

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*,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 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,² WHO fact sheets,³ FDA press releases,⁴ U.S.

¹ With apologies to Clint Eastwood and Sergio Leone (1967).

² Associated Press, *FDA: Al-Qaida Could Poison Medicines*, MSNBC, Aug. 12, 2004, available at <http://msnbc.msn.com/id/5682351>.

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].

⁴ Press Release, U.S. Food and Drug Admin., FDA Alerts U.S. Residents to Recall of Counterfeit “Lipitor” Sold in the United Kingdom (July 29, 2005), available at <http://www.fda.gov/bbs/topics/NEWS/2005/NEW01216.html>; Press Release, U.S. Food and Drug Admin., FDA Takes Action Against Foreign

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.¹² Instead, I

Websites Selling Counterfeit Contraceptive Patches (Feb. 12, 2004), available at <http://www.fda.gov/bbs/topics/NEWS/2004/NEW01023.html>.

⁵ HHS TASK FORCE ON DRUG IMPORTATION, U.S. DEP'T OF HEALTH AND HUMAN SERVICES, REPORT ON PRESCRIPTION DRUG IMPORTATION IX-X (Dec. 2004), available at <http://www.hhs.gov/importtaskforce/Report1220.pdf>.

⁶ See Anthony F. Andrisano, Jr., *To the U.S. Government: Whether or not Reimportation Is the Answer, Something Must Be Done to Help Americans Afford Their Necessary Prescription Drugs!*, 23 PENN STATE INT'L L. REV. 897, 900 (2005) (discussing generally the advent of counterfeit drug sales over the Internet); see also Bryan A. Liang, *International Drug Importation: Issues in Public Policy, Patient Safety, and the Public Health*, 36 CAL. W. INT'L L.J. 1, 4-5 (2005) (explaining that Americans spend approximately \$800 million in medicines from across the Mexican border, much of which is counterfeit).

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).

⁸ See, e.g., Judith A. Oulton, Commentary, *Counterfeits Kill—What Are We Doing About Them?*, 52 INT'L NURSING REV. 91 (2005), available at <http://www.icn.ch/INR/INR52-2%20InsideView.pdf> (stating that “[c]ounterfeit medicines make up more than 10% of today’s global medicines”).

⁹ Robert Cockburn et al., *The Global Threat of Counterfeit Drugs: Why Industry and Governments Must Communicate the Dangers*, 2 PLOS MEDICINE 302, 303 (2005), available at http://medicine.plosjournals.org/archive/1549-1676/2/4/pdf/10.1371_journal.pmed.0020100-L.pdf.

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).

¹¹ Pharmaceutical Security Institute, About PSI, <http://www.psi-inc.org/about.cfm> (last visited Oct. 1, 2006).

¹² See E-mail from Dr. Sebastian J. Mollo, Pharmaceutical Security Institute, to Kevin Outtersson (on file with author).

was directed to the FDA, WHO and news reports.¹³ 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.¹⁴ Further, “[WHO] estimates that one in ten medicines sold worldwide is fake, with no medical effect whatsoever.”¹⁵ Yet another statistic is that “[i]n developing countries, up to 25% of the medicines used are counterfeit or substandard.”¹⁶ In fact, the WHO reports that “[s]ome estimates place the annual earnings from counterfeit medicines at over \$32 billion globally.”¹⁷ 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.”¹⁸ But the WHO doesn’t really defend this figure when pressed, and generally cites figures from the U.S. FDA.¹⁹

In the U.S., the FDA cites the WHO figures for global counterfeiting estimates.²⁰ 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.”²¹

¹³ *Id.*

¹⁴ Oulton, *supra* note 8; Press Release, Int’l Council of Nurses, Nurses Raise the Alarm: Counterfeit Medicines Kill (May 11, 2005), *available at* http://www.icn.ch/PR09_05.htm [hereinafter Nurses Raise the Alarm].

¹⁵ Nurses Raise the Alarm, *supra* note 14.

¹⁶ *Id.*; Int’l Perspectives, ICN asks Nurses to Help Protect Patients From Counterfeit Medicines, 52 INT’L NURSING REV. 85 (2005), *available at* http://www.icn.ch/fr_INRsubscribe.htm.

¹⁷ Nurses Raise the Alarm *supra* note 14.

¹⁸ INT’L COUNCIL OF NURSES, NURSES FOR PATIENT SAFETY: TARGETING COUNTERFEIT AND SUBSTANDARD MEDICINES, *available at* <http://www.icn.ch/indkit2005.pdf> (Providing an “Information and Action Tool Kit” for International Nurses day 2005).

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.*

²¹ Elizabeth Cady Brown, *Pharmaceutical Fakery*, LONG ISLAND PRESS, June 9, 2005, *available at* http://www.longislandpress.com/?cp=188&show=article&a_id=4250.

European officials also rely on the WHO estimates.²² 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%.”²³

The pharmaceutical industry historically was reticent to discuss counterfeiting, for obvious reasons.²⁴ With the advent of consumer drug purchasing over the Internet, suddenly the industry was faced with cross-border arbitrage pressure.²⁵ 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.²⁶ 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.

²² See Maud de Boer-Buquicchio, Deputy Secretary of the Council of Europe, Opening Speech on the Occasion of the Seminar “Counteract the counterfeiters!”, (Sept. 21, 2005) (transcript available at http://www.coe.int/T/E/Com/press/News/2005/20050921_disc_sga.asp).

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).

²⁵ Kevin Outterson, *Pharmaceutical Arbitrage: Balancing Access and Innovation in International Prescription Drug Markets*, 5 YALE J. HEALTH POL’Y L. & ETHICS 193, 277–79 (2005) [hereinafter *Pharmaceutical Arbitrage*].

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.²⁷ Less precise terms are used in press accounts²⁸ and by the U.S. and E.U. drug regulatory agencies.²⁹ 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].”).

²⁹ See *Importation of Prescription Drugs into the U.S. and the use of the Internet: Hearing Before the S. Comm. on the Judiciary*, 108th Cong. (2004) (statement of William K. Hubbard, U.S. FDA Associate Comm’r for Policy and Planning), *available at* <http://www.fda.gov/ola/2004/importeddrugs0714.html> [hereinafter William K. Hubbard]; Heather Won Tesoriero, *Fake-Drug Sites Keep a Step Ahead: One is Busted for Selling Bogus Pharmaceuticals; