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During the 13th Congress, the Senate unanimously passed a bill that lowered the prices of medicines by allowing the parallel importation of affordable medicine, and by amending crucial provisions of the Intellectual Property Code to ease the iron grip of transnational companies on drug patents. The legislative measure, however, was not enacted into law, because the House of Representatives failed to pass its counterpart of the Cheaper Medicines Bill. The bills had to be refiled in the 14th Congress and the process had to start from square one. Sen. Manuel Roxas II, chair of the Committee on Trade and Commerce and principal author of SB1658, or the "Quality Affordable Medicines Act" refiled the Senate's version, and similar cheaper medicines-related bills were also filed in the House of Representatives.

As part of our *Shame of the Nation* series, the UP-CIDS conducted its fourth forum on October 2, 2007 at the UP College of Medicine, and invited Dean Alberto Roxas to be the Forum Chairperson. The roundtable discussion (RTD) entitled "Improving Accessibility to Cheaper Medicines" was honored with the participation of Congressman Joseph Emilio A. Abaya, Congressman Ferjanel Biron, and Bayan Muna Representative Satur Ocampo, who were the main resource speakers. Reactors were Dr. Robert So of the Department of Health (DOH); Dr. Fely Marilyn E. Lorenzo of the UP College of Public Health, Department of Health Policy; Ms. Clara Tisocki, a pharmacology expert working with a European Union-funded program managed by the European Commission (EC) in Manila and the DOH; Ms. Marilou Bautista Buensuceso of the Philippine Chamber of Pharmaceutical Industry

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# SHAME

## OF THE NATION SERIES

ACADEMIC DISCUSSIONS ON  
BURNING AND EMERGING ISSUES

# IMPROVING ACCESSIBILITY TO CHEAPER MEDICINES

## Backgrounder

**Dr. Alberto B. Roxas**

Forum Chairperson  
Dean, UP College of Medicine

**Our objective** is to have cheaper medicines in the country. As I understand, there are now 25 bills related to this issue in the House of Representatives and about nine in the Senate. Yet there is a need to develop one law that is acceptable to everybody. This discussion is an effort on our part to be enlightened on the issues.

The World Health Organization (WHO) defines essential medicines as those that satisfy the health care needs of the majority of the population; they should be available at all times in the proper dosage forms to all segments of society. Access to medicines is anchored on four important pillars: rational use, affordable cost, sustainable financing, and reliable supply systems. Likewise, the Philippine National Drug Policy enunciated by President Cory Aquino in April 1987 also listed four pillars to ensure access to essential medicines by all Filipinos. These are quality assurance, rational use of drugs, self-reliance, and targeted procurement.

In this time of economic crisis, access to medicines for Filipinos means affordability of drug prices. Unfortunately, the latest WHO Health Action International Survey revealed that Filipinos buy medicines at prices 3.4 to 18 times higher than the international reference index. The study revealed that core essential medicines, particularly generic drugs, were of very low availability. Only 11.5% of these medicines are available in the public sector and only 15% in the private sector. The cost of medicines in the Philippines has remained the second highest in Asia next to Japan. This high cost has

seriously affected access to essential medicines for the majority of the population. On top of this, only 3.4% of the financing for medicines comes from the government budget. About 45 to 90% of funds for medicines are out-of-pocket, i.e., from the people's own money.

The Philippine government has made formal pronouncements that making the cost of medicines cheaper is one of its priorities. One of the strategies is to amend the current intellectual property law to incorporate the flexibility provided for in the TRIPS (Trade-related Aspects of Intellectual Property Rights) Agreement, such as parallel importation and compulsory licensing provisions. This work was started in the Senate in the 13<sup>th</sup> Congress by Senator Mar Roxas. There is a counterpart bill in the House of Representatives, authored by Congressman Joseph Abaya.

Another strategy being looked at is the creation of a Drug Price Regulatory Board. Congressman Biron authored the bill that incorporates this provision. The need to take a comprehensive look at a health care system that incorporates health system development and community participation, as well as the need to review existing laws and ensure their implementation, is the thrust that Rep. Satur Ocampo is pursuing. Hence, there is also a need to re-examine the Philippine National Drug Policy and the Generics Act, and ensure their implementation.

Strengthening the generics and local drug industry can already bring about a substantial reduction in drug prices and indeed make low-cost, efficacious and quality medicines available to all Filipinos at all times. Our invited reactors will give us various stakeholders' views on how the current legislative thrust can have an impact on this urgent need to make medicines affordable for our people. Today's forum hopes to give us a clear picture of the situation of drugs in the Philippines and provide us with different perspectives on courses of action to take.

## Creating a Level Playing Field: House Bill 1758

**Cong. Joseph Emilio Abaya**

Representative, First district of Cavite

We welcome this opportunity to engage stakeholders in the health industry. Congress is presently in the midst of committee deliberations concerning the measure of lowering the prices of medicines. A total of 25 bills have been filed, which shows how much interest there is in this area.

The prices of medicines in the Philippines are the highest in the ASEAN region. According to the DOH Pharma 50 program, the cost of medicines in the Philippines remains higher by 40 to 70% compared to other ASEAN countries. This is a big factor in the continuing decline of the Philippine health care system.

DOH has also pointed out that generally, 50 to 60% of medical needs are paid out of pocket, while government expenditure is less than 10 percent. Since people cannot afford the drugs they need, they resort to under-medication for essential drugs such as antibiotics and over-medication for the cheaper symptomatic preparations. The reality is that the prices of medicine are exorbitant, and this effectively hinders Filipinos from obtaining even basic health care. The persistence of this scenario is due to the present laws that prevent the development of a level playing field, and which largely protect multinationals. These multinational corporations have used the present intellectual property system to maximize their profits. It is therefore apparent that bolder measures are required to significantly cut the prices of medicine.

