COUNTERFEIT DRUGS: THE GOOD, THE BAD AND THE UGLY

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I. INTRODUCTION

When I chose the title, Counterfeit Drugs: The Good, the Bad and the Ugly, 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 Food and Drug Administration (FDA) and the World Health Organization (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.

II. THE DATABASE ON COUNTERFEIT MEDICINES IS UNRELIABLE

Information about counterfeit medicines is everywhere: press reports, WHO fact sheets, FDA press releases, U.S.

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1 With apologies to Clint Eastwood and Sergio Leone (1967).
3 See WORLD HEALTH ORG., FACT SHEET NO. 275, SUBSTANDARD AND COUNTERFEIT MEDICINES (Nov. 2003), available at http://www.who.int/mediacentre/factsheets/2003/fs275/ (reporting that the FDA estimates that 10% of the global medicine market is made up of counterfeits and “up to 25% of the medicines consumed in poor countries are counterfeit or substandard.”) [hereinafter WHO FACT SHEET].
government task forces, law review articles, medical journals, and international trade associations.

Statistics are one thing; useful statistics are quite another. Empirical, reliable and transparent statistics about drug counterfeiting are virtually nonexistent. In an excellent article, Robert Cockburn and his co–authors examined the paucity of transparent data and called for mandatory public reporting. Drug companies are reluctant to release information that might harm the marketing efforts for their branded products. 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. 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.


7 See Liza Gibson, Drug Regulators Study Global Treaty to Tackle Counterfeit Drugs, 328 BRIT. MED. J. 486 (2004), available at http://bmj.bmjournals.com/cgi/content/full/328/7438/486-c (stating that the counterfeit drug trade affects between 5% and 7% of the worldwide market).


10 Id. at 302–04. See Robert Cockburn, Death by Dilution, AM. PROSPECT, Dec. 20, 2005, available at http://www.prospect.org (describing a situation where GlaxoSmithKline refused to release information about potential counterfeits because of the negative effect it would have on business).


12 See E-mail from Dr. Sebastian J. Mollo, Pharmaceutical Security Institute, to Kevin Outterson (on file with author).
was directed to the FDA, WHO and news reports. The “data” begins to resemble a house of mirrors as each group cites the other as the source of the information.

For example, one widely–cited “fact” attributed to the WHO is the claim that “[c]ounterfeit medicines make up more than 10% of today’s global medicines” available in the market. Further, “[WHO] estimates that one in ten medicines sold worldwide is fake, with no medical effect whatsoever.” Yet another statistic is that “[i]n developing countries, up to 25% of the medicines used are counterfeit or substandard.” In fact, the WHO reports that “[s]ome estimates place the annual earnings from counterfeit medicines at over $32 billion globally.” Another example is the often–repeated claim that “World Health Organization . . . figures suggest that developing countries account for around 60% of all reported cases of counterfeit and substandard drugs.” But the WHO doesn’t really defend this figure when pressed, and generally cites figures from the U.S. 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.”

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13 Id.
15 Nurses Raise the Alarm, supra note 14.
17 Nurses Raise the Alarm supra note 14.
19 Compare, e.g., U.S. Food & Drug Admin., Counterfeit Drugs Questions and Answers, http://www.fda.gov/oc/initiatives/counterfeit/qa.html (last visited Oct. 1, 2006) (“It is estimated that upwards of 10% of drugs worldwide are counterfeit, and in some countries more than 50% of the drug supply is made up of counterfeit drugs.”), with WHO FACT SHEET, supra note 3 (“[E]stimates put counterfeits at more than 10% of the global medicines market . . . In some countries, the figure [of counterfeit medicines consumed in developing countries] is thought to be as high as 50%.”).
20 See id.
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%.”

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

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.

