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Counterfeit Drugs: The Good, the Bad and the Ugly

Albany J of Science & Technology (2006)

Kevin Outterson* & Ryan Smith♦

When I chose the title, *Counterfeit Drugs: The Good, the Bad and the Ugly*,¹ some of my colleagues at this symposium blanched. They understood counterfeit drugs as *Bad* and *Ugly*, but resisted categorizing any counterfeit drug as *Good*. This article is intended to be provocative, challenging some of the conventional wisdom concerning counterfeit drugs.

We start with the fact that reports about the scope of pharmaceutical counterfeiting are remarkably anecdotal rather than empirical. As a professor once chided me, the plural of anecdote is not data. The FDA and the WHO must undertake comprehensive market surveillance to establish the true scope of the counterfeiting problem.

We also must speak more clearly about counterfeit drugs, with an improved lexicon. It is misleading to pretend that cross-border drugs from Canada and contaminated water passed off as erythropoietin (Epoetin alfa) by criminal gangs are similar issues. They have quite distinct causes, effects and indicated solutions.

Finally, and perhaps most controversially, this article identifies the underlying cause of drug counterfeiting as the legal system of intellectual property laws. We briefly explore alternative systems which would accomplish recovery of R&D expenditures without the patent rents which attract counterfeiting.

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¹ With apologies to Clint Eastwood and Sergio Leone (1966).

I. The Database on Counterfeit Medicines is Unreliable

Statistics about counterfeit medicines are everywhere: press reports,² WHO fact sheets,³ FDA press releases,⁴ U.S. government task forces,⁵ law review articles,⁶ medical journals,⁷ and international trade associations.⁸

Statistics are one thing; useful statistics are quite another. Empirical, reliable and transparent statistics about drug counterfeiting are virtually non-existent. In an excellent article, Robert Cockburn and his co-authors examined the paucity of transparent data and called for mandatory public reporting.⁹ Drug companies are reluctant to release information that might harm the marketing efforts for their branded products.¹⁰ The only comprehensive global collection point for counterfeit drug information is the Pharmaceutical Security Institute (PSI), a trade organization established by the security directors of 14 major global drug companies.¹¹ In October 2004, one of us (KO) asked PSI for access to their database as a researcher, but was told they do not release information to the public. Instead, I was directed to the FDA, WHO or news reports.¹² The “data” begins to resemble a house of mirrors as each group cites the other as the source of the information.

2 Associated Press, *FDA: Al-Qaida could poison medicines*, Aug. 12, 2004, available at <http://msnbe.msn.com/id/5682351> (last visited Mar. 19, 2006).

3 World Health Organization. FACT SHEET NO. 275: SUBSTANDARD AND COUNTERFEIT MEDICINES (November 2003), available at http://www.who.int/mediacentre/factsheets/2003/fs_275/en.

4 U.S. Food and Drug Administration, FY 2003 PERFORMANCE REPORT TO THE PRESIDENT AND THE CONGRESS, available at <http://www.fda.gov/oc/pdufa/report2003/default.htm> (last visited March 19, 2006).

5 US Department of Health and Human Services, HHS TASK FORCE ON DRUG IMPORTATION: REPORT ON PRESCRIPTION DRUG IMPORTATION 37-38 (December 2004).

6 Benjamin A. Drabiak, *Reimportation of prescription drugs: Long-lasting relief or a short-term analgesic?* 4 WASH. U. GLOBAL STUD. L. REV. 135, 143-144 (2005).

7 L. Gibson, *Drug regulators study global treaty to tackle counterfeit drugs*, 328 BRIT. MED. J. 486 (2004).

8 See, e.g., International Council of Nurses, COUNTERFEITS KILL (May 12, 2005), available at www.icn.ch.

9 Robert Cockburn, Paul N. Newton, E. Kyeremateng Agyarko, Dora Akunyili & Nicholas J. White, *The Global Threat of Counterfeit Drugs: Why Industry and Governments Must Communicate the Dangers*, 2 PLOS MEDICINE 0302-0308 (April 2005), available at www.plosmedicine.org.

