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The Generics Act of 1988: Policy Formulation and Implementation Under Pressure

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The Generics Act Law has stirred up controversial confrontations between those who advocate its existence and those who perceive it as a bane to the medical profession, if not to society as a whole. This article analyzes how and why the policy was even considered in the first place, the antecedent and existing circumstances which led to its formulation, the pressures brought to bear by factions directly or indirectly opposed to the measure, the manner by which all these were handled by the formulators of said policy and its gradual implementation in spite of the known obstacles surrounding it. The views of contending parties to this issue have also been dealt with in detail, including the final word on the matter as handed down by the final judicial arbiter of the land—the Supreme Court.

Introduction

Before the passage of Republic Act No. 6675 or the Generics Act of 1988, the drug industry was regulated by Republic Act No. 3720 then known as the Food, Drug and Cosmetics Act of 1963. The latter law bore no provisions relative to the regulation of marketing and other related practices of pharmaceutical companies, and this led to their "pill-for-every-ill" attitude and the enormous profits they have obtained through the years.

Although RA No. 3720 had penal provisions on misbranding and mislabeling of drugs, the phrase "false and misleading" to describe unlawful labeling left many legal loopholes and allowed for rampant and indiscriminate violation of the law.

Even the subsequent RA No. 3740 called Fraudulent Advertising, Mislabeling or Misbranding Act did not serve as an improvement because no specific government agency was mandated to enforce the provisions of the Act.

The above state of affairs remained static and geared toward profit for those who controlled the drug industry throughout the years, culminating in the lucrative trade that it was during the Marcos regime.

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As may have been true with other sectors of Philippine society, the unique EDSA Revolution of 1986 provided the impetus for change not only to the drug industry but for the Department of Health (DOH) as a whole. Where before it took a lackadaisical stance on matters concerning this particular industry vis-a-vis health care for the vast majority of the populace who are on the poverty level, circumstances and events caused a drastic reevaluation, reassessment and redirection of the Department's thrusts, objectives and goals.

Several factors were cited as having contributed to this phenomenon, namely: (1) the installation of a new government and a new management team at the DOH; (2) the presence of sensitive development managers such as Health Secretary Alfredo R. Bengzon and Undersecretary Rhais Gamboa and their dedicated team who, being aware of the needs of the marginalized sector, grabbed the opportunity for a major policy initiative in the pharmaceutical field; (3) the strongly-felt need to provide good quality and affordable drugs to the people; and (4) the worldwide concern on the problem of inadequate access to essential drugs and irrational use of drugs which led to the launching of the World Health Organization's Essential Drug Action Program in 1981.

Health officials soon realized that the country did not have a long-term comprehensive drug policy at all. Drugs were purchased on an *ad hoc* basis compounded by the fact that some favored groups or companies operated more lucratively than those which did not have the blessings of highplaced government officials. To their minds, therefore, the establishment of a National Drug Policy could serve to effectively curtail two evils, that of graft and corruption as well as the lack of an urgently needed comprehensive policy for the drug industry.

The evolutionary process which followed, leading to the enactment of the Generics Act of 1988 and its eventual implementation provides an interesting example of the dynamics of policy formulation and its concomitant result.

Evolution of the National Drug Policy and the Generics Act of 1988

In most of her out-of-town trips and regional consultations with the people, President Aquino was confronted with the problem of drugs and medicine not being within the reach of those belonging to the poorer sector of Philippine society. The issue of drug availability had to be addressed frontally because it appeared that leaving market forces to correct the situation was no longer a viable solution. Government had to step in and do something drastic if any change was ever hoped to be achieved, considering that no less than the 1987 Constitution mandated under Section 15 of Article II on State Policies that "the State shall protect and

promote the right to health of the people and instill health consciousness among them."

Process Involved in Policy Formulation

As a consequence of the foregoing events, the DOH launched a process of policy formulation with four basic components: (a) determination of the need, scope and process for policy formulation; (b) conduct of orderly and documented consultations; (c) conduct of local research; and (d) conduct of international research.

In June 1986, a Task Force on Pharmaceuticals was created to help the DOH in dealing with issues and concerns such as drug prices, perceived unethical practices in the sales and marketing of drugs, and the presence in the market of drugs with questionable efficacy, such as appetite stimulants and tonics. This body was directed to identify causes and possible solutions to drug-related problems aside from undertaking an extensive, intensive and fair approach to solving them. To aid it in its task, the body decided to gather as much information as it could through research, interviews, consultations, solicited position-papers, seminar-workshops and conferences. Having agreed to develop the new policy, the DOH conducted consultations from November 1986 to March 1987 and covered two major multisectoral conferences with 61 organizations represented and 99 individual participants. Participants who joined and later submitted their position papers came from 25 organizations. They were fully instructed on what was expected of them in terms of the framework of their proposals and some basic rules were laid down which were adhered to by participants.