23 Id.
24 See Vivienne Parry, A Lack of Chemistry, TIMES ONLINE, July 9, 2005, available at http://www.timesonline.co.uk/article/0,,8122-1684914,00.html (stating that pharmaceutical companies are wary of discussing topics that may hurt consumer confidence or open the door to litigation).
26 For example, the FDA recently announced a new prescription drug information format that will help healthcare professionals find information regarding prescription dosage and administration, boxed warnings, and other prescribing information. See Press Release, FDA Announces New Prescription Drug Information Format to Improve Patient Safety (Jan. 18, 2006), available at http://www.fda.gov/bbs/topics/news/2005/NEW01272.html.
III. 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. Less precise terms are used in press accounts and by the U.S. and E.U. drug regulatory agencies. In some cases, the terms *fake* or

27 *See* WHO FACT SHEET, supra note 3:
“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. COUNTERFEIT DRUG TASK FORCE, U.S. FOOD DRUG AND ADMIN., COUNTERFEIT DRUG TASK FORCE INTERIM REPORT (Oct. 2003), available at http://www.fda.gov/oc/initiatives/counterfeit/report/interim_report.html [hereinafter COUNTERFEIT DRUG TASK FORCE INTERIM REPORT]. This definition conflates counterfeits with poorly manufactured or stored products.

28 *See*, e.g., Prescription for Danger Counterfeit Drug Trade Grows, CBS NEWS, Aug. 2, 2001, available at http://www.cbsnews.com/stories/2002/01/31/health/main327265.shtml (“There’s 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].”).

counterfeit have included a wide range of drug products, from those resulting in criminal acts of homicide, to placebos, to safe and effective drugs from Canada.\textsuperscript{30}

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.”\textsuperscript{31} These drugs may be poorly produced, or too strong by U.S. standards, but they should not be lumped together with criminal counterfeits.\textsuperscript{32} 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.

\textbf{A. The Good}

Good drugs are safe, effective and less expensive, but can violate some technical requirement of U.S. law.\textsuperscript{33} A prime example is prescription drugs purchased by U.S. citizens from

\begin{footnotesize}
\begin{enumerate}
\item Tesoriero, supra note 29, at D4; see also Mark McClellan, supra note 29 (discussing “unapproved, imported pharmaceuticals” and “unsafe and illegal drugs” with “ineffective, counterfeit drugs”). McClellan was the Commissioner of the Food and Drug Administration at the time; he currently heads the Centers for Medicare and Medicaid Services.
\item The trade association of European pharmaceutical research companies and the WHO use the broader definition. EFPIA, supra note 29 (explaining that “[c]ounterfeiting can apply to both branded and generic products and ... may include products with the correct ingredients, wrong ingredients, without active ingredients, with insufficient quantity of active ingredient or with fake packaging.”). My point is not to argue whose definition is “right,” but to demonstrate the analysis which is possible when using a narrower definition.
\item See Internet Drug Sales: Hearing Before the H. Comm. on Gov’t Reform, 108th Cong. (2004) (statement of William K. Hubbard, Associate Comm’r, Federal Drug Administration), available at http://www.fda.gov/ola/2004/internetdrugs0318.html (noting that legitimate Internet pharmacies provide important services to patients but some sell unapproved drugs, drugs without a required prescription or drugs to patients without valid health problems).
\end{enumerate}
\end{footnotesize}
brick and mortar pharmacies in Canada. The purchase is legal, but the FDA states that bringing these drugs back into the United States violates federal law. These are safe and effective drugs purchased in person in Canada, but the consumer violates the U.S. personal importation rule by bringing them back to the United States for personal use.

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 U.S. market. In fact, they are cheaper which makes them more effective because patient compliance with prescription drug regimes is higher when the drugs are affordable.