10 Id. at 0303-0304.

11 Pharmaceutical Security Institute, www.psi-inc.org (last visited March 19, 2006).

12 Personal correspondence with the author, October 4, 2004.

For example, one widely-cited “fact” attributed to the WHO is the claim that “[c]ounterfeit medicines make up more than 10% of the global medicines available in the market”¹³ and “WHO estimates that one in ten medicines sold worldwide is fake, with no medical effect whatsoever. In developing countries, up to 25% of the medicines used are counterfeit or substandard. Some estimates place the annual earnings from counterfeit medicines at over \$32 billion globally.”¹⁴ Another example is the often-repeated claim that “[t]he World Health Organization (WHO) figures suggest that developing countries account for around 60% of all reported cases of counterfeit and substandard drugs.”¹⁵ But the WHO doesn’t really defend this figure when pressed, and generally cites figures from the US FDA.

In the U.S., the FDA cites the WHO figures for global counterfeiting estimates. Domestically, the FDA estimates that less than 1% of U.S. drugs are counterfeit, but “officials admit that this figure is not based on any scientific studies.”¹⁶ European officials also rely on the WHO estimates. The Deputy Secretary General of the Council of Europe said “WHO estimates that counterfeit medicines make up for 8% to 10% of the European pharmaceutical market and in some countries even as much as 12%.”¹⁷

The pharmaceutical industry historically was reticent to discuss counterfeiting, for obvious reasons. With the advent of consumer drug purchasing over the internet, suddenly the industry was faced with cross-border arbitrage pressure.¹⁸ After consumer focus groups identified safety as a primary concern with internet drug purchases, the industry and the FDA began to publicly discuss the problem. Publicly discussing counterfeiting is

13 International Council of Nurses, COUNTERFEITS KILL at 5 (May 12, 2005) available at www.icn.ch.

14 Id. at 38 (citing World Health Organization (2003). Fact Sheet no. 275, SUBSTANDARD AND COUNTERFEIT MEDICINES).

15 Id. at 11 (citing World Health Organization (2004) ESSENTIAL DRUGS AND MEDICINES POLICY, Overview).

16 Elizabeth Cady Brown, *Pharmaceutical Fakery*, LONG ISLAND PRESS, June 9, 2005, available at http://www.longislandpress.com/?cp=188&show=article&a_id=4250 (last visited March 19, 2006).

17 Maud de Boer-Buquicchio, Deputy Secretary General of the Council of Europe, Opening speech on the occasion of the seminar “Counteract the counterfeiters!”, *Limiting the risks of counterfeit medicines to public health in Europe by adequate measures and mechanisms* (Sept. 21, 2005), available at

http://www.coe.int/T/E/Com/press/News/2005/20050921_disc_sga.asp.

¹⁸ Kevin Outterson, *Pharmaceutical Arbitrage*, *supra* note , at .

an important tool to enforce the industry's price discrimination structures across borders, enhancing overall industry profits.¹⁹

To remedy this insufficient data, the federal government should fund independent market surveillance to identify and describe problems with the U.S. drug supply chain. Randomized purchases should be made across the U.S. market, in various channels, and the purchased drugs should be tested in all regards for compliance with U.S. law. When non-compliance is found, investigators should track the problems back to the source. The full results must then be transparently available to all researchers and the public. Similar undertakings could occur in other countries on a recurring basis. Market surveillance on this level would provide the basic facts necessary to truly understand the threat to our drug supply, and to separate public relations campaigns from genuine threats to public health.

II. A New Pharmaceutical Lexicon Is Needed

One of the most important challenges is unpacking what is meant by the terms *fake* or *counterfeit* drugs. The WHO has a widely-disseminated definition which emphasizes deliberate mislabeling as to identity or source.²⁰ Less precise terms are used in press accounts²¹ and by the U.S. and E.U. drug regulatory agencies.²² In some cases, the terms *fake* or

¹⁹ Id. at .

²⁰ World Health Organization. FACT SHEET NO. 275: SUBSTANDARD AND COUNTERFEIT MEDICINES (November 2003), available at <http://www.who.int/mediacentre/factsheets/2003/fs275/en> (“Counterfeit medicines are part of the broader phenomenon of substandard pharmaceuticals. The difference is that they are deliberately and fraudulently mislabeled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products and counterfeit medicines may include products with the correct ingredients but fake packaging, with the wrong ingredients, without active ingredients or with insufficient active ingredients.”). The FDA definition is broader, including drugs with improper dosages, sub-potent or super-potent ingredients, or contamination. U.S. Food & Drug Admin., FDA’s COUNTERFEIT DRUG TASK FORCE INTERIM REPORT 5 (2003), available at http://www.fda.gov/oc/initiatives/counterfeit/report/interim_report.html (last visited Oct. 1, 2004). This definition conflates counterfeits with poorly manufactured or stored product.