Likewise, prices of medicines don't usually follow the simple laws of supply and demand, but more often follow the principle of what the market can bear. In support of this agenda, I have authored House Bill 1758 which seeks to amend Republic Act No. 8293 or the Intellectual Property (IP) Code to incorporate and take advantage of the flexibilities under the Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS). I will focus on the amendments to the Intellectual Property Code. They aim to make patent and trademark laws more responsive to the Filipinos' health care needs by legitimizing the following:

- a. Early development of patented medicines (or the "Bolar" provision);
- b. Parallel importation of medicines and international exhaustion of intellectual property rights and patents;
- c. Restructuring of government use;
- d. Provision for exemptions to the application of trademarks in favor of parallel import, and
- e. Disallowing coverage by a separate or new patent of new uses or derivatives of a patented drug.

The present IP Code already incorporates some of the recognized TRIPS-compatible safeguards, including rights of government use, issuance of compulsory licenses, and limited exceptions to patent applications. But there are still a number of structural and policy measures allowed by the TRIPS Agreement, as advocated by House Bill 1758 and other bills filed in the House, that if undertaken would help create an environment that promotes market competition. Hopefully, this will lead to lower prices of drugs and provide the Filipino people with cheaper alternatives. I would also like to mention that these amendments are not exclusively in our bill; they are also incorporated in the bill filed by Cong. Biron.

The first is the Bolar provision. The Bolar provisions are permitted under article 30 of the TRIPS Agreement, which contains an exception to exclusive rights conferred by patent. This provision, also called the “early working doctrine,” will enable generic drug companies to experiment and test generic versions of patented drugs before their patents expire; it will also allow them to produce and sell generic versions of patented drugs immediately upon their patents’ expiration. This is important, because if an early working or Bolar exception is not provided, firms manufacturing generic medicines will not be able to enter the market for an additional year and a half, or maybe two or even three years – however long it takes to obtain approval after patent protection expires on the drug. If the experimentation phase is factored in, it could take much longer before a generic version can be introduced in the market. This would effectively extend the patent of the drug – and the monopoly of the original drug maker – by the three or so years needed to experiment on and register a generic alternative. This Bolar provision will make sure that once the patent expires, generic and cheaper counterparts can be introduced to the market immediately.

House Bill 1758 proposes to amend our IP Code so as to limit the rights of patent holders only to the first sale, meaning that these patent holders will have no legal claims on sales subsequent to the first. Thus, once a drug is offered for sale anywhere in the world, a buyer can purchase it, bring it into the country, and resell it at whatever price. Currently, our Intellectual Property Code adheres to the principle of domestic exhaustion. We are proposing that we convert to the doctrine of international exhaustion, which is accepted or allowed by the TRIPS flexibilities. For example, let us say that Nike has a patent on “air tsinelas,” so if that patent is existing in Philippine law, no one can sell, manufacture or import “air tsinelas,” whether from the United States, or from India or Pakistan. But if this amendment is allowed, even if Nike has a patent on “air tsinelas” in the Philippines which expires sometime in 2020, but the same item is currently sold in India or in the US, then any importer could buy it from the US, bring it here, and sell it further. This example also applies to medicines.

A big issue here would be the bringing in of counterfeit or fake medicines. For multinationals, this would be the very first issue they would raise. The right approach to addressing such concerns would be to strengthen the BFAD; it shouldn’t be a reason to stop the bill.

The third strategy is to restructure government use. The IP Code already provides for the grant of compulsory licenses and government use of inventions. These provisions define

the instances when government can intervene and exercise measures to make medicines available, particularly in cases of national emergencies such as a pandemic. The bill grants the government discretion in use of patents when public health is at stake, and provides a framework for ample compensation to the patent holder.

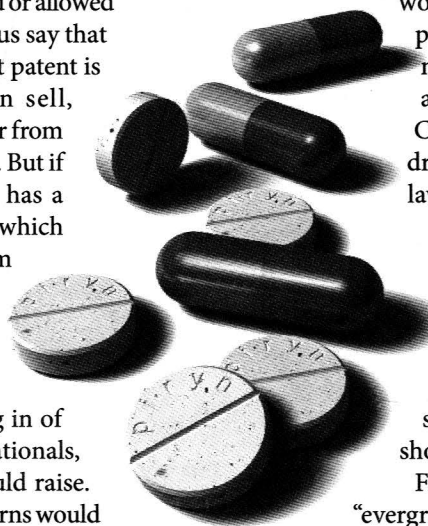
At present, the government is required to apply for a license before it can use the patented medicines or processes for manufacture. The proposed law does away with compulsory licensing, making it easier and quicker to respond to public health threats without fear of lawsuits. This has been done in Thailand, and in Africa, where HIV-AIDS is prevalent.

The fourth strategy is providing for additional exceptions to the use of trademarks and trade names. These cover the importation of branded generic drugs or off-patent drugs. This is a complementary proposal to parallel importation, which provides exceptions to the exclusion right of the owner of a registered mark. This exception is significant because it is possible for pharmaceutical corporations to attempt to restrict access to drugs and medicines by asserting that parallel importers may not use local trademarks for drugs brought in through parallel importation, even if these drugs are put in the market by trademark holders in other markets. Or they can even do so by claiming trademark rights in the colors of tablets and capsules.

Going back to our example of “air tsinelas,” if its patent in the Philippines expired in 2005, technically it would already be off-patent and could be imported. An importer in 2007 would then import “air tsinelas” from India. Upon arrival here, there would be no violation of patents because the product itself is already off-patent. But what multinationals have resorted to was filing a case against the Philippine International Trading Corporation (PITC), which imports these generic drugs not under patent law but under trademark law. The PITC case is still in the Supreme Court.