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

36 Young, supra note 34; 21 U.S.C. § 331(a), (d), (t); 21 U.S.C. § 381(d)(1); see also OFFICE OF REGULATORY AFFAIRS, U.S. FOOD AND DRUG ADMIN., REGULATORY PROCEDURES MANUAL CH. 9: IMPORT OPERATIONS/ACTIONS, SUBCHAPTER: COVERAGE OF PERSONAL IMPORTATIONS (2002), available at http://www.fda.gov/ora/compliance_ref/rpm_new2/ch9pers.html. (Chapter 9 is currently under revision as of Jun. 21, 2006). 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.
38 Id. Drugs purchased from Canada may actually be safer than similar drugs purchased in the U.S. RAM KAMATH & SCOTT MCKIBBIN, OFFICE OF SPECIAL ADVOCATE FOR PRESCRIPTION DRUGS, ILL. DEPT OF CENT. MGMT. SERVICES, REPORT ON FEASIBILITY OF EMPLOYEES AND RETIREES SAFELY AND EFFECTIVELY PURCHASING PRESCRIPTION DRUGS FROM CANADIAN PHARMACIES 18 (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).
drug trade. This leads to the second distinction: this trade is not driven by criminals. United States 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. prices are supra-optimal. 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

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40 See Young, supra note 34 (noting that consumers will continue to purchase drugs from Canada until the United States can lower drug prices).
41 See id. (indicating that professional organizations made up of physicians and pharmacists are among those promoting the purchase of prescription drugs from Canada).
42 See Christopher Rowland, U.S. Steps Up Seizures of Imported Drugs: Warnings Sent for Prescriptions, BOSTON GLOBE, Mar. 26, 2006, at A1 (discussing how one American consumer was purchasing prescription drugs from a Canadian Internet pharmacy because it was less expensive, even with Medicare coverage).
44 See Marcia Angell, Excess in the Pharmaceutical Industry, 171 CAN. MED. ASS’N J. 1451 (2004) available at http://www.cma.ca/cgi/reprint/171/12/1451.pdf (stating “[e]xcess profits are, of course, the result of excess prices”); see also Barry, supra note 37 (quoting U.S. Senator Chuck Grassley who reported that drug companies “do not want to see their lower-priced products from other countries coming into the U.S. It undermines their profits here, and they will want to do everything they can to stop drug importation.”).
46 Pharmaceutical Arbitrage, supra note 25, at 197.
47 Id. at 195; see generally Outterson, supra note 43 (explaining how charging higher prices to low-income populations often results in mortality for those unable to afford the drugs).
unknown. Most studies ignore the effect of lower prices in improving access, 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 second generation AIDS drug, Kaletra. US trade officials responded with quite intemperate language. A compromise was reached before the compulsory license was issued. 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. Many of these drugs were pre- qualified by the WHO. Some have now even been approved by the FDA, 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 and drugs

50 See Outterson, supra note 43.
51 Todd Benson, Brazil to Copy AIDS Drug Made by Abbott, N.Y. TIMES, June 25, 2005, at C12.
52 Todd Benson, Brazil and U.S. Maker Reach Deal on AIDS Drug, N.Y. TIMES, July 9, 2005, at C2.
54 See Vanishing Public Domain, supra note 53, at 73; Hirschler, supra note 53.
55 Hirschler, supra note 53.
containing negligent or deliberate contaminants or poisons.\footnote{\textcopyright 2006] COUNTERFEIT DRUGS 535}{57} 

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.\footnote{\textcopyright 2006] COUNTERFEIT DRUGS 535}{58} However, applying these criminal laws to Good or Ugly drugs would be a mistake, and would misdirect resources to attack a market with some social value.

\subsection*{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.\footnote{\textcopyright 2006] COUNTERFEIT DRUGS 535}{59} Ugly drugs are intended to be therapeutic and legitimate, but are substandard in some way, such as labeling which complies with Canadian or EU law but not U.S. FDA standards.\footnote{\textcopyright 2006] COUNTERFEIT DRUGS 535}{60} 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.\footnote{\textcopyright 2006] COUNTERFEIT DRUGS 535}{61} 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.\footnote{\textcopyright 2006] COUNTERFEIT DRUGS 535}{62} For limited English proficiency (LEP) populations, receiving a prescription with the proper U.S. FDA labels is practically useless.\footnote{\textcopyright 2006] COUNTERFEIT DRUGS 535}{63} For example, it


