the maximum price at which any basic necessity or price commodity may be sold to the general public;

ARTICLE II
Regulatory Measures

Section 1. (a) Pricing Policies.--All drugs and pharmaceutical products classified as essential by the Department of Health shall be considered basic necessities that shall be subject to mandatory price ceiling and controls and other prize stabilization measures that may be imposed by the Secretary of the Department of Health. The provisions dealing with these matters stated in R.A. 7581 otherwise known as the "Price Act" shall apply suppletorily with the said measures.

(b) Price Advisory Board.--The Department of Health shall appoint and convene a Price Advisory Board, hereinafter referred to as the Board, in coordination with the Department of Trade and Industry, which shall be primarily tasked to formulate and recommend to the Government relevant and efficacious strategies to stabilize the prices of essential drugs and pharmaceuticals. It shall be composed of the following members:

1) Deputy Director of the Bureau of Food and Drugs who shall act as Chairman of the Board;
2) One (1) representative of the Office of the Secretary who shall act as the Board Secretary;
3) One (1) representative from the local manufacturing sector of the pharmaceutical industry and one (1) from the multinational drug companies;
4) Two (2) representatives from the consumer's sector;
5) One (1) representative from the drugstore's association of the country;
6) One (1) representative from the NGO's with health concerns;
7) One (1) representative from healthcare service providers;
8) One (1) representative from the hospital association of the country.

The Board shall convene every quarter of the year and whenever the Chairman of the Board deems necessary. Each member shall not be entitled to any emolument except reimbursements for transportation and printing expenses.

(c) Price Monitoring Officers.--The Department of Health (DOH) shall appoint two (2) Price Monitoring Officers (PMO) for every administrative region of the country except in the National Capital region which shall have four (4) PMOs. They shall be primarily charged with the monitoring of prices of drugs and pharmaceuticals and in the filing of appropriate action against erring drug firms and distributors.

(d) Reports from LGUs and DTI. All local government units (LGUs) through its Local Health Boards and the Department of Trade and Industry (DTI) shall help ensure the implementation of pricing policies of the Department of Health by submitting quarterly reports to the latter to effectively monitor and forestall any sudden or unreasonable increase in the prices of medicine and all necessary support sanctioned by their agency's authority and jurisdiction.

Section 2. Moratorium of Entry of New Branded Drugs and Medicine.

(a) ***Period of Moratorium.*** -- A moratorium of entry of new branded drugs shall be observed within a period of five (5) years to start upon the effectivity of this Act. This shall not be applied, however, to pioneer or innovator drugs, to be determined by the Bureau of Food & Drugs and those that are included in the parallel importation program of the Department of Trade & Industry.

(b) ***Review of Moratorium.*** – Said moratorium is subject to a review every year by the congressional committee on health which can only recommend its lifting two (2) years after such moratorium took effect.

After the moratorium is lifted by the BFAD, such products may be allowed for commercial distribution but only when said products are entered under their generic names and have complied with all the requirements of BFAD and the Generics Act of 1988 as hereby amended.

Section 3. Drug Distributorship. Parallel importation shall be allowed by granting more than one (1) Philippine importer to enter into a Foreign Agency Agreement with a foreign supplier. The importer must be a locally owned drug establishment accredited and chosen by the DOH.

Section 4. Good Manufacturing Practice Standards. -- All manufacturers shall follow the Good Manufacturing Practice guidelines set by the Bureau of Food & Drugs taking into account the standards set by the World Health Organization. The BFAD shall publish an annual list of drug manufacturers who abide with GMP standards that shall be conspicuously posted in all drug outlets.

Section 5. Transparency of Promotional and Marketing Expenses of Drug Manufacturers and Distributors. -- All drug companies and distributors shall submit to the DOH a detailed list of the advertising, promotional and marketing expenses of pharmaceutical companies which shall include but not limited to literature and documentation, samples, scientific seminars, advertisements and entertainment and representation and the recipients, financial incentives and other persons therein involved. The Professional Regulations Commission (PRC) shall also require the submission of annual reports from doctors of such sponsorships and related activities for their individual and professional advancement made possible through the cooperation and involvement of drug establishments.

Section 6. Marketing, Advertising and Promotions (MAP) Code for Drugs and Pharmaceuticals. – A MAP Code for Drugs and Pharmaceuticals shall be drawn by the DOH and BFAD in coordination with resource persons from the advertising industry, pharmaceutical groups, mass media and the Department of Education sixty (60) days after the passage of this Act.