²¹ See, e.g. CBSNews.com, *Prescription for Danger: Counterfeit Drug Trade Grows*, available at <http://www.cbsnews.com/stories/2002/01/31/health/main327265.shtml> (Aug. 2, 2001) (“There is no single definition for counterfeit drugs. They may contain dangerous substitutes instead of the real ingredients. Or they may be much like ‘the real thing’—only expired, or not approved for sale in the [United States].”).

²² For discussion of the FDA’s definition, see EXAMINING THE IMPLICATIONS OF DRUG IMPORTATION: HEARING BEFORE THE SENATE JUDICIARY COMM., 108th Cong. (2004) (statement of William K. Hubbard, U.S. FDA Associate

counterfeit have included a wide range of drug products, from criminal acts of homicide, to placebos, to safe and effective drugs from Canada.

These terms are frequently conflated in unhelpful ways. For example, an August 10, 2004 article on Internet drug purchases in the Wall Street Journal used the words *fake* or *counterfeit* many times before mentioning that FDA lab tests “showed that most of the drugs contained too much active ingredient, making the fakes potentially harmful.”²³ These drugs may be poorly produced, or too strong by U.S. standards, but they should not be lumped together with criminal counterfeits.²⁴ Each of these categories feature distinct causes, effects, and potential remedies. Conflating these categories needlessly confuses the issues. The following sections begin the process of building a pharmaceutical lexicon that is more descriptive and helpful.

A. The Good

Commissioner for Policy and Planning), available at <http://www.fda.gov/ola/2004/importeddrugs0714.html>. See also Heather Won Tesoriero, *Fake-Drug Sites Keep a Step Ahead*, WALL ST. J., Aug. 10, 2004, at D4 (describing generic versions which were substituted for brand name drugs still patented in the United States as “counterfeits”); OPTIONS FOR SAFE AND EFFECTIVE PRESCRIPTION DRUG IMPORTATION: HEARING BEFORE THE SENATE COMM. ON COMMERCE, SCIENCE, & TRANSPORTATION, 108th Cong. (2004) (statement of Mark McClellan, Commissioner of the FDA), available at http://commerce.senate.gov/hearings/testimony.cfm?id=1105&wit_id=3132 (discussing “unapproved, imported pharmaceuticals” and “unsafe and illegal drugs” along with “ineffective, counterfeit” drugs). See also FDA, COUNTERFEIT DRUG TASK FORCE INTERIM REPORT 5-7 (2003), http://www.fda.gov/oc/initiatives/counterfeit/report/interim_report.html (noting that counterfeit drugs may “pose significant public health and safety concerns,” as they “may contain only inactive ingredients, incorrect ingredients, improper dosages, sub-potent or super-potent ingredients, or be contaminated.”); Eur. Fed’n of Pharm. Indus. & Ass’ns, *International Exhaustion of Trade Mark Rights* 7 (2001) (describing the range of products that may be considered counterfeit by the WHO and the European pharmaceutical trade association and corresponding concerns).

²³ Heather Won Tesoriero, *Fake-Drug Sites Keep a Step Ahead*, WALL ST. J., Aug. 10, 2004, at D4. See also Mark McClellan, Testimony before the Senate Committee on Com., Sci. & Transp., March 11, 2004 (discussing “unapproved, imported pharmaceuticals” and “unsafe and illegal drugs” with “ineffective, counterfeit” drugs) (McClellan was at the time the Commissioner of the Food and Drug Administration; he currently heads the Centers for Medicare and Medicaid Services).

²⁴ The trade association of European pharmaceutical research companies and the WHO use the broader definition. Eur. Fed’n of Pharmaceutical Industries & Ass’n, *International Exhaustion of Trade Mark Rights* 5 (April 2001). My point is not to argue who’s definition is “right,” but to demonstrate the analysis which is possible when using a narrower definition.