Personally, I think that it is a poor attempt at blocking parallel importation because in trademark law, the only measure or standard followed is if the products are confusingly similar. In this case, there is actual importation of drugs from the same company, so it is the same trademark and same party. Logically, there should not be any trademark violation.

Fifth is the exclusion of new uses or “evergreening” as an exception to patent rights under the TRIPS Agreement. The criteria for patentability are limited to: (1) novelty, (2) inventiveness, and (3) industrial applicability. Since the TRIPS Agreement does not define these terms, World Trade Organization (WTO) members may determine how these criteria should be interpreted and applied.



The proposed measures will bar patent owners from extending patents on the basis of a new use for existing substances. The practice of extending patents on such grounds has allowed patent owners to maintain a hold on the patent even if the new use does not result in a product, or could even be deemed an obvious use. This is called “evergreening” which the proposed bill aims to curtail. Going back to the “air tsinelas” example, let us say its patent expires in 2010. Then, Nike USA or Nike Philippines discovers in 2008 or 2009 that “air tsinelas” is a good eraser for permanent markers. Under existing laws, they would basically be given an extension of the patent for a use which they inadvertently (or probably intentionally) discovered.

House Bill 1758 aims to bring down the prices of medicines through amendments in the IP Code. This bill, however, does not purport to be the panacea for all the ills that plague our health care system. Certainly, there are other directions in legislation that can be undertaken in separate measures to meet other needs. Some other areas where current bills are filed are the strengthening of our health insurance system or PhilHealth. As earlier mentioned, in most medical cases, 50 to 60 percent are out-of-pocket expenses. If PhilHealth is strengthened, it can contribute to the solution by improving the population reach and covering the cost of medicine. Corollary to that, government spending on medicine can be pooled by such agencies as DOH, PhilHealth and PITC. Pooled volume purchases will enable these agencies to be in a position to bargain for lower prices of medicine. Strengthening the generics industry, strengthening BFAD, and amendments to the pharmacy law are all incorporated to ensure a more effective implementation capability.

While we approach this issue in a holistic and a long-term manner, we are just taking the first step. We are merely paving the way for our children and generations to come by creating an environment that will lower the prices of medicine through increased competition among drug companies. Prices are principally determined by supply, and as long as pharmaceutical companies are able to control the supply of drugs in the market, prices will always remain high and medicines inaccessible to Filipinos who need these services most. The essence of House Bill 1758 is to loosen the control that pharmaceutical companies now have over supply, thereby creating a level playing field which encourages the forces of competition to dictate prices while providing the government with better policy tools to significantly influence the supply

and demand of medicines. After all, the drug industry is imbued with public interest and it is the duty of the state to make sure that public interest is served.

## Putting a price regulation scheme in place: HB No. 01

Cong. Ferjanel Biron

Representative, Fourth district of Iloilo

Patented products are a problem considering that there are about 3,500 products that remain patented. But of the 40,000 registered products with the BFAD, 95% are off-patented and this too, creates a problem.

Developing countries like the Philippines and India are often beset with infectious diseases, pulmonary problems, and so on. One such problem is “hika” or asthma. Filipinos spend some US\$400 million for pulmonary-related problems. So we need salbutamol. In India, salbutamol comes as an inhaler and costs only 85 pesos. It is manufactured, marketed and distributed by Glaxo-SmithKline India. In the Philippines, what we import from Australia is actually an identical replica of the “Ventolin” marketed in India, and it costs 410 pesos. We can cite hundreds and hundreds of examples, but the bottom line is that prices here are at least 500 to 1,000 percent higher than what we can get in India, in Pakistan and even Thailand.

While we recognize the importance of amending our IP Code, I think the discussions of Congressman Abaya are all incorporated in House Bill 01. House Bill 01 was filed and approved in the 13<sup>th</sup> Congress, but did not reach the third reading for lack of quorum. But now, that is no longer a problem.

While we want to address patents and encourage parallel importation by government and by entities authorized by government, I believe we cannot just allow the free market to work to bring down costs of medicines in this country. For this, I think we need legislative intervention. In India, they have a drug price control order. It was last amended in 1995, but the law has been there since 1971. In fact, this is the reason why the Indian pharmaceutical industry is one of the biggest industries in the world today, because prices were regulated or otherwise controlled. Eight years ago, Thailand also undertook their own drug price control through what is called the Prices of Goods and Services Act of 1999. That law provides mechanisms for regulation of prices of all pharmaceutical products in Thailand.

Pharmaceuticals are a PhP100 hundred billion industry in the Philippines. 80 percent of this is in the hands of the multinationals, while only 20 percent is in the hands of UniLab and the rest of the smaller companies in the country today. Some 40% of the budget of an ordinary Filipino household goes to drugs and medicines. One-third of the hospital bill that you pay when you undergo a surgical operation is for drugs and medicines.

In the country today, we see that pharmaceuticals are practically a monopoly, from manufacturing to distribution. 80% of the total manufacturing of multinational companies is done by one company, Interphil. About 65 to 70% wholesale distribution is handled by its own company, Zuellig, and by another company, Metro Drug. In retail, 600 branches of Mercury Drug control the retail market in the Philippines. The entry of Watsons aggravated the whole retail monopoly in this country. For every PhP100 pesos worth of medicines that you buy from Mercury and Watsons, the gross profit of these retail giants is 38%. So for the PhP410 Ventolin that you buy from Mercury or Watsons, they earn 38% of this. But go to Bangkok, where no single company controls the retail prices, and the medicine should be at least 40 to 50% cheaper than what you buy in the Philippines. To give a concrete example, the highest-revenue-earning anti-hypertensive product today is amlodipine or Norvasc, which is sold by Pfizer in the Philippines. Norvasc costs the Filipino 80 pesos per 10-milligram tablet. In India, it is marketed under a different name, Amlogard. It is also produced, marketed and distributed by Pfizer, but it only costs the Indian people eight pesos per tablet.

