Making medicines affordable: the role of innovation, competition and taxation

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I. Introduction

Societies develop because of continuing innovation of citizens. New innovations on old inventions as researchers discover new facts and understand the atoms and molecules of their subjects make the new inventions more effective and more powerful for the ever-expanding needs of the people. Thus, countries that have plenty of innovations in communication and information technology have the edge in modern gadgetries for its people. Countries that have more innovations in medicines, medical equipment and services, have citizens who are healthier and more productive economically.

On the other hand, societies can stagnate if there is over-regulation, monopolization, high taxation and price controls that slow down, if not discourage, innovation and new discoveries.

Having secure intellectual property rights (IPR) is among the best incentives for the composers, inventors and innovators of society. If their inventions are really useful and novel in supplying certain needs of the people, then the inventors can expect plenty of material and intellectual rewards, including enormous profit for their hard work.

Medicine innovation is an important area that must be undertaken by pharmaceutical companies if they want to remain relevant to the public, the physicians and patients in particular. Diseases evolve, so must be the medicines to eliminate or neutralize those new diseases. Even pests and insects in rice and other crops evolve, that is why agro-industrial companies or organic farming practitioners also innovate on new formulations or practices to neutralize those pests that can possibly wipe out a farmers' potential harvest. Even cellular phone manufacturers never cease to innovate new models, discovering new uses to previously underutilized features of other cell phone models.

Unfortunately, the public was made to accept that IPR through patents can be tweaked and skipped when public welfare and public health are at stake. The catchword "patients over patents" summarizes it. But IPR is an important matter that should be respected and

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strengthened, not weakened, if we want to encourage continuing innovation to have more effective medicines.

And when we talk of "cheaper/affordable" medicines, we are referring only to effective and good quality medicines. Because there are plenty of cheap medicines, generic drugs, that are already available in the country now. The only problem is that many of them are of dubious quality, do not pass bioequivalence testing for drug efficacy and safety, while some are outrightly counterfeit. In the observation of Dra. Suzette Lazo, faculty member at the Department of Pharmacology, UP College of Medicine, "not all generic drugs in the RP market have been tested; in fact only a very small minority has undergone this crucial testing because currently they are not required to do so."[2]

Thus, "cheap at all cost" is not the way to go. We are only after good quality, effective and safe medicines. So the big challenge is how to make these medicines more available and more affordable to our people, and a corollary challenge is how to eradicate the entry and sale of those cheap but ineffective, unsafe, if not fatal drugs.

II. The affordable or cheaper medicine bills in Congress

The Senate version (SB 1658, "Quality Affordable Medicines Act of 2007") and House version (HB 2844, "Cheaper Medicines Act of 2007") are now ready in the Bicameral conference committee meeting. In these two bills, various factors suspected of contributing to the high price of medicines have been identified. These are:

(1) The patent system in the existing Intellectual Property Code (IPC) of the Philippines favors multinational pharmaceutical companies and disadvantage generics manufacturers, thus preventing the production of more off-patent and generic versions which are cheaper than their branded counterparts.

(2) In cases of national health emergencies, there are no measures to regulate or control drug prices, especially those "essential medicines".

(3) Many local physicians are patronizing multinational pharmaceutical companies that produce branded and more expensive medicines, and patients have no choice but obey their physicians.

(4) The current Pharmacy Law does not democratize drug retailing to other outlets that are more convenient to patients.

[2] See the entire letter at Billy Esposo's article, http://www.chairwrecker.com/index_a.php?col=354

Chart below summarizes the identification of problems and proposed solutions by the current Congressional bills:

Why medicine prices are high	How to make medicines cheaper
1. Current patent system discourages production and marketing of otherwise off-patent medicines.	→ Amend the IPC, disallow patents for new uses, parallel importation, early working, government use.
2. No measures to regulate medicine prices in national health emergencies.	→ Empower the President to regulate drug prices; or create Drug Price Regulation Board.
3. Local physicians favor branded and expensive medicines.	→ Amend Generics Law: physicians should prescribe "generics only".
4. Drug retailing is limited to a few established drug stores	→ Amend Pharmacy Law: allow non-pharmacists in groceries and convenience stores to sell medicines.