Good drugs are safe, effective and less expensive, but violate some technical requirement of US law. A prime example is prescription drugs purchased by US citizens from brick and mortar pharmacies in Canada. The purchase is legal, but the FDA states that bringing these drugs back into the US violates federal law.²⁵ These are safe and effective drugs purchased in person in Canada, but the consumer violates the US personal importation rule by bringing back to the US for personal use.²⁶

In many important respects these drugs should not be confused with contaminated products peddled by criminal gangs. The first difference is safety and efficacy. Canadian drugs are just as safe and effective as drugs sold in the US market.²⁷ In fact, they are more effective because they are cheaper. Patient compliance with prescription drug regimes is higher when the drugs are affordable.²⁸

The FDA studiously avoids this important point about financial access to drugs, despite the fact that financial access is the primary reason for the Canadian cross-border prescription drug trade. This leads to the second distinction: this trade is not driven by criminals. Law abiding individuals seek treatment for themselves or relatives. US residents fill prescriptions in Canada because the products appear fungible with a transparent price differential.

The primary negative effect of Canadian cross-border foot traffic is the lost pharmaceutical patent rents. The patent-based pharmaceutical companies make a smaller profit when the prices are lower. Evaluation of whether this trade is socially positive must balance the benefits from more affordable drug access (static gains) against the potential dynamic losses from reduced patent rents. The dynamic effects may be positive if indeed current U.S.

²⁵ Prescription Drug Marketing Act

²⁶ Many critics conflate this foot-traffic market, which is undoubtedly safe, with purchasing from internet sites claiming to be from Canada. These are entirely different markets, with very different profiles on safety and efficacy.

²⁷ Drugs purchased in person from a traditional Canadian pharmacy are fully covered by the Canadian drug regulatory system and may actually be safer than similar drugs purchased in the U.S. Ram Kamath & Scott McKibbin, III. Office of Special Advocate for Prescription Drugs, REPORT ON FEASIBILITY OF EMPLOYEES AND RETIREES SAFELY AND EFFECTIVELY PURCHASING PRESCRIPTION DRUGS FROM CANADIAN PHARMACIES 11-16 (2003) (finding Canadian and U.S. systems equivalent for most aspects, but finding the Canadian system superior in preventing the introduction of counterfeit drugs and incident reporting for internal process errors).

²⁸ Health Affairs

prices are supra-optimal.²⁹ Social welfare is improved if the market expands by selling therapeutically-equivalent drugs to lower-income populations with highly elastic demand curves. Whether parallel trade is a net gain is unknown. Most studies ignore the effect of lower prices in improving access,³⁰ as well as the larger question of global optimality of pharmaceutical patent rents.

A second example of a Good drug is the unlicensed generic antiretroviral (ARV) drugs produced to address the AIDS treatment crisis in low- and medium-income countries. The Brazilian health minister threatened to issue a compulsory license for a 2nd generation AIDS drug, Kaletra.³¹ US trade officials responded with quite intemperate language. A compromise was reached before the compulsory license was issued.³² Likewise, access to ARVs in Africa and other low-income populations was made possible when several companies and groups produced and used unlicensed generic ARVs.³³ Many of these drugs were pre-qualified by the WHO.³⁴ Some have now even been approved by the FDA,³⁵ and yet they violate intellectual property (IP) law. These drugs provide affordable access to millions of people with AIDS.

B. The Bad

Bad drugs include blatant attempts to defraud consumers by selling placebos lacking the correct active ingredient, or drugs containing negligent or deliberate contaminants or poisons.³⁶

29 Kevin Outterson, *Pharmaceutical Arbitrage: Balancing Access and Innovation in Int'l Prescription Drug Markets*, 5 YALE J. HEALTH POL'Y L. & ETHICS 193 (2005). [hereinafter, *Pharmaceutical Arbitrage*]

30 Peter West & James Mahon, BENEFITS TO PAYERS AND PATIENTS FROM PARALLEL TRADE (May 2003) (unpublished working paper, on file with the York Health Econ. Consortium) (estimating direct savings of €631 million in 2002 from legal pharmaceutical arbitrage (parallel trade) within the EU) (funded by a grant from European parallel traders); Panos Kanavos et al., THE ECONOMIC IMPACT OF PHARMACEUTICAL PARALLEL TRADE IN EUROPEAN UNION MEMBER STATES: A STAKEHOLDER ANALYSIS 15-16 (London Sch. of Econ. & Pol. Sci., Special Res. Paper, 2004), <http://www.lse.ac.uk/collections/LSEHealthAndSocialCare/documents/otherpaperseries.htm>.