\footnote{\textcopyright 2006] COUNTERFEIT DRUGS 535}{58} \textit{Id.}


\footnote{\textcopyright 2006] COUNTERFEIT DRUGS 535}{61} \textit{Id.}


\footnote{\textcopyright 2006] COUNTERFEIT DRUGS 535}{63} See 21 C.F.R. \S 201.15(c) (2004) (requiring labels to appear in English); \textit{see also} Leighton Ku \\& Glenn Flores, \textit{Pay Now Or Pay Later: Providing Interpreter Services In Health Care}, 24 \textit{HEALTH AFF.} 435, 436 (Mar/Apr 2005); Leighton Ku
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.  

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. Instead, most of the non-functional counterfeit drugs in the United States appear to have domestic origins or domestic networks. The cause of this trade is simply the price differentials across borders. The preferred solution of the FDA is to shut the trade down. 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 Congress and State-based
importation plans, such as I-Save Rx, 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.

IV. INTELLECTUAL PROPERTY LAWS ARE AN UNDERLYING CAUSE OF COUNTERFEIT DRUGS

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 an 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. The IP system creates the opportunity that 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 anti-retroviral triple combination drug regime in the United States costs over $12,000. The marginal price is not publicly known, but can be estimated. Unlicensed generic companies sell the same drugs in sub-Saharan Africa for under $200 per year. These drugs are sold at 60 times their marginal

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72 See Vanishing Public Domain, supra note 53, at 91.
73 See Parry, supra note 24. In some uncompetitive generic drug markets, even generics might sell at a substantial premium over the marginal cost of production, and thus attract counterfeiters. This uncompetitive market may well be related to a hang-over effect from related pharmaceutical laws, even with the expiration of the patent. See Pharmaceutical Arbitrage, supra note 25, at 254–55 (citing an example of a generic drug which has been counterfeited and sold at a price considerably above the actual value).
74 Vanishing Public Domain, supra note 53, at 91 (discussing how the Medical R&D Treaty would diminish exploitation of the IP system by counterfeiters by lowering the cost of pharmaceuticals).
cost (a “pricing ratio” of 60:1). 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, 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 264:1. Others have found pricing ratios of 200:1 in global markets for vaccines and contraceptives.

Table 1. Rx Pricing Ratios


77 See Drugstore.com, supra note 75; MEDECINS SANS FRONTIERES, supra note 76 (showing that the price charged in the United States is approximately sixty times the price charged in sub-Saharan Africa for the same drug).


79 Pharmaceutical Arbitrage, supra note 25, at 254.

80 Ellen 't Hoen & Suerie Moon, Pills and Pocketbooks: Equity Pricing of Essential Medicines in Developing Countries 222 (Medecins Sans Frontieres, DND Working Group 2001), available at http://www.accesmed-
By way of comparison, one of us (KO) has previously estimated the pricing ratio for cocaine at 25:1.\textsuperscript{81} The potential returns from parallel importation of some patented drugs are higher than cocaine by an order of magnitude.\textsuperscript{82} Patented drugs are especially attractive if the markets are less crowded and law enforcement is less diligent.\textsuperscript{83}

The story gets worse. These ratios are built by comparing safe and effective versions of a drug sold in different markets.\textsuperscript{84} All of these pricing ratios assume that the criminal intends to deliver actual functional pharmaceuticals.\textsuperscript{85} 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.