That is why we have to address the issue of rising costs of medicines by way of regulation. While we also want to address the issue of patent, we should be more aggressive in responding to the issue of prices of off-patent products. In the SONA (State of the Nation Address), the President clearly identified and realized that we need a law to address the high cost of medicines in the country.

The first portion of the bill contains the price regulation provisions. It is the policy of the state to protect and promote the right to health of the people and to instill health consciousness among them. This particular House Bill calls for the creation of a drug price regulation board which will be attached to the Department of Trade and Industry (DTI) and will be composed of the Chairman of the DTI, the Secretary of Health, the BFAD Director, and seven others to be appointed by the President. Just like in Thailand and India, there is a governing board which fixes the maximum retail price of essential medicines. We have clearly identified the medicines or pharmaceutical formulations that should be under a price regulation scheme, and the common denominator is that all these medicines are indicated for management of chronic illnesses, are required for prolonged treatment, and those that are needed for life-threatening conditions.

We hope that the House of Representatives will realize the importance of bringing into the picture the price regulation scheme. We appealed to the members of the committee not to confine the list to the essential drugs list of the DOH. This is because not all medicines prescribed by private physicians are included in the said list. The wisdom of having an essential drug list drafted by the Department of Health is to make these cost-

efficient medicines available to poor patients confined in DOH-administered and supervised hospitals. That is why we similarly thought it wise to have our own list in the law to cover medicines that are in use in both government and private practice. This list of medicines is based on therapeutic classes, so we don't regulate per formulation. All medicines included in the particular therapeutic class as identified and provided for in this bill will be under price regulation.

For example, three years ago IV (intravenous) fluids in this country were being sold for PhP25. Today, only one pharmaceutical plant controls IV fluids in this country. So it would cost a patient PhP105 because it has become a monopoly. With price regulation, this cannot be done anymore, because all companies will be forced by this law to disclose their costs from the time the product is manufactured. The maximum retail price is printed on the immediate packing and labeling to prevent arbitrary pricing and hoarding. The moment the product is manufactured, its price will be printed on the packet to protect consumers anywhere in the Philippines. The maximum retail price is universal. Whether you buy your medicine in Baguio or Zamboanga, it should cost the same. Thus, we hope that the price regulation method or scheme will be adopted in the final draft of this bill.

## **Developing a self-reliant and independent national drug manufacturing industry: HB 2492**

**Cong. Satur Ocampo**

Party list representative, Bayan Muna

We at Bayan Muna have no argument against both bills presented by Cong. Abaya and Cong. Biron. But in accord with our party mandate as representatives of the marginalized sectors advocating and fostering the interest of Filipino entrepreneurship, Filipino industry and the development of a Philippine drug industry, we looked into the situation and at the provisions of the Constitution pertaining to the health policy of the government. House Bill 2492 took off from Cong. Biron and Abaya's bills but added components of providing support for local drug manufacture; for the production of low-cost, safe, and quality medicine; and for other purposes. This means we look at the urgent need to bring down prices of medicines needed by our people, but we also look at the longer-term perspective.

To expand the concise declaration of principles in Cong. Biron's House Bill 01, House Bill 2492 is more extensive and

more detailed to reflect the true intent of our Constitution. We started from the development of our drug manufacturing industry, which is highly dependent on and monopolized by transnational firms as far as the manufacture of drugs globally and nationally is concerned. Yet, our Constitution says that "it is the policy of the state to adopt an integrated and comprehensive approach to health development which shall endeavor to make essential goods, health and other social services available to all people at affordable cost" and to protect and promote the right to health of the people and to instill consciousness among them. This is incorporated in Cong. Biron's bill.

The Constitution also says that "the state shall develop a self-reliant and independent economy effectively controlled by Filipinos." If we translate this to the specific arena of drug manufacturing, we should follow the mandate to develop a self-reliant and independent national drug manufacturing industry. There is also a provision which says that the state shall protect Filipino enterprises against unfair foreign competition and trade practices, and this is addressed by Cong. Abaya's bill. Article II, section 20 of our Constitution says: "The State recognizes the indispensable role of the private sector, encourages private enterprise, and provides incentives to needed investments." So our bill simply makes extensive the declarations of policy covered by the two bills. This is to cover various areas that need to be addressed and could be interpreted in many ways. For example, the Generics Law is still not being implemented properly even 20 years later. The same is true for the 1998 Magna Carta for Health Workers.

In our declaration of principles, we lined up nine specific issues, among them protection, promotion and ensuring availability of health services to all people at affordable cost. Second, strengthen the local drug industry by giving incentives and developing a self-reliant and independent drug and pharmaceutical industry effectively controlled by Filipinos. Third, ensure the strict implementation of the Generics Act of 1988 from prescribing, disposing, and manufacturing to advertising, and particularly, ensure the compliance of key players in the pharmaceutical industry and in the country's health delivery system. And then, provide technological and infrastructure assistance to local pharmaceutical establishments to develop a truly Filipino drug industry responsive to the medical and health needs of the people. Other components of our bill have to do with the composition of the drug regulatory board, which should include the health secretary as chairperson, trade and industry secretary as vice chairperson, the BFAD director

as member, one representative from the manufacturing sector and the pharmaceutical industry, one representative from the consumers, one representative from the Drugstore Association of the Philippines, one representative from non-government organizations with health concerns, two representatives from health care services providers, physicians and pharmacists, a representative from among the hospital associations, and one representative from the academe. This academic representative is not in the other provisions.

