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ADDRESSING THE NORTH-SOUTH DIVIDE IN PHARMACEUTICAL
COUNTERFEITING

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Recent cases of product adulteration¹ and contamination² have focused the public's attention on the safety of the products we consume. In no field is this more important than medical products; the very notion that one might inadvertently consume a drug that is not safe or effective is truly frightening, particularly when one faces a life-threatening illness. Unfortunately, the profits attainable through intentionally counterfeiting pharmaceuticals create immense incentives that fuel extraordinary efforts to defeat regulatory safeguards for illicit gain.³ The forum exists for a struggle of global proportions.

In light of the stakes involved, greater attention is being directed to the global effort to combat pharmaceutical counterfeiting, and both public and private actors are being called to the fight.⁴ While there have been successes, more clearly needs to be accomplished. The counterfeiting of medical products remains a prominent obstacle

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¹ Anna Wilde Mathews & Thomas M. Burton, *FDA Identifies Contaminant in Heparin Batches*, WALL ST. J., Mar. 20, 2008, at A4 (describing the deliberate alteration of a blood thinner with animal cartilage).

² Angel Jennings, *Thomas the Tank Engine Toys Recalled Because of Lead Paint*, N.Y. TIMES, June 15, 2007, at C3 (detailing lead contamination in RC2's toy trains, which is one of many lead contamination incidents to be announced in 2007).

³ Douglas W. Stearn, *Deterring the Importation of Counterfeit Pharmaceutical Products*, 59 FOOD & DRUG L.J. 537, 548-50 (2004).

⁴ See, e.g., Walt Bogdanich & Jake Hooker, *Battle Against Counterfeit Drugs Has New Weapon: Pollen*, N.Y. TIMES, Feb. 12, 2008, at A10 (describing an "unusual coalition of scientists, public health workers and police investigators" working together to trace counterfeiting in China through pollen).

to a fully effective health care system in many countries. In order to fine-tune the system, anti-counterfeiting initiatives tend to focus on strengthening technical, informational and legal measures across all nations. But the tendency to maximize the same attributes throughout the world may fail to address fundamental differences in the nature of counterfeiting among countries at different stages of economic development. Significantly, there is evidence that striking distinctions necessitate a more nuanced approach in combating pharmaceutical fakes on a global scale. However, this so-called North-South divide⁵ is generally not seriously considered in formulating solutions to the problem. This is an important failure, as an understanding of the factors that influence counterfeiting in respective economic regions is extraordinarily valuable. Solutions that specifically respond to such factors can make far more effective strategies.

This article takes a step toward a better understanding of the North-South divide in the context of pharmaceutical counterfeiting. It considers the most important influences in terms of economic actors and suggests that an important tool for addressing the divide may exist in incentive mechanisms for private anti-counterfeiting efforts. More specifically, in part I, the article explains that both the extent of counterfeiting and types of drugs involved differ between developing and developed nations. The significant role of essential medicines in developing country counterfeiting is highlighted. In part II, the article explores underlying factors in the North-South divide, and posits that the role of industry is a more significant part of the equation than is generally acknowledged. Part III of the article provides a description of two basic approaches for increasing industry involvement in anti-counterfeiting efforts in developing countries. By better utilizing the immense wealth and knowledge of private industry, the article concludes that counterfeiting in developing nations may be significantly curtailed.

I. The Global Nature of Pharmaceutical Counterfeiting

Safe medical product distribution is critical to public confidence in the health care system. When an approved drug or medical device turns out to be more dangerous than originally

⁵ The “North-South divide” is a phrase that is often used to describe differences between economically developed countries and those still developing. See Rafael X. Reuveny & William R. Thompson, *The North-South Divide and International Studies: A Symposium*, 9 INT’L STUD. REV. 556, 557 (2007) (relating the development of the phrase). Developed countries are more commonly (but obviously not exclusively) located in the northern hemisphere and developing countries in the southern hemisphere.

expected, it is a problem addressed by regulators⁶ and, particularly in the United States, through private tort litigation.⁷ By requiring rigorous testing, the system aspires to keep these problems to a minimum. However, when it comes to counterfeit medical products, all bets are off. If such products contaminate the distribution lines of legitimate drugs and devices, the system is in serious peril. Patients may suffer serious medical harm, future customers may avoid the market, government health care efforts may be stymied, and legitimate industry can lose profits. It is a global problem, with no country entirely safe from its effects.

When commentators refer to pharmaceutical or medical device counterfeiting, they usually mean products palmed off as those of another. It could be a simple substitution of labels on a cheaper generic product for a branded product. The practice could also include the unauthorized sale of generic drugs in a market in which a branded company has exclusive rights.⁸ Most commonly, however, counterfeiting involves the substitution of a substandard or entirely fake product for a legitimate one. The counterfeiter's goal is, obviously, to collect the branded price for what is essentially a worthless good. While some would include inadvertent source confusion as a form of counterfeiting,⁹ it is more useful to apply the label only to intentional acts of deception, with the former designated as simple, common infringement.¹⁰

⁶ Major industrialized nations, such as the United States, the members of the European Union and Japan, have a rigorous drug assessment and approval process. See Thomas M. Moore & Siobhan A. Cullen, *Impact of Global Pharmaceutical Regulations on U.S. Products Liability Exposure*, 66 DEF. COUNS. J. 101, 102-105 (1999). That regulatory authority includes post-marketing surveillance of adverse events.

⁷ Daniel R. Cahoy, *Medical Product Information Incentives and the Transparency Paradox*, 82 IND. L.J. 623, 637-41 (2007) (describing how the tort system acts as a second track for creating incentives for marketing safe drugs).

⁸ Kevin Outterson states that unauthorized generic drugs are occasionally referred to as counterfeit products. Kevin Outterson, *Pharmaceutical Arbitrage: Balancing Access and Innovation in International Prescription Drug Markets*, 5 YALE J. HEALTH POL'Y, L. & ETHICS 193, 268-69 (2005). In fact, this is not the most common use of the term and is probably more of an industry push against the practice.

⁹ See Outterson, *supra* note 8, at 268-69.

¹⁰ The international agreement known as the Trade-Related Aspects of Intellectual Property, or "TRIPS," provides a common definition of counterfeiting that follows this paradigm: "counterfeit trademark goods shall mean any goods, including packaging, bearing without authorization a trademark which is identical to the trademark validly registered in respect of such goods, or which cannot be distinguished in its essential aspects from such a trademark, and which thereby infringes the rights of the owner of the trademark in question under the law of the

Counterfeiting touches on a host of legal issues, including fraud, malpractice and violation of customs regulations. But at its core, counterfeiting is an offense against private intellectual property rights. Passing off goods as those of another by virtue of fraudulent or confusing packaging is a form of trademark harm.¹¹ In addition, if the substituted good contains some aspect of the legitimate product, it is possible that patent infringement could be asserted.¹² And to the extent that character-based logos and product inserts are copied, there is even a case for copyright infringement.¹³ Depending on the jurisdiction, acts of counterfeiting may implicate criminal or civil law, or even both.

Of course, in the medical products field, it is also quite possible that counterfeiting will lead to serious health consequences. This is certainly the case if drugs or devices for emergent conditions — like antibiotics to treat a serious infection, anti-malarial drugs, or surgical patches — are substituted with counterfeits.¹⁴ Death may even result. On the other hand, some counterfeit substitutions may go relatively unnoticed.¹⁵ A cholesterol lowering drug that has a long-term, cumulative effect may be replaced by a counterfeit without any immediate ill effects. A counterfeit sleeping pill or erectile dysfunction drug may provide a sufficient psychological effect as to minimize the noticeable impact of the fake. Even when a reduced therapeutic effect is detected, it may be ascribed to simple patient

country of importation.” Agreement on Trade-Related Aspects of Intellectual Property Rights, art. 51, n. 14, Apr. 15, 1994, 1869 UNTS 322 (1995), 33 ILM 1217 (1994). [hereinafter TRIPS].

