Access to Medicines via Competition Not Protectionism and Price Regulation

Bienvenido “Nonoy” Oplas, Jr.

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Abstract

This paper will discuss a presentation made by a respected physician and health NGO leader in the country on “right to health”. Several topics were tackled there, from drug prices and price control, to drug availability, patent for new medicines, health insurance, among others. No heavy quantitative data analysis employed in this exercise. Rather, focus is on the philosophy of “health is a right” juxtaposed with “health is personal responsibility”. In addition, the wisdom or lack of it, in proposing that government should further stretch its resources and authority to develop the local pharmaceutical industry, is also discussed. The “law of unintended consequences” is discussed in relation to the people’s experience of the drug price control policy

The paper concludes that more than favoring one group of pharma companies and demonizing another, public policy should focus on expanding the people’s options in choosing the right mixture of medicines and healthcare that are appropriate for them given their existing resources and health needs.

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Introduction

The drug price control policy of the Department of Health (DOH) and the Office of the President (OP) is now six months old. Two programs under one policy are implemented. One scheme is the so-called "voluntary" price cut of 50 percent under the Government-Mediated Access Price (GMAP). Note that the acronym can also be read as (President) Gloria Macapagal Arroyo (GMA) Price.

The other scheme is the "mandatory" price cut of 50 percent under the President's Executive Order declaring Maximum Drug Retail Price (MDRP). It should be noted too, that this acronym MDRP is never ever used or mentioned, in the law (RA 9502) and its Implementing Rules and Regulations (IRR). Both documents specifically and explicitly used MRP (maximum retail price). The transition from MRP to MDRP, like the timing of declaration of the policy and the use of GMAP, is because of politics.

Within the past six months, the public and industry players – pharmaceutical companies, hospitals, drugstores, HMOs and PhilHealth – waited for some objective assessment by the government if the policy indeed achieved its goal: to make more people, especially the poor, have access to those deemed expensive medicines. If the answer is a clear Yes, then the program can be continued, if not expanded. If the answer is a clear No, then there is no reason why it is being continued.

But the DOH has not produced any study yet. Or perhaps it is done already but not yet made public. Other government health agencies have produced potshots of studies. Like PhilHealth's study on the impact of the policy on its drug reimbursement spending. Now the DOH is expanding the price control policy by asking the multinational pharma companies to produce another list of drugs that can be covered by "voluntary" price cut.

There is danger here with preoccupation with politics. First in forcing and coercing drug suppliers to bring down the price of their most saleable drugs. Those which "voluntarily" brought down their prices perfectly knew that there will be an EO to coerce them to bring down their price anyway. And second, in continuing and expanding the policy even in the absence of an objective assessment by the implementing agency, the DOH.

In the absence of such study by the DOH, some industry and NGO leaders have produced their own preliminary studies if the price control policy indeed achieved its goal or not.

MeTA Forum 2010

During the 3rd Medicines Transparency Alliance (MeTA) - Philippines Forum last January 26-27, 2010, one session tackled the impact of drug price control policy on the poor's access to essential medicines. I made a brief discussion of the panel, see "Uncontrolled passion for price control", http://www.thelobbyist.biz/perspectives/columns/back_to_personal_responsibility/824.html.

In summary, from the discussions by one health NGO leader, by one local pharma player, by some drugstore representatives, the policy is a failure in terms of improving the access of the poor to those deemed essential but expensive drugs. Only the rich and middle class, the non-target beneficiaries of the policy, benefited. The "law of unintended consequences" would very often sneak in to spoil a party.

A better solution, articulated by some speakers, is for government to procure those essential medicines and just give them free to the really poor. This makes sense. Subsidy to consumers, if it has to be done, is a function of the government, not private players.

UP Forum 2010

A week after the 3rd MeTA Forum, from February 1 to 5, 2010, there was a 5-days UP Forum, "Beyond 2010: Leadership for the Next Generation", held at the UP College of Law. See the program and presentation papers here, http://law.upd.edu.ph/new/index.php/the-news/153-beyond-2010-leadership-for-the-next-generation.

One of the topics or panels in the said forum was on "right to health". The presenters were Dr. Alberto Romualdez, former DOH Secretary and Chairman of MeTA-Philippines; Dr. Delen dela Paz, faculty member of the UP College of Medicine, as well as Executive Director of the Health Action Information Network (HAIN); and two other faculty members at the UP College of Medicine.