However, many patented drugs do not deliver an effect that is immediately observable to the patient. If a patient takes a placebo instead of a drug such as atorvastatin calcium (Lipitor), the patient may not notice the lack of therapeutic effect for months.\textsuperscript{86} By the time it is noticed, it may be very difficult to retrace the supply chain to the point where the counterfeit was introduced.\textsuperscript{87} Some commentators reluctantly acknowledge that

\begin{itemize}
\item \textsuperscript{81} See Pharmaceutical Arbitrage, supra note 25, at 262 (comparing the street price in producing countries and the street price in the US).
\item \textsuperscript{82} See id. at 254 (showing that the Cipro pricing ratio is 246:1 as opposed to cocaine at a ratio of 25:1).
\item \textsuperscript{83} Liang, supra note 57. Brian Liang and others have decried the poor law enforcement resources dedicated to pharmaceutical counterfeiting.
\item \textsuperscript{84} See Pharmaceutical Arbitrage, supra note 25, at 263–64 (discussing a case where patented drugs were packaged for the African market but sold to the European market).
\item \textsuperscript{85} Liang, supra note 57.
\item \textsuperscript{86} See, e.g., Brown, supra note 21 (recounting an incident where it took several weeks before a patient became aware that the Epogen he was taking was counterfeit, even where there were noticeable side effects). 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. Gaul & Flaherty, supra note 67, at A1, A15.
\item \textsuperscript{87} See Brown, supra note 21 (noting that one victim’s counterfeit drugs changed hands “at least 11 more times” after it first entered the marketplace).
\end{itemize}
counterfeit drugs are something of a “perfect crime.”

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.

At this point the reader may complain that blaming the IP system for counterfeiting is akin to blaming the law for crime. 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” 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.’” 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.

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89 Brown, supra note 21 (discussing methods used to create counterfeit drugs). See Pharmaceutical Arbitrage, supra note 25, at 205–06 (explaining that parallel trading involves purchasing drugs in lower-priced markets and re-selling them in higher-priced markets).


92 Romans 4:15 (New International Version).

93 Id. at 7:7.

A. Counterfeiting Is A Major Threat To Pharmaceutical Innovation

Counterfeits are an imminent danger to innovation. While the FDA still considers it a relatively rare practice,95 counterfeiting is nevertheless growing rapidly in the United States and in other high-income markets.96 In 2000, the estimated value of EU pharmaceutical counterfeiting was more than 1.5 billion Euros.97 In 2003, the United Kingdom–based Anti–Counterfeiting Group estimated that 5.8% of pharmaceutical company annual revenue is lost due to counterfeiting,98 and recent estimates range even higher.99 Given a pharmaceutical global market exceeding $500 billion, the total lost to counterfeiting may exceed $30 billion per year.100 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.

95 COUNTERFEIT DRUG TASK FORCE INTERIM REPORT, supra note 27.
97 Pharmaceutical Arbitrage, supra note 25, at 269–70.
99 See Bryan A. Liang, supra note 57 (stating that expenditures in the U.S. for prescription drugs is about $230 billion, while the worldwide sales of counterfeit drugs equals approximately $32 to $35 billion dollars annually, meaning an average loss of 13% of sales revenues to the counterfeit markets).
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 efforts as “price controls.” 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 Veterans’ Administration, or the Federal Supply Schedule. The sum of the allegedly lost patent rents equals no more than $7.5 billion per year, and is likely to be much smaller, as low as $355 million. 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. Broadly similar

103 Kevin Outterson, supra note 45 at 55–56.
104 Id. at 58.
105 Id. at 59 (stating that a report based on industry data estimates increased revenues from raising foreign prices would result in $5.3 to $8 billion in additional Research and Development (R&D), but pointing out the controversial nature of the feasibility of raising prices and predicting the potential revenue increases will be limited to approximately 1/4 of that estimated by the industry).
106 See infra Part III.A. (stating that approximately $30 billion is spent annually on counterfeit medication which could otherwise be spent on licensed pharmaceuticals which would increase R&D funds by approximately $9 billion, assuming, as the Department of Commerce did, that 1/3 of profit increases will be reinvested into R&D).
107 See, e.g., Tim Hubbard, Remarks at Colombia Univ.: Alternatives to the Price System (Dec. 4, 2003), available at
approaches are currently being discussed at the WHO Executive Board.\(^{108}\) Supporters generally seek to enhance financial access to patented pharmaceuticals by low and medium income populations.\(^{109}\)

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 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.

V. 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 counterfeiteres 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.


\(^{109}\) Id.