¹¹ See, e.g., 15 U.S.C. § 1125(a) (2006) (civil cause of action for false designation of origin); 18 U.S.C. § 2320 (2006) (criminal penalties for trafficking in counterfeit goods or services); ORGANIZATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT (OECD), THE ECONOMIC IMPACT OF COUNTERFEITING AND PIRACY (DRAFT), pt. III, ¶ 5.9 (2007), available at <http://www.oecd.org/dataoecd/36/34/39543417.pdf> [hereinafter OECD REPORT].

¹² See Daniel R. Cahoy, *Patent Fences and Constitutional Fence Posts: Property Barriers to Pharmaceutical Importation*, 15(3) FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 623, 654 (2005); OECD REPORT, *supra* note 11, at pt. III, ¶ 5.8.

¹³ See, e.g., Bryan A. Liang, *Fade to Black: Importation and Counterfeit Drugs*, 32 AM. J.L. & MED. 279, 292 (2006) (describing the prosecution of the mastermind of a UK counterfeit ring on copyright infringement charges); OECD REPORT, *supra* note 11, at pt. III, ¶ 5.10.

¹⁴ World Health Organization (WHO), Counterfeit Medicines, Fact Sheet No. 275 (Nov. 14, 2006), <http://www.who.int/mediacentre/factsheets/fs275/en/> [hereinafter WHO Fact Sheet] (“The regular use of substandard or counterfeit medicines can lead to therapeutic failure or drug resistance. In some cases, it can lead to death.”).

¹⁵ Robert Cockburn et al., *The Global Threat of Counterfeit Drugs: Why Industry and Governments Must Communicate the Dangers*, 2 PLOS MED. 302, 302 (2005) (“The effects on patients of counterfeit medicines are difficult to detect and quantify, and are mostly hidden in public health statistics.”).

variation.¹⁶ Whether the consequences of counterfeiting transcend economics is highly drug dependent.

More striking than the variance in counterfeiting impact by drug is the difference by country. Although many international reports refer to counterfeit drugs as a uniform issue, it is quite clear that the problem is vastly different in developed nations than it is in developing nations. In fact, the difference is so great that one might almost imagine two separate industries are respectively involved. Acknowledging the North-South divide is the first step to providing more comprehensive solutions to global pharmaceutical counterfeiting.

A. The Lifestyle Risk in Developed Nations

There is no question that counterfeiting is a problem in developed nations, as evidenced by the vast resources marshaled to counter its impact.¹⁷ Major government entities like the U.S. Food and Drug Administration (“FDA”) and the European Union’s (“EU”) European Medicines Agency (“EMA”) have made a concerted effort to address the problem through enforcement, coordination, and information dissemination.¹⁸ Industry groups such as the Pharmaceutical Research and Manufacturers of America (“PhRMA”) and the International Chamber of Commerce have also raised warning flags and promised cooperation to address the issue. Without question, a serious problem is facing a major counterattack.

Given the effort and focus in developed countries, it is not surprising that the incidence of counterfeiting is generally low, at least

¹⁶ See Bryan A. Liang, *Parallel Trade in Pharmaceuticals: Injecting the Counterfeit Element into Public Health*, 31 N.C. J. INT'L L. & COM. REG. 847, 873-74 (2006).

¹⁷ Pfizer Senior Corporate Counsel, Jim Hilboldt, recently authored a brief but comprehensive overview of the global effort to fight counterfeiting outside the United State. See generally Jim Hilboldt, *Counterfeit Medicines Outside the United States: Challenges and Responses*, 878 PRAC. L. INST./PAT. 869 (2006).

¹⁸ In particular, the FDA has created a “Counterfeit Drug Task Force,” which has issued reports on the viability of various anti-counterfeiting technologies. FDA, Counterfeit Drug Task Force Report: 2006 Update 1-3 (2006), available at http://www.fda.gov/oc/initiatives/counterfeit/report6_06.pdf. Among the most promising is the use of radio frequency identification (RFID) technology to identify legitimate pharmaceuticals. *Id.* at 11. The EMA’s stated goal with regard to counterfeiting is to cooperate with the European Commission and national drug agencies by “facilitating information sharing and coordinating actions (including recalls and testing) in the case of centrally authorized product counterfeits.” See European Medicines Agency (EMA), *Counterfeit Medicines*, <http://www.emea.europa.eu/Inspections/Counterfeits.html> (last visited Apr. 10, 2008).

compared to total pharmaceutical sales.¹⁹ For example, some have estimated the percentage of counterfeit drugs on the U.S. market at less than one percent.²⁰ However, the nature of counterfeiting in developed countries is not simply an issue of magnitude. There is a qualitative aspect to counterfeiting that is particular to the industrialized world, and it distinguishes North from South.

Most importantly, the types of pharmaceuticals subject to widespread counterfeiting in developed countries tend to be “lifestyle drugs”²¹ or drugs to treat chronic conditions.²² These are medicines that are not immediately required for emergency purposes but involve some degree of choice and budgeting. This is not to say such drugs are not important. Rather, the distinguishing factors are that patients have some time to shop around, and there may be some room for recovery in the event of a failed purchase.

Examples of counterfeit-sensitive drugs in developed countries²³ include those used to treat age-related conditions, such as statins²⁴ to lower cholesterol, hormone replacement therapy²⁵ to

¹⁹ See WHO Fact Sheet, *supra* note 14. Precise figures on the amount of counterfeiting as a percentage of the global pharmaceutical market are widely divergent. OECD REPORT, *supra* note 11, at pt. III, ¶ 5.21; Cockburn et al., *supra* note 15, at 302. In fact, even the size of the legitimate global pharmaceutical market is difficult to define. OECD REPORT, *supra* note 11, at pt. III, ¶ 5.4.

²⁰ See, e.g., WHO Fact Sheet, *supra* note 14 (“Although precise and detailed data on counterfeit medicines is difficult to obtain, estimates range from around 1% of sales in developed countries to over 10% in developing countries, depending on the geographical area.”); International Medical Products Anti-Counterfeiting Taskforce (IMPACT), *Counterfeit Medicines: An Update on Estimates* 1 (Nov. 15, 2006), <http://www.who.int/medicines/services/counterfeit/impact/TheNewEstimatesCounterfeit.pdf> [hereinafter IMPACT Estimates].

²¹ A lifestyle drug is generally defined as a treatment that is not medically necessary but addresses a condition related to comfort or overall satisfaction such as mild obesity, baldness, or erectile dysfunction. See Tim Atkinson, *Lifestyle Drug Market Booming*, 8 NATURE MED. 909, 909 (2002).

²² A chronic condition, as opposed to acute, can be defined as one that is life threatening, but only in the long term. See MedlinePlus Medical Encyclopedia: Chronic, <http://www.nlm.nih.gov/medlineplus/ency/article/002312.htm> (last visited Apr. 14, 2008). The need for care is therefore ongoing. See, e.g., Wenke Hwang et al., *Out-of-Pocket Medical Spending for Care of Chronic Conditions*, 20 HEALTH AFF. 267, 268-69 (2001). For example, hypertension, diabetes and epilepsy are serious conditions that dramatically affect one’s health, but they are treated incrementally over time and are unlikely to change dramatically over a period of a days or even months.

²³ OECD REPORT, *supra* note 11, at pt. III, ¶ 5.15.

²⁴ See Omudhome Ogburu, *Statins*, <http://www.medicinenet.com/statins/article.htm> (last visited Apr. 14, 2008).

regulate the effects of menopause, and diuretics²⁶ and beta blockers²⁷ to control high blood pressure. While these medicines must be ingested regularly to have a positive impact, patients have a great deal of knowledge about their future needs and can plan ahead to secure a supply. In addition, the developed country class of counterfeited drugs includes those that are more or less medically optional.²⁸ This is particularly true in the case of medicines used to treat a condition that a user may find somewhat embarrassing and may not want to pursue through standard medical channels.²⁹

TABLE 1
Types of Drugs Counterfeited

Developed Countries	Developing Countries
Epogen/Procrit	Anti-Malarial
Steroids	Antibiotic
Erectile Dysfunction	Anti-retroviral
Statins	Anti-tuberculosis
Hypertension	Analgesics
Hormone Replacement	Anti-inflammatory
	Vitamins

Source: OECD Phase I Report on Counterfeiting³⁰

Significantly, some of these chronic or optional medicines may not be fully or even partially covered by a health insurance program.³¹

²⁵ See Ruchi Mathur, Hormone Therapy (Estrogen Therapy, Estrogen/Progestin Therapy), http://www.medicinenet.com/hormone_therapy/article.htm (last visited Apr. 14, 2008).

²⁶ See John P. Cunha et al., High Blood Pressure Treatment, http://www.medicinenet.com/high_blood_pressure_treatment/article.htm (last visited Apr. 14, 2008).

²⁷ See *id.*; Melissa Stöppler, Why Take a Beta Blocker?, <http://www.medicinenet.com/script/main/art.asp?articlekey=41879> (last visited Apr. 14, 2008).

²⁸ See OECD REPORT, *supra* note 11, at pt. III, ¶ 5.15.

²⁹ The most prominent example in this regard is PDE5 inhibitors that are used to treat erectile dysfunction. See P.J. Wright, *Comparison of Phosphodiesterase Type 5 (PDE5) Inhibitors*, 60 INT'L J. CLINICAL PRAC. 967, 967 (2006) (noting common PDE5 inhibitors as well as the taboo that typically surrounds the discussion of erectile dysfunction).

³⁰ OECD REPORT, *supra* note 11, at pt. III, ¶ 5.15. See also WHO Fact Sheet, *supra* note 14.

³¹ See John Carroll, *When New Drugs are Costly, How High to Raise Copays?*, MANAGED CARE, June 2006, at 20, available at <http://www.managedcaremag.com/archives/0606/0606.tiers.html> (discussing a trend in which insurance companies are

Even if coverage exists, it may still be so expensive that patients are driven to alternate supply routes. That inclination to step outside of standard medication distribution channels may be one of the most important sources of counterfeit drugs in the developed world. By opening one's pocketbook over the Internet³² or to cross-border importers, the exposure to unscrupulous and hard to prosecute counterfeiters increases.

Another type of counterfeiting that is gaining more attention in the developed world is worth mentioning, primarily because it is such a different animal. The recent news has carried several stories of counterfeit ingredients being incorporated into mainstream drugs.³³ Often, the source of the counterfeit ingredient is a developing country. China, in particular, has been implicated, which is not surprising since it is the source of so much of the world's raw pharmaceutical ingredients and regulation standards have traditionally been less stringent.³⁴ However, this type of counterfeiting is significantly more controllable since companies that manufacture drugs can implement stronger safeguards. They can simply decide to acquire materials from a more secure source (in most cases).³⁵ And since those companies have the ultimate responsibility in marketing those drugs, they have a very strong incentive in the form of tort liability to ensure that

moving lifestyle drugs to reimbursement categories that require greater patient contributions).

³² John A. Vernon et al., *The Internet and Pharmaceutical Importation: Economic Realities and Other Related Issues*, 16 ALB. L.J. SCI. & TECH. 545, 550-51 (2006) (describing the ease with which counterfeit drugs are distributed over the Internet and providing examples of such incidents and enforcement); January W. Payne, *FDA Warns of Web Sites Selling Bogus Drugs*, WASH. POST, May 22, 2007, at HE08 (describing thousands of websites purportedly selling counterfeit drugs); Brian Grow, *Bitter Pills*, BUSINESS WEEK, Dec. 18, 2006, at 110 (describing criminal operations that supplied counterfeit drugs to U.S. consumers through the Internet).

³³ See, e.g., Walt Bogdanich, *China Prohibits Poisonous Industrial Solvent in Toothpaste*, N.Y. TIMES, July 12, 2007 at C4 (diethylene glycol in toothpaste); Manuel Roig-Franzia, *Intended Tainting Suspected in 21 Deaths in Panama*, WASH. POST, Oct. 13, 2006, at A18 (diethylene glycol in cough syrup). See also OECD REP., *supra* note 11, at pt. III, ¶ 5.12-5.14; *Chemical Exports Skirt Drug Oversight*, HOUS. CHRON., Oct. 21, 2007, at A11 (stating that counterfeit drug ingredient manufacturers are easily accessible at international trade show).

³⁴ See Jake Hooker and Walt Bogdanich, *Agreement with China to Regulate Some Drugs*, N.Y. TIMES, Dec. 12, 2007, at C3 (noting that a regulation accord was sought with China due to "gaps in that country's regulatory system").

³⁵ Some pharmaceutical compounds are produced only in a few locations around the globe, so alternate sources may not be readily available. For example, Roche's anti-flu drug Tamiflu requires a compound called shikimic acid derived from star anise, a fruit grown only in China. Corky Siemaszko, *Rare Fruit may be Key to Cure*, N.Y. DAILY NEWS, Nov. 2, 2005, at 8. This would appear to be the exception rather than the rule.

counterfeits do not make it into the system. While global outsourcing may have increased this risk over the last few years, one would assume that the risk would be much reduced in the future now that the danger is more evident. Therefore, in terms of the severity of the problem and the necessity for global action, it is not as useful to lump ingredient substitution in with end-product counterfeiting.

B. A Basic Health Care Obstacle in Developing Nations

To some extent, the danger of counterfeiting viewed from the perspective of developed countries does not seem all that dramatic. However, such is not the case for developing nations. The drugs that are commonly counterfeited are subject to emergent need. In developing nations, counterfeiting is literally a life or death issue. Coupled with the generally-acknowledged fact that developing country counterfeiting rates are much higher — between ten percent and thirty percent³⁶ — the economic bias of the problem is clear.

The most common drugs counterfeited in developing countries are those used to treat AIDS, malaria, tuberculosis, and bacterial infections.³⁷ Examples tracked by the U.S. Pharmacopeia Drug Quality and Information (USP DQI) Program³⁸ fills almost forty pages in the organization's Matrix of Drug Quality Reports.³⁹ Some of the more egregious instances include fake versions of the antivirals Triomune and Duovir discovered in the Congo in 2003,⁴⁰ counterfeit amoxicillin and penicillin that contained less than half of the active ingredient found in Indonesia in 2003,⁴¹ and 162 batches of counterfeit drugs under forty-seven names pulled from the market in Russia in 2004.⁴² Lifestyle and chronic condition drugs are counterfeited as

³⁶ See WHO Fact Sheet, *supra* note 14; IMPACT Estimates, *supra* note 20, at 1.

³⁷ OECD REPORT, *supra* note 11, at pt. III, ¶ 5.15. See also WHO Fact Sheet, *supra* note 14.

³⁸ The USP DQI is primarily funded through a cooperative agreement between the U.S. Agency for International Development (USAID) and the U.S. Pharmacopeia (USP). USP, Program Support, <http://www.usp.org/worldwide/dqi/support.html> (last visited Mar. 30, 2008). Its purpose is to provide outreach and education on drug quality to governments in USAID-priority countries. USP, Fulfilling the need for Quality and Information, <http://www.usp.org/worldwide/dqi/> (last visited Mar. 30, 2008).

³⁹ UNITED STATES PHARMACOPEIA DRUG QUALITY AND INFORMATION (USP DQI), MATRIX OF DRUG QUALITY IN USAID-ASSISTED COUNTRIES (updated Jan 7, 2008), available at <http://www.usp.org/pdf/EN/dqi/ghcDrugQualityMatrix.pdf> [Hereinafter DQI Matrix].

⁴⁰ *Id.* at 2.

⁴¹ *Id.* at 20.

⁴² *Id.* at 29.

well, but the incidents seem to be fewer as compared to the critical medicines.⁴³

Some developing nations appear to be making progress in the fight against counterfeiting. For example, according to USP's Matrix, Nigeria was able to reduce the incidence of fake drugs on the market from seventy percent in 2001 to twenty percent in 2004.⁴⁴ However, given the marketplace demand dynamics, it is reasonable to assume that the relative proportions of the types of drugs counterfeited remain the same. This is a story likely to be repeated across the developing world, making it even more critical that such counterfeiting be addressed as quickly and strongly as possible.

II. Understanding the North-South Divide

In order to combat counterfeiting as a global phenomenon, it is important to understand underlying reasons for the differences in its nature in the developing and developed world. If such distinctions are ignored, there is a risk that the problem will not be sufficiently addressed in one economic stratum. More importantly, it may prevent the global community from engaging resources that are insufficiently employed under the current system.

A. Factors Influencing the Incentive to Counterfeit

Pharmaceutical counterfeiting may have significant implications for the health and welfare of consumers, and one who engages in such behavior would appear to be lacking in any moral grounding. It is possible, therefore, that some counterfeiting occurs because intentional harm is desired. The famous case of contaminated Tylenol in the United States may be the best example of this phenomenon.⁴⁵ But this reason is likely rare and isolated.⁴⁶ The more

⁴³ While precise figures are not available, one can get a general impression of the ratios through reports of counterfeiting. For example, of the DQI Matrix listings that refer to specific types of pharmaceuticals, it appears that approximately twenty-one percent refer to lifestyle drugs like Viagra and diet pills. *See generally id.* Moreover, of those that actually name the drug involved, approximately sixty-five percent involve a generic compound. *Id.*

⁴⁴ *Id.* at 6.

⁴⁵ *See* James A. Henderson, Jr., *Product Liability and the Passage of Time: The Imprisonment of Corporate Rationality*, 58 N.Y.U. L. REV. 765, 780 n.63 (1983) (detailing the 1982 incident in Chicago wherein seven people died of cyanide poisoning that was traced to bottles of Extra-Strength Tylenol).

⁴⁶ This is probably because tampering or fakery without any economic return is a relatively expensive endeavor given the security measures in place on most drugs. *See* Tom Cramer, *Look Twice: How to Protect Yourself Against Drug Tampering*,

common and, therefore, important reason for counterfeiting is simple economic benefit.⁴⁷ By substituting a fake good procured at a low cost and selling it at a price commensurate with a legitimate good, the counterfeiter profits.

The economic benefits of counterfeiting can be quite large. Current estimates put the cost to the pharmaceutical industry in the billions of dollars per year⁴⁸ and potentially comprise ten percent of the global market.⁴⁹ Counterfeiters recoup some percentage of that, though how much depends on the type of counterfeiting that is undertaken. A medicine that is fraudulently sold to a government or hospital may capture most of the branded price. Whereas a counterfeit drug sold on the secondary market to an individual who purchases primarily because of the apparent substantial savings takes in a small fraction of the full price.⁵⁰ However, in the latter case, the profit may still be substantial in comparison to the costs of producing the counterfeit.⁵¹

Not surprisingly, the large potential for profit means that counterfeiting is very attractive to organized criminal enterprises. It has been reported that secular criminal gangs as well as terrorist organizations engage in drug counterfeiting as a source of income.⁵²

FDA CONSUMER (Oct. 1991), *available at* <http://www.fda.gov/bbs/topics/consumer/CON00114.html> (describing the genesis and extent of tamper-resistant packaging on pharmaceuticals). If one simply wishes to cause harm or mischief, there are more efficient ways to do so.

⁴⁷ OECD REPORT, *supra* note 11, at pt. III ¶ 5.40 (noting that the primary objective of counterfeiting is financial gain, but that secondary objectives can include political aims).

⁴⁸ *See, e.g.*, WHO Fact Sheet, *supra* note 14 (“The US based Centre for Medicines in the Public Interest predicts that counterfeit drug sales will reach \$ 75 billion globally in 2010, an increase of more than 90% from 2005.”); Maria Nelson et al., *Counterfeit Pharmaceuticals: A Worldwide Problem*, 96 TRADEMARK REP. 1068, 1068 (2006) (citing figures for various sources).

⁴⁹ Nelson, *supra* note 48, at 1068; Stearn, *supra* note 3, at 539-40. These numbers are certainly arguable given that it is so difficult to obtain reliable figures on the market, let alone the level of counterfeiting; *See supra* note 19. It has been suggested that both government and industry have strong incentives to keep the incidence of pharmaceutical counterfeiting under wraps. *See* Robert Cockburn et al., *The Global Threat of Counterfeit Drugs: Why Industry and Governments Must Communicate the Dangers*, 2 PLOS MED. 302, 302-303 (2005).

⁵⁰ *See* OECD REPORT, *supra* note 11, at pt. III ¶ 5.31 (describing the lower profit realized from selling counterfeit Procrit to individuals).

⁵¹ *Id.*

⁵² *Id.* at ¶ 5.39-5.40; Bryan A. Liang, *Parallel Trade in Pharmaceuticals: Injecting the Counterfeit Element into Public Health*, 31 N.C. J. INT'L L. & COM. REG. 847, 869-70 (2006); Ved P. Kumar, *Global Syndicates and the Threat to Third World Health*, in *THE PHARMACEUTICAL CORPORATE PRESENCE IN DEVELOPING COUNTRIES* 161, 161-62 (Lee A. Tavis & Oliver F. Williams eds., 1993).

It has even been suggested that rogue governments may play a role. For example, the United States has specifically accused the government of North Korea of such activity.⁵³ With the global reach of such organizations, the extent of pharmaceutical counterfeiting is not at all surprising.

Apart from the global marketplace, one can identify particular aspects of the pharmaceutical industry's business model that readily accommodate counterfeiting. Branded pharmaceuticals are often sold for a significant profit over the cost of the materials.⁵⁴ That profit may compensate for a drug's research and development costs,⁵⁵ the costs of developing a company's entire portfolio,⁵⁶ or it may simply represent a kind of windfall in return for the risks of drug development.⁵⁷ Whatever the case, consumers are accustomed to drug prices that bear no relation to the apparent cost of the underlying materials.⁵⁸ Unlike, for example, a luxury handbag, a visual inspection of a pharmaceutical to determine its quality is a pointless endeavor. Thus, it is quite a simple matter to substitute low-cost materials without raising suspicion.

While almost all counterfeiting relates to profit, it does not entirely define the landscape. Significantly, if profit were the only motivator, one would expect the practice to primarily impact the most

⁵³ See Raphael F. Perl, Cong. Research Serv., *Drug Trafficking and North Korea: Issues for U.S. Policy*, CRS-14 (2006), available at <http://italy.usembassy.gov/pdf/other/RL32167.pdf> ("In addition to production and trafficking in heroin and methamphetamines, major sources of revenue from criminal activity for the DPRK now include...counterfeit pharmaceuticals (for example, "USA" manufactured viagra [sic] . . .").

⁵⁴ See Stearn, *supra* note 3, at 549.

⁵⁵ See Joseph DiMasi et al., *The Price of Innovation: New Estimates of Drug Development Costs*, 22 J. HEALTH ECON. 151, 166-68, 180 (2003) (reporting that the research conducted under the Tufts Center for Drug Development found that research and development costs are \$802 million, and nearly \$900 million if post-approval research and development is taken into account).

⁵⁶ See Daniel R. Cahoy, *Confronting Myths and Myopia on the Road from Doha*, 42 GA. L. REV. 131, 166 (2007) ("[T]here are many failures for every successful blockbuster drug, and the funds sunk in producing the failures might not be entirely reflected in a successful drug's direct research and development costs. Additionally, so-called 'excess profits' can be used to fund less valuable but important drug development programs.").

⁵⁷ See F.M. Scherer, *The Pharmaceutical Industry-Prices and Progress*, 351 NEW ENG. J. MED. 927, 929 (2004) (explaining that pricing according to research and development costs is fallacy and that for rational profit maximizers "the position of the demand curve . . . and the variable costs of production and distribution" matter most); see also Ernst R. Berndt, *Pharmaceuticals in U.S. Health Care: Determinants of Quantity and Price*, 16 J. ECON. PERSP. 45, 58 (2002) ("Price reflects marginal value, not marginal production cost.").

⁵⁸ See Berndt, *supra* note 57, at 58.

expensive drugs in the highest priced markets. Indeed, some commentators have suggested that this is the dominant paradigm, coupling it with a call to lower the cost of drugs in order to reduce the incentives.⁵⁹ However, the high-profit model fits only part of the pharmaceutical market. As described above, pharmaceutical counterfeiting is *more* widespread in low-income markets where it occurs with generic drugs.⁶⁰ Closer examination reveals that this is not as counterintuitive as it seems. Countervailing factors create strong disincentives for counterfeiting in most high profit markets. The presence of these factors is probably income specific if not country specific.