From here on, I will refer to Dr. dela Paz as simply "Delen" as she is a friend and her NGO is also a member of our Coalition for Health Advocacy and Transparency (CHAT), along with Minimal Government Thinkers and other health and research NGOs. Delen was one of the panel speakers on price control during the 3rd MeTA Forum. She is a respected academic, physician and NGO leader, and highly in-demand speaker on health issues in the Philippines. Thus, it is worth reading and analyzing her papers.

Delen's Paper

Delen's paper was entitled "Ensuring access to safe, affordable and quality essential medicines", 55 slides and generally comprehensive, http://law.upd.edu.ph/new/Academic-Congress-February-1-5,2010/Day-2/Session-4/Dr.%20Edelina%20Padilla-Dela%20Paz%20-%20Ensuring%20Access%20to%20Safe,%20Affordable%20and%20Quality%20Essential%20Medicines.pdf.

Readers will better appreciate this paper if they will also read Delen's presentation.

Let me now tackle several points in that paper.

1. Main message

Her main message is set at the beginning of her paper,

> "Health is a basic human right.
> Access to medicines is a basic part of primary health care."
>
> (From the International Covenant on Economic, Social and Cultural Rights, and the Declaration of Alma Ata)

Most people would not object to the "Health is a basic human right" declaration. In fact, others would extend it to also say, "Education is a basic human right", "Decent housing is a basic human right", "Cheap and abundant food is a basic human right", and so on.

The term "right" often implies and connotes entitlement. That is, regardless of the circumstances why one person or household or community has/have become sickly, they should be entitled to decent healthcare to be provided at a low cost if not free by the government, local or national.

And this can be a big source of public debate between those who demand entitlement and those who question it. For the latter, for every "right" there is a concomitant "responsibility." Thus, while people can demand that health care is their basic right, they are also expected to assume certain responsibilities about their bodies and their lifestyles. More on this in the succeeding discussions.

2. "Very high" medicine prices in the Philippines.

This is a subject that keeps repeating in many papers and discussions. One table given by Delen showed how many times Philippine drug prices are more expensive compared to an "International reference price" (IRP). Even the lowest price generic products in the Philippines were several times more expensive than the IRP:

> Diclofenac 50 mg, a pain reliever; 23x more expensive than IRP;
> Metronidazole 500 mg, an anti-biotic, 22x more expensive than IRP; and
> Omeprazole 20 mg, for peptic ulcer disease, 15x more expensive than IRP.

The IRP itself was not shown, from what country it was based or lifted, when the IRP was surveyed, and so on. So it is not possible to verify the figures. One will just wonder

how come that even the cheapest, the lowest-price generic in the Philippines can be 15x, 23x, higher than that IRP. Could the IRP been lifted from the cheapest drug in the world, instead of the average price for low- and medium-income countries in the world? If this is so, it should not be considered as an "international reference".

3. Cheaper but less available.

Cheaper does not mean that the product is also easily available. Delen showed a table on the availability of their chosen essential medicines.

> Medicines availability, 30 selected essential medicines:
>
> Private sector original brand products, 48.1 %
> Private sector generic products, 61.1%
> Public sector generic products, 31.0%
>
> Note: Botika ng Barangay outlets not included in public sector survey.
> Source: HAIN medicine prices and availability survey 2009

After bringing down the price of drugs so that the poor will be able to afford them, the drugs have become less available to them. So one may ask, what is the use of cheaper medicines if the poor can hardly find and use them?

It is possible that some traders bought the cheaper drugs from government outlets and resell in another place where there are no public sector drug outlets at a higher price. Or those traders were just hoarding the cheaper drugs and hoped that the government cannot sustain supplying the public sector outlets, then they can resell those drugs at a higher price. If it is the latter, then government should continue supplying those cheap drugs and let those hoarding traders stock up on unsold drugs, driving them to bankruptcy later on.

4. Drug sales as percent of GDP

There is one slide that contained wrong data, which Delen lifted from a GMANews.tv special report 2009:

> "Sixteen of the top 20 drug companies in the Philippines are multinational firms with combined sales of P58.23 billion in 2007 *nearly eight times more* than the Philippines' P7.39 billion GDP in 2008."

This is wrong. The Philippines' GDP in 2008 was P7.42 trillion, not billion. Thus, P58.23 billion was just 0.08 percent of GDP.

5. Patent, cost of R&D, and profit

This concept below is prevalent among people who are critical of multinational pharma companies, also in Delen's presentation:

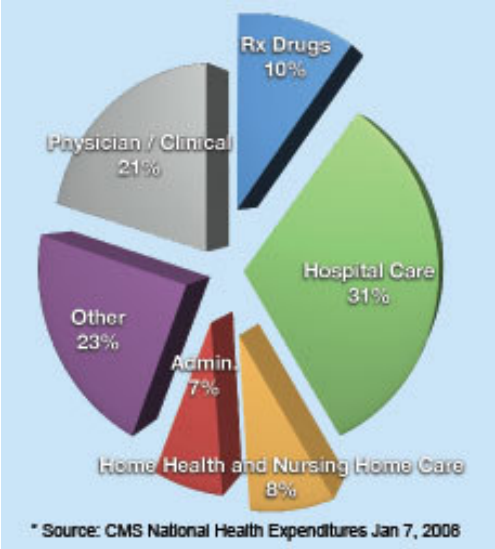
> "Patent essentially grants the patent holder a monopoly for 20 years…
> Industry estimates for R&D on each new drug range from $350-500 million,

while independent estimates range from $30-160 million… Revenues from a single patented drug can reach over $1 billion in a year."

Here's the data from the industry, specifically the Pharmaceutical Research and Manufacturers of America (PhRMA):

> "Only one of every 10,000 potential medicines investigated by America's research-based pharmaceutical companies makes it through the research and development pipeline and is approved for patient use by the United States Food and Drug Administration. Winning approval, on average, takes 15 years of research and development and costs over $800 million dollars." (Source: http://www.phrma.org/innovation)

In addition, prescription drugs in the US comprise just 1/10 or 10 percent of all healthcare spending. The bulk of health spending is shown in this chart,



Source: http://www.phrma.org/publications/fact_sheets/health_care_dollar

Pre-clinical trials and repeated clinical trials from the time a patent has been applied and granted, takes several years. Some multinationals put the "profit period" of only 8 to 10 years out of the 20 years patent life.

About "patent monopoly". A product monopoly is different from industry monopoly. Take this analogy.

When Toyota invented the Vios, Honda, Ford, Nissan, Hyundai, Benz, BMW, etc. can also invent and manufacture a car with similar features as Toyota's Vios, but they cannot call it as "Honda Vios" or "Ford Vios" and so on. Toyota already got the product monopoly and brand for Vios. The other manufacturers can call their new car with similar engine power and other features and call it as Honda "Vias" or Hyundai "Bios" or Ford "Gios" or whatever hypothetical name. There is no industry monopoly in developing a sedan say, for the "C/D" market, but there are lots of car model or product monopoly as each car manufacturer creates its own model.

The same goes for medicines. If 30 different pharmaceutical companies will invent a drug against a new strain of malaria or breast cancer, and assuming they all succeeded in coming up their own drugs, then there are 30 patent monopolies from 30 different drug manufacturers. There is nothing wrong with this as there is competition and hence, the people and their physicians have a wide range of choices to treat their patients, depending on the health condition and needs of the patient, depending on the household budget and/or health insurance coverage, and so on. The important point, again, is that there are choices and options available for the patients.

On "ever-greening" of patents, the Cheaper Medicines Law already has provisions against non-patentable inventions.

6. <u>On transfer pricing</u>

Delen wrote,

> "A study in Pakistan on transfer pricing found that parent companies export at rates as high as 300-700 times the price of the raw materials in the open market."

A monopolist that produces a product with very high demand will be tempted to over-price its product by 100 times, 1,000 times, or even more. Only when consumers find an alternative to its product, that said manufacturer will be forced by competition, not by government regulation, to bring down its price. Otherwise, it will simply over-price itself to bankruptcy.

Such rate of transfer pricing, assuming that the figures are correct, are possible only for a monopolistic structure. It is important therefore, to demonopolize all sub-sectors or sub-sections of the economy and the various industries, to avoid the ugly aspects of transfer pricing.