31 Benson, T. 2005. *Brazil and U.S. maker reach deal on AIDS drug*. NEW YORK TIMES, July 9, 2005

32 Benson, T. 2005. *Brazil and U.S. maker reach deal on AIDS drug*. NEW YORK TIMES, July 9, 2005.

33 Kevin Outterson, *Pharmaceutical Arbitrage*, *supra* note 29, at 10.

34 Kevin Outterson, *Pharmaceutical Arbitrage*, *supra* note 29, at 10.

35 Kevin Outterson, *Pharmaceutical Arbitrage*, *supra* note 29, at 10.

36 Bryan A. Liang, *Fade to Black: Importation and Counterfeit Drugs*, 32 Am. J.L. & Med. (2006).

Bad drugs are produced and marketed by criminals. The products are at best placebos and at worst positively dangerous. Patients derive no therapeutic benefit whatsoever; all money spent on them is wasted. Nothing of social value is produced. This trade deserves the enhanced criminal sanctions that Bryan Liang and others call for.³⁷ However, applying these criminal laws to Good or Ugly drugs would be a mistake, misdirecting resources to attack a market with some social value.

C. The Ugly

Ugly drugs are generally safe and effective but come to the consumer through an insecure supply chain or with other deficiencies which may or may not represent a safety risk. Ugly drugs are intended to be therapeutic and legitimate, but are sub-standard in some way, such as labeling which complies with Canadian or EU law but not U.S. FDA standards.

Ugly drugs present an entirely different profile than Bad drugs. These manufacturers and wholesalers are not criminals. They may be resource-constrained or require enhanced procedures at the plant and in the supply chain. They may even be negligent by US standards; but they are not criminals.

Foreign drugs which are imported into the US with foreign-language labeling present an example of an Ugly drug with possibly positive social value. About 12 million people in the United States are linguistically isolated.³⁸ For limited-English proficiency (LEP) populations, receiving a prescription with the proper U.S. FDA labels is practically useless.³⁹ For example, it would be better for a recent LEP immigrant from the Philippines to import a drug from home because not only is it cheaper, but the label in Tagalog is both readable and culturally competent. The indicated solution here would either be to permit importation in foreign language labels for LEP communities or to permit dual-language labeling for these communities.

³⁷ Id.

³⁸ US Census Bureau, LANGUAGE USE AND ENGLISH-SPEAKING ABILITY: 2000 (Oct. 2003).

³⁹ Health Affairs

Ugly drugs might also include products imported from legitimate internet pharmacies. Empirical evidence suggests that virtually none of the internet drugs arriving in the United States are non-functional counterfeits; their importation simply violates technical restrictions on parallel importation, FDA labeling, or similar rules.⁴⁰ Instead, most of the non-functional counterfeit drugs in the United States appear to have domestic origins or domestic networks.⁴¹ The cause of this trade is simply the price differentials across borders. The preferred solution of the FDA is to shut the trade down.⁴² Criminal counterfeiting must be recognized as a major threat to the integrity of our health care system and must be shut down. But the Ugly drug trade is not necessarily a criminal enterprise. An alternative is to legalize and regulate it, bringing this trade out of the grey market. The Dorgan-Snowe Bill in Congress⁴³ and State-based importation plans, such as I-Save Rx,⁴⁴ are prominent examples of this approach. Mindlessly conflating criminal placebos with importation under Dorgan-Snowe only serves the interest of drug company profits rather than a serious discussion of public health.

III. Intellectual Property Laws Are An Underlying Cause of Counterfeit Drugs

40 See, e.g., Press Release, FDA, RECENT FDA/U.S. CUSTOMS IMPORT BLITZ EXAMS CONTINUE TO REVEAL POTENTIALLY DANGEROUS ILLEGALLY IMPORTED DRUG SHIPMENTS (Jan. 27, 2004) (mentioning many categories of unapproved drugs but never indicating that any of them contained no active ingredient). FDA, Counterfeit Drug Task Force Interim Report 5-7 (2003), http://www.fda.gov/oc/initiatives/counterfeit/report/interim_report.html (noting that counterfeit drugs may “pose significant public health and safety concerns,” as they “may contain only inactive ingredients, incorrect ingredients, improper dosages, sub-potent or super-potent ingredients, or be contaminated.”); European Federation of Pharm. Indus. & Ass’ns, INTERNATIONAL EXHAUSTION OF TRADE MARK RIGHTS 7 (2001) (describing the range of products that may be considered counterfeit by the WHO and the European pharmaceutical trade association and corresponding concerns).

41 Gilbert M. Gaul & Mary Pat Flaherty, *U.S. Prescription Drug System Under Attack: Multibillion-Dollar Shadow Market Is Growing Stronger*, WASH. POST, Oct. 19, 2003, at A1.