We have a specific article calling for the implementation of the National Drug Policy and the Generics Act. In the drug policy, it says that the Department of Health shall immediately undertake the full implementation of the National Drug Policy pursuant to E. O. 174 and 175, as well as amendments to RA 5921 or the Pharmacy Law and Republic Act 3720 or the Food, Drug and Cosmetics Act in order to provide guidelines for rational use of quality drugs. The implementation of the National Drug Policy should ensure the availability and affordability of safe, effective, and quality medicines, and shall strictly and comprehensively monitor the importation, manufacture, marketing, and consumer utilization of drugs or medicines and their intermediaries. It

is provided further that the Philippine National Drug Formulary shall continuously monitor and print updates on the list of drugs or medicines that are most essential for diseases and conditions encountered in the Philippines, describing appropriate choices and the essential drugs or medicines for them.

Next to this is the provision on parallel importation. The only difference in our proposal is that it should be selective, not across-the-board. This is to ensure that we focus parallel importation only on selected drugs or medicines that are life-saving, that the local manufacturer cannot afford to produce. This is also to boost the Generics Law and the local manufacturing industry.

As for our proposed support to the local pharmaceutical industry, among others, there will be tax incentives – for instance, importing materials VAT (value-added tax)-free, sale of drugs or medicines and other materials needed for manufacturing, production, productivity support, technical credit assistance, and other incentives. But we were told by the chair of the technical working group (TWG) that it might be a problem to incorporate this part because it would lengthen the debate and require more time. Possibly, it should just be presented as a separate piece of legislation. Since we are latecomers to this issue, we do not want to hinder the legislative progress

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of the other bills relating to cheaper medicines.

But we will continue to stress that we should not only focus on mere adjustments in the existing mechanisms. After all, the key to safe and affordable medicines is a nationalized drug industry based on willingness to serve the people and not just to satisfy the thirst for profit. Profit is what motivates the transnationals who have monopoly of drug manufacture, distribution, and marketing. Having a local industry that can manufacture its own products is the only way to lower the prices of medicines over the long term.

The transnationals' control over the local drug industry must end. The government must assist local drug manufacturers to build up their research and development capabilities in providing cheaper alternative medicines, tapping abundant indigenous plants as raw materials, and improving the productivity, efficiency, and sustainability of the Philippine pharmaceutical manufacturing sector instead of promoting importation and liberalization. The government must work towards a self-reliant drug industry and strengthen the production and manufacturing capabilities of a national drug industry that is responsive to the medical and health needs of the people, and where service to the needy takes precedence over profit. We need to apply a broader perspective to our problems in health services and the supply of quality, affordable medicines.

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## Reactors

**Dr. Robert So**

Department of Health

I would also like to improve accessibility to cheaper medicines, but my question is, do we really like or want cheaper medicines? Is cheaper really better? We have been looking at aspects of affordability, but there is another aspect that we usually overlook, which is availability. When we break down the issue of access, we usually have to face greedy multinational companies or even some local companies. These companies don't share information with us, don't tell us how much they spent to make those drugs, etc. We don't know because nobody shares with us the information that we actually need.

Aside from the lack of transparency on prices, there are proponents that actually dictate the prices because of the presence of monopolies or oligopolies. Cong. Biron emphasized earlier that we only have limited players in the market at all levels – the manufacturing level, distribution level, and even at the retail level. Then we have smear campaigns against generics and questions on quality. As doctors, we are actually part of this sin, and part of the enemy of the nation because of our actual behavior in terms of prescribing, or for the pharmacists, in terms of dispensing.

So when we look at the issues of medicines and accessibility, it's not limited to just one aspect. We have to actually engage all stakeholders at all levels. How do the health care providers, like doctors, actually contribute to these ill effects? When you go to the OPD (outpatient department) in second year in medical school, you already have prescription pads with the generic and the brand names written on them. Then you have a ball pen which says Cefaclor or whatever drug, you use it and you are so happy that you have a free pen and you don't have to buy it. But if you go a little higher – let's say you're a resident; you get better perks like free dinners, etc. Then, when you graduate, you get to celebrate your graduation in fancy hotels. When you really look at all these "perks," who pays for all of these things? It is the multinational companies. Where do they get the money? It's from the sick. And who gets sick more often? It's the poor. They are the most vulnerable of all. So who pays for the ball pens that you are using right now to jot down notes?

I don't know how many of our residents and consultants actually ask about the prices of the drugs that they prescribe to their patients. They'd usually say it is the cheapest, but is it really the cheapest or is it just cheaper? Or is it the most expensive and you really don't care?

We definitely agree with the IP Code amendments, which will allow us to get more drugs into the country and provide for the needs of our countrymen. But the best part of these amendments is letting the generics companies thrive with the Bolar or "early working" provision described earlier. This will allow the better generic companies to thrive, and in effect, get better competition into the market for the 3,000 or so off-patent drugs, and even those that are expiring or nearing the expiry of their patents. I'm actually asking: are we going to allow "cheaper" or are we really espousing "cheapest"? "Cheapest," as far as I can see, can be achieved through the best competition, a level playing field, and better regulations.

We just want to raise some questions, though we remain supportive of the bills. For one, given our institutional structure, will drug price regulation work? Do we have studies on this? Are we ready for it? Do we have the infrastructure? Do we have the people ready to implement this? Have we exhausted all measures and means to attain the best competition in the market, or are we once again making another law just to see what will happen? I think there is a proposal that some board members will come from the pharmaceutical industry. But isn't that one of the problems that we raised earlier? We have greedy companies not sharing with us all the information that we need, and now they're going to be part of a board that will tell us what the right price is. What is the consequence of regulation on the other aspects? Will there be price controls for other products as well?

One last point to remember is that when you make a policy and a law, there are two aspects that you can take into consideration. These are implementation and appropriation, which means money, people, and enforcement. This means doctors not prescribing a branded product, or not getting ball pens that are being paid for by the patient that they actually shoo away when he comes for a consultation in the wee hours of the morning. We have to exhaust all existing remedies under the law, even as we make new ones and try to build up capacity. Lastly, we would like to end with the fact that generics are of very good quality. BFAD can assure you of that.

### Dr. Fely Marilyn Lorenzo

Professor, UP Department of Public Health

**We are dealing** with very difficult policy issues here. First of all, we're looking at both market and government failure. If our market does not fail, we should have a good balance of supply and demand, and the price equilibrium will then be dictated by a robust supply and a well-informed demand. But we don't have all of these, and that is why our prices have gone awry. Certainly in a sense, what constitutes our market is information asymmetry. Our people do not know what drugs to take, what prices our drugs should have, and the availability of alternatives like traditional herbs.

A case in point: people take a lot of cough syrups because we, the health providers, prescribe also a lot of cough syrups. This is because we don't want to be accused of not doing anything when our patients are coughing. But we all know that cough syrups do not really help that much, and so we make our people buy about PhP500 worth of syrups when you know that their cough will go away at the end of three or four days – not because of the cough syrup, but maybe because it was just a viral infection. Yet they're poorer by five hundred pesos, or even more, if they buy the higher-costing

new drugs on the market that are touted to be the best. Information asymmetry has really hounded us, and we haven't really solved it.

Another item that I think is effectively addressed by the proposed bills is the monopoly in the market, which comes about because of several reasons. One is because of the barriers to entry. We do not have the resources of First World countries to be able to come out with research on the active ingredients that we know are already here in the Philippines but we have not really been able to develop. I think some of the bills are actually addressing these, but we need also to address where our government has failed.

We have failed to actually come out with good or strong agencies that will regulate our drugs, their prices and quality, and rational drug use. All of these need to be regulated to some extent. All we have for now, unfortunately, is BFAD, which, while valiantly trying to fulfill its mandate, is really incapacitated to do all that it is tasked to do. BFAD has a myriad of functions to fulfill; aside from the quality of drugs, it also licenses food handlers. All the itinerant vendors outside the Colleges of Public Health and Medicine should be licensed by BFAD. But can BFAD do all that, considering that it is just one agency and even its regional offices are very under-staffed?

In relation to the more comprehensive stand of Rep. Ocampo, we offer one study by the Institute of Health Policy and Development Studies at the National Institutes of Health. This is the Assessment of Philippine Drug Security, which was accomplished last year and commissioned by the DOH. In this study, we looked at availability, affordability, rational drug use, and other aspects which will ensure drug security. So what is drug security? We had to look at the concept akin to food security: make sure that every Filipino will have access to drugs if and when they need them, and not only by coming up with the cheaper or cheapest medicines, but also with the right quality of drugs.

We looked at vulnerable provinces in the Philippines and identified the absolutely necessary drugs based on epidemiologic analysis. We only looked at 200 drugs that need to be made available at all times and calculated the quantities at which they are needed during normal times, and during epidemics and calamities. Second, we identified how rational drug use might be assured, and this is one of the biggest problems. As Dr. So has said, we as health providers actually become accomplices in this problem. So we are suggesting that there should be a short-term government subsidy for

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certain drugs to be provided at every provincial health office and distributed all the way down to the municipal level. But this subsidy should stop in a few years, with the local government pitching in with their IRAs (internal revenue allotment). We are asking for government subsidy now because there are certain drugs that are needed to wipe out communicable diseases like TB (tuberculosis). We want to take out the sources of infection in the short term so that we can better provide health care on a more relaxed stance in the medium term.

I would like to entreat the Honorable Congressmen to kindly look at the provisions of your bills in terms of short-term, medium-term, and long-term provisions. The Abaya bill provides us with the medium-term solution; the Biron bill gives us the short term and necessary impetus; and the Ocampo proposal comes with a more comprehensive solution. If we could come up with a conglomeration of these and add provisions that will make our Generics Act and Philippine National Drug Policy more up-to-date, then we can ensure not only cheaper medicines but also drug security. Those of us working on these issues hope to see some change within our lifetime, and to contribute significantly to attaining it.

### Ms. Clara Tisocki

European Union Consultant to the Bureau of Food and Drugs

It is very interesting to hear that all our three congressmen very clearly identified monopoly as one of the main problems. My question would be: if we look at effectiveness, how do we address monopoly? What are the solutions for monopoly? What is going to create a competition to break the monopoly as well as the right of the monopoly holders to keep their prices where they want to fix them? Several answers were offered in the presentation by Cong. Biron. Obviously, the inclusion of the TRIPS flexibilities in the IPR law is in the right direction, toward improving the accessibility to generic drugs by allowing the companies to market and manufacture these drugs as soon as the patent protection of the monopoly expires.

As far as parallel importation and compulsory licensing are concerned, we learned from different countries like Brazil and Thailand that these TRIPS flexibilities, if applied in the right context of the WTO Agreement, can make a huge difference on drug prices. I think all developing countries can use these within the limits of the industrial trade agreements.

It was also pointed out that it is very important to look at drug price controls in terms of effectiveness. Is it feasible to implement drug price controls? Does the country have the

technical know-how to decide on what is the fair price? Is it going to be based on the information that is submitted by the industry or on international price comparisons? Does DOH have a committee that can work on this? Who would provide the technical input? Is a 50% reduction a good enough price, or do we need to cut the prices by 80%? What happens then?

There is China's experience, for instance. As soon as it started to control the prices of certain products, those products disappeared from the shelves. New products that were not under price control started to emerge. I have seen this in the saddest way just a month ago in Zimbabwe, which is one of the poorest countries with the highest inflation rate. Its government, in desperation to try to respond to this, introduced price controls on all sorts of essential goods – even on food and medicines. In July, I saw this with my own eyes that the supermarkets were empty within two weeks. People rushed in for the price-controlled products, and the supermarkets were not able to replace them. As regards medicines, stores often refused the pharmacists' medication because they would not be able to replace their stocks. The economic reality when you introduce a very strict price control or price freeze is that some people will go out of business, so to counter this, access will be decreased. It should be part of the risk assessment to see that both levels of price controls are going to achieve what they are supposed to.