It is important to note that unlike other policies espoused by the national government, the National Drug Policy was founded upon a thorough and deliberate consultation process which centered on the following activities: (1) planning of the consultation process in order to learn from different sectors their own perspective and perception on various issues and concerns; (2) preparation of reference papers consisting of a list of various drug-related areas for investigation; (3) launching of the consultation process where the ground rules were presented; (4) preparation of position papers to solicit reactions from different sectors; (5) conduct of studies in major areas of concern including data-gathering on experience of other developing countries to come up with a situational analysis on pharmaceuticals and related products and to raise inputs from the position papers to a macro-level; (6) conduct of clarificatory meetings to clarify points raised in the position papers on drugs so as to identify points of agreement/disagreements within sectoral groupings; (7) preparation of working papers for the multisectoral conference; (8) preparation of reaction papers to the working papers of the multisectoral conference, so that participating organizations are afforded the

opportunity to study and review the different positions taken; (9) multisectoral conference to provide a venue for participants to react to the positions taken by others; (10) workshop on the National Drug Policy to formulate the new policy after consultation procedure has been done; (11) study trips to Thailand, Indonesia and Bangladesh in order to gather first-hand information on the policies, problems, successes and failures as well as the pharmaceutical development programs of these Asian countries; and finally, (12) formulation of the final draft of the NDP.

Identified Problem Areas

The literature search done simultaneously with the above conferences referred not only to local studies and publications but also to those done by entities such as the World Health Organization (WHO) and other international bodies.

These studies and publications together with the interviews and consultations and position papers submitted by various participants from the academe, the pharmaceutical industry, governmental and nongovernmental organizations, as well as the consumer groups were analyzed and synthesized by the Task Force resulting in the identification of 7 areas of concern such as: (1) essential drug list or EDL; (2) use of generic names; (3) advertising and promotions; (4) procurement and self-sufficiency; (5) self-medication; (6) basis for registration of pharmaceuticals; and (7) pricing.

Included in the working papers on the seven issues are various responses/reactions given by at least ten groups i.e., Citizens' Alliance for Consumer Protection (CACP), the UP College of Pharmacy, Medical Action Group (MAG), Drug Association of the Philippines (DAP), Drugstores Association of the Philippines (DSAP), Lingap para sa Kalusugan ng Sambayanan (LIKAS)/Center for Social Policy (CSP) Ateneo de Manila University, Chamber of Filipino Drug Manufacturers and Distributors, Inc. (CFDMO), Department of Health League of Pharmacists (DHLP), American Chamber of Commerce of the Philippines (AMCHAM) and the group of Dr. Manuel Dayrit.

Based on the analyses made by all the participating individuals and groups of the drug situation in the Philippines, the following findings and conclusions were made and included in the final report on the National Drug Policy:

A. There are four major reasons why majority of the Filipinos cannot avail of drugs. These are:

   (1) Seventy percent of the population are below the poverty line.

(2) Drug prices are high due to cost factors pertinent to raw materials, advertising and promotions and distribution.

(3) The absence or lack of drug outlets in many parts of the rural areas make drugs physically inaccessible to many Filipinos.

(4) Some essential drugs are not available commercially.

B. The continued presence in the market of fake, adulterated, misbranded and banned drugs may be attributed to the inconsistent and ineffective implementation of the regulations on safety, quality and efficacy by the Bureau of Food and Drug (BFAD) so that it can carry out its regulatory function with greater efficacy.

C. The irrational use of drugs have been found to be caused by:

(1) The proliferation of branded drugs have been found which at times leads to confusion among physicians and consumers.

(2) The current prescribing habits of physician which are characterized by preference for certain brand names and sometimes by overprescribing.

(3) The practice of self-medication by an inadequately informed consuming public.

(4) Selling of ethical drugs over-the-counter even without prescriptions.

(5) The presence in the market of irrational, ineffective and spurious drugs.

The irrational use of drugs can be eliminated and/or prevented by the use of generic names and a more efficient and effective implementation of the BFAD rules and regulations.

Four Major Components of the Policy

Based on these findings, there was a clearly-felt need to develop and maintain a long-term comprehensive policy, so that on 30 April 1987, during the inauguration of the new Bureau of Food and Drug Laboratories in Alabang, Muntinlupa, President Aquino announced the National Drug Policy and the government's commitment to its implementation. In her speech, she cited Section 12 of the Article on Social Justice and Human Rights of the 1987 Constitution

which enjoins the State "to establish and maintain an effective food and drug regulatory system " and expounded on the major elements of this policy.

The first component is the assurance of the safety, effectiveness and usefulness of pharmaceutical products through quality control, in other words, *quality assurance.* The President maintained that since the policy will be "built on the bedrock of competent, fair, honest, effective and thorough regulation, the BFAD would be strengthened legally, organizationally, technically and financially." The DOH itself would be reorganized to allow for substantial expansion of the Bureau's capabilities in this regard.

The second component centers on a more aggressive participation in the procurement, production and distribution of drugs and pharmaceuticals or *tailored procurement.* In connection with this aspect, plans were afoot to systematize procurement, to engage in bulk purchasing and contract manufacturing and to pursue the *Botica sa Barangay* project to be linked with the national network of drug distribution for rural health units and hospitals.