ARTICLE III
Related Regulatory Measures

To ensure the adequate supply of quality drugs with generic names at the lowest possible cost, promote generic use and strengthen the Generics Act of 1988, the following measures are instituted:

Section 1. Amendments to the Generics Act..

1-A. Paragraphs (b), (c) and (d) of Section 6 of R.A. 6675 are hereby amended to read as follows:

"**(b)** X X X

The prescription must not carry a "No Substitution" or a similar phrase or notice except in the following instances:

1. if the prescribed drug or medicine is an innovator or pioneer drug;

2. if the prescribed drug or medicine is ethical and has no known generic counterpart or substitute;

3. if the prescribed drug or medicine is listed in the Essential Drug List/Philippine National Drug Formulary of the Department of Health.

"**(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 *manufacturer's name followed by distributor's name* [brand] in all product labels as well as in advertising and other promotional materials. *The brand name shall be the least conspicuous in the product label. The expiry date of the drug or medicine shall be as prominent as the distributor's name. Only pioneer or innovator drugs shall be exempted from this labeling requirement until its patent life expires".*

"**(d)** Drug outlets, including drugstores, hospital and non-hospital pharmacies and non-traditional 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 their walls and counters a list of essential drug products with the same generic name and their corresponding prices."

1-B. Sub-paragraphs (a), (b), (c) and (d) of par. A of Sec. 12 of R.A. 6675 are hereby amended to read as follows:

"A. Any person who shall violate Sec. 6(a) or 6(b) of this Act shall suffer the penalty graduated hereunder, viz:

"(a) for the first conviction, he shall suffer the penalty of [reprimand] *a six (6) months suspension in the practice of his profession* which shall be officially recorded in the appropriate books of the Professional Regulation Commission if he or she is registered therein."

"(b) for the second conviction, the penalty of fine in the amount of not less than [two thousand pesos (P 2,000.00)] *thirty thousand pesos (P 30,000.00)* but not exceeding [five thousand pesos (P 5,000.00)] *fifty thousand pesos (P 50,000.00)* at the discretion of the court and another six (6) month suspension as provided for in the preceding article."

"(c) for the third conviction, the penalty of fine in the amount of not less than [five thousand pesos (P 5,000.00)] *fifty thousand pesos (P 50,000.00)* but not exceeding [ten thousand pesos (P 10,000.00)] *seventy-five thousand pesos (P 75,000.00)* and *a one (1) year* suspension [of his license] to practice his profession [for thirty (30) days at the discretion of the court.].

"(d) for the fourth conviction and subsequent convictions, the penalty of fine of not less than [ten thousand pesos (P 10,000.00)] *one hundred thousand pesos (P 100,000.00)* and [suspension] *revocation* of his license to practice his profession [for one (1) year or longer at the discretion of the court] *or dismissal from government service, or both, if applicable*"

1-C. paragraph B of Section 12 of R.A. 6675

"B. Any juridical person who violates Section 6(c) , 6(d), 7 or 8 shall suffer the penalty of a fine of not less than [five thousand pesos (P 5,000.00)] *fifty thousand pesos (P 50,000.00)* nor more than [ten thousand pesos (P 10,000.00)] *three hundred thousand pesos (P 300,000.00)* and suspension *of at least one (1) year* or revocation of license to operate such drug establishment or drug outlet at the discretion of the Court: Provided, That its officers directly responsible for the violation shall suffer the penalty of fine and suspension or revocation of license to practice profession, if applicable, and by imprisonment of not less than six (6) months nor more than one (1) year or both fine and imprisonment at the discretion of the court: and Provided, further, That if the guilty party is an alien, he shall be ipso facto deported after service of sentence without need of further proceedings."

Section 2. Manufacturing and Distribution Standard.--All drug establishments shall manufacture and distribute at least 70% generic products for each branded product for market distribution and consumption except in the case of pioneer or innovator drugs and of others whose patent life have not yet expired in the country where it originated or where it was first applied.

Section 3. Report of Manufactured Generic Products.--An official copy of the monthly volume of generic products manufactured and sold in the markets shall be submitted within ten (10) days for every quarter of the year by all drug companies.

Section 4. Report of Manufacturing and Distribution Cost.--All drug establishments shall also furnish the Bureau of Food & Drugs a detailed listing of their manufacturing and distribution cost that shall include, among others, the cost and source of raw materials and pricing schemes in wholesale and retail distribution.