7. <u>On drug advertising</u>

This is also a recurring issue when people discuss "irrational use" of drugs. Delen observed that

> "Big, aggressive campaigns virtually ensure market dominance and brand premium. In a four week monitoring period, of the 10 most frequently aired drug-related TV ads, 8 were from a single company (Unilab)."

Unilab, indeed, is the biggest spender on drug advertising – in tv, radio, newspaper, billboards, etc.

For many people who do not have private health insurance, or who have no physician-friends, or are far from government health clinics, drug ads have become the substitute "physician". So when they have a headache or cough, they go straight to a drugstore and buy what is most heavily advertised on radio, tv or in billboards.

8. The Botika ng Barangay (BnB)

Delen mentioned the European Commission (EC) 2009 study on functionality, monitoring and cost of the BnB program:

> "Low turnover and lack of up to date prescription registers indicate not only that economic viability is often still low but that there is also little control and information on dispensing behavior."

This is related to the discussion above on low availability of cheaper drugs in public sector outlets. The above assessment is not good considering that there are thousands of BnB around the country.

9. Stunted local industry

> "Almost wholly dependent on imports—95% of raw materials are imported. No manufacturer of active pharmaceutical ingredients in the country, and research and development of innovations very limited."

While this is true, it should not lead us to suggest that the national government should pump money and resources to develop the local pharmaceutical industry. Public transportation (from tricycles to buses) is very important for the people. There is no government program with government funding to develop local motorcycle, jeep, car or bus manufacturing industry, and yet we are fine. Courtesy of competition among various producers and suppliers of those vehicles, and competition among various bus lines, various taxis, various tricycles, and so on.

Towards the end of Delen's presentation, she outlined several "Challenges". I will outline here those challenges she made that I agree with, and those that I do not agree. First, my agreement with her.

a. Drug price control policy did not benefit the poor

> MDRP "Does not make medicines more affordable for the poor. Determining a 'fair price' based on actual cost is very difficult due to the opaque drug industry."

The price control policy benefited the middle class and the rich, not the poor. The rich who used to buy a brand of amlodipine at P44 per tablet before, would be paying only P22 after the policy. But the poor who patronize the cheaper generic amlodipine at P8 would not shift to a still expensive P22 per tablet.

b. Provide medicines to the poor for free

This is a more sensible proposal than continued drug price control policy. Subsidizing consumers, should it be done, is a function of government, not the industry players.

Of course, moral hazards problem should be minimized and controlled too. Put some cap, say "free up to xx amount" per year per patient. This will limit irrational drug use

(people get drugs even for minor reason because they are heavily advertised and drugs are free anyway), limit fiscal bleeding of the government, and limit corruption in government procurement of drugs.

The standard caution apply. That government procured medicines should be properly stored and monitored for temperature control, clean storage area, and adulterated and expired medicines should be disposed, not dispensed to poor patients.

Another alternative is for government not to procure medicines itself, but enter into an arrangement with some drugstores nearby for some discounts. Poor patients will get the medicines at those drugstores for free, say up to a certain amount, then government will pay the drugstores later.

The advantage of this arrangement is that government need not hire and train personnel for medicine storage, warehousing, monitoring and dispensing. Also set aside space for such drug storage.

c. Remove VAT on medicines

Another sensible proposal. Government is responsible for expensive medicines by at least 12 percent of the retail price of drugs. If this is removed, then that should be a significant "price discount" for the patients.

This move will require legislation. Hence, this should be one of the priority legislative advocacies by various consumer groups and health NGOs when the next Congress convenes this coming July.

d. Government to "promote good health and prevention of illness, through the attainment of optimal economic and social conditions, such that the people will need only the minimum amount of medicines."

When people have stable jobs, they will have steady income source so they can eat better, live in cleaner environment, have better education. This alone is a good preventive measure so that people will have better health.

Below are some weak proposals in the paper that I do not agree with. In the earlier discussion above (items 1 to 9), I already discussed my disagreement with some of them.

i. Questionable definition of "self-reliance" in drug production

> "Government must support local drug manufacturers through tax exemptions, technical assistance, loans, discounts or exemptions from regulatory fees. Develop local capacity to produce raw materials, eventually including active pharmaceutical ingredients. Production of certain drug types can eventually be restricted to local manufacturers only."

This is putting the government too cozy with local pharma companies. When we propose the abolition of VAT on medicines, we refer to all medicines, whether these are domestically produced by local or multinational pharma companies, or imported from

abroad. There is no favoritism and protectionism there. Now when we propose that tax exemptions and regulatory fee exemptions should apply only to local pharma companies while the burden of such heavy taxes and fees should apply only to multinationals, that's imposing double standards and two type of laws, one for the locals, one for the foreigners.

It is not good to demonize and over-regulate the existing foreign companies in the country. The world is full of so many multinationals based in different countries – from the US, Europe, Japan, India, Korea, China, etc. – that can be invited to come into the country to put up additional competition to existing multinationals.

So instead of sending bad signals that foreign companies will be treated like enemies here while local companies will be given all sorts of friendly policies, better invite the top pharma companies from abroad to come in. India has more than 22,000 pharma companies, from the backyard type to the biggest. Let us invite their 10 biggest local pharma companies to come. Also the 10 biggest local pharma companies in China, in Pakistan, and so on.

The end goal of public health policies should be to empower the patients to have more choices in finding medicines and healthcare that respond to their needs and budget, not to favor local companies and demonize foreign companies. Whether such medicines and healthcare are provided by local or foreign companies, it does not make much difference. People do not complain that there is no prestigious Philippine-made car or van. What is important for them is that they can choose from among the Japanese, Korean, American, European, Indian, Chinese, and other cars that are available in the country.

2. Government support for R&D of herbal medicines

> "Increase research on curative potential of herbal medicines. Strongly promote the use of scientifically validated herbal medicine."

This suggestion will further spread government resources for healthcare more thinly. Bulk procurement of essential medicines to be given away for free to the poor, giving the poor free hospitalization and diagnostic tests, etc. will already cost big amount of money. Also expanding the personnel and equipment of the Food and Drugs Administration (FDA) to monitor for registration and safety of more drugs, more skin whiteners and breast enhancers, more food and sauces, more drinks, that are brought into the country will also cost a big amount of money.

If the government will spend further in drugs R&D, then advocacies and promotion of herbal and drugs, that's spreading resources too thinly. Other departments (education, agriculture, agrarian reform, military, police, etc.) will also not allow that their budget will be slashed so that government can spend more on health.

Let the existing local pharma companies, or new group of investors, develop and market those scientifically-validated herbal drugs. There will be buyers for those drugs and hence, there will be profit to be made.

Concluding Notes

Delen's paper is comprehensive enough and it has shown a number of important data that deal with medicine availability, irrational drug use, among others. Bravo to that.

But what is lacking in the perspectives shared by Delen, is that healthcare is both a right and a responsibility. In particular, healthcare is first and foremost, a personal and parental responsibility. People should not over-drink, over-smoke, over-eat, over-fight, over-sit in sedentary lifestyle. People should not live in dirty places and should observe basic personal hygiene like washing hands carefully before eating.

Health inequity results not just because of income and social inequity, but also because of people's unequal inputs in taking care of their body. A poor person who does not over-drink and over-smoke and observe personal hygiene in his daily life will have a better health outcome than a rich person who over-drinks, over-smokes, over-eats and over-sits. The former, even without a private health insurance, all other things being equal, will less likely develop lifestyle-related diseases like hypertension, high cholesterol and obesity.

For people living in dirty places like under the bridge or beside dirty and stagnant creeks, pulling them out from such places that are sure to generate various forms of diseases and move them to a cleaner environment, will probably be the "best medicine" that government can do.

Of course children of poor households who have been exposed to dirty places for several years will more likely have weaker lungs and other internal organs. This is where government can possibly put its limited resources – giving essential medicines for free to these patients.

Public policy on health or any other sector should be guided by empowering patients and the public to have more choices, more options. It is not advisable that politicians and health officials will come in anytime to coerce drug price control or coerce compulsory licensing (CL).

The damage to the country's investment environment as a result of no-time table drug price control policy should be big by now. Many revolutionary drugs, new disease-killer drugs that are available in other countries around the world, may no longer be introduced and sold in the Philippines. The most adversely affected then will be the poor and some middle class. The rich, the politicians and government administrators who pushed the price confiscation policy, will have the means and network to buy such drugs from abroad. But they are not the target beneficiaries of all those public policies.

The "law of unintended consequences" is kicking in, again.