The third component consisted of a package of initiatives designed to provide the right information to physicians and patients on the *rational use of drugs.* In order to control the flood of brand name drug products and to focus scarce resources on the most essential drugs, the adoption of generic labeling was seen as the tool for educating doctors and patients on the characteristics and use of various therapeutic preparations.

The final component was the coordination of investment and trade policies in order to achieve *self-sufficiency* in pharmaceuticals while assuring good quality and affordable prices for the people. By its very nature, this entails a long-term program which could be presently developed in view of an existing 10-year well-coordinated productive Research and Development program on medicinal plants under the National Integrated Research Program on Medicinal Plants (NIRPROMP).

For this purpose, the BFAD was activated to carry out the National Drug Policy and the appointment of Dr. Quintin Kintanar as Assistant Secretary for Standards and Regulation and Dr. Cecile Gonzales as BFAD Director really spurred the program toward its avowed objectives. According to Dr. Kintanar, there has been an intensive manpower training here and abroad for BFAD personnel in order that work on the four "pillars" of the policy could really have a headstart.

The Need for Action by the Legislature

All too soon, the formulators of the National Drug Policy realized that to effect the needed reform in the pharmaceutical system, the enactment of a law to speed up the transformation envisioned by the National Drug Policy in both Houses of Congress had to be given full support. The Senate version of the bill on the Generics Act of 1988 was sponsored by Senator Orlando Mercado while that calendared for consideration in the House of Representatives was authored by Congressman Narciso D. Monfort.

In every step of the legislative process, the DOH officials concerned made it a point to keep close watch on developments. Despite this kind of monitoring, an amendment was sought to be introduced by some quarters allowing the prescriber to write "No Substitution" or similar words after having written the generic and brand names of a drug that is being prescribed. Inclusion of such a phrase would have nullified the object of the law which is to allow participation by the patient in the final selection of the product to buy. Alert DOH officials saw through this scheme and members of the Joint Conference Committee which drafted the harmonized version of the two bodies deleted the so-called "killer" amendment.

It must be observed that much attention was given by the Department in the process of monitoring the passage of the bill since one-high level DOH official or staff was assigned to each key legislator to explain the rationale of each provision and to ensure their continued support of the bill throughout. The Secretary of Health himself was deeply involved in seeing to it that progressive and reformist provisions of the Generics Act were preserved even to the extent of rallying support from the Chief Executive and the Executive Secretary, aside from direct consultations with the legislators involved.

Strategy for Implementation

The *Generics Act of 1988* was signed into law by President Aquino on 13 September 1988 and during this occasion, she rallied support from all sectors for the full implementation of the law in a speech delivered at Malacañang. Dr. Kintanar started to prepare the various draft implementing guidelines the first of which was Administrative Order No. 51 called *Implementing Guidelines for DOH Compliance to the Generics Act of 1988.* All these DOH issuances were again subjected to the consultation process by way of seminar-workshop conducted by the NDP Management Committee and the DOH national, regional, provincial and district level personnel involved in drug transactions or use. It was agreed that the aforementioned AO 51 would be implemented by 1 March 1989.

Other departments of the government were sent notices regarding the plan of implementation stated above. A very significant development was the issuance by the Commission on Audit of COA Circular No. 298 stating that all procurements of drugs should comply with the provisions of the Generics Act, otherwise they shall not be passed in postaudit beginning on 1 March 1989. By this measure, full implementation of procurement using generic terminology by the entire government system was effected.

For the pharmaceutical industry. DOH officials recognized that in order for prescribing doctors and dispensing pharmacists to comply with the requirements of the law, availability of pharmaceutical products bearing generic names prominently had to be ensured. Hence, the *Implementing Guidelines on Generic Labeling* (AO 55 s. of 1988 as amended by AO 64 s. of 1989) was formulated in consultation with manufacturers, traders who own the products, and other interested parties. In view of circumstances affecting the latter, which they conveyed to DOH officials during their meetings, full implementation was deferred until 1 July 1989.

Similarly, in finalizing the *Implementing Guidelines on Advertising* (AO 69), input from the pharmaceutical companies, advertising companies and other interested parties such as nongovernmental organizations and consumer groups were solicited.

For the private professional sector. As has become quite obvious, this sector has shown the most resistance to the Generics Act, particularly the provisions on generic dispensing on "substitution," and the penalty clauses among doctors who do not comply with requirements laid down by the law.

Under the *Implementing Guidelines on Prescribing* (AO 62 s. of 1989) *and Dispensing* (AO 63 s. of 1989), the patient will now have the option to choose from among generically equivalent products prescribed by the doctor. Naturally, it did not sit well with some doctors that their hitherto unbridled prerogative was being subjected to limitations under the law. The issues for and against the Generic Act of 1988 will be tackled in the succeeding portion of this paper.