Section 5. Report of Research and Development Cost.--All drug companies shall furnish the DOH and BFAD a detailed report concerning its research and development cost annually.

Section 6. Disclosure of Selling Prices.--All drug companies operating in the Philippines shall disclose their drug selling prices in the country vis-à-vis prices they apply or follow in other countries.

Section 7. Sales Report of Drug Outlets.--All drug outlets shall also submit its monthly volume sales to DOH and BFAD that shall contain a detailed listing of the drugs sold as well as a record of drugs prescribed by medical, dental or veterinary practitioners.

Section 8. Record of Drugs Prescribed.--All medical, dental and veterinary practitioners shall submit to the Bureau of Food and Drugs a report that that shall include, among others, a record of all the drugs and medicines they prescribed every six (6) months to help the State effectively monitor the use and promotion of generic products and which shall be duly recorded by any drug outlet upon presentation.

All drugstores or pharmacies, including hospital pharmacies/dispensaries shall also furnish BFAD inspectors a copy of all the prescriptions every three (3) months presented thereat which are recorded in a prescription book that can be inspected at anytime during the business hours of the outlet.

Section 9. Distribution of drug samples--

(a) No person may sell, purchase, or trade or offer to sell, purchase, or trade any drug sample which is a unit of a drug not intended to be sold but is solely intended to promote its sale.

(b) Drug manufacturers or distributors shall store drug samples under conditions that will maintain their stability, integrity, and effectiveness and will assure that the drug samples will be free from contamination, deterioration, and adulteration.

(c) Drug manufacturers or distributors shall conduct, at least annually, a complete and accurate inventory of all drug samples in the possession of representatives of the manufacturer or distributor. Drug manufacturers or distributors shall maintain lists of the names and addresses of each of their representatives who distribute drug samples and of the sites where drug samples are stored. Drug manufacturers or distributors shall maintain records for at least three (3) years of all drug samples distributed, destroyed, or returned to the drug manufacturer or distributor, of all inventories maintained under this paragraph, of all thefts or significant losses of drug samples, and of all requests made by practitioners in the medical profession and allied sciences.

(d) Records and lists mentioned in the preceding paragraph shall be made available by the drug manufacturer or distributor to the DOH and BFAD.

(e) Drug manufacturers or distributors shall notify the DOH and BFAD of any significant loss of drug samples and any known theft of drug samples.

(f) Drug manufacturers or distributors shall report to the DOH and BFAD any conviction of their representatives for violations of this section or a law because of the sale, purchase, or trade of a drug sample or the offer to sell, purchase or trade a drug sample.

ARTICLE IV
Incentives to Drug Companies and Drug Establishments

Section 1. Tax Incentives to Locally-owned Drug establishments. -- The State shall adopt and implement economic, trade and fiscal policies that shall strengthen the position and enhance the competitiveness of locally-owned drug establishments. In line with this policy, Section 10 of R.A. 6675, otherwise known as the Generics Act of 1988, is hereby amended to read as follows:

> "Sec. 10. Authority to Import. -- X X X The importation of raw materials *shall be* tax and duty-free *including auxiliary materials, equipment and other necessary components in the company's sale, processing, manufacturing and continuing research and developmental activities concerning essential drugs included in the Core List of the Philippine National Formulary of the DOH within ten (10) years from the passage of this Act subject to another extension that may be granted by Congress for another five (5) years.* The DOH Secretary shall ensure that the imported raw materials are allocated fairly and efficiently among Filipino-owned or controlled drug establishments. He shall submit to the Office of the President and to Congress a quarterly report on the quantity, kind and value of the raw materials imported.

Section 2. Other Incentives for Local Drug Companies. -- The following incentives shall be enjoyed by local drug companies who will be able to manufacture pioneer and innovator drugs, maintain a good standing with BFAD especially in its conformity with current good manufacturing practice (CGMP) concerning off-patent drugs and a good track record of distribution of affordable and quality generic drugs and other notable achievements in the drugs and pharmaceutical industry that supports the overall national health policy of the government:

a) tax credits as may be determined by the Department of Finance;

b) priority grant in the importation of drug products in accordance with the policy of the government governing parallel importation;

c) a guaranteed access to a fair share of government contracts and related incentives and preferences;

d) technical assistance in the following areas:

   1. re-packing of drugs and pharmaceutical products and other operational processes if available and within the expertise of any government agency or corporation;

   2. loan applications and credit assistance and stronger linkages with the government banks and financing institutions agencies;

   3. research, training and developmental skills to be provided by reputable state universities and government experts at reasonable and discounted rates;

   4. mergers and consolidations of two or more locally-owned drug companies.