The Senate version identifies only problem numbers 1 and 2 above and proposes said measures to address them, while the House version identifies all 4 and consequently proposes all those 4 measures.

This paper will argue that those 4 problems identified above miss the point, that even if a new law that contains all the 4 proposed measures is enacted, local prices of good quality medicines will remain high and unaffordable to many patients. What could be worse that can happen is that some of those measures will facilitate the manufacturing and distribution of cheap but counterfeit and ineffective medicines, which can endanger the health and lives of many patients.

Sections III to V below will discuss problems #1 to 4 above. Then section VI will discuss alternative measures that can make quality medicines be more available and affordable, and the last section will summarize the arguments.

III. Patent and medicine prices

There is a prevailing public thinking that patents, especially by multinational pharmaceutical companies, is the main culprit why the poor do not have access to quality medicines and health care. References to India of having medicines "a lot cheaper" than those in the Philippines are often heard. But in India, only 20 percent of its total health expenditures goes to drugs. And all of India's 74 "essential drugs" are already generic or

off-patent, so production is cheap. And yet, not all of these drugs are accessible to those who need them (Rozanski, 2007).

Expanding this example to the global market, World Health Organization (WHO) figures show that only 1 percent of WHO's "Essential Medicines" are patented, meaning 99 percent of them are already off-patent and their generic versions are already available. So if we follow the "patented = expensive" formulation, then 99 percent of those "essential medicines" should be affordable to the world's poor because they are already outside the patent system. How come that many poor people still cannot afford those off-patent drugs? The problem should lie somewhere.

Pushing further the "off-patent = cheap" line of thinking, and if only 1 percent (or even 5 or 10 percent) of essential medicines is the problem, what's the enthusiasm for altering the patent system for all medicines, so that drugs for skin whitening or eye-bag and wrinkles and wart removal and related medications be made "more affordable"?

The following are important provisions of both the Senate and House bills that effectively weaken the patent system for innovators and shift the favor to non-innovators and importers.

(1) Prohibiting the granting of new patents to discoveries of new form or new property of a known substance, new use for a known substance; or new use of a known process.

Innovation is a continuing process. Sometimes the full potential of a new or known substance can be discovered and patented, sometimes not, and realization of their new uses and curative properties come later. As medical researchers' understanding of existing diseases expand, medicine innovators' discovery of new uses of existing medicines and substances also expand

By not recognizing as inventive step to new uses of known substances, the policy can reduce the incentives for drug innovators and research companies for continuing innovation and dampen their interest to explore further uses and new curative capabilities of known substances. In addition, this may pressure drug innovators to price their patented products at even higher levels during patent period to recover the expensive costs of R&D and bringing the product to the market. This is because effective "profitability period" of patented medicines is only around 7-10 years out of the 20 years life of a patent.

Consider this analogy too: you are an agri-biotech company. You have developed a rice variety that can help its consumers boost their immunity against malaria, tuberculosis, and diarrheal diseases. It took you many years of painstaking R&D, employing some of the brightest and most dedicated (and most expensive) scientists and researchers in the world. Because of the long period of R&D including biological and clinical trials, the

“profitability period” under patent protection has become short. Naturally you should price your rice high, several times the price of ordinary rice, in order for you to recover the big expenses you spent and make some profit from your hard work.

With continuing innovation and exploration, you discovered that some substances in your rice variety can also boost a person’s immunity against dengue or hepatitis. Meaning the nutritional and medical capacity of your rice variety just keeps on improving. But government will disallow you to have another patent and exclusive right to the new uses of your rice variety (ie, additional immunity booster against dengue or hepatitis). How would you feel?

Most likely you will feel bad. Meanwhile, non-innovators and copy-caters come in to seize on the revolutionary uses and potentials of your rice variety, employ wonderful packaging and marketing schemes and sell at a lower price because they never spent huge amount of money in R&D and several years of trial and error phases. Some people will call this “more competition” among sellers of the miracle rice variety when in fact there was only one or a few innovators and several dozen copy-caters who just waited for the patent of the innovator/s to expire and jump on the bandwagon later.

Medicine prices under this scheme can come down, yes. But the incentives to innovators to develop a new round of revolutionary and “miracle” products that can improve public health in the long-run will be adversely affected. In the words again of Dra. Lazo, “Drug development and manufacture involve very complicated technical processes and inputs from various scientific disciplines ranging from chemistry, pharmacy, molecular biology, statistics and medicine. Some drug molecules are more difficult to formulate than others and history is fraught with tragedies involving additions of excipient substances to the principal drug molecule.”

Many people think that a patent life of drugs of 20 years are entirely "profit period". This is wrong. Once approved by a government patent office, the company that has submitted the innovation for examination must bring the new chemical entity through an extensive period of clinical trials. The experience in the US and Europe shows that regulatory hurdles in developing new medicines – clinical trials, post-approval marketing, packaging, etc. – have increased dramatically. Clinical trials alone now eat about 8 to 12 years of the 20 years patent life. In effect this significantly raises the costs to bring a medicine to market.

With few innovators wanting to risk under this scheme, the price of future effective medicines will be very high. Overall, we cannot expect “cheaper quality medicines” to be available later on.

<u>(2) Parallel importation allowed, importation and distribution of drugs bought cheaply abroad will be sold domestically even without the permission of the local patentee.</u>

This scheme looks cute and attractive, except that while the local patentee went through various patent and related regulations set by the government and paid various government taxes, the importers are exempted from these bureaucratic paper work and fees. In addition, parallel imports of drugs may have to be repackaged before distribution to local consumers to comply with local packaging and labeling requirements. Some unintended problems may arise such as incorrect or missing expiry dates, missing or wrong patient information leaflets.

The WHO estimates that about 30% of medicines supplied in developing countries are fake. India with more than 8,000 pharmaceutical companies, leads in counterfeit drug production, and has been estimated by WHO to have as much as 42% counterfeit rate. These fake drugs can easily find their way to the country via parallel importation.

In this light, one question that can be asked under this scheme is this: Supposing a patient develops bad allergies, if not died, after taking the imported medicines (maybe it's a fake or mislabeled or mis-stored or mishandled, that reduced or negated their effectiveness, if any) by non-patentees, who will be accountable? (a) the importer who brought the medicines, or (b) the foreign wholesaler, or (c) the foreign manufacturer, or (d) the local patentee who sells the same drugs domestically, or (e) the physician who gave the prescription, or (f) the government which allowed and encouraged the entire scheme?

Unfortunately, the answer to this question could not be determined from both the Senate and House versions. So if parallel importation only ensures "cheap medicines at all cost" without ensuring that those drugs that are brought in are effective and safe, then it does not really achieve its avowed goal of having "affordable quality medicines". Parallel importation therefore, is a bad scheme.

(3) Government use or appropriation of patented medicines or processes

Here, government or its authorized representative or subcontractor, can use or appropriate a medical invention without the consent of the patent owner, when "public interest, in particular, national security, nutrition, or health or the development of other sectors" so requires.

Consider this hypothetical case: Supposing there is AIDS or bird flu epidemic in the country, even if the cases are isolated but the government has ruled there is "national emergency". From among many pharmaceutical companies that sell anti-AIDS or anti-bird flu drugs, where many drugs can cure an average AIDS patient from 3 to 8 years, government will likely use or appropriate a drug, even if it's under patent, that can cure a patient in 1 to 2 years. If the manufacturer of that drug will protest since it has not fully recovered its sky-high cost of R&D and various clinical trials, it can be painted by the

state and the public not as a revolutionary innovator, but rather a “greedy capitalist” who does not understand the urgency of “patients over patents”.

One impact of this government use scheme like compulsory licensing, is that the patentee/s and drug innovator/s can lose money. Then other patients suffering other diseases will suffer as the affected pharmaceutical company/ies will seek to recoup revenue elsewhere, leading to higher prices across the board (Stevens, 2007).

IV. Price control will result in higher medicine prices

The Senate version (SB 1658) proposes that the President, upon the recommendation of the DOH and DTI Secretaries, can regulate or control medicine prices under certain circumstances for no specific period of time. The House version (HB 2844) proposes the creation of a new bureaucracy, the Drug Price Regulation Board.

Price control empowers some bright men and women in government bureaucracies to determine and dictate which products are useful to people and which prices of these products should be allowed and which ones should be controlled. But can price control lead to lower price and good health?

The usual suspects why medicine prices are high – the pharmaceutical companies’ high profits and their high advertising costs, not high and multiple taxes, high cost of R&D in medicine innovation, related costs – are often over-stated. When prices are controlled, producers who can possibly make some “miracle” products and medicines at sky-high costs will be discouraged from innovating and producing those products. It is unfair when government puts up uncontrolled taxes, fees and regulations, then control the price of commodities later. What can rein in prices is more competition among manufacturers and sellers, not more bureaucracies. Besides, the “ceiling price” set by a government price regulatory body is usually based at prices for older technologies, not the latest medicines and therapies that produce better health result for the patient.

Better allow price segmentation – different prices for different products or services for different people. This way, people from different economic status can be served. Poorer patients can have cheaper medicines, say anti-biotics to cure viral infection, and recover in 1 to 2 weeks. Middle class patients can have medium-priced medicines for the same disease and recover in 1 week or less. While richer patients can have expensive medicines but they can recover in 1 to 2 days. The drug manufacturer makes big profit from more powerful medicines consumed by richer patients, so that it can sell less powerful but nonetheless safe, effective and cheaper drugs to poorer patients.

”Price abuse” by certain companies is definitely a possibility if the economy is not competitive enough and if there is no level playing field. If a country allows only a few,

say a dozen, innovator companies to operate by virtue of dozens upon dozens of regulations and restrictions, and there are hundreds of copy-caters, then that country can be at the mercy of the few innovators.

V. Regulating patient-physician trust is counter-productive

When a person is sick, he sees a physician, not a mechanic or lawyer or congressman. The patient puts his trust on the physician, otherwise he would not see the latter. The physician listens to the patient's feelings, the symptoms, his other sickness if any (is he asthmatic, diabetic, with hypertension, has allergies, etc.). From a list of several dozen potential medicines on that particular disease, plus consideration of the patient's condition, the physician chooses one and gives a prescription to the patient, including dosage and frequency of taking the medicine.

One factor that the doctor considers in recommending a particular medicine, say brand C, is its proven effectiveness to other patients who have similar disease. Or he used to prescribe medicine brands A and B before, but they proved ineffective to his other patients; then he suspects the quality of brands D, E and F. So this time, he is prescribing brand C.

The state should not regulate this trust by the patient to his physician. It should also not regulate the physician's trust on particular medicines made by particular medicine innovators. Patient-physician trust is a matter of personal relationship. It can even be a matter of life and death for some cases. The same way, the physician-pharmaceutical manufacturer trust is a matter of personal relationship too.

The proposal to criminalize physicians who will prescribe certain brands to their patients can endanger patients' health. Since doctors will be required to prescribe "generics only", then patients will have to ask the non-physicians, could even be non-pharmacists, in the drug stores or super-markets or convenience stores or variety ("sari-sari") stores that sell medicines, which of several drugs in the same generic category is the cheapest. It looks cute, except that it could be risky for the patients. Physicians and pharmacists observe that different brands under one generic category are capable of causing different effects, delayed effects, or allergic reactions to different patients. That is why doctors often ask the symptoms and feelings of the patients, previous history of contracting that disease, any allergies or related diseases, before prescribing a particular brand.

One reason given why the "brands disallowed, generics only" intervention is proposed, is because doctors are suspected of being under the influence of big multinational pharmaceutical companies. This wholesale suspicion and distrust of physicians is unfair if not dangerous, and the danger will be transmitted to the patients. There is a possibility later that some drug manufacturers and importers will shift giving gifts and perks from physicians to drug store and convenience store staff so that the latter will endorse their products.

VI. Alternative schemes to lower medicine prices

Since the above congressional proposals are not likely to bring down the price of good quality and safe medicines over the long-term, below are some proposals that can achieve the stated goal of the 2 congressional bills.

1. Reduce if not abolish taxes on medicines

At present, medicines are slapped with (a) import tax of 5 percent and (b) value added tax of 12 percent. If these taxes are drastically cut by half at least, then medicine prices can immediately go down, so we will have cheaper quality medicines.

My older brother, our eldest in the family, died of prostate cancer nearly 2 year ago. His earlier hormonal chemo-theraphy cost around P25,000 per session excluding the physician's fee. Of that amount, government VAT collection alone was P3,000 per session. After about 8 sessions, he did not get well. He was later given chemo that cost P90,000 per treatment, of which government's VAT was nearly P11,000 per session. Excluded here are the import tax, corporate income tax, business permit and other taxes on pharmaceutical companies and drug stores that they pass on to patients.

Aside from import tax/duties and VAT, other indirect taxes and fees on medicines that are applied at least in other countries are port charge, inspection fee and pharmacy board fee. The total burden of combined taxes, charges and fees slapped on medicines, as a percent of retail medicine prices, can be as high as 55 percent (India), to 34 percent (Nigeria), 33 percent (Pakistan), 29 percent (Bangladesh), 28 percent (China), to 24 percent (Mexico). [See “Increasing access to medicines” by Ahmad, Cudjoe, Davie, Krause, Mitra, Oplas, et al, in Stevens, editor, Fighting the Diseases of Poverty, 2007]

The state and the officials that run it, including the legislators that created or retain the current taxes, should also bear their share of sacrifice if they are indeed sincere in having cheaper or affordable quality medicines to the people whom they promise to serve.

2. Reduce regulations that discourage the entry of more reliable pharmaceutical companies from other countries

Currently, there are about 45 multinational pharmaceutical companies in the country. But not all of them are competing in each product category. For instance, some companies do not have pediatric products, so they do not compete with other pharmaceutical firms that sell medicines for babies and children.

One time-proven mechanism to reduce the price of something is to have as many producers and innovators of good quality products and let them compete with each other. Let us have more competition among many innovators, not between a few innovators and

many copy-caters. Unfortunately, the 2 Congressional bills may result in discouraging the entry of more innovator companies, and instead attract more generics companies that do not engage in expensive and time-consuming R&D.

If existing government regulations – from local governments to the BIR and DTI to BFAD and DOH – are relaxed, plus proposed measures that weaken IPR for their products and innovation are shelved, then there should be more multinational pharma companies that can come in and pose additional competition to the incumbent firms here.
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In addition, it will also be a better alternative to parallel importation. If the (a) foreign manufacturer, (b) foreign wholesaler, (c) importer, and (d) local patentee, are the same, then identifying who will be accountable in cases of ineffective or unsafe and counterfeit drugs will be clearer and easier.

Lucky that a proposal by some groups and individuals to "nationalize" the pharmaceutical industry was not considered, although the provisions on "government use" and compulsory licensing is the closest thing to this proposal. Because using the market to drive investment will be efficient in providing the most drugs at the most sustainable prices to the people who most need them. Market-driven investment, whether in pharmaceutical multinational companies or partnership with local production enterprises, helps countries realize Ricardian gains from trade (Bate, 2008).

VII. Conclusion

Having "cheap at all cost" medicines is not the goal of the current Congressional bills. It is expanding the supply of effective medicines, even if they are initially expensive. Something like instead of a medicine that can remove a patient's viral infection (and the pain) in 1 to 2 weeks, go for a medicine that can do the same job in just 4 days or less. So one obvious solution is to expand the number of innovator companies, whether local or multinational, and let them compete with each other in giving us more effective medicines. It is competition, not over-regulation and high taxation (as done by many governments) that can bring down the price of anything.

Given the potential pernicious effects of the proposed provisions on medicine innovation and competition, not to mention the danger of facilitating the entry of more counterfeit medicines from abroad, it is possible that we do not have a new "cheaper medicines" law if the current form and provisions are retained. Instead, Congress should enact a law that will drastically cut the taxes on medicines, if not exempt medicines from at least import tax and VAT. Then work to relax the business environment to attract the entry of more reliable pharmaceutical companies, domestic or multinationals, that will add more competitive pressure in the local market for effective and safe medicines.

When the legislators who are in the frontline now telling the public that their legislation can indeed bring down the prices of medicines, run for the same or higher offices in 2010, they and the public will be in for a big disappointment. And the same legislators who were in the frontline enacting said legislation will be forced to look for another set of scapegoats since the public will ask them why prices of quality and safe medicines are still high.

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