Seeing the initial response to the law, and to make provision for proper education, information and learning as well as adjustment time, the implementation for the private professional sector was scheduled in three phases, namely:

Phase I — Education and Information Dissemination
March to May 1989

Phase II — Voluntary Compliance with Monitoring but Without Penalties June to August 1989

Phase III — Full Implementation with Monitoring and Penalties beginning 1 September 1989 (but which was later moved to 1 January 1990)

Again, these guidelines for generic prescribing and dispensing was finalized only after a nationwide consultation was undertaken with doctors and drugstore owners from all 13 regions of the country in February of 1989.

If only to underscore their objections to the Generics Act of 1988 as well as the Implementing Guidelines on Prescribing, the officers of the Philippine Medical Association, the national organization of medical doctors in the Philippines, questioned the constitutionality of the foregoing law and guidelines before the Supreme Court of the land. This matter will be discussed more extensively in the latter part of this paper.

Pressures Brought to Bear on Policy Formulators

Sometime during the legislative process while the bill for the Generics Act was being considered by both Houses of Congress, Mr. A. Gordon Westly, President of the American Chamber of Commerce wrote Secretary Bengzon expressing his organization's "deep concern over the reported regulatory thrust of the Department as well as written statements quoted in media that cast some of our members in an adversarial light."

Westly noted that "globally owned and operated manufacturers and marketers that operate here have an essential role to perform in the development of Philippine economy," that "it is (their) firm belief that the internationally affiliated pharmaceutical providers in the Philippines are part of the health care solution, and not a part of the health care problem." He also reiterated that in prospering economies, "government intervention has worked best where it has supplemented instead of supplanted private activities," and culminated in a thinly-veiled threat that "this (the Generics Act) will have a chilling effect on the entire foreign business community and a devastating effect on the possibilities for job generating investments by foreign concerns."

In his letter-response on 24 June 1988, Secretary Bengzon stated that the key goal of government policy, which is the provision to both the physicians and the public of basic, adequate and honest information as a basis for personal action on drugs, was a clear hallmark of democracy around which the government sought to promote sound regulation, rational use of drugs and basic national self-sufficiency.

In a straightforward manner, the Secretary retorted that the DOH could not rely on Westly's Chamber nor of its "members to take the initiative to protect Filipino consumers, nor to develop an honest-to-goodness local pharmaceutical industry, nor to widen the access of poor Filipinos to drugs that they need," because as businessmen (and foreign ones at that), their primary goal is to ensure profit.

He went on to state that the government's task is "to devise ways that would allow any foreign entity to make their profits *only* when they respect our national interests, *only* when their activities serve the real needs of our people, and *only* when they truly contribute to our economy."

On the other hand, great encouragement had been provided by the WHO to the DOH in this program. The WHO had convened a panel of experts to discuss the selection of essential drugs and to develop guidelines for establishing a list of such drugs way back in 1982. The guidelines recommended that the international nonproprietary name (generic name for drugs or pharmaceutical substances) should be used whenever available. It is this writer's personal opinion that the unstinting and dedicated support given by the WHO, a highly-recognized international entity, may have contributed significantly in emboldening the Health Secretary to respond as he did to the President of the American Chamber of Commerce.

As pointed out earlier, other pressures were exerted at every bend while the law was being enacted, notably the insistence of some quarters that the phrase "no substitution" be allowed. With vigilant monitoring, this provision was excluded and not allowed in the final version of the law.

Even after the passage of the law, continued defiance has been displayed by the private practitioners who have also embarked on a media campaign against the Generics Act of 1988, and this has kept the DOH on its toes since full implementation was mandated on 1 January 1990.

Issues Raised by Contending Sides

Positive Points Stressed by Formulators of the Policy

Since much of the controversy revolves around the use of generic name versus brand names, there is need for a definition of these terms. *Generic name* is the international nonproprietary name (INN) of a drug most commonly used in scientific literature and by which many physicians and pharmacists learn about a particular drug product in professional schools, while the *brand name* refers to the proprietary or trade mark given by companies to distinguish their product

from those of their competitors which may be identical insofar as the active ingredients are concerned.

Under the Generics Law, medical practitioners and manufacturers are required to use the generic terminology in the importation, manufacturing, distribution, marketing, advertising and promotion, prescription and dispensing of drugs. As stated, *generic terminology* refers to scientific names of the active ingredients of drugs, the chemical component responsible for the therapeutic effect of the prescribed medicine.

(1) *It will provide a wider choice of equivalent drugs with different pricing.* The patient becomes an active participant in the therapeutic process. He is now given the choice to buy effective medicine at a price he can afford. Even poor patients are assured of affordability of drugs they need.

(2) *It will lower the cost of drug therapy because generic products are significantly cheaper than branded products.* Even for drugstores and pharmacies, this will mean lower investment and inventory cost.

To substantiate this claim, a *Cost-Benefit Analysis of selected groups of Generics and Branded drugs* had been prepared by the DOH (see Annex A) to illustrate that generic drugs are generally lower in prices or cheaper than branded ones, both in the Philippines and the United States.

For example, the generic drug in the Ampicillin group (capsule form) cost much cheaper than the branded drugs. Among the 250 mg. and 500 mg. capsules, the use of generic name appears to be more advantageous for the buying public. Branded ampicillin capsules cost as much as 17% to 90% more for the 250 mg. and 45% to 88% more for the 500 mg. form.

(3) *It will promote rational drug use.* The use of generic names will help avoid drug duplication especially when a patient is under the care of several physicians. Overdosage or toxicity is thereby preverted. It also avoids drug interactions which can be serious or life threatening, minimizes medication errors and abolishes irrational fixed dose combinations.

(4) *The generic name, being the official and international nonproprietary name (INN) is universally understood.* Furthermore, a generic drug

name usually contains an informative stem reflecting the pharmacological class to which the drug belongs.

(5) *Brand names have led to a considerable waste in research expenditures, as each company wants to develop its own "patentable product."* A large part of R and D expenditure now appears to go to imitative R and D which merely adds to existing products new ones that are only slightly different in terms of their effect but are chemically sufficiently different to be patented.

Even in those countries where most of the world's pharmaceutical R and D is done, expenditures in marketing drugs is far higher than in drug research. In the USA, marketing expenditures are 3 to 4 times R and D expenditures and about one-third of the value of drug sales.

(6) *Charging of high price of branded products encourages small and dishonest imitation giving rise to manufacture of spurious drugs.*

Negative Effects Perceived by Medical Practitioners and Drug Manufacturers

Leading the group of practitioners who have spurned the Generics Act are the doctors affiliate of the Philippine Medical Association, manufacturers belonging to the Drug Association of the Philippines and a group led by Dr. Homobono Calleja, a cardiologist who is one of the most vocal critics of the new law. The following are the negative effects they perceived the law has created and which were published in a Special Report by Joel Palacios in the *Bulletin Today* issues of 22-24 March 1990:

(1) It poses a danger to public health and safety essentially because "generic drugs have allegedly not undergone clinical trials as to their efficacy on a regular basis unlike brand name products which have proven effective based on the doctor's experience in past prescriptions".

(2) The mandatory use of generics may be considered as an infringement on their right and responsibility to choose the medicine to prescribe to patients.

(3) The prescription system is cumbersome and dangerous and may lead to unnecessary loss of lives. The tedious prescription form also takes much of their time.

(4) Most of the 9,000 drugstores all over the country do not have the competent personnel to handle generic prescription and a mistake resulting in the dispensing of wrong drug is a distinct possibility. For this reason, generic should be applied only to simple ailments such as headache and not to serious illnesses because the sales clerk might make a mistake and dispense "poison instead of medicine."

(5) They insist that drug prices should not be a reason for government to regulate medical practice because a doctor does not withhold treatment just because the patient is too poor to pay. If the government wants to bring down the prices of drugs, it should instead cut the taxes on pharmaceuticals and not force doctors to prescribe generic medicines, which may not be as effective as the brand-name drugs.

(6) The government is not fully equipped to test all newly produced generic drugs that have flooded the market.

Aside from all the above, the Drug Association of the Philippines has advanced other arguments for the use of brand names as against the exclusive use of generic names:

(1) Brand names improve quality; generic drugs would be inferior since the manufacturer would have less commitment to the quality of their products.

(2) With the use of generics, shortages of many essential drugs are likely to arise because their manufacturers are rendered uneconomical. This may, in turn, give rise to the manufacture of spurious drugs.

(3) Any alleged savings to be made will be more than doubled by the expenses to be incurred, if enough appropriations are made for the regulatory agencies to control generic manufacturing. Great cost would also be incurred in advertising and promoting the generic product thus increasing the drug prices also.

(4) The exclusive use of generic product will result in the immediate disappearance from the market of those products protected by lawful patent as the owners of such products will not allow their products to be copied by generic manufacturers, i.e., the possible black market for drugs.

(5) It amplifies the consumer's search for specific products.

(6) It provides greater efficiency for product recalls in case of undesirable reactions.

(7) It builds psychological confidence in the effectiveness of medication.

(8) It facilitates continuity of purchases if a given brand is satisfactory, or against further purchase if the product is not satisfactory.

(9) It provides the basis from past reputation, for evaluating new products of the manufacturer.

(10) It gives incentives for the drug company to produce new products and encourages it to supply pertinent medical information on the product and related subject.

The Supreme Court Issues Its Verdict

On the class suit filed by Dr. Santiago A. del Rosario, Dr. George Gacula and the 14 other officers of the Philippine Medical Association, the Supreme Court handed down its decision four days before Christmas, 1989.

In a clear exercise of its judicial erudition, the Tribunal in an *en banc* decision unanimously upheld the validity and constitutionality of the Generics Act and the Implementing Administrative Order No. 62 of the Secretary of Health on generic prescribing, declaring that the justices "cannot heed the petitioners' plea to kill it aborning i.e., before it has had a chance to prove its value to our people as envisaged by its makers."

The arguments raised by petitioners del Rosario, *et al.*, were set aside one by one by the high court in the body of the decision, thus:

(1) The requirement of writing the generic terminology with the brand name of the drug in parenthesis below it applies equally to *all*, hence the absence of any distinction between government and private physicians.

(2) The allegation that the salesgirl at the drugstore counter is authorized under the Generics Act to "substitute the prescribed medicine with another medicine belonging to the same generic group" is a distortion of the clear provisions of the law. Implementing AO No. 62 directs the pharmacist *not to fill* "violative prescriptions" i.e., where the generic name is not written or the prescription of a brand name is accompanied by the doctor's instruction not to substitute it, or "impossible prescriptions." Even the doctor's "erroneous prescriptions" shall be filled but

this is subject to reporting to the DOH Task Force later. Moreover, the other Implementing Guideline on Dispensing (AO 63) enjoins the drug outlets "not to favor or suggest" or "impose" a particular brand or product on the customer.

The salesgirl at the drugstore counter merely informs the customer, but does not determine all the other drug products or brands that have the same generic name. Besides, the list of such generic drug and the corresponding brand names is required by law to be posted in a conspicuous place in the premises for the information and choice of the customer alone.

(3) The purpose of the Generics Act is to carry out the policy of the State in the implementation of the constitutional mandate for the State "to protect and promote the right to health of the people" and "to make essential goods, health and other social services available to all the people *at affordable cost*" (Section 15, Article II and Section 11, Article XIII, 1987 Constitution).

(4) The prohibition against the use by doctors of "no substitution" and/or words of similar import in their prescription, is a valid regulation to prevent the circumvention of the law.

(5) Petitioners' allegation that the penalties imposed i.e., reprimand, fines and suspension of physician's license to practice violate the constitutional guarantee against excessive fines and cruel and degrading punishment has no merit. Penal sanctions are indispensable if the law is to be obeyed, no different from the penalty of suspension or disbarment that the Supreme Court inflicts on lawyers and judges who misbehave or violate the laws and the Codes of Professional and Judicial conduct.

Conclusion

After all sides have been heard and the matter of validity of the law has been put to rest, it must now be emphasized that if the Generics Act of 1988 has fared relatively well despite the propaganda war being waged against it, it may have been due to the fact that aside from its solid base with a foundation which has health, human right and social justice implications, this landmark policy and legislation had been subjected to democratic participation and consultation both during the formulation and implementation stages.

It now appears evident that after various sectors had been consulted, the complaints and biases brought forth by groups opposed to the measure were more

easily overcome by arguments in favor of the law put forth by the cause-oriented groups, the NGOs and by other governmental entities themselves since it is rooted in the fundamental law of the land.

In answer to the fears expressed by the oppositors of the law, Dr. Ernesto O. Domingo, U.P. Manila Chancellor stated thus:

> At any rate the Generics Act of 1988 does not remove the doctor's right and prerogative. He remains the decisionmaker on the choice of drugs for his patient, which he writes on the prescription using the generic name of the active ingredient and including the brand name, if he so desires. What the law allows is the participation of the patient who afterall takes the medicine and pays for it. He, the patient, may choose the preparation with the same dosage formulation, active ingredient, pharmacologic action and therapeutic effect as the one prescribed, which he can best afford. The pharmacist is not allowed to make therapeutic substitution, only generic dispensing (upon the decision of the patient) within the same generic name (Domingo 1989).

In the case of the Generics Act, we also see how the branches of government when imbued with a proper sense of direction and devoid of any consideration other than the attainment of the goals of a sound policy, may effectively join hands and work toward more and better programs and endeavors if they so wish. From the Chief Executive to the Senate and House of Representatives and finally the Supreme Court, the new drug policy received tremendous support.

Having achieved its present status, the story does not end here, for the real test lies ahead. Dr. Kintanar has, even now, identified certain problem areas such as in television advertising where the generic name appears but without the corresponding audio mix which could have been deliberately excluded. Another concern which need further study and evaluation is the matter of problem drugs which have had a history of inconsistency as appearing in world medical literature reports.

Suffice it to state that although some of the negative reactions sprung from real concerns and not merely from misinformation and misperception, the Generics Act of 1988 being the social legislation that it is and not merely a "practice of medicine" law, must be seen in the larger context of society as Dr. Domingo (1989) put it, and not merely through the prism of profession.

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Annex A

Cost-Benefit Analysis of Selected Group of Generics and Branded Drugs

On the basis of the list of drugs to compare generics vis-a-vis branded drugs, our analysis shows that *generic drugs are generally lower in prizes or cheaper than branded ones, both in RP and US* whether in the form of capsules, tablets, vials and suspensions.

A detailed comparative table of each group (anti-biotics, anti-malaria, anti-tuberculosis, analgesics, vitamins, etc.) is attached, to include a summary of observations relative to cost benefit analysis of each group. (Exhibit "A")

It is important to note that the United Laboratories (UL) manufactures most of the generic drugs in the country except for Tetracycline which is also manufactured by UPJOHN but priced 164.69% higher.

For the selected group of generic drugs in the US, the Brand group is much more expensive than the other groups of drugs as shown in the attached list showing Percentage Comparison of Brand and Branded Generic Drugs with Quality Generic Drugs. (Exhibit "B") Similar to the UST experience, Quality Generic drugs are very much cheaper compared to Branded drugs. Among the Branded groups, peserpine 0-1 mg. has the widest difference in price, with as much as 733% higher than Quality Generic, i.e., 10.2350/tablet when branded as against $0.0282/tablet when sold in generic name. All the rest has its varying degree of difference in prices similar to experiences in the Philippines.

Exhibit A

Percentage Comparison of Branded Drugs with Generics (Cost in Pesos)

	125 mg.				*250 mg.*				*500 mg.*			
	Generic	*Branded*	*Diff.*	*%*	*Generic*	*Branded*	*Diff.*	*%*	*Generic*	*Branded*	*Diff.*	*%*
A. AMPICILLIN GROUP												
CAPSULES												
Ampicillin UL					₱1.5665				₱2.8445			
Ampicin						₱2.5608	₱0.9943	63.47		₱4.14	₱1.2955	45.5
Pensyn						2.28	0.7135	45.55		4.14	1.2955	45.5
Flexicil		₱1.3119				1.8395	0.273	17.43				
Amopen						2.9839	1.4174	90.48		5.371	2.5265	88.8
Penbritin						2.7729	1.2064	77.01		5.0042	2.1597	75.9
Pentrexyl						2.45	0.8835	56.4		4.30	1.4555	51.1
Omnipen						2.6755	1.109	70.79		5.1197	2.2752	79.9

For capsules, the generic drug in the Ampicillin group cost much cheaper than the branded drugs. Among the 250 mg. and 500 mg. capsules, the use of generic name appears to be more advantageous for the buying public. Branded ampicillin capsules cost as much as 17 to 90% more for the 250 mg. and 45 to 88% for the 500 mg.

SUSPENSION

Ampicillin UL	₱18.15				₱33.50			
Ampicin		₱29.50	₱11.35	62.50				
Pensyn		30.50	12.35	68.04		₱52.00	₱18.50	55.22
Amopen		39.75	21.60	119.01		65.59	32.09	95.79
Penbritin		36.51	18.36	101.16		63.55	30.05	89.7
Pentrexyl		33.00	14.85	81.82		51.75	18.25	54.48
Omnipen		33.14	14.99	82.59		54.81	21.31	63.61

For the suspension in the Ampicillin group, branded ampicillin are much higher in price ranging from 62% to 119% mark ups. For a 250 mg. by 60 ml. suspension, the generic drug is the cheapest, costing ₱33.50. All the branded drugs cost higher by as much as 54% to 96%.

B. CHLORAMPHENICOL GROUP

CAPSULES

Chloramphenicol					₱0.8245			
Choloromycetin						₱2.1925	₱1.368	165.92

The only data available for the second group are for the 250 mg. capsules. So far the generic name cost cheapest at ₱0.8245 per capsule, cheaper by ₱1.368 or 165.92% than the branded products.

	125 mg.				250 mg.				500 mg.			
	Generic	*Branded*	*Diff.*	*%*	*Generic*	*Branded*	*Diff.*	*%*	*Generic*	*Branded*	*Diff.*	*%*
C. ERYTHROMYCIN GROUP												
CAPSULES												
Erythromycin					₱1.4015				₱2.6795			
Erythrocin						₱3.3028	₱1.9013	135.66		₱5.5756	₱2.8961	108.0
Erymax						3.515	2.1135	150.8				

In the Erythromycin Group, the generic drug costs cheaper in both 250 mg. and 500 mg. capsules than the branded drugs by as much as 136% for the 250 mg. and 108% for the 500 mg.

D. PENICILLIN GROUP

CAPSULES

Penicillin	₱0.2305			
Sumapen		₱1.1	₱0.8695	377.22
Megapen		2.388	2.1575	936.01

For the penicillin group, only the 125 mg. are available. The generic drug is less expensive compared to the branded drug. The generic drug cost only ₱0.2305 per capsule while the branded drugs are more expensive by 377% to 936% mark ups.

E. TETRACYCLINE GROUP

CAPSULES

Tetracycline UL	₱0.6675			
Tetracycline UPJOHN		₱1.7668	₱1.0993	164.69
Ambracyn 250		1.6005	0.933	139.78

For the Tetracycline group, tetracycline manufactured by United Drug Laboratories costs ₱0.6675 while Tetracycline UPJOHN costs ₱1.7663, higher by ₱1.0993 or 165%. The branded drug Ambracyn 250 is higher by ₱.993 or 140% from that of the UL and yet lower from UPJOHN by ₱0.1663 or 9%.

	20 mg.				60 mg.				80 mg.			
	Generic	*Branded*	*Diff.*	*%*	*Generic*	*Branded*	*Diff.*	*%*	*Generic*	*Branded*	*Diff.*	*%*
F. GENTAMYCIN GROUP												
Gentamycin	₱11.90				₱20.10				₱34.75			
Garamycin		₱18.00	₱6.10	51.26		₱47.25	₱27.15	135.08		₱63.00	₱28.25	81.3

Among the Gentamycin group, the generic drug cost cheapest compared to the branded drug in all levels of 20 mg., 60 mg. and 80 mg.