Finally, I would like to mention a couple of untouched issues which I think are important, again for the effectiveness of the regulation. We should consider evidence-based policy making. For one, there is nobody talking about the issue of canceling taxes and offering some incentives to direct companies to lower the prices of medicines which are the most expensive and most unaffordable for the poor. We have seen this from several international studies. A tax or a duty applied early in the mark-up chain of the drug can have a huge impact, up 20 to 30% on the price. But even 10 or 12%

can make it unaffordable for the poorest in society. Besides, if you remove the actual revenue to government, which is usually in the range of 0.1 to 0.2 percent, it is so little that it is hardly noticeable.

Another issue is financing, specifically, how PhilHealth can use its purchasing power to bargain for better prices. Many European and other countries have done that. Instead of direct controls and sanctions, can PhilHealth instead use its financial power to negotiate? In many countries in the EC with universal health insurance coverage, this is how they are able to control prices and

achieve transparency within the supply system.

We can look into how can we unite, pool the funds available for medicines, and purchase on larger economies of scale. That is a potential solution that might be helpful. On the

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demand side, obviously, education of the public is incredibly important. If the public believes that generics are of poor quality, that cheap drugs are bad, there won't be a demand for cheap drugs. As mentioned earlier, generic drug sales make up only four percent of the total drugs sale. We need to look into that and to educate people about this, so that they can instead buy generic and enjoy savings. Parallel to that, we also need to look at ethical issues related to drug promotion to the doctors.

### Ms. Marilou Bautista Buensuceso

President, Elin Pharmaceuticals, Inc

It was only recently that we in the pharmaceutical industry banded together and organized ourselves more, because of competition and the urgent need for cheaper medicines in our country. The real answer for cheaper medicines is generic competition, whether it's Filipino, Indian, or US. What we are offering is our own Filipino brand of competition. Generics are not just unbranded products; generics are all the off-patent products. If a product is off-patent internationally, it is known as a generic product. Unfortunately in the Philippines, generics have been given a bad name, and have been limited to the unbranded genre. We have almost completely forgotten that in fact, most of the generics that you see are actually off-patent products.

What does the IP Code amendment address? The first and most important intervention for generic competition is the patent issue, because here, one is finally defining what a patented product is and isn't. Once that is established, we can do all the structural reforms we need to do in our generic industry. The patent issue in our country is very critical to the public health system. Remember that all our products start as generic. If a product is patented, that's a monopoly. So the first step in breaking that monopoly is to identify what that monopoly is and how it was created. It is the Intellectual Property Code of the Philippines that defines our patent system. That has a very big impact on the public because all the medicines we use and will continue to use are patented. This is a world-accepted and internationally agreed-upon system that we have to live with.

The patent flexibilities that we are now trying to implement work within that international global system. There is a way by which that transnational monopoly created by the patent can be shortened. I would just like to comment on one particular product that Dr. Biron mentioned. Norvasc is very expensive in the Philippines and is sold at about Php77.00, but in India, it's just about

Php8.00. This is because Norvasc was patented and has just been off-patent since June of this year. Because there's no competition, the price is high. In India, there is no patent, nor does it recognize patents, and as a result, it has a very robust drug industry. The smaller 5 mg Norvasc tablet is Php44.75. Three of our generic counterparts are priced at Php17.50 from Unilab, Php11 from Pascual, and Php11 from Lloyd Laboratories. However, the other problem is that there is no demand for the cheaper generics. The industry is demand-driven; manufacturers cannot produce what doctors do not want to prescribe even if patients need cheap medicines. The doctor wants and prescribes Norvasc, so drugstores ask for prescriptions for Norvasc. Even if we say there is an eleven-peso counterpart, it will still not be purchased and it will rot on our display shelves. So it's also within our power to demand and look for the cheaper and better products in the market, whether you are a consumer or a prescriber of these products.

It is really something that is very urgent, but nothing will happen even if we tell everyone that there are cheaper products out there in the market. In the Generics Act, for instance, there is a provision that the DOH should start an information and education drive to start promoting generics, but that never happened. I think we still retain the "colonial mentality" that anything imported is better. One cannot simply blame the doctors, because it's a patented monopoly. A certain medicine, for example, will be promoted to them constantly through marketing, and they will end up thinking that it is the best.

The practice is that if amlodipine besylate has become generic (off-patent), the company will just invent amlodipine tricylate. It will seem better, and of course, the good doctor will always look for what's better and prescribe that. It will again be expensive because it's patented, and the whole cycle starts again. The drugstores will now look for amlodipine tricylate instead of the amlodipine besylate that the generic companies are starting to produce. It's a very tricky market, and price regulation definitely will not be enough if there is not enough information.

If we strengthen BFAD, we can assure the medical practitioners that whatever generic products out there in the drugstores are as good as branded products. The price regulation board will be moot and academic. For now, our message is for all to try the generics; this is the first and most important intervention that we can do in our health care system.

I think we still retain the "colonial mentality" that anything imported is better.

**Dr. Gene Nisperos**

Community Medicine Development Foundation

The problem is as complex as it is chronic and longstanding. I would like to focus on three aspects of this whole issue. The first is urgency. I was only a first-year student in 1988 when the generics issue came about, and it was all about access to affordable, safe and efficacious medicine even then. Now, some 20 years after, we're talking about the same thing. But if the issue was urgent 20 years ago, surely it is even more urgent now. True enough, the only way we can come up with accessible, sustainable drugs available for our people is to come up with a national industry by supporting our national manufacturers, but that will not happen tomorrow or even next year. In the meantime, we cannot let our patients die while waiting for market forces to come into play. And this is why even stop-gap measures have a place right now.