42 See EXAMINING THE IMPLICATIONS OF DRUG IMPORTATION: HEARING BEFORE THE SENATE JUDICIARY COMM., 108th Cong. (2004) (statement of William K. Hubbard, U.S. FDA Associate Commissioner for Policy and Planning), available at <http://www.fda.gov/ola/2004/importeddrugs0714.html>.

43 S.334, 109th Cong. (2005) (A bill to amend the Federal Food, Drug, and Cosmetic Act with respect to the importation of prescription drugs, and for other purposes).

44 See Kamath & McKibbin, *supra* note (describing the Illinois program).

One outcome of enhanced lexical precision will be a sharper focus on the most dangerous areas of concern: Bad drugs sold by criminals. It also permits us to focus on the underlying cause, which is the legal system of intellectual property (IP) for patented drugs.

An underlying cause of counterfeit drugs is the IP system, particularly patents and trademarks. Criminals follow the money. They typically counterfeit expensive patented drugs rather than generics.⁴⁵ The IP system creates the opportunity which counterfeiters exploit.

The marginal cost of producing most name-brand drugs is a small fraction of the commercial price. An annual supply of a well-known antiretroviral triple combination drug regime in the United States costs over \$11,000.⁴⁶ The marginal price is not publicly known, but can be estimated. Unlicensed generic companies sell the same drugs in sub-Saharan Africa for \$244 per year.⁴⁷ These drugs are sold at 45 times their marginal cost (a “pricing ratio” of 45:1). This ratio would not be possible absent IP laws and the related branding efforts of drug companies. High pricing ratios attract counterfeiters.

This is not an isolated example. Many patented drugs exhibit this profile (see Table 1). Industry estimates suggest that the average variable cost of patented drugs accounts for an average of 15% of the final price,⁴⁸ yielding an average pricing ratio of more than 6:1. Some pricing ratios are much higher: generic ciprofloxacin is sold in some places at less than 0.4% of the price of the most expensive sources in the U.S., a pricing ratio of 246:1.⁴⁹ Others have found pricing ratios of 200:1 in global markets for vaccines and contraceptives.⁵⁰

45 In some uncompetitive generic drug markets, even generics might sell at a substantial premium over the marginal cost of production, and thus attracting counterfeiters. This uncompetitive market may well be related to a hang-over effect from related pharmaceutical laws, even with the expiration of the patent.

46 Data from drugstore.com for the triple drug combination 3TC/4dT/NVP.

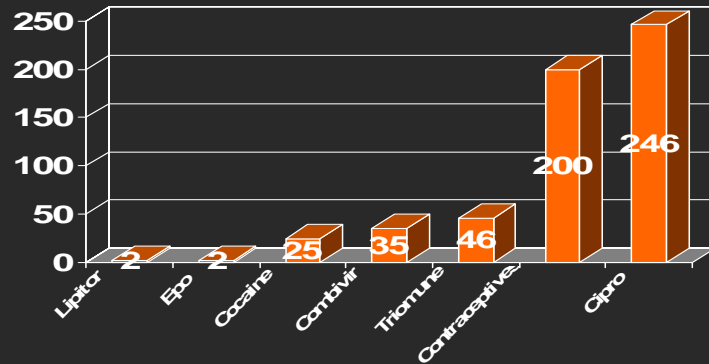
47 MSF, Untangling the Web [pincite]

48 J. Watal & F.M. Scherer, *Post-TRIPS Options for Access to Patented Medicines in Developing Countries*, 5 J. INT'L ECON. L. 913-939 (2002).

49 Pharmaceutical Arbitrage, *supra* note , at 254-55.

50 S. Moon & E. t'Hoen, *Pills and Pocketbooks: Equity Pricing of Essential Medicines in Developing Countries* (2001), available at www.accessmed-msf.org/upload/ReportsandPublications.

Table 1. Rx Pricing Ratios



Outterson, *Pharmaceutical Arbitrage*, 5 *Yale J H Pol'y, L & Ethics* 193 (2005).

By way of comparison, one of us (KO) has previously estimated the pricing ratio for cocaine at 25:1.⁵¹ The potential returns from parallel importation of some patented drugs are higher than cocaine by an order of magnitude. Patented drugs are especially attractive if the markets are less crowded and law enforcement is less diligent.⁵²

The story gets worse. These ratios are built by comparing safe and effective versions of a drug sold in different markets. All of these pricing ratios assume that the criminal intends to deliver actual functional pharmaceuticals. This assumption is generally true in illegal narcotic markets. When criminals market cocaine, they need to deliver the expected (and observable) biochemical effect: customers want to get high. Delivering a placebo will not only destroy customer loyalty and repeat business, but it may also result in violence.

⁵¹ Comparison of the street price in producing countries and the street price in the US. *Pharmaceutical Arbitrage*, *supra* note , at 262.

⁵² Brian Liang and others have decried the poor law enforcement resources dedicated to pharmaceutical counterfeiting. Bryan A. Liang, *supra* note .

However, many patented drugs do not deliver an effect which is immediately observable to the patient. If a patient takes a placebo instead of atorvastatin calcium (Lipitor), the patient may not notice the lack of therapeutic effect for months.⁵³ By the time it is noticed, it may be very difficult to re-trace the supply chain to the point where the counterfeit was introduced. Some commentators reluctantly acknowledge that counterfeit drugs are something of a “perfect crime.”⁵⁴

For drugs that do not produce an immediately observable therapeutic effect, criminals need not go to the trouble to procure and ship the actual drugs. Any placebo will do, at a fraction of the cost of either obtaining the correct API to manufacture pills, or obtaining cheaper versions of the medicine via parallel trade. Criminal enterprises may be increasingly involved in pharmaceutical counterfeiting.⁵⁵

At this point the reader may complain that blaming the IP system for counterfeiting is akin to blaming the law for crime.⁵⁶ That position may not be as controversial as it may first appear. The Apostle Paul, writing to the Church in Rome said: “And where there is no law there is no transgression”⁵⁷ and “Indeed I would not have known what sin was except through the law. For I would not have known what coveting really was if the law had not said, ‘Do not covet.’”⁵⁸ However, we are not opening a discussion of law and sin. The narrower point is that if the ostensible goal of pharmaceutical IP law is to promote innovation, then counterfeiting demonstrates that the law is ill-suited to achieving that goal. This is especially true if alternatives are available which fund R&D without creating the pricing ratios found attractive by counterfeiters.

53 For other drugs, such as analgesics or erectile dysfunction drugs, it may well be possible for the patient to quickly identify the therapeutic failure. But if the counterfeit drug was introduced into the supply chain at an unknown point, it might still be difficult to find the counterfeiter.

54 L. Kontnik, PHARMACEUTICAL COUNTERFEITING: PREVENTING THE PERFECT CRIME 2 (2004), available at http://www.fffenterprises.com/web_files/fff_wht_ppr_111804.pdf (last visited January 10, 2005).

55 Alliance Against Counterfeiting & Piracy, *supra* note 54, at 2 (“This document provides clear and unambiguous evidence of organised crime controlling, exploiting and benefiting from intellectual property fraud. It is on the increase.”).

56

57 Romans 4:14b (New International Version).

58 Romans 7:7b.

A. Counterfeiting Is A Major Threat To Pharmaceutical Innovation

Counterfeits are an immanent danger to innovation. While the FDA still considers it a relatively rare practice,⁵⁹ counterfeiting is nevertheless growing rapidly in the United States and in other high-income markets.⁶⁰ In 2000, the estimated value of EU pharmaceutical counterfeiting was more than 1.5 billion Euros. In 2003, the United Kingdom-based Anti-Counterfeiting Group estimated that 5.8% of pharmaceutical company annual revenue is lost due to counterfeiting,⁶¹ and recent estimates range even higher.⁶² Given a pharmaceutical global market exceeding \$500 billion, the total lost to counterfeiting may exceed \$30 billion per year. If true, counterfeiting is a major threat not only to public health, but also to innovation, far outstripping the limited potential damage from government reimbursement systems and equitable access programs.

B. Government Reimbursement Systems In High-Income Countries Are A Less Significant Threat

The patent-based drug industry argues that European-style government reimbursement systems threaten pharmaceutical innovation. The industry and the US Department of Commerce have attacked high-income countries for their price-conscious reimbursement systems for drugs, labeling these

59 FDA, COUNTERFEIT DRUG TASK FORCE INTERIM REPORT 3 (2003).

60 The FDA estimates that pharmaceutical counterfeiting has increased four-fold in the past few years. See, e.g., Mary Pat Flaherty & Gilbert M. Gaul, *Anti-Counterfeit Steps Drugmakers Sought: Legislators' Goal Is To Halt Illegal Sales*, WASH. POST, Jan. 17, 2004, at A11; Mary Pat Flaherty & Gilbert M. Gaul, *Miami Man Charged with Selling Counterfeit Lipitor*, WASH. POST, Dec. 6, 2003, at E1; Mary Pat Flaherty & Gilbert M. Gaul, *Lax System Allows Criminals To Invade the Supply Chain*, WASH. POST, Oct. 22, 2003, at A1. These articles were part of a series of articles on counterfeit drugs by Mary Pat Flaherty and Gilbert M. Gaul that ran in the Washington Post during Fall 2003/Winter 2004. The Wall Street Journal has also covered the story. E.g., Anna Wilde Mathews & Heather Won Tesoriero, *Murky Channels: Bogus Medicines Put Spotlight on World of Drug Distributors*, WALL ST. J., Sept. 29, 2003, at A1.

61 The Anti-Counterfeiting Group, WHY YOU SHOULD CARE ABOUT COUNTERFEITING 14, http://www.acg.com/docs/why_you_should_care.pdf (last modified June 22, 2004).

62 See Bryan A. Liang, *supra* note 61, at 14.

efforts as “price controls.”⁶³ Name calling of this sort ignores the fact that many US government programs employ similar or more restrictive techniques, including Medicaid, the US Public Health Service, the Veteran’s Administration, or the Federal Supply Schedule.⁶⁴ The sum of the allegedly lost patent rents equals no more than \$7.5 billion per year,⁶⁵ and is likely to be much smaller, as low as \$355 million.⁶⁶ In any case, these numbers are much smaller than the pharmaceutical patent rents lost to counterfeiting.

C. Alternatives To Patent-Based R&D Cost Recovery May Eliminate The Incentive To Counterfeit

A possible solution to reduce the incentive to counterfeit would be to remove R&D costs from the retail pricing system. Generally, these proposals fund R&D as a global public good through a variety of approaches. A prominent example of this approach is the Hubbard-Love R&D Treaty.⁶⁷ Broadly similar approaches are currently being discussed at the WHO Executive Board.⁶⁸ Supporters generally seek to enhance financial access to patented pharmaceuticals by low- and medium-income populations.

If R&D cost recovery is removed from the retail price system, then the pricing ratios described above collapse. All medicines would be sold essentially as generics. This result satisfies the access needs of the poor, and it also destroys the vast majority of the incentive to counterfeit. The best

⁶³ US Dept. of Commerce, International Trade Administration, *Pharmaceutical Price Controls in OECD Countries: Implications for U.S. Consumers, Pricing, Research and Development, and Innovation* (Dec. 2004) [hereinafter, the Commerce Department Study].

⁶⁴ Testimony of Kevin Outterson, Associate Professor, West Virginia University, Before the Committee on Health, Education, Labor & Pensions, United States Senate, Hearing On: *Drug Importation: Would the Price Be Right?* February 17, 2005.

⁶⁵ Id.

⁶⁶ Id.

⁶⁷ See, e.g., Tim Hubbard, *ALTERNATIVES TO THE PRICE SYSTEM* (Presentation at Columbia University, Dec. 4, 2003), available at http://www.earthinstitute.columbia.edu/cgsd/accesstomedicines_papers.html; James Love, Presentation at Columbia University: *A NEW TRADE FRAMEWORK FOR GLOBAL HEALTHCARE R&D* (Dec. 4, 2003), available at http://www.earthinstitute.columbia.edu/cgsd/accesstomedicines_papers.html. A recent treatment of these subject is Peter Drahos, *An Alternative Framework for the Global Regulation of Intellectual Property Rights* (Centre for Governance of Knowledge and Development, Working Paper No. 1: October 2005) (forthcoming in *Austrian Journal of Development Studies*) available at <http://cgkd.anu.edu.au/menus/publications.php#drahos>.

⁶⁸ EB 2006

solution to the scourge of counterfeit drugs may involve radical examination of our society's reliance on IP law for recovery of pharmaceutical R&D costs.

CONCLUSION

Very little is really known about the scope and nature of counterfeit drugs. Congress should obtain real facts before it criminalizes behavior which may be socially valuable. We need data on counterfeiting which is free from industry control and bias. Our primary focus should be protecting our pharmaceutical supply chain from criminal counterfeiters that serve no positive social value. This problem also presents an opportunity to re-evaluate the foundations of the pharmaceutical IP systems to see if a better world is possible.