	20 mg. Generic	20 mg. Branded	20 mg. Diff.	20 mg. %	60 mg. Generic	60 mg. Branded	60 mg. Diff.	60 mg. %	80 mg. Generic	80 mg. Branded	80 mg. Diff.	80 mg. %
G. CHLOROQUINE GROUP												
TABLETS												
Chloroquine	₱0.49375											
Aralen		₱3.355	₱2.86125	579.49								

For Chloroquine Group of anti-malaria drugs, the generic drug Chloroquine is very much cheaper than the branded name Aralen, by ₱2.86125 or as high as 579%.

	100 mg. Generic	100 mg. Branded	100 mg. Diff.	100 mg. %	400 mg. Generic	400 mg. Branded	400 mg. Diff.	400 mg. %	Generic	Branded	Diff.	%
H. INH GROUP												
TABLETS												
INH	₱0.0790				₱0.2270							
Nydrazid		₱0.1324	₱0.0534	67.59								

For the anti-tuberculosis agents, the generic drug is also much cheaper than the branded drugs. Among the INH group, INH costs lower by ₱0.0534 or by 68% than Nydrazid, a popular branded drug in the same group.

	Tablet Generic	Tablet Branded	Tablet Diff.	Tablet %	Liquid Generic	Liquid Branded	Liquid Diff.	Liquid %
I. PARACETAMOL GROUP								
Paracetamol					₱6.55			
Biogesic						₱13.96	₱7.31	111.60
Tempra						19.40	12.85	196.18
Pinpress						14.90	7.45	113.74
J. GLAFENINE GROUP								
Glafenine	₱1.1955							
Revalan		₱2.28	₱1.0845	90.72				
Glafen		2.28	1.0845	90.72				
Glifanan		2.586	1.3905	116.31				

As in the other Analgesic groups, the Glafenine generic drug also shows lower prices when compared to the branded drugs of the same group. Glafenine tablet costs only ₱1.1955 each, lower by ₱1.0845 or 91% to ₱1.3905 or 116% than the branded drugs.

Exhibit B

Percentage Comparison of Brand and Branded Drugs with Quality Generic Drugs (Average Wholesale Price Per 100 Tablets)

Product	*Brand*	*Quality Generic*	*Diff.*	*%*	*Branded Generic*	*Quality Generic*	*Diff.*	*%*
Meprobamate, 200 mg.	5.42	1.24	4.18	337.1	-	1.24	-	-
Penicillin G pot., 400 mg.	10.04	3.23	6.81	210.84	4.99	3.23	1.76	54.49
Prednisone, 5 mg.	3.64	1.92	1.72	89.58	2.70	1.92	0.78	40.62
Chlorpromazine, 25 mg.	4.10	2.42	1.68	69.42	-	2.42	-	-
Reserpine, 0.1 mg.	-	2.82	-	-	23.50	2.82	20.68	733.33
Propoxyphene Compound, 65	10.05	3.56	6.49	182.30	6.30	3.56	2.74	76.97
Amoxicillin, 250 mg.	26.10	-	-	-	26.27	-	-	-
Erythromycin, 250 mg.	15.49	8.43	7.06	83.75	13.52	8.43	5.09	60.38
Tetracycline, 250 mg.	3.93	2.29	1.64	71.62	3.97	2.29	1.68	73.36
Ampicillin, 250 mg.	14.91	9.03	5.88	65.12	12.32	9.03	3.29	36.43
Penicillin VK, 250 mg.	9.85	3.69	6.16	166.94	6.47	3.69	2.78	75.34
Hydrochlorothiazide, 25 mg.	4.01	2.41	1.60	66.39	4.65	2.41	2.24	92.95
Papaverine HC1, 150 mg.	-	3.50	-	-	10.67	3.50	7.17	204.86
Imipramine HC1, 25 mg.	9.72	4.20	5.52	131.43	7.42	4.20	3.22	76.67
Phenobarbital, 15 mg.	-	1.81	-	-	-	1.81	-	-
Chlorothiazide, 250 mg.	4.06	3.44	0.62	18.02	-	3.44	-	-
Dexamethasone, 0.5 mg.	13.06	5.42	7.64	140.96	7.93	5.42	2.51	46.31
Amitriptyline, 25 mg.	10.57	6.79	3.73	55.67	8.83	6.79	2.04	30.04
Oral Hydrate, 500 mg.	5.52	2.82	2.70	95.74	-	2.82	-	-
Quinidine sulfate, 200 mg.	-	9.75	-	-	-	9.75	-	-
Potassium Chloride 10%, liquid	1.93	-	-	3.80	1.93	1.87	96.89	
Diphenoxylate w/ Atropine, 2.5 mg.	11.68	5.21	6.47	124.18	7.86	5.21	2.65	50.86
Chlordiazepoxide, 5 mg.	6.58	3.01	3.57	118.6	-	3.01	-	-
Nitroglycerin, 25 mg.	-	2.77	-	-	6.95	2.77	4.18	150.9
Dimekin, 0.25 mg.	-	5.25	-	-	8.79	5.90	3.39	49.76