   5. information dissemination campaigns and entrepreneurship education;

   6. establishment of regional branches or centers

e) Access to bonded manufacturing/trading warehouse system in all areas required by the project subject that shall be maintained by the government for their exclusive use;

f) discounts and exemptions in the payment of registration and accreditation fees and similar impositions by the BFAD;

g) exemptions from wharfage dues and any export tax, duty, impost and fee;

h) use of government-owned laboratories and facilities in the testing of their products and for other product research and developmental activities at reasonable and discounted rates;

i) Employment of foreign nationals in technical and advisory positions for a period not exceeding ten (10) years from the passage of this Act, extendible for limited periods by the Board of Investments upon recommendations by the BFAD;

j) Such other incentives and assistance that the DOH and BFAD may establish to promote investments in the drug and pharmaceutical industry and to strengthen the position and enhance the competitiveness of local drug establishments upon prior consultation with the Department of Finance, Department of Trade and Industry and Department of the Interior and Local Government.

ARTICLE V
State Support for Drug Distribution

Section 1. Full Expansion of "Gamot sa Presyong DOH". -- The Department of Health shall immediately undertake a full expansion of "Gamot sa Presyong DOH" as provided for in DOH A.O. No. 113-A s. 1991 and A.O. No. 47 s. 1999 so as to cover all government hospitals and medical centers; Provided, That participating hospitals shall procure their drugs and pharmaceutical products from drug establishments accredited by the DOH where local drug companies shall be given the first preference and that their initial purchase shall cover those drugs listed in the Essential Drugs List/Philippine National Drug Formulary, current edition; Provided, further, That the existing Revolving Trust Fund within such program for indigent patients be increased to fifty percent (50%).

Section 2. Community Managed Drug Financing Program. – The DOH shall help establish the formation and operation of community managed drug financing programs (CMDFP) in remote and poor barangays and coastal areas that shall ensure the availability and affordability of essential drugs in its generic form.

ARTICLE VI
Prohibited Practices

Section 1. Dispensing Prohibition. -- It shall be unlawful for any medical practitioner, including medical interns and other members of the medical staff, to dispense and distribute any brand or type of drugs to the public.

Section 2. Compulsion of Patients. -- It shall be unlawful for any medical staff of a hospital to require, obligate, direct or request patients to purchase drug and pharmaceutical products from the pharmacy therein if these are highly or unreasonably priced compared to prevailing market prices.

The doctors, medical consultants and other medical staff of a hospital assigned to patients admitted either for treatment or confinement are jointly responsible at all times in advising the patients in obtaining or procuring cheaper drug alternatives for drug medication. Failure to do so will constitute negligence and will give rise to administrative and civil liabilities.

Section 3. Advertising violations.-- It shall be unlawful to post unethical, unscientific, manipulative and inappropriate advertisements in any medium of advertisement, including those that do not have any prior clearance from BFAD. These shall be summarily pulled out after reasonable notice and compliance with the requirements of the law.

ARTICLE VII
Penalties

Section 1. Penalties.--Any person, natural or juridical, violating any provision hereof shall be subject to the same penalties as may be applicable provided in Sec.1 of Article III of this Act.

ARTICLE VIII
Miscellaneous Provisions

Section 1. Appropriations.--The amount necessary for the implementation of this shall be included in the General Appropriations Act for the year following its enactment and every year thereafter.

Section 2. Implementing Rules.--The Department of Health, in coordination with the Bureau of Food and Drugs, Department of Trade & Industry, Department of the Interior and Local Government, Department of Finance and Professional Regulations Commission shall draw the implementing rules and guidelines of this Act sixty (60) days after the passage of this Act.

Section 3. Repealing Clause.--Laws or part of laws, executive orders, circulars, regulations and memoranda inconsistent or incompatible with this Act are hereby repealed or amended accordingly.

Section 4. Separability of provisions. If any part, section or provision of this Act shall be held invalid or unconstitutional, no other part, section or provision shall be affected thereby.

Section 5. Effectivity. This Act shall take effect upon its approval.

Approved,