Drug regulation is necessary. The Health Ministry did some drug price regulation during the time of Marcos. Even now with the DOH Pharma 50, if Ponstan is available in the market for PhP22, PITC can import it at a price of PhP3 to PhP5. So why are we selling it for PhP11? Because of Pharma 50.

We should not nitpick and figure out what is the cheapest price. If we can reduce prices by 70 to 80% and make an ordinary Filipino buy the most essential drugs, then I think we have already made a point. And if we can do that within the next three years, while our industry is strengthening itself through other forms of intervention, then maybe we have done our job. Parallel importation and compulsory licensing are still not the answer, but they will have their place now as far as sustainability is concerned. This is where government failure comes in.

We have the prestige of having one of the first drug policies to be articulated. This was in 1987, and yet up to now, 20 years later, we have no concrete programs, yet most of the bills are focused on programs. Only the Bayan Muna bill and Sen Loren Legarda's bill in the Senate actually focus on how to make the National Drug policy an institutionalized program with enough support. But I think it would also require the DOH or other line agencies from government to say that the National Drug Policy must be implemented in order to sustain whatever gains we have with short-term measures.

My second point is that we can only sustain these moves if we look at it not on a program or an intervention level, but in terms of policy and again, relating it to the national health care delivery program. And we segue into the last point:

relevance. At the end of the day, can we say that we have done something for the patient? Some people would like to say that yes, we have made drug prices cheaper and drugs more accessible. I would like to ask, if we are able to do these, will the condition of those who are ill become better? Have we actually improved the health care delivery system in this country by making cheaper medicines available at a specific time?

Other branches of government should also play a role. And I think that is where we, and not just the patients, are stakeholders. Ms. Buensuceso hit it right on the head when she said that we all have a role because our prescribing habits

are largely affected and influenced, not by what we learned in medical school, but by what we actually practice. Before acceptance, any college of medicine will ask you: why do you want to take up medicine? I am 101% sure that the answer is always, "I want to serve." I would like to believe that that is true for all of us. Being involved with the issue of accessible medicines is only one step; at the end of the day, I hope we can look not just at our patients but ourselves, and say that we as stakeholders have made our claim.

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**Open Forum**

In the Open Forum., the following points were raised:

- Dr. Sally Vios of the UP Department of Physiology shared the insights she gathered during a recent forum on the off-patent prospects of a drug nearing its patent expiry. According to the physicians in the forum, many Filipinos are still skeptical of the effectiveness of (cheaper) generic drugs, and many middle-class patients in particular prefer the more expensive and "assured" branded medicines. Dr. Vios then suggested that the academe participate in the quality assurance process, and agreed that it is important to educate our people about generics. She also urged the DOH and BFAD to work on strategies to improve their relationship with the medical community.
- Dr. So pointed out that information on generics is readily available, and that doctors have the

power to check on the quality of generic drugs. He then asked why there are no reports from doctors on any adverse reactions caused by generic drugs or on the inferiority of generic medicines. Secondly, he asserted that the BFAD process of determining the effectivity, efficacy and quality of drugs involves various consultations with doctors and is strictly monitored by the DOH. He gave assurance that BFAD is already undergoing its needed strengthening, and will vouch for the quality and safety of the products they register. He also mentioned that since the counterfeiting of drugs usually involves the more profitable ones, people should also be wary of branded medicines in this respect.

- Ms. Tisocki argued that if the capacity of the BFAD to assure quality of drugs is questioned, then the quality of brand products is not guaranteed as well. In stating that the quality of generics is an issue of perception, beliefs and evidence, she emphasized that the BFAD, including our doctors, needs to be more transparent and to publicly declare that, as indicated by evidence, generics are of good quality.
- Ms. Buensuceso and Dr. Delen de la Paz affirmed the importance of information and education. Ms. Buensuceso reported that based on evidence, generic users are comprised mostly of the more informed A and B market, while the more expensive branded ones are used by the C, D and E market. Dr. dela Paz, on the other hand, urged the DOH to take on the challenge of implementing the National Drug Policy and the Generics Act (particularly its education component), and for medical schools to also strengthen education about generics.
- Dr. Lourdes Capito, Chairperson of the UP Department of Obstetrics and Gynecology agreed with the earlier suggestion for the DOH and BFAD to work on a marketing strategy to improve their relationship with the medical community, and appealed for everyone to be united in solving once and for all the excessive cost of medicines in the country.

## Editorial (continued from page 1)

(PCPI); and Dr. Gene Alzona Nisperos, who has worked for a long time with the Community Medicine Development Foundation. Dr. Edeline De la Paz acted as moderator.

The UP-CIDS thanks UP Manila Chancellor Dr. Ramon Arcadio (represented by Vice-Chancellor Dr. Isidoro Sia) who, in his welcome remarks, expressed the urgent need to make quality medicines accessible, and urged everyone to take part in efforts towards this end. He stressed that it is particularly important to come up with constructive, practical solutions to address this critical problem.

UP-CIDS considers this topic of vital importance, considering that many Filipinos live a hand-to-mouth existence and face severe health problems. Despite these, medicines are often exorbitantly priced and unaffordable for ordinary people. We hope that policy makers will put aside political differences and center their attention instead on bringing down the prices of medicines through means such as the amendment of Republic Act No. 8293 (the Intellectual Property Code of the Philippines), particularly the provisions pertaining to non-patentable inventions (section 22), limitation of patent rights (section 72), use of inventions by government (section 74), and limitations on rights conferred on trademark owners in importation of medicines (section 147). The people who elected our Senators and Congresspersons expect nothing less from them.



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