The most important countervailing force is the regulated drug delivery system. Major industrialized nations employ what is known as a “closed” pharmaceutical distribution system.⁶¹ This means that the manufacture and sale of drugs must take place as part of a highly scrutinized supply chain that attempts to track the process from beginning to end. In general, drugs that do not enter through the approved framework are difficult to obtain.⁶² This high level of control has the effect of greatly reducing counterfeiting.

Some countries provide a slight opening into their protected systems by permitting pharmaceutical importation.⁶³ In fact, it is even encouraged among the countries of certain trading regions, such as the European Union.⁶⁴ However, countries that permit importation can continue to maintain a high level of control over imported drugs by

⁵⁹ In particular, see Kevin Outterson & Ryan Smith, *Counterfeit Drugs: The Good, the Bad and the Ugly*, 16 ALB. L.J. SCI. & TECH. 525, 537-40, 542-43 (2006) (linking the incentive to counterfeit with high-priced, patented drugs and suggesting that alternatives to patent-based research may eliminate the threat).

⁶⁰ See *supra* note 30.

⁶¹ DEPT. OF HEALTH AND HUMAN SERVICES, HHS TASK FORCE ON DRUG IMPORTATION, REPORT ON PRESCRIPTION DRUG IMPORTATION, 37-38 (2004) [hereinafter HHS REPORT].

⁶² *Id.* at 37 (“[T]here are limited channels of entry into the American drug supply, thereby reducing the opportunity to place counterfeit or poor quality medications into the U.S. commercial distribution system.”).

⁶³ See, e.g., AUSTL. PRODUCTIVITY COMM’N INT’L PHARM. PRICE DIFFERENCES, 16 n.4 (July 2001) (describing parallel importation rules and noting the European Union and New Zealand as examples of countries that permit it); See also Daniel R. Cahoy, *Patent Fences and Constitutional Fence Posts: Property Barriers to Pharmaceutical Importation*, 15 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 623, 657-58 (2005) (explaining patent exhaustion as a means for avoiding intellectual property barriers to importation, and detailing U.S. and international rules).

⁶⁴ See HHS REPORT, *supra* note 61, at 61. The European Union promotes circulation of products among its members. Cahoy, *supra* note 63, at 659-60.

incorporating them into the traditional drug delivery pathway.⁶⁵ In doing so, end-users are not left to determine the safety and efficacy of the drugs on their own. To date, the United States has rejected an effective importation system (with the potential for counterfeiting as an important rationale),⁶⁶ but pending legislation in Congress suggests that this could change.⁶⁷ A recent government report posits that such importation could be introduced safely if a high level of control was maintained.⁶⁸ With great care, importation is probably not a major threat to the integrity of a closed system.

A second countervailing force, that may in many circumstances have an impact almost as significant as government control, is private-sector security. Although a pharmaceutical may be safely produced and delivered with a minimum of specialized packaging,⁶⁹ branded companies often increase its use specifically to deter counterfeiting.⁷⁰ Some such measures rely on sophisticated technologies that are very hard to copy for all but the most advanced counterfeiters. Examples include the use of holograms (or other variable optical devices) on packaging,⁷¹ authentication codes,⁷² and specialized printing.⁷³ In addition, many companies are in the process

⁶⁵ See, e.g., HHS REPORT, *supra* note 61, at 61 (analogizing the EU's parallel importation policy to one between U.S. states due to the high level of regulatory control across the Union).

⁶⁶ Technically, a system for importation does exist in the U.S. An exception created by the Medicine Equity and Drug Safety (MEDS) Act of 2000, Pub. L. No. 106-387, 114 Stat. 1549 (2000) (codified at 21 U.S.C. §§ 333, 384 (2006)) would permit importation by non-manufacturers. 21 U.S.C. § 384(a) (2006) (abrogating the authority of the Secretary to regulate imports under 21 U.S.C. § 381(d)(1) (2006)); William Davis, *The Medicine Equity and Drug Safety Act of 2000: Releasing Gray Market Pharmaceuticals*, 9 TUL. J. INT'L & COMP. L. 483, 487-88 (2001). However, it requires the HHS Secretary to vouch for the safety and effectiveness of drugs imported through this procedure. 21 U.S.C. § 384(l) (2006). To date, HHS Secretaries who have held office after the enactment of MEDS have concluded that no such demonstration can be made.

⁶⁷ See, e.g., Pharmaceutical Market Access Act of 2007, S. 251, 110th Cong. (2007).

⁶⁸ HHS REPORT, *supra* note 61, at 41-44.

⁶⁹ For example, in the U.S., common over-the-counter medications include little more than tamper-resistant packaging as a security measure. 21 C.F.R. § 211.132 (b) (2007) (stating that over-the-counter drugs must include "tamper-evident" packaging).

⁷⁰ See Nelson, *supra* note 48, at 1081-82 (providing examples of private industry technology initiatives to deter counterfeiting); OECD REPORT, *supra* note 11, at pt. III ¶¶ 5.55-5.61 (detailing a variety of private industry technology initiatives to deter counterfeiting).

⁷¹ OECD REPORT, *supra* note 11, at pt. III ¶ 5.56 (describing sophisticated holograms, but noting that they have been counterfeited).

⁷² *Id.* ¶ 5.55.

⁷³ *Id.*

of incorporating radio-frequency identification (RFID) systems into even the smallest of pharmaceutical packaging.⁷⁴ Unless the purchaser is so unsophisticated as to be unable to authenticate such devices, they are possibly more effective than government control. Additionally, some kinds of pharmaceutical packaging, like blister packs,⁷⁵ are not necessarily technologically advanced, but they nonetheless deter counterfeiting due simply to the cost of duplication.⁷⁶

Related to the above security measures as countervailing influences is the enforcement of legal rights of private companies. When a counterfeit mimics the identity of a legitimate company, there is obviously a strong incentive to take legal action to stop the confusion. Certainly this can take the form of a trademark infringement action if source confusion is at issue.⁷⁷ More importantly, if the company has the right to exclude others from making and selling some aspect of the pharmaceutical through patent rights, an infringement lawsuit may result even if there is no source confusion.⁷⁸ The specter of litigation may cause some counterfeiters to refrain from operating with a particular drug.⁷⁹ At the very least, the potential of spurring the court system into action may give a private company increased incentive to uncover counterfeiting.

Consumer⁸⁰ behavior may serve as an additional obstacle to counterfeiting, at least under some circumstances. It is empirically evident that consumers place great value on medicines manufactured under a trusted brand, even if the cost is greater.⁸¹ This suggests that a

⁷⁴ *Id.* ¶¶ 5.59-5.60 (describing RFID incorporation, but noting its expense).

⁷⁵ *Id.* ¶ 5.55.

⁷⁶ Peter G. Mayberry, *Current Trends in Pharmaceutical Packaging and Distribution Practices – U.S. vs. E.U.*, BUS. BRIEFINGS: U.S. PHARMACY REV., 24, 25 (2004), available at www.touchbriefings.com/pdf/1092/Maybury.pdf (stating that blister packaging is much more common in Europe, and “it is much more difficult for criminals to create and pass-off bogus drugs if they must also produce counterfeit blister cards and leaflets.”).

⁷⁷ OECD REPORT, *supra* note 11, at pt. III ¶ 5.25; Nadine Leavitt Slak, *United States Intensifies Fight Against Counterfeit Drugs* (Dec. 1, 2006), available at <http://www.america.gov/st/washfile-english/2006/December/20061201120711LNkaiS0.2569086.html> (noting that more aggressive federal enforcement on criminal trademark laws could be an effective means of combating counterfeiting).

⁷⁸ Cahoy, *supra* note 63, at 664-66.

⁷⁹ Nelson, *supra* note 48, at 1082-83 (describing examples of private enforcement against counterfeiters).

⁸⁰ In the context of pharmaceuticals, a consumer could be the end-user when the medication is actually obtained by a private individual or a hospital or other health care provider and then an end-user submits herself to care.

⁸¹ Perhaps the best evidence of this is the continued sales in the U.S. of branded over-the-counter pharmaceuticals in the face of lower cost, generic versions that by

consumer might be willing to pay more for a reliable source of medical products. But, of course, the foregoing refers to a consumer with *means* and a *choice*. If a consumer is forced to choose between the counterfeit or no medicine at all,⁸² a more assured distribution system that is prohibitively expensive may not serve as a countermeasure. Similarly, if the decision to use the medicine is prompted only by a lower counterfeit price,⁸³ a more reliable source may not be viewed as a viable alternative.

law are bioequivalent. 21 U.S.C. § 355(j)(2)(A)(iv) (2006). The impact has been demonstrated to be significant in this context. *See, e.g.,* Zahra Ladha, *Are Consumers Really Influenced by Brands When Purchasing Pharmaceutical Products?* 7 MKTG. STRATEGY 146, 149 (2007) (“While the respondents perceived a difference in price between generic and branded drugs, they placed much more importance on brand name as a key decision-making influencer in purchasing nonprescription drugs than prescription drugs.”). Moreover, generic substitutes that are “branded” can maintain a price premium. Manchanda et al., *Understanding Firm, Physician and Consumer Choice Behavior in the Pharmaceutical Industry*, 16 MKTG. LETTERS 293, 302 (2006) (referring to the effect in Europe as demonstrated by Danzon and Furukawa). In the context of prescription drugs, the influence of brand is less significant due to insurance-mandated generic substitution. *See id.* at 302-303

⁸² In some cases, the counterfeit may be the only version available. This might occur if the medicine was distributed as part of a government-sponsored program. OECD REPORT, *supra* note 11, at pt. III ¶ 5.51.

⁸³ For example, some users of lifestyle drugs may be motivated by the low cost of the counterfeit rather than any true medical need. It is generally acknowledged that certain drugs, like those for erectile dysfunction, are used optionally. *See* Joseph S. Alpert, *Editorial: Viagra: The Risks of Recreational Use*, 118 AM. J. MED. 569, 569 (2005) (“It seems reasonable to me that recreational use of Sildenafil may even exceed medical use.”).

TABLE 2
Nature of Market for Counterfeiting

	Developed Countries	Developing Countries
Proprietary Nature of Drug	Primarily Branded, On-Patent; Single Company	Primarily Generic, Off- Patent or Unpatented; Multiple Non-IP-Centric Companies
Conditions	Lifestyle or Chronic, Long Term	Life-Threatening Conditions
Purchaser	Consumer	Consumer; Government; NGO
Intellectual Property Rights at Issue	Patents; Trademarks; Copyrights	Trademarks; Copyrights
Percentage of Market	Less than 1%	Up to 30% (possibly higher)

The positive and negative forces work in different combinations in various countries. As noted above, the distinct divide in instances of counterfeiting appears to be drawn relatively among income lines. A traditional explanation has been that the first countervailing influence, government enforcement, is less available.⁸⁴ The lack of power and the potential for corruption make developing nations inherently more vulnerable to counterfeiting, or so the argument goes. However, it is possible that the absence of other countervailing factors contribute equally to the favorable environment in developing nations. Most prominently, the absence of private sector enforcement could be significant.

⁸⁴ Stearn, *supra* note 3, at 550 (“WHO has noted that the lack of fear concerning arrest and prosecution, and the lenient penal sanctions for counterfeiting, encourage the practice”); WHO Fact Sheet, *supra* note 14 (“Because of inadequate regulation and enforcement, the quality, safety and efficacy of both imported and locally manufactured medicines in many developing countries cannot be guaranteed.”).

B. The Problem of the Absent Private Sector in Developing Nations

The vast majority of essential medicines used in developing countries are generic.⁸⁵ This is obviously an economic issue, as countries with less economic ability will not have the means to purchase cutting-edge, high-cost drugs.⁸⁶ It is also a legal issue. The main barrier to generics — patent protection — is not as prominent in developing countries.⁸⁷ Even among those that are members of the TRIPS agreement, a transition period exists to permit the introduction of pharmaceutical patents that will not expire until 2016.⁸⁸ Therefore, even if a medicine is patentable in developed countries, it is likely to have a generic equivalent available in developing countries.⁸⁹

⁸⁵ See Amir Attaran, *How do Patents and Economic Policies Affect Access to Essential Medicines in Developing Countries*, 23 HEALTH AFF. 155, 157-59 (2004) (finding that only seventeen items on the World Health Organization's Essential Medicines List had even the possibility of being patented in developing countries, and in most cases these patent rights were not pursued); Mohamed Omar Gad, *Impact of Multinational Enterprises on Multilateral Rule Making: The Pharmaceutical Industry and the TRIPS Uruguay Round Negotiations*, 9 L. & BUS. REV. AM. 667, 670 (2003) (“[P]ost-patent generic drugs . . . account for a high percentage of the pharmaceutical industry in key developing countries.”); Letter from James Love, Director of CP Tech, to Margaret Chan, Director-General Elect of the World Health Organization (Dec. 1, 2006) (on file with author), available at <http://www.cptech.org/blogs/ipdisputesinmedicine/2006/12/letter-asking-who-review-of-essential.html> (finding that only fourteen of the 312 medicines on the World Health Organization's Essential Medicines 2006 List were under patent in the U.S. at that time, though a disproportionate number of the patented medicines related to AIDS treatment)

⁸⁶ This is bolstered by global pharmaceutical sales data, which indicates that eighty-seven percent of global pharmaceutical sales in 2006 came from North America, Europe, and Japan, with forty-seven percent coming from North America alone. IMS Health, *Global Pharmaceutical Sales by Region, 2006*, http://www.imshealth.com/ims/portal/front/articleC/0,2777,6599_80528184_80528215,00.html (last visited Apr. 2, 2008).

⁸⁷ See Attaran, *supra* note 85, at 158-59.

⁸⁸ Council for Trade-Related Aspects of Intellectual Property Rights, *Decision of the Council: Extension of the Transition Period Under Article 66.1 of the TRIPS Agreement for Least-Developed Country Members for Certain Obligations with Respect to Pharmaceutical Products*, IP/C/25 (June 28, 2002), available at http://www.wto.org/english/tratop_e/TRIPs_e/art66_1_e.htm.

⁸⁹ Professors Reichman and Abbott describe India's world-class generic drug industry, which thrived during the WTO transition period for developing countries enacting patent protection for pharmaceutical compounds. Frederick M. Abbott & Jerome H. Reichman, *The Doha Round's Public Health Legacy: Strategies for the Production and Diffusion of Patented Medicines Under the Amended TRIPS Provisions*, 10 J. INT'L ECON. L. 921, 934 (2007) (stating that India “developed and maintained a world-class generic production capacity for drugs that were otherwise on-patent in developed (and many developing) countries”).

Additionally, initiatives to permit developing countries (least-developed countries, specifically) to circumvent patent rights⁹⁰ will likely ensure that generic medicines remain the primary force in such countries for some time.

The prevalence of generic medicines has a very important effect. It reduces the incentives of private actors to discover and preclude counterfeiting. Consider a typical example involving a branded drug. A pharmaceutical company with patent protection over a valuable drug has the capacity to make monopoly rents due to the lack of competition.⁹¹ This often results in a profit margin that constitutes a very large portion of the sales price of the actual drug product.⁹² However, if counterfeit drugs exist, there is a good argument that purchasers would have obtained the branded drug if not for the presence of the counterfeit.⁹³ In other words, every sale of a counterfeit is a lost sale of the branded drug. That provides a great deal of incentive to invest significant resources in stopping the counterfeiting.⁹⁴

On the other hand, generic manufacturers can legitimately face competition from a practically unlimited number of companies making the same drug.⁹⁵ In the context of generic counterfeiting, there is a good chance that, if the counterfeit did not exist, the drug would

⁹⁰ Cahoy, *supra* note 56, at 151-52.

⁹¹ *Id.* at 140-41.

⁹² CONGRESSIONAL BUDGET OFFICE (CBO), RESEARCH AND DEVELOPMENT IN THE PHARMACEUTICAL INDUSTRY 4 (2006) (“[P]rices in the [pharmaceutical industry] are usually much higher than the cost of providing an additional unit of the product . . .”).

⁹³ This is a version of the basic “lost profits” argument in patent law. *See, e.g.*, *Grain Processing Corp. v. Am. Maize-Prods. Co.*, 185 F.3d 1341, 1349 (Fed. Cir. 1999). Clearly, the validity of the example is highly related to the price and necessity of the drug in question. Branded drugs with optional, life-style indications may be counterfeited and sold to a population that would not have purchased the branded drug at full price. *See* Alpert *supra* note 83.

⁹⁴ For example, World Bank Pharmaceutical Specialist Ved Kumar stated in 1990 that the involvement of the “Large manufacturing sector ever watchful of protecting their good will and profits” is a main factor in the lower incident of counterfeiting in developed countries. Kumar, *supra* note 52, at 163.

⁹⁵ Regulatory barriers to entry can exist, of course. But, because many developed countries rely on developed country determination of safety and effectiveness (or have attempted to harmonize laws to ensure that at least the rules are similar), if a generic is marketable in one developing country, it is likely marketable in most others. *See* Ileana Dominguez-Urban, *Harmonization in the Regulation of Pharmaceutical Research and Human Rights: The Need to Think Globally*, 30 CORNELL INT’L L.J. 245, 252, 257 (1997) (“[M]ost developing countries apparently rely on the regulatory processes of the developed countries through use of a certification scheme which permits the drug’s use in the developing country if the drug has been approved for use in the country of manufacture.”).

simply have been purchased from the next lowest cost-producer, which may not be the brand that was counterfeited. Unlike the situation in developed countries, every sale of a counterfeit is not necessarily a lost sale for the infringed product's manufacturer. In addition, even if counterfeiting does result in lost sales, the profit margin is small enough that only large-scale substitution would warrant action. Certainly, it is true that the counterfeiting of a particular generic company may cause some reputational harm, and that is worth addressing.⁹⁶ But is not comparable to the monopoly profits lost when a branded-drug is counterfeited. Thus, generic companies have a much lower incentive to stop counterfeiting.

The lack of private sector participation may mean that expensive countervailing measures are not used extensively. The eyes and ears of company officials are not put to use in detecting counterfeits. Extensive warnings may not go out to consumers. The burden of policing falls largely on the government. To some extent, non-governmental organizations (NGOs) may play a role as well. Unquestionably, without private sector intervention an important actor is absent.

C. Current Initiatives May Exacerbate the Private Sector Gap

The effort to combat pharmaceutical counterfeiting is international in scale. All nations realize that widespread availability of dangerous fakes puts their own citizens at risk, at least indirectly. And it is certain that pharmaceutical companies have a strong interest in preventing the disruption to the safety and security of the market. Therefore, it is not surprising that a number of anti-counterfeiting initiatives have emerged with government-industry partnerships.⁹⁷ However, it appears that these initiatives will have a much more significant impact in the developed world, effectively widening the North-South chasm and potentially drawing attention away from the more socially-significant area of concern.

One of the more recent and prominent initiatives is the World Health Organization's International Medicinal Products Anti-Counterfeiting Taskforce ("IMPACT").⁹⁸ The taskforce consists of all WHO member states and includes representatives from the major anti-

⁹⁶ OECD REPORT, *supra* note 11, at pt. III ¶ 5.48 (describing the loss of confidence in the safety of a product due to counterfeiting).

⁹⁷ See Hilboldt, *supra* note 17, at 874-881.

⁹⁸ International Medical Products Anti-Counterfeiting Taskforce (IMPACT), About Us, <http://www.who.int/impact/about/en/> (last visited Apr. 4, 2008).

counterfeiting “players” such as manufacturers and NGOs.⁹⁹ It attempts to improve coordination and harmonization between the groups. At this stage, it appears to be primarily a networking entity that enables countries to share their information on best practices. The taskforce takes a holistic approach to counterfeiting, focusing on legislative remedies, technology and communication.¹⁰⁰ While IMPACT could provide a useful platform of ideas for a country that is truly serious about resolving a counterfeiting problem, it has no power to impose change or a budget to fund country-specific prevention measures. Moreover, it offers no suggestions for increasing the incentives for private actors. Its referenced guidelines, written in 1999, advocate that developing countries foster partnerships with industry, but they do little more than list obvious steps that industry players should be “encouraged” to take.¹⁰¹

Private industry coalitions include the International Federation of Pharmaceutical Manufacturers and Associations’ (“IFPMA”) Pharmaceutical Security Institute (“PSI”).¹⁰² The PSI consists of twenty-one pharmaceutical companies cooperating in the battle against counterfeiting.¹⁰³ However, by its own admission, the PSI concentrates in industrialized countries where they can effectively monitor distribution activities.¹⁰⁴ According to the Federation’s Director General, Harvey Bale, “there is not sufficient capacity and intelligence for the pharmaceutical industry to do the same in developing countries.”¹⁰⁵

Clearly, anti-counterfeiting initiatives have the most influence in countries where there is already a powerful coalition of stakeholders. Governments, manufacturers, and NGOs may already be working together to institute safety measures. Unfortunately, in developing countries, industry incentives are lacking and government corruption or deadlock may be too powerful to overcome,¹⁰⁶ so there

⁹⁹ *Id.*

¹⁰⁰ IMPACT, IMPACT Activities, <http://www.who.int/impact/activities/en/> (last visited Apr. 4, 2008).

¹⁰¹ See generally WHO, GUIDELINES FOR THE DEVELOPMENT OF MEASURES TO COMBAT COUNTERFEIT DRUGS (1999), available at http://whqlibdoc.who.int/hq/1999/WHO_EDM_QSM_99.1.pdf.

¹⁰² Pharmaceutical Security Institute (PSI), <http://www.psi-inc.org/index.cfm> (last visited Apr. 4, 2008).

¹⁰³ PSI, About PSI, <http://www.psi-inc.org/about.cfm> (last visited Apr. 4, 2008).

¹⁰⁴ Harvey Bale, Counterfeit Medicines: The Role of Industry and Pharmacists (May 17, 2002), <http://www.ifpma.org/News/SpeechDetail.aspx?nID=25>.

¹⁰⁵ *Id.*

¹⁰⁶ See Merri C. Moken, *Fake Pharmaceuticals: How They and Relevant Legislation or Lack Thereof Contribute to Consistently High and Increasing Drug Prices*, 29 AM. J.L. & MED. 525, 534 (2003) (“Because of government corruption, or even

may be little additional pressure on counterfeiters. While developing nations impose high technology walls against fake drugs, many developing countries may remain essentially at a standstill.

Even worse, criminal entities that have come to depend on profits from counterfeiting¹⁰⁷ may shift their focus to countries with less stringent protection. Similar to the way a car thief may avoid a vehicle with a visible steering wheel lock or blinking alarm indicator in favor of a less clearly protected car, current anti-counterfeiting initiatives may actually funnel the activity to the easy targets. Given the lack of dependable statistics on worldwide counterfeiting, it is impossible to establish this cause and effect at this point in time, but it is an entirely reasonable and extremely concerning possibility.

III. Invigorating the Private Sector in Developing Countries

The foregoing suggests that leveraging the power of the private sector could provide a powerful tool to reduce counterfeiting in developing countries. Significantly, this involvement is not likely to happen on its own. Simply asking private companies to increase their efforts to help combat generic counterfeiting is unlikely to elicit much response. There must be a clear incentive for involvement. The myriad of potential incentive mechanisms can be categorized as either negative or positive.

A. Negative Anti-Counterfeiting Incentives

In the current global legal environment, the most straightforward way to motivate increased industry involvement is to punish lagging behavior. Through the use of new legal mechanisms and information dissemination, countries may be able to coerce firms into more aggressive anti-counterfeiting efforts.

One possibility is to impose tort-like liability for the failure to utilize sufficiently rigorous anti-counterfeiting technology. While cases have been brought under existing tort regimes, they have generally not met with success.¹⁰⁸ To be effective, countries would

sympathy with local business engaging in counterfeiters' synthesis and sale, many authorities will not prevent the open sale of fake pharmaceuticals.”).

¹⁰⁷ OECD REPORT, *supra* note 11, at pt. III ¶¶ 5.39-5.40.

¹⁰⁸ *Id.* at ¶ 5.49 (describing a failed claim by a victim of counterfeit drugs for failure to use effective technology). *But see* Nicholas D. Cappiello, *Note, Counterfeit-Resistant Technology: An Essential Investment to Protect Consumers and to Avoid Liability*, 2 J. HEALTH & BIOMEDICAL L. 277, 289-95 (2006) (acknowledging that

have to establish a clearer legal duty to engage in anti-counterfeiting efforts. Setting predictable standards for such liability could pose a problem due to the changing nature of the technology and the need to take into account economic feasibility.¹⁰⁹ But it would not be significantly different than the issues that arise in strict products liability cases wherein a design defect is alleged.¹¹⁰

Another negative incentive could entail the enhancement of reputational effects. The fact that a company's products have been subject to counterfeiting can generate distrust in the minds of consumers and may lead them away.¹¹¹ By making the public more aware of such events, these impacts could be increased. If counterfeiting awareness were promoted as part of a standardized information dissemination program (whether globally or locally),¹¹² the reputational incentives may compel a company to engage in greater anti-counterfeiting efforts. The combination of shame and loss of market share may be enough to induce greater efforts.

To be sure, negative pressure may have significant downsides. The most obvious is that a pharmaceutical company facing either increased liability or risk of reputational harm may simply decide to pull out of the market.¹¹³ The effect could be blunted somewhat if such standards are set forth in regional trade agreements,¹¹⁴ as it would

legal liability has yet to be tested but proposing several U.S. legal theories under which it could be successfully pursued).

¹⁰⁹ See Cappiello, *supra* note 108, at 289-95.

¹¹⁰ Cahoy, *supra* note 7, at 638-39 (describing the nature of a design defect case against pharmaceutical products in general).

¹¹¹ OECD REPORT, *supra* note 11, at pt. III ¶ 5.48.

¹¹² It has been alleged that information about counterfeiting has been traditionally buried by companies and governments alike. See Cockburn, *supra* note 15, at 302.

¹¹³ For example, in a recent paper, Fisk & Atun argue that litigation risk is one factor in the lack of new drugs available for use during pregnancy. Nicholas M. Fisk & Rifat Atun, *Market Failure and the Poverty of New Drugs in Maternal Health*, 5 PLoS MED. 22, 26 (2008) ("High-profile product withdrawals leading to rapid falls in share price and revenues, increasing litigation, stronger regulation, the rising cost and complexity of R&D from new technologies, and high costs of commercialization and post-marketing surveillance have encouraged risk aversion . . ."). While litigation risk and reputational harm may not be the only – or even the most significant – risks in marketing a drug in a developing country, increasing them could tip a close decision toward avoiding the market.

¹¹⁴ See General Agreement on Tariffs and Trade, art. XXIV, ¶¶ 4-5, Oct. 30, 1947, 61 Stat. A-11, 55 U.N.T.S. 194 [hereinafter GATT] (facilitation of trade between countries in a region through regional trading agreements that liberalize policies). See also Understanding on the Interpretation of Article XXIV of the General Agreement on Tariffs and Trade 1994, Annex 1A, ¶ 4 (1994), available at <http://www.jurisint.org/pub/06/en/doc/09.htm>.

tend to diffuse the inclination to retaliate.¹¹⁵ However, if the markets in question are simply not that economically significant, it is certainly possible that a pharmaceutical company will not see benefits outweighing the costs. Most worrisome, low-cost competitors would likely be the first to make this conclusion, significantly impacting competition in the marketplace.

In addition, the application of negative incentives would seem inappropriate when a pharmaceutical company's marketing efforts are more altruistic than economic. Several companies have programs in which drugs are distributed to impoverished populations for free or at a significant discount.¹¹⁶ Ratcheting up liability or the disclosure of negative publicity may force a company to rethink the value of its donations. Clearly, in some cases, negative incentives impose societal costs that outweigh the benefits unless countered by significant positive incentives.

B. Positive Anti-Counterfeiting Incentives

Companies might be effectively led into employing stronger anti-counterfeiting measures if the economic benefits of doing so in developing nations are increased. Rather than decreasing revenue for undesirable behavior, positive incentives attempt to engage companies that are eager to take advantage of new opportunities in emerging markets (a pull rather than a push, one might say). A successful mechanism could take many forms and even be balanced against negative incentives.

One direct possibility might be to simply reward private anti-counterfeiting efforts. To a great extent, this is already accomplished through information dissemination that conveys reputational benefits.¹¹⁷ However, governments and international organizations might achieve greater success with actual economic awards. This could take the form of subsidies or tax benefits for increased security. It could also be provided through outcome-based prizes or awards that specifically incent reductions in the metrics of counterfeiting. The

¹¹⁵ If a regional trade agreement had a membership large enough to constitute a sizable share of the global market, it could be very difficult for a pharmaceutical company to abandon it entirely.

¹¹⁶ See, e.g., Leo L. Clarke & Edward C. Lyons, *The Corporate Common Good: The Right and Obligation of Managers to Do Good to Others*, 32 U. DAYTON L. REV. 275, 287 n.41 (2007) (listing several examples of pharmaceutical company drug donations); PhRMA, *Pharmaceutical Companies Lead the way in Corporate Philanthropy* (Fall 2003), available at <http://www.phrma.org/files/2004-01-20.884.pdf> (trade association document detailing a sampling of several donation programs).

¹¹⁷ See OECD REPORT, *supra* note 11, at pt. III ¶¶ 5.67-5.69.

industry already presents its own awards for such efforts (not necessarily specific to pharmaceuticals),¹¹⁸ but they could be usefully supplemented by government action specific to the developing world.

A somewhat more complex and esoteric approach would be to introduce a mechanism that attempts to replicate dynamics of developed world markets that are missing in Southern economies. In the developed world, the magnitude of lost sales in incidents of counterfeiting can be sufficient to induce companies to deploy expensive anti-counterfeiting technology.¹¹⁹ As mentioned above, the direct relationship of lost sales to counterfeiting is related to the power to exclude competitors through intellectual property rights.¹²⁰ It is logical to assume that the introduction of some supplemental market exclusion mechanism in developing countries could support at least a portion of the same private expenditures. The form would have to be different than intellectual property *per se*, as it would be impractical and diplomatically impossible to reform these rights for such a narrow purpose. However, there may be less radical options. Of course, any market new exclusion mechanism may conflict with international policy regarding preferential treatment for domestic industries¹²¹ or restraint of free trade. This fact makes the option intriguing, but certainly less likely and realistic.

V. Conclusion

The importance of the global campaign against counterfeiting requires the consideration of all available mechanisms to stem the tide. Against this backdrop, the deep differences between developed and developing nations are underexplored in guiding anti-counterfeiting design. To the extent that such differences figure into anti-counterfeiting efforts at all, it is generally to argue that stronger employment of standard mechanisms is necessary in the developing world. However, real distinctions in the nature of counterfeiting

¹¹⁸ See, e.g., *Dr. Reddy's Gets 'WorldStar' Award for Omez Packaging*, BUS. LINE, May 14, 2004, <http://www.thehindubusinessline.com/bline/2004/05/15/stories/2004051500600200.htm> (describing an award presented to an Indian pharmaceutical company for anti-counterfeiting technology); Lew Kontnick, *Counterfeits: The Cost of Combat*, 23 PHARM. EXEC. 46, 54 (referring to Glaxo-Wellcome's receipt of a "Global Anticounterfeiting Award" for global anti-counterfeiting strategy).

¹¹⁹ See OECD REPORT, *supra* note 11, at pt. III ¶ 5.46 ("For example, the cost of anti-counterfeiting measures for one product in one jurisdiction has been estimated at 10-20% of total sales per annum.").

¹²⁰ See *supra* notes 91-93, and accompanying text.

¹²¹ See, e.g., GATT, *supra* note 114, at art. I, ¶ 1 (most-favored-nation treatment).

among nations suggest a more directed approach could be more effective. One of the most important factors in this regard is the predominance of generics in the developing world, which create a lack of private industry incentives to devote significant resources to the effort. Engineering incentive structures to encourage greater private industry participation in the developing world has the potential to help bridge the North-South divide in counterfeiting prevention.