

PHAP ADVOCACY POSITION ON HOUSE BILL NO. 2844

House Bill No. 2844 (“HB 2844”), providing for a “Cheaper Medicines Act of 2007” seeks to promote the “right to health of the people” by providing to them “safe and cheaper medicines”. To accomplish this objective, HB 2488 proposes to introduce amendments to the following laws:

1. the Intellectual Property Code (Republic Act No. 8293);
2. the Generics Acts of 1988 (Republic Act No. 6675); and
3. the Pharmacy Law (Republic Act No. 5921).

HB 2844, like its counterpart bill in the Senate, also seeks to establish government price control mechanisms to regulate or control the prices of drugs and medicines “when the public interest so requires” even in the absence of any declared national health emergency.

At the outset, the Pharmaceutical and Healthcare Association of the Philippines (“PHAP”) respectfully states that it agrees fully with the laudable intention of the House of Representatives to promote the people’s right to health and that it supports the government’s continuing efforts to improve the general healthcare situation of the country. This is a legitimate aspiration and PHAP is doing its share in promoting this objective. Having said that, PHAP believes that the proposed amendments to the aforementioned laws will not automatically translate to improvements in healthcare in the Philippines. In fact, PHAP submits that there are very serious safety and health welfare issues that could arise with the enactment of the proposed legislation for which the Philippines, as of this time, is ill-equipped to handle for lack of proper infrastructure and adequate administrative mechanisms. Furthermore, PHAP is compelled to comment on certain provisions of HB 2844 as being discriminatory and violative of the due process and equal protection clauses of the Constitution, in addition to being inconsistent with some of the international treaty obligations of the Philippines.

For a thorough assessment of the issues concerning the proposed legislation and its impact on health research and development and on the overall healthcare situation in the country, PHAP therefore respectfully submits this position paper and requests the Honorable Members of the House of Representatives to consider the following points during the deliberations of HB 2844:

I.
THE PROPOSED AMENDMENTS TO
THE INTELLECTUAL PROPERTY CODE

HB 2844 includes amendments to the Intellectual Property Code (“IP Code”) which seek to, among other things, exclude certain types of pharmaceutical inventions from patent protection, expand the concept of experimental use, allow early working of pharmaceutical patents, institutionalize parallel importation of drugs and medicines covered by existing patents and trademark registrations, and liberalize use of pharmaceutical inventions by the government. It appears to be a basic assumption of HB 2844 that introducing these amendments will create an environment that will lower the prices of medicine and will ensure availability and accessibility of essential medicines to the Filipino public, thereby improving the healthcare system in the country.

PHAP respectfully submits that the proposed IP Code amendments will weaken the patent system, but that doing so will NOT translate into real, tangible, and long term improvements in the country’s healthcare system. Much reference has been made to the lower prices of medicines in India, but a closer look at the Indian healthcare system has to be made in order to assess the advisability of adopting some aspects of the Indian model into the Philippines’ healthcare and IP system.

According to Indian economist and think tank expert Bibek Debroy, the problem lies not in patents but in the lack of adequate safe drinking water, sanitation, sewage treatment, and immunization, which is mainly attributable to state failure and bad governance. This is none the more concretely exemplified than in India, which has both an inadequate healthcare system and a weak patent system. India is often held up as a model of healthcare delivery in Asian countries such as the Philippines, but reality speaks otherwise. India is still **failing** on healthcare. Some parts of India have worse rates of infant mortality, maternal mortality and immunization than much poorer parts of sub-Saharan Africa or neighboring Bangladesh. In many parts of India, simple technology such as sewerage is simply not available: an estimated 400,000 Indian children under five die each year from medieval diseases such as preventable diarrhea. According to Debroy, the corruption-riddled health system in India¹ and the government-maintained bureaucratic barriers that prevent the development of medical insurance in the country are also to blame. Debroy concludes that if the developing world is to significantly improve its health profile, problems relating to availability of safe drinking water, sanitation, sewage treatment and immunization will have to be primarily addressed.²

¹ According to a 2005 report by Transparency International, the health system is the most corrupt service sector in India.

² See Bibek Debroy, “Patents help the sick, poor globally”, The China Post, October 11, 2007, <http://www.chinapost.com.tw/editorial/2007/10/11/126199/Patents-help.htm>

The Philippines appears to be similarly situated. According to a recent report, the ten (10) leading causes of morbidity in the Philippines in 2005 are as follows:³

1. Acute Lower Respiratory Infections and Pneumonia
2. Acute Watery Diarrhea
3. Malaria
4. Typhoid & Paratyphoid Fever
5. Schistosomiasis
6. Measles
7. Acute Bloody Diarrhea
8. Dengue Hemorrhagic Fever
9. Hepatitis
10. Leprosy

Notably, most of these diseases such as acute watery diarrhea, malaria, typhoid fever, schistosomiasis⁴, acute bloody diarrhea, dengue fever, and certain types of hepatitis⁵, are attributable to the lack of safe drinking water, poor sanitation and lack of sewerage treatment systems. While access to medicines for these diseases draws support, the government must realize that the general state of health of the Filipinos, especially those in depressed rural areas or in city slums, will not be significantly improved unless these other problems are addressed. The notion that health is merely the absence of disease is a fallacy. This clearly illustrates the need for a comprehensive approach to healthcare in the Philippines.

PHAP respectfully directs the attention of the Honorable Congressmen to the following public policy arguments concerning the perceived invalidity of the following proposed amendments to the IP Code:

³ Report by Prof. Emmanuel A. Leyco, Director, Health Management Programs, Asian Institute of Management.

⁴ Schistosomiasis is a chronic illness that results from infection of the blood with a parasitic flatworm (schistosome). It causes debilitation and causes liver and intestinal damage. It is most commonly found in Asia, Africa, and South America, **especially in areas with water that is contaminated with fresh water snails, which contain the parasite.**

From <http://en.wikipedia.org/wiki/Schistosomiasis>.

⁵ Hepatitis A or infectious jaundice is caused by a [picornavirus](http://en.wikipedia.org/wiki/Picornavirus). It is transmitted by the [orofecal](http://en.wikipedia.org/wiki/Orfecal) route, transmitted to humans through methods such as contaminated food. **Hepatitis A can be spread through** personal contact, consumption of raw sea food or **drinking contaminated water**. This occurs primarily in third world countries. Infected people excrete the hepatitis A virus with their faeces two weeks before and one week after the appearance of jaundice. The time between the infection and the start of the illness can run from 15 to 45 days, and approximately 15% of sufferers may experience relapsing symptoms from six months to a year following initial diagnosis. From <http://en.wikipedia.org/wiki/Hepatitis>.

1. HB 2844 seeks to amend Sec. 22 of the IP Code by excluding certain types of pharmaceutical inventions from patent protection.

HB 2844 proposes to treat the following inventions as non-patentable subject matter and, thus, incapable of being granted Philippine patents:

- (i) In case of drugs or medicines, mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance;
- (ii) In case of drugs or medicines, mere discovery of any new property or new use for a known substance; or
- (iii) In case of drugs or medicines, mere discovery of a new use of a known process, unless such known process results in a new product that employs at least one new reactant.⁶

The above amendment violates the equal protection clause of the Philippine Constitution as it creates an invalid and unreasonable distinction between new forms or uses of chemicals in the pharmaceutical field as compared to those of chemicals in the industrial or agricultural fields. There are no distinguishing characteristics between pharmaceutical chemicals and agro-industrial chemicals that would warrant their different treatment under our patent law, awarding patent protection to innovators in one field while withholding it from the other. Researchers and innovators in the pharmaceutical field have as much right to protect their inventions involving new uses, new forms, or new properties of known substances as researchers and innovators in the agro-industrial field, or for any other field of technology for that matter, provided that their inventions are new, non-obvious, and industrially-applicable. Both groups of innovators must therefore be treated similarly.

Moreover, the above amendment appears to be inconsistent with paragraph 1, Article 27, Section 5 of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), which provides:

Subject to the provisions of paragraphs 2 and 3 below, **patents shall be available for any inventions**, whether products or processes, **in all fields of technology**, provided they are new, involve an inventive-step and are capable of industrial application.

⁶ The above amendment is similar to Section 3(d) of the Patents Acts of India, as amended in 2005. Despite this provision in India's patent law, however, as noted earlier, India is still failing on healthcare: an estimated 400,000 Indian children under five die each year from medieval diseases such as preventable diarrhea.

Subject to paragraph 4 of Article 65⁷, paragraph 8 of Article 70⁸ and paragraph 3⁹ of this Article, **patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.** (Emphasis supplied.)

Article 27(1), Section 5 of the TRIPS clearly requires that patents be made available without discrimination with respect to the field of technology. HB 2844, by providing that patent protection will not be granted to inventions relating to new uses, forms, or properties of known pharmaceutical substances or new uses

⁷ Paragraph 4 of Article 65 does not apply to the Philippines since the Philippines has granted protection to pharmaceutical inventions even prior to its accession to the TRIPS (see old patent law, Republic Act 165). Paragraph 4 of Article 65 states:

“4. To the extent that a developing country Member is obliged by this Agreement to extend product patent protection to areas of technology not so protectable in its territory on the general date of application of this Agreement for that Member, as defined in paragraph 2, it may delay the application of the provisions on product patents of Section 5 of Part II to such areas of technology for an additional period of five years.”

⁸ Paragraph 8 of Article 70 does not apply to the Philippines since the Philippines has made available patent protection for pharmaceutical and agricultural chemical products even prior to its accession to the TRIPS (see old patent law, Republic Act 165). Paragraph 8 of Article 70 states:

“8. Where a Member does not make available as of the date of entry into force of the WTO Agreement patent protection for pharmaceutical and agricultural chemical products commensurate with its obligations under Article 27, that Member shall:

- (i) notwithstanding the provisions of Part VI, provide as from the date of entry into force of the WTO Agreement a means by which applications for patents for such inventions can be filed;
- (ii) apply to these applications, as of the date of application of this Agreement, the criteria for patentability as laid down in this Agreement as if those criteria were being applied on the date of filing in that Member or, where priority is available and claimed, the priority date of the application; and
- (iii) provide patent protection in accordance with this Agreement as from the grant of the patent and for the remainder of the patent term, counted from the filing date in accordance with Article 33 of this Agreement, for those of these applications that meet the criteria for protection referred to in subparagraph (b).

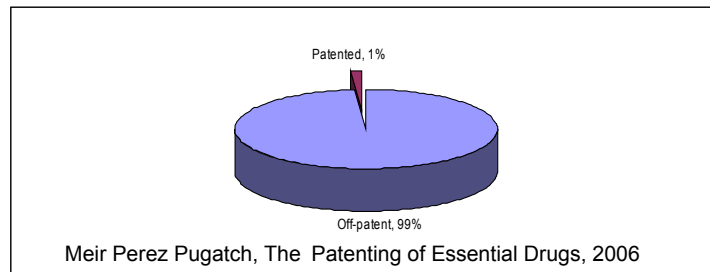
⁹ Paragraph 3 of Article 27 states:

- “Members may also exclude from patentability:
 - (a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals;
 - (b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement.”

The HB 2844 proposal to amend Section 22 of the IP Code may exclude some new forms and uses of drugs and medicines that are patentable under TRIPS Article 27 and do not fall within these permissible exceptions to patentability. As long as new forms, uses or compounds of drugs – including salts of known chemical entities or combinations of known chemical entities (which can also be inventions) meet the basic requirements

of known processes, clearly discriminates against these types of pharmaceutical inventions, contrary to the provision of the TRIPS to which the Philippines is a signatory. While it is true that the DOHA Declaration on the TRIPS Agreement and Public Health affirms the right of WTO Members to interpret and implement the provisions of the TRIPS in a manner supportive of the Members' rights to protect public health and, in particular, to promote access to medicines for all,¹⁰ the DOHA Declaration also: 1) recognizes "that intellectual property protection is important for the development of new medicines;¹¹ 2) requires the Members in recognizing the flexibilities under the TRIPS Agreement to maintain the commitments in the TRIPS Agreement;¹² and 3) does not sanction discrimination between different fields of technology on what is patentable subject matter in the granting of patents.

Furthermore, **there appears to be no direct and clear correlation between the non-granting of patents to these types of inventions and access to medicines, specifically essential drugs.** In any case, as reported in 2006, only 1% of the drugs in the World Health Organization's List of Essential Drugs are patented drugs; 99% of the world's essential drugs are off-patented.



for patentability under Article 27, they must be patentable, unless they are specifically excluded under Article 27. Article 27(3)(a) permits exclusions from patentability of therapeutic or surgical methods used with humans or animals. This exclusion does not apply to a new form of a known substance itself. In addition, there are new uses of a known substance that do not constitute a therapeutic or surgical method. (However, this exclusion of patentability can apply to a new use of a known substance if it can be considered as a therapeutic method). This exclusion would also not apply to the use of a known process if the language of this proposal is intended to cover the processes of making drugs and medicines, as it appears to do so. Article 27(3)(b) permits exclusions from patentability of plants and animals other than microorganisms which would also appear unlikely to be applicable to new forms, uses and compounds of drugs and medicines. At the very least, the specific exclusions from patentability under Article 27 do not apply either to a new form of a known substance related to drugs and medicines, certain new uses of a known substance or, to the use of a known process making drugs and medicines and so, such inventions must be patentable under Article 27(1).

¹⁰ Paragraph 4, Doha Declaration on the TRIPS Agreements and Public Health, adopted on 14 November 2001.

¹¹ Paragraph 3, Doha Declaration on the TRIPS Agreements and Public Health, adopted on 14 November 2001.

¹² Paragraph 5, Doha Declaration on the TRIPS Agreements and Public Health, adopted on 14 November 2001.

Thus, any changes to the patent law will not have a significant impact on the access to medicines in the market. It thus appears that the present interference by government is not reasonably necessary to the attainment of the objective of the proposed legislation.

The legislature may not, under the guise of protecting the public interest, arbitrarily interfere with private business, or impose unusual and unnecessary restrictions upon lawful occupations.¹³ The exercise of the State's sovereign police power must be justified by the existence and concurrence of the following factors:

- (1) the interests of the public generally, as distinguished from those of a particular class, require such interference; and
- (2) the means are reasonably necessary for the accomplishment of the purpose, and not unduly oppressive upon individuals.¹⁴

While it can be advocated that the interest of the general public, and not merely those of a particular class, will be served by HB 2844's purpose of creating "an environment that will lower the prices of medicine," it has to be noted nonetheless that the **means employed** by the proposed bill (*i.e.*, to exclude certain types of pharmaceutical inventions from patent protection) does not appear to be relevant for the accomplishment of its stated purpose considering that 99% of the world's essential drugs are outside the patent system. On the other hand, the proposed changes will adversely impact the patent rights of innovators with respect to drugs that are considered "non-essential" by the World Health Organization. In this regard, the interference on the rights of innovators does not now seem justified: the interference is not for a public purpose and the means employed is not only unnecessary but unduly oppressive to innovators as well.

It may be presumed that the sponsors of HB 2844, in introducing amendments to Art. 22 of the IP Code, may have been motivated by the idea of preventing or minimizing the proliferation of "evergreening"¹⁵ patents. It should be noted that under our current patent law and practice, "mere discoveries" are already excluded from patent protection.¹⁶ Thus, patents are not granted to "mere discoveries", unless these discoveries are of a technical character, *i.e.*, they provide a technical solution to a problem in a particular field of technology, which

¹³ Fabie v. City of Manila, 21 Phil. 486; Balacuit vs. Court of First Instance of Agusan del Norte, G.R. No. L-38429, June 30, 1988

¹⁴ U. S. vs. Toribio, G.R. 5060, January 26, 1910, 15 Phil. 85; U.S. vs. Villareal, G.R. No. 9480, November 13, 1914; Fabie v. City of Manila, 21 Phil. 486; Balacuit vs. Court of First Instance of Agusan del Norte, G.R. No. L-38429, June 30, 1988.

¹⁵ Evergreening, in one common form, occurs when the brand-name manufacturer obtains separate 20-year patents on multiple attributes of a single product. These patents can cover everything from aspects of the manufacturing process to tablet colour, or even a chemical produced by the body when the drug is ingested and metabolised by the patient. Downloaded from <http://www.egagenerics.com/gen-evergrn.htm> (last visited October 8, 2007)

¹⁶ Section 22.1, IP Code.

solution is new, inventive, and industrially applicable. (E.g., a technical problem in the pharmaceutical industry could relate to the low thermal stability of a certain drug. The discovery through research efforts of a new crystal form or salt of such drug with the same therapeutic activity as the original form of the drug but which has a significantly improved thermal stability, such that it is able to withstand warmer storage conditions or have a significantly longer shelf-life, presents a “technical solution” to a problem, which should be patentable.)

It has to be stressed that our present patent law already provides adequate safeguards against double patenting and evergreening. Firstly, our IP Code expressly provides that patent protection can only be granted to inventions that are new, non-obvious and industrially applicable.¹⁷ Hence, inventions that are already covered by existing patents can no longer be protected in subsequent patents, for then such inventions would lack novelty. Secondly, the IP Code expressly prohibits the filing of parallel applications involving the same subject matter, one for a patent and the other for a utility model registration, whether simultaneously or consecutively.¹⁸ Moreover, the IP Code provides procedural safeguards against double patenting, prior to grant and even after grant of a patent. After publication of a patent application, any person may submit written “third party observations” to the Intellectual Property Office concerning the patentability of the invention.¹⁹ These written observations will be considered by the patent examiner in deciding whether or not to grant a patent on a particular invention. Even after a patent has been granted, any interested person may petition to cancel the patent or any claim thereof, or parts of the claim, on any of the following grounds under Section 61 of the IP Code:

- (a) That what is claimed as the invention is not new or patentable;
- (b) That the patent does not disclose the invention in a manner sufficiently clear and complete for it to be carried out by any person skilled in the art; or
- (c) That the patent is contrary to public order or morality.²⁰

Considering the presence of these safeguards in our patent law, there seems to be no reasonable justification for the outright exclusion from patent protection of the pharmaceutical inventions mentioned in the HB 2844.

PHAP believes that there is no fundamental reason why pharmaceutical inventions of the types enumerated in the proposed amendment should be less capable of patent protection than any other. The amount of work involved in making the invention, the potential benefit to the public, and the potential commercial importance may all be as great for the inventions mentioned in the

¹⁷ Section 21, IP Code.

¹⁸ Section 111, IP Code.

¹⁹ Section 47, IP Code

²⁰ Section 61, IP Code.

HB 2844 as for the invention of a new chemical entity having a pharmaceutical utility.²¹

PHAP believes that the amendments to Section 22 unduly limits the extent of patent protection that may be obtained by drug innovators and research companies and will give way to an environment which may discourage them from exploring further uses and new treatment modalities of known substances. This is inimical to drug research efforts.

New discoveries result in new and more effective treatment modalities, including those involving already known substances. Drug research companies should be adequately rewarded for their efforts, not just for discovering and developing “new” substances but further improving or discovering new uses of known substances as well. The justification for the patent system is that it provides an incentive for investment in **new ideas**, without which technological development would be much slower and more difficult.²² It should be remembered that patents and intellectual properties have driven the discovery of cures and better ways to deal with health concerns. In the Philippines, centuries of patent-backed discoveries and innovations have helped raise the average life expectancy from 50 to 71 years over the last 50 years. There is therefore considerable incentive to encourage innovations in the pharmaceutical field, knowing what they have contributed in the past and what they potentially might contribute today and in the future.

PHAP Recommendation: The proposed amendment to Section 22 should be removed completely because:

- It appears to be violative of the equal protection clause of the Constitution.
- It is likely to be found inconsistent with patentability and non-discrimination requirements under Article 27(1) of the TRIPS Agreement.
- Removing the phrase “...in the case of drugs and medicines...” to make the amended section compliant with the non-discrimination requirement in Article 27.1 of TRIPS, and thus expanding the scope of non-patentability of new forms and uses to all fields of technology is likely to have a significant negative impact on domestic Philippine industrial and agricultural chemical manufacturers. It would likewise place a chill on the incentive for innovation in other sectors and technologies.

²¹ P. Grubb, *Patents for Chemicals, Pharmaceuticals and Biotechnology*, Oxford University Press, 1999, p. 218

²² P. Grubb, *Patents for Chemicals, Pharmaceuticals and Biotechnology*, Oxford University Press, 1999, p. 14

2. HB 2844 seeks to amend Sec. 61 of the IP Code by providing an additional ground for the cancellation of patents, i.e., “in the case of drugs or medicines”, the person to whom the patent was issued was not the true and actual inventor or did not derive his rights from the true and actual inventor.

The above amendment appears to violate the equal protection clause of the Philippine Constitution and is inconsistent with paragraph 1, Article 27, Section 5 of the TRIPS since it discriminates against drugs and medicines, as explained above.

Moreover, the proposal appears to be misplaced in Sec. 61. It should be stressed that Section 61 (together with Sections 62 to 66) pertains to administrative cancellations of patents. The new ground sought to be included in Sec. 61 refers to a matter (issue on inventorship or ownership of the patent) on which the Intellectual Property Office, under the IP Code, has no authority or jurisdiction to hear or decide. Jurisdiction to decide issues or controversies involving ownership of an invention is vested in the regular courts, as can be gleaned from Sections 67 and 68 of the IP Code, which read as follows:

Sec. 67. Patent Application by Persons Not Having the Right to a Patent.

- 67.1. If a person referred to in Section 29 other than the applicant, **is declared by final court order or decision as having the right to the patent**, such person may, within three (3) months after the decision has become final: (a) Prosecute the application as his own application in place of the applicant; (b) File a new patent application in respect of the same invention; (c) Request that the application be refused; or (d) Seek cancellation of the patent, if one has already been issued.

Sec. 68. Remedies of the True and Actual Inventor. - If a person, who was deprived of the patent without his consent or through fraud **is declared by final court order or decision to be the true and actual inventor**, the court shall order for his substitution as patentee, or at the option of the true inventor, cancel the patent, and award actual and other damages in his favor if warranted by the circumstances. [Emphasis supplied.]

Unlike the previous patent law, Republic Act No. 165, which used the “first-to-invent system” and which authorized the then Bureau of Patents, Trademarks, and Technology Transfer to take cognizance of controversies known as “interference proceedings” and determine priority of invention (*i.e.*, issue of inventorship/ownership) between two patent applicants claiming the same invention, the current Intellectual Property Code has done away with such system and has adopted the “first-to-file” system whereby the person/applicant who first files a patent application for the invention is presumed to be the legitimate owner of that invention and patent, unless the court declares

otherwise. Under the present provisions of the IP Code, therefore, the Intellectual Property Office has no jurisdiction or authority to resolve issues pertaining to the ownership of a patent or an invention covered by a patent. As can be noted, the current grounds for cancellation of a patent found in Section 61 of the IP Code (*i.e.*, invention claimed is not new or patentable; disclosure of invention is insufficient and unclear; patent is contrary to public order or morality) are all within the technical competence of the IPO. The provision of an additional ground in Sec. 61 is thus misplaced.

PHAP Recommendation: The proposed amendment to Section 61 should be removed completely because:

- It appears to be violative of the equal protection clause of the Constitution.
- It is likely to be found inconsistent with Article 27(1) of the TRIPS.
- The additional ground for cancellation of patents appears to be in conflict with the first-to-file patent granting system adopted by the IP Code. Moreover, the Intellectual Property Office has no jurisdiction to resolve issues of ownership of patents as jurisdiction over the same is with the regular courts.

3. HB 2844 seeks to amend Sec. 72.1 of the IP Code by adopting the so called “international exhaustion of rights” as regards drugs and medicines, thereby allowing parallel importation of drugs covered by existing Philippine patents.

The proposed amendment to Section 72.1 appears to be inconsistent with the equal protection clause of our Constitution and with the non-discrimination requirement under Article 27(1) of the TRIPS since it discriminates against patents on drugs and medicines.

Parallel importation of drugs and medicines, whether patented or not, is objectionable because it raises serious safety and other concerns, specifically:

- (i) Uncontrolled parallel importation may compromise safety and potency of medicines and may adversely affect patient safety.

Parallel imports of drugs and medicines may need to be repackaged before distribution to consumers in the Philippines to comply with local labeling and packaging regulations. As such, it would not be surprising that some unintended consequences may arise such as incorrect or missing product expiry dates, lack

of correspondence between the batch numbers on the boxes and those on the blister packs, and missing or erroneous patient information leaflets.²³

Erroneous patient information leaflets and anomalous practices of re-packaging often lead to a lack of patient compliance. Many patients receiving the wrong packaging and inappropriate information simply fail to take the doses that they should. The following actual situations provide a snapshot of how parallel imports and incorrect labeling could compromise patient safety:

- Zoladex is an injectable medicine for prostate cancers. A pack was displayed that had come in as a parallel import. The packaging was in Spanish with a very small overlabel with English on it. The English translation said that the drug was to be used either in cancer or premenstrual problems resulting in pain. Actually, the drug is indicated for prostate cancer or the treatment of a severe disease called endometriosis, not premenstrual problems. The translation also said that the drug can be injected either into the abdomen or into the chest. In reality, it was not intended by the drug manufacturer for injecting into the chest.²⁴
- There was a lipid lowering agent made by Zeneca. In this case, there should have been a patient information leaflet in English going into the pack. The product had been imported from Holland, and still had all its labeling in Dutch.²⁵
- Another product was shown as tablets in a blister pack. Patients needed to pop out the tablets in the right order. The French days were translated into English in the wrong order.²⁶

It is also possible that pharmaceutical products imported through parallel trade might deteriorate through incorrect handling, or become contaminated or adulterated during their repacking or storage.²⁷ All PHAP member innovator companies have active pharmacovigilance programs throughout the life of their pharmaceutical products. PHAP member companies employ systems that enable them to track the products they manufacture and distribute, initiate product recalls and monitor reporting of and liability for adverse events. This is not the case with parallel imports. In fact, it is not even clear under the proposed legislation as to who shall be responsible for providing pharmacovigilance with

²³ See S. Pollard et al., *The Human Cost of Pharmaceutical Price Controls in Europe: a Case for Reform*, p. 16

²⁴ S. Pollard et al., *The Human Cost of Pharmaceutical Price Controls in Europe: a Case for Reform*, p. 18-19 citing transcripts of examination of witnesses found in U.K. Committee on Trade and Industry, Eighth Report, July 1999

²⁵ *Ibid.*

²⁶ *Ibid.*

²⁷ S. Pollard et al., *The Human Cost of Pharmaceutical Price Controls in Europe: a Case for Reform*, p. 16

respect to parallel imported drugs and medicines: should it be the parallel importer, the foreign wholesaler, the foreign manufacturer, the local patentee, or the government? Surely, the local patentee or licensee cannot be saddled with such responsibility considering that it has no control over the parallel imports and that such importation was done without its consent in the first place.

- (ii) Uncontrolled parallel importation will lead to proliferation of substandard medicines and counterfeit drugs

WHO statistics indicate that 30% of medicines supplied in developing countries are fake. India leads in counterfeit drug production, with as much as 35% of the world production originating there, and has been estimated by WHO to have as much as 42% counterfeit rate. These counterfeit drugs can easily find their way to the Philippines, if not here already.

Counterfeiting incidents have caused hundreds of deaths in the developing world. According to WHO, thousands of patients around the world have lost their lives because they took counterfeit medicines:

- During a meningitis epidemic in Niger, more than 50,000 people were inoculated with fake vaccines, resulting in 2,500 deaths.
- 89 children died in Haiti and 30 infants died in India due to the consumption of a paracetamol cough syrup prepared with diethylene glycol (a toxic chemical used in antifreeze).
- In Cambodia, at least 30 people died after taking counterfeit anti-malarials.
- In China, in the year 2001 alone, 192,000 people died because of counterfeit drugs.²⁸

Opening Philippine borders to parallel imports of drugs could increase the flow of counterfeit drugs into the Philippines, potentially harming hundreds of thousands of Filipino patients. Presently, there are no adequate infrastructure and effective monitoring systems to monitor parallel imports and prevent entry of counterfeit drugs into the country.

- (iii) Parallel importation will detract from developing local industry.

Parallel imports will now be in direct competition with pharmaceutical products manufactured or imported into the Philippines under existing Philippine patents. This may adversely affect the financial viability of local drug companies in the long run.

²⁸ News article, "PHAP Worried Counterfeit Drugs May Become Rampant", Manila Bulletin, May 2, 2007.

PHAP Recommendation: PHAP respectfully urges the Honorable Congressmen to reconsider the institutionalization of parallel importation until such time as the Philippines is able to establish adequate infrastructure and adopt effective mechanisms to monitor parallel imports and effectively control entry of counterfeit drugs.

4. HB 2844 seeks to amend Section 72.3 of the IP Code by expanding the concept of non-infringing use of pharmaceutical patents and Section 72.4 by allowing early working of patents on drugs and medicines.

HB 2844 seeks to amend Section 72.3 of the IP Code by expanding the scope of non-infringing use with respect to experimental use of patented inventions so as to include experimental use for (i) scientific or educational purposes; and (ii) such other activities directly related to such scientific or educational experimental use; or (iii) non-commercial use that does not unreasonably conflict with a normal exploitation of the patent and does not unreasonably prejudice the legitimate interests of the patent owner, taking into account the legitimate interests of such third parties. HB 2844 also introduces a “new” Section 72.4, which is analogous to the Bolar exemptions²⁹ in U.S. patent law.

As pointed out above, since the proposed amendments to Section 72.3 only applies “in the case of drugs and medicines”, they discriminate against patents on drugs and medicines and their owners and are thus in conflict with the equal protection clause of our Constitution as well as with Article 27(1) of the TRIPS. To be compliant with the non-discrimination provisions of the Constitution and with TRIPS, the phrase “in the case of drugs and medicines” should be deleted.

The “new” Section 72.4 appears to require the Intellectual Property Office to promulgate rules for protecting submitted data related to acts covered by the Bolar-type exception from **unfair commercial use** in a manner consistent with

²⁹ The term “Bolar exemptions” became known after a U.S. case involving experimental use of a patented drug decided by the Court of Appeals for the Federal Circuit and the subsequent enactment of the Hatch/Waxman Act overruling such court decision. In *Roche Products Inc. vs. Bolar Pharmaceutical Co. Inc.*, 221 USPQ 937 (CAFC 1984), Bolar had been making preparations to introduce in the USA a generic version of a Roche pharmaceutical product as soon as Roche’s patent expired, and had carried out clinical testing of its product while the patent was still in force, relying on earlier case law which held that experimental use did not amount to infringement. The Court held that the exception for experimental use must be construed narrowly; experimentation for pure speculative research was not infringement, but as soon as the experiments were directed to a clear commercial goal, infringement occurred. However with the enactment of the Hatch/Waxman Act of 1984, the U.S. Congress overruled the decision in *Roche vs. Bolar*, specifying that it was not infringement to make, use, or sell a patent invention “**solely for uses reasonably related to the development and submission of information under a Federal law which regulate the manufacture, use, or sale of drugs.**” [Emphasis supplied.]

Article 39(3) of the TRIPS, but does not protect such data from **disclosure** as required by Article 39(3) of the TRIPS.

Article 39(3) of the TRIPS specifically states:

Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. **In addition, Members shall protect such data against disclosure**, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use. [Emphasis supplied.]

Thus, rules should be promulgated not only to protect undisclosed test data or other information from **unfair commercial use**, but also from **disclosure**, subject to certain conditions under Article 39(3) of the TRIPS.

The implementation of a Bolar-type exception to patent infringement must ensure that an adequate and effective system is in place to prevent infringing copies of patented inventions from entering into the Philippine market. Moreover, the implementation of this exception should also ensure that the Bolar provisions will be used only for research and development purposes and not for manufacturing and stockpiling generic versions of the drug prior to the patent expiry.

Lastly, it can be noted that HB 2844 does not fix the period within which interested parties can commence early working of patented inventions for the purpose of obtaining regulatory approvals with the relevant government agencies. So, in order to avoid objections that this feature constitutes undue delegation of legislative powers, a definite period should be fixed by Congress in order to make the bill constitutionally compliant. The determination of such period should not be left to the discretion of administrative agencies.

PHAP Recommendation: The phrase “in the case of drugs and medicines” found in the proposed Section 72.3 should be deleted because:

- It appears to be violative of the equal protection clause of the Constitution.
- It is likely to be found inconsistent with Article 27(1) of the TRIPS.

The proviso found in new Section 72.4 should be amended to read as follows:

“...Provided, that, in order to protect the data submitted by the original patent holder from unfair commercial use AND DISCLOSURE, the Intellectual Property Office, in consultation with the appropriate government agencies, shall issue appropriate rules and regulations to fully implement and comply with Article 39.3 of the TRIPS Agreements not later than...”

Moreover, Congress should set the period within which interested parties can commence “early working” of patents (e.g. 2 years or 3 years prior to patent expiry). Congress should likewise set standards and safeguards to ensure that the implementation of the Bolar exemptions will not lead to the entry of infringing copies of patented inventions into the Philippine market nor allow manufacturing and stockpiling of generic versions of the patent inventions prior to the patent expiry.

5. HB 2844 also seeks to amend Section 74.1 of the IP Code by providing additional grounds authorizing use of a patented invention by the Government or third person authorized by the Government even without agreement of the patent owner. HB 2844 also introduces a new Section 74.3 and further amends Sections 93, 94, and 95 on the granting of compulsory licenses.

The proposed amendments to Section 74.1, 74.3, 93, 94 and 95 pertain only to “drugs and medicines”. These amendments are discriminatory in nature and are therefore inconsistent with the equal protection clause of our Constitution as well as with the non-discrimination requirement under Article 27(1) of the TRIPS.

Section 10 of HB 2844 seeks to amend Section 93 of the IP Code by including an additional ground for the grant of a compulsory license: “Where the demand for patented drugs or medicines is not being met to an adequate extent and on reasonable terms, as determined by the Department of Health.” A similar provision is included as Section 74.1(E) on “Use of the Invention by the Government”. Under new Section 74.3 in relation to Section 74.1(E), it is **not** clear whether, in invoking this additional ground (“Where the demand for patented drugs or medicines is not being met to an adequate extent and on reasonable terms, as determined by the Department of Health.”), the government is required to first obtain authorization from the patent owner on reasonable commercial terms and conditions over a reasonable period of time as required by Article 31 of the TRIPS. To the extent that it does not require the government to do so, the provision conflicts with Article 31 of the TRIPS.

Under Article 31 of the TRIPS, the **GENERAL RULE** is that use by the government or parties authorized by the government of a patented invention without the authorization of the patent holder may only be allowed if, “prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time“. This requirement may only be waived:

- (i) when there is a national emergency or other circumstances of extreme urgency;
- (ii) in cases of public non-commercial use; or
- (iii) when the use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive.

The additional ground provided in Section 74.1 (“Where the demand for patented drugs or medicines is not being met to an adequate extent and on reasonable terms, as determined by the Department of Health.”) is not among the exceptions stated in Article 31. Thus, any use of the patented invention by the government or any third party based on this ground must first comply with the requirement to seek authorization from the patentee on reasonable commercial terms and conditions.

The proposed amendments to Section 74.1 and 74.3 appear to be overbroad and ambiguous as it gives the Department of Health a wide latitude of discretion in determining the applicability of the additional ground allowing use of the invention by the government without authorization from the patent holder. Moreover, the amendment to Section 94.2 in relation to Section 93.6, waiving the normal 3-4 year waiting period for filing a petition for compulsory license based on this new ground raises serious transparency concerns as well. No adequate standards or guidelines are set out to define when or how “the demand for the patented article in the Philippines is not being met to an adequate extent and on reasonable terms”.

6. Section 11 of HB 2844 proposes the inclusion of a new Section 93-A, implementing paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health.

The proposed amendment appears to be inconsistent with Art. 31 of the TRIPS as it allows the issuance of a compulsory license without requiring the proposed user to “make efforts to obtain authorization from the right holder on reasonable commercial terms and conditions “. The proposed amendment also does not provide for other safeguards set out Art. 31 of the TRIPS, such as the provision for judicial review.

7. HB 2844 also seeks to amend Section 147 of the IP Code by providing that no trademark infringement occurs with respect to the sale or importation of drugs and medicines under amended Section 72.1 (allowing parallel importation of patented drugs) and to the sale or importation of off-patent drugs and medicines, provided that the trademarks are genuine.

“Parallel imports” of genuine trademarked goods or “gray goods” refers to a fact pattern in which someone other than the Philippine trademark owner or designated exclusive Philippine importer buys genuine trademarked goods outside the Philippines and imports them for sale in the Philippines in competition with the Philippine trademark owner or exclusive importer.³⁰

Parallel importation runs counter to the territoriality principle of trademark protection. A Philippine trademark owner or licensee has a goodwill in the Philippines separate and distinct from the goodwill of the foreign producer. Purchasers of parallel imports are likely to be confused because they assume that the goods have a manufacturer’s warranty, which they do not. Even if there were no possibility of confusion as to source of origin when a product is “genuine”, there might still be a confusion as to sponsorship when a “genuine” product is manufactured by a foreign manufacturer but distributed in the Philippines without the authorization of, and in competition with, the Philippine trademark owner or authorized trademark user.³¹ The Philippine trademark owner or authorized trademark user has a property right in its trademark, the deprivation of which, without due process or adequate compensation, is proscribed by no less than our Constitution.

³⁰ See 4 McCarthy on Trademarks and Unfair Competition §29:46 (1996)

³¹ See 4 McCarthy on Trademarks and Unfair Competition §29:51 (1996)

II. THE PROPOSED DRUG PRICE REGULATION PROVISIONS

The government price control regime proposed under Sections 16 through 18 of HB 2844 raises serious transparency and accountability issues. The bill creates a Drug Price Regulation Board, which basically has broad and unfettered authority to determine “fair” prices, set maximum prices and take measures to lower the prices for any drug or medicine without any apparent judicial review mechanism.

Further, HB 2844 specifically excludes representatives from pharmaceutical companies, pharmacists, physicians and hospitals from serving on the Drug Price Regulation Board. Thus, the proposed legislation appears to deny pharmaceutical manufacturers and health care providers with any mechanism to provide input or have equal representation with other interested parties in government drug pricing determinations.

Article 3.9 of the General Agreement on Tariffs and Trade (GATT), to which the Philippines is a party, requires that any Member which applies maximum price control measures (such as the proposal in HB 2844) must “take account the interests of exporting contracting parties with a view to avoiding the fullest practicable extent such prejudicial effects”. Therefore, the pharmaceutical manufacturing industry and health care providers must have the proper mechanism to ensure adequate representation and opportunities to provide input in any government drug price regulation process.

There are serious transparency and accountability concerns about price regulation determinations by the Board, given the vagueness of terms such as “fair” price, and “any other measures” to “effectively” reduce the cost of drugs, the lack of any criteria for such determinations, and the apparent lack of any judicial review mechanisms.

Under Section I.C of the U.S. – Philippine Trade and Investment Framework Agreement (TIFA), the Philippine Government affirmed “the importance of promoting a more open, transparent and predictable environment for international trade and investment.”

Therefore, if a drug pricing regulation system is to be established, the Philippine Government must honor its commitment to transparency and enter into a meaningful dialogue with the pharmaceutical manufacturing industry (and health care providers) to ensure adequate and effective transparency for the drug pricing determination process. PHAP respectfully urges the Honorable Congressmen to establish appropriate mechanisms for accountability, due process and judicial review for any price regulation determinations by the government.

In addition, there are basic considerations against the establishment of government price control mechanisms of drugs and medicines.

The great French economist, Frederic Bastiat, in his essay “What is Seen and What is not Seen” noted that human actions are attended by two kinds of consequence. The first are the intended consequences. These are highly visible, and usually beneficial. The second are the unintended consequences. These are generally invisible and often deeply harmful.³²

1. The unintended and harmful consequences of the proposed legislation may outweigh in the long run the intended beneficial consequences of the bill.

Government control of the price of drugs and medicines has both “seen” and “unseen” consequences as shown by prior experience. The readily apparent or “seen” consequence of instituting price controls is that it will hold down medical costs, thereby *theoretically* allowing wider access to treatment by the public. Its “unseen consequences” are to diminish the range of treatments available in the long term and to increase medical costs.

Why does government price control diminish the range of treatments available in the long term? Because price control leads to conditions which dampen innovation.

It takes substantial resources for a pharmaceutical company to bring a new product to the market but it is allowed only a limited time to recover developmental costs. It is estimated that, it takes about US\$800 million to bring a single new product to the market, taking into account research and development (R&D) and regulatory compliance costs. Many of these costs are incurred whether or not the product is actually put onto the market. For every one new product put in the market, 5,000 chemical formulations do not make it there. Once on the market, a new product only has a few years of exclusivity – before the patent protection expires, or before a competitor releases a similar or improved version of the product into the market. As one third party source has opined, pharmaceutical companies therefore *have to* adopt different pricing strategies to enable them to recover the costs of their R&D and other development costs.³³

Price control has been shown, in the long term, to reduce the number of new products introduced to the market because price control leads to conditions which stifle investment in R&D. By pushing prices of drugs towards a certain ceiling regardless of the amount of investment needed to bring each new product on the market – profits (and therefore the ability to recoup R&D investment) of

³² S. Pollard, S. Gabb, and A. Mingardi, The Human Cost of Pharmaceutical Price Control in Europe: A Case for Reform

³³ Ibid.

producers of innovative drugs inevitably fall. Price control has been shown to take away the incentive to invest in new research to develop new products.³⁴

The European experience provides a concrete example of how price control has limited the profitability of European pharmaceutical companies in their home markets and has crippled those companies' willingness and ability to spend on development of new products:

- Until the 1980's continental Europe had a dynamic and innovative pharmaceutical sector. With the exception of Britain, all these sectors are now in decline because of price control mechanisms adopted in varying forms across Europe. In 1990, pharmaceutical companies spent \$7.2 billion on research in Europe, and \$4.9 billion in the U.S. By 2000, spending in Europe had risen to \$16.9 billion, but in the U.S. to \$23.7 billion. Put another way, Europe's share of world pharmaceutical research had fallen from 32% to 22%.³⁵
- Germany, in particular, has long had a distinguished record in pharmaceutical invention – from morphine and heroin to aspirin. But German investment in pharmaceutical research has been declining in recent years. Germany held 16% of the world's new drug patents in the years 1980 to 1985, but that significant share in innovation dropped **BY HALF** to 8% in the years 1986 to 1990. In France today, there is almost no innovation – yet France in 1970 was third in the world in terms of new patents for pharmaceutical products.³⁶

Why does government price control increase medical costs in the long term?
Because price control, whether direct or indirect, has been shown to stifle competition and keep prices artificially high.

As one author has explained, the price of a product is a powerful conveyor of information, both from the seller to the buyer, and from the buyer to the seller. If buyers are resistant to a price point offered by a seller, the seller has to lower it to a point that buyers are willing to pay. If there isn't such a price point, the seller will have to change its business plan or fail. When government attempts to dictate prices through price controls, it distorts this flow of information. The controlled price does not allow market feedback that will benefit both the sellers and the buyers.³⁷

³⁴ See M. Matthews, A Primer on Price Controls, IPI Ideas: Innovative Insights on Today's Policy Debates, No. 38, February 2006.

³⁵ S. Pollard, S. Gabb, and A. Mingardi, The Human Cost of Pharmaceutical Price Control in Europe: A Case for Reform

³⁶ Ibid.

³⁷ M. Matthews, A Primer on Price Controls, IPI Ideas: Innovative Insights on Today's Policy Debates, No. 38, February 2006.

When governments decide to impose price controls, they have usually selected a level that is lower than the top price that the seller would like to sell at, but higher than the lowest price the seller may be willing to sell at. Thus, consumers must pay a higher price than they would otherwise have had to pay if prices were free to move following market forces. The lack of competition – restraint of trade – has resulted in higher prices for everyone.

2. Determination of price ceilings for drugs and medicines by the government involves a complex process, which may pose additional administrative burdens to our already overburdened government agencies. Moreover, government-imposed price ceilings give bureaucrats the power to make decisions that should be made by qualified medical practitioners.

The setting of price ceilings by the government, as it is practiced in other countries, usually entails categorization of individual medicines into groups of products deemed to have similar indications or are comparable and interchangeable in terms of therapeutic effect. A single “ceiling price” is then presumably set for all the medicines in a particular group.

When medications are grouped together for the purpose of determining government price ceilings, an important assumption is made that these drugs will provide the same benefits to all patients. This assumption ignores the fact that not all patients are the same; each individual reacts differently to medications in terms of tolerability and effectiveness. In addition the ceiling price is usually based at the level of prices for older technologies rather than the latest medicines, despite substantial evidence that newer therapies produce a better health outcome for the patient. In this regard, pricing relies on definitions of interchangeability and equivalence that are based on interpretative bureaucratic judgments rather than on established protocols of the medical profession.

3. Health and Economic Incentives Must Combine

Access to medicines should be a paramount goal of healthcare systems. But government price controls, in general, and price ceilings, in particular, have shown little impact in improving access to medicines.

China, projected to be the seventh largest pharmaceutical market by 2009 is already experiencing accelerated growth in drug spending that has made Chinese health policy makers worried.

A study performed in two Chinese hospitals on containing drug expenditures suggested that “utilization, more than price, determined drug expenditures.” According to the study, containment of drug expenditures could be better

achieved through “improved rational use of drugs and correcting the present incentive structure for hospitals and drug prescribers.”³⁸

In another study that looked at the potential impact of price controls on drugs in the United States³⁹, it was found that “pharmaceutical price regulation has a negative effect on the firm (research and development) investment.” The study suggested that drug price regulation could lead to R&D investment decline between 36% and 47% and concluded that such policy could “impose a very high cost in terms of foregone medical innovation.”

The two studies point out that access to medicines cannot be facilitated by purely employing a drug price regulation without foregoing long-term and unintended costs.

To achieve a broader access to medicines, a more comprehensive approach should be undertaken. Such policy must strike a delicate balance between broader access and rational use of quality medicines without diluting the incentives that stimulate research and development of life saving drugs.

³⁸ [Meng Q, Cheng G, Silver L, Sun X, Rehnberg C, Tomson G.](#), *The impact of China's retail drug price control policy on hospital expenditures: a case study in two Shandong hospitals* Center for Health Management and Policy, Shandong University, http://www.ncbi.nlm.nih.gov/sites/entrez?cmd=Retrieve&db=PubMed&list_uids=15840634&dopt=AbstractPlus

³⁹ Vernon, Jordan *Drug Research and Price Controls*, University of Pennsylvania, <http://www.cato.org/pubs/regulation/regv25n4/v25n4-7.pdf>

II. **THE PROPOSED AMENDMENTS TO THE GENERICS ACT OF 1988**

Mandatory Generics Prescribing

HB 2844 mandates medical practitioners, under pain of suspension and/or payment of fine, to write prescriptions using the generic name unless “the prescribed drug or medicine is an innovator, pioneer, or ethical drug that has no known counterpart or substitute here or abroad.” The proposal effectively restricts a medical practitioner’s discretion to prescribe a brand name.

It is well known that the trade mark offers an underlying assurance to the consumer on the origin and quality of the product and on reliability of the manufacturer. From an industrial perspective, a trade mark is a fundamental asset for a company, irrespective of which goods are concerned. In the pharmaceutical domain, the brand is particularly important since both doctors (for prescription products) and patients (for both prescription and over-the-counter products) rely on the quality of the manufacturers behind that brand. In most cases they would not want to change their therapeutic choice if the concerned drug is effective.⁴⁰

Establishing a mandatory generic prescribing system could have potential adverse effects. The main concerns for the patients, the doctors, and the pharmaceutical industry may be summed up as follows

From the patients’ and the doctors’ perspective:

A) Abandonment of the doctor’s treatment choice:

Non-mandatory generics prescribing at least allows the doctor to exercise his freedom of treatment choice. But if the system becomes mandatory, doctors have no more freedom to choose and prescribe what they believe to be the most appropriate medicine for their patients. Patients may respond differently to a similar but not identical product. This is particularly true for biological medicinal products (e.g. Erythropoietin, G-CSF, Insulin): the immunogenic response might be quite different from patient to patient.

According to a noted health practitioner, “It is a time honored dictum in medicine that no two patients are the same given the same disease”.⁴¹ Physicians should have the liberty to prescribe based on their assessment of the best treatment for their patient. Physicians, by schooling, training, and practical experience, are

⁴⁰ EFPIA Position Paper on Generic Prescription, 2006

⁴¹ Homobono B. Callega, M.D., “In Defense of the Physician”, p. 24, © 1999.

committed to toward preserving human life and giving it the best quality of care. Any physician in the pursuit of saving the life of his patient should be given the fullest freedom and no law of men should ever abridge this freedom.⁴²

B) Potential risks for the patients:

With compulsory generics prescribing, doctors are prevented from using a brand. This may prejudice the doctor-patient relationship since the doctor will no longer have control over the specific medicinal product which will be delivered to the patient. This could result in a loss of confidence from the patient, in particular from older patients with chronic diseases, as well as confusion arising from frequent change of medicine. Elderly patients who are used to taking several medicines together (polymedication) would have to remember several generic names most of which are not easily distinguishable from each other. In case of need, such patients might not be able to say exactly which drugs they have taken in the last 24 hours. Moreover, when a product is made of 2 or more active principles, the possibility to remember (and even pronounce) the generic name is further reduced. Instead of increasing the security of the patients, all these factors could play a negative role on patient compliance.

C) Doctor's liability in the area of prescription/ Pharmacovigilance issues:

A compulsory generic name prescribing system raises questions in terms of liability: who will be liable if doctor voluntarily and knowingly prescribes by generics and a patient suffers a severe adverse reaction: manufacturer, doctor, pharmacist, authorities? Clearly the doctor's liability is likely to be modified and that would introduce a high level of uncertainty, to the detriment of public health interests. In addition, the effectiveness of the applicable pharmacovigilance system might be at risk, particularly if one considers that only a few generic manufacturers maintain an efficient internal network of pharmacovigilance experts⁴³.

From the industry's perspective:

D) A measure which distorts competition:

Compulsory generics prescribing would effectively prevent competition at the physician's level between manufacturers of branded off-patent and generic products. Moreover, advertising a product via its trademark to the doctor would be completely useless while, on the other hand, generic manufacturers could immediately upon launch take advantage of the physician's awareness of the specific active ingredient, for which the originator company generated a huge volume of scientific information over the years, at its own cost.

⁴² Id. p. 25

⁴³ The risk of medication errors when using generic names/INNs is reported as increasing : see *WHO Drug Information*, Vol. 20, N° 2, 2006; many examples available on *FDA Safety Page*, 'Drugs Topics', 6th October 2003.

E) Fair competition leads to best savings for healthcare systems

Competitive market conditions will cause the price of off-patent, branded generic medicines to fall. Measures to foster a competitive generics market should equally apply to all off-patent medicines, not only to generics *sensu stricto*. That implies that the branded product after patent expiry has the same opportunity to compete as the generics. Greatest savings to the health care system result in conditions where there is no discrimination but an equal playing field for all competitors. Those policies aiming to foster the development of generic markets should be applied in full respect of existing intellectual property rights and should not lead to any formal or informal substitution between different active ingredients. Compulsory generics prescribing distorts market conditions and is likely to artificially maintain prices at a higher level than they would otherwise be if true competition were allowed.

PHAP Position

PHAP respectfully submits that the issue of determining the most appropriate and effective drug treatment for an individual should be in the hands of the medical practitioner treating that individual. Taking away the ability to prescribe a possibly more effective brand name drug can be detrimental to a patient's welfare. The current law is more than adequate in promoting the prescription of generic drugs, while still allowing the medical practitioner the discretion to include a brand name drug as well. Therefore, this proposed amendment should be removed and the current law should be left intact.

Mandatory Production of Unbranded Generics

HB 2844 also makes it obligatory for all entities engaged in manufacturing, importation, or trade of branded drugs or medicines in the Philippines "to produce, distribute, and make widely available to the general public an unbranded generic counterpart of their branded product". This provision could be considered as an unlawful taking of property without just compensation. Pharmaceutical companies with existing trademark registrations should be freely allowed to exploit their trademarks in the manner they see fit in accordance with law. Trademark owners invest much effort, time, and resources to procure trademark registrations as well as develop the business goodwill in their trademarks. Forcing trademark owners to produce and release generic versions of their products will deny to them the benefits which properly pertain to them. This may be considered an unlawful taking without payment of just compensation as trademark owners are unable to fully exploit the economic rights in their trademarks, which by law are granted to them.

II.
THE PROPOSED AMENDMENTS TO THE PHARMACY LAW

The proposed amendment to the Pharmacy Law, Republic Act 5921, allows “non-prescription or over-the-counter-drugs to be sold in their original packages, bottles, container, or **in small quantities, not in their original containers** to the consuming public through supermarkets, convenience stores, and other retail establishments.”

Very high risks of mislabeling and mishandling will be involved in allowing generic drugs to be sold in small quantities in non-original containers. While allowing sales of generic drugs in this manner can expand the retail availability of said drugs, adverse health and safety issues may arise, such as incorrect or missing product labels which could lead to erroneous dispensing of medicines, decrease in the therapeutic activity of drugs due to incorrect packaging, and other hygienic issues. Congress needs to seriously consider and address the various safety concerns regarding dispensing of generic drugs under this proposed amendment prior to any implementation of measures to allow sales of drugs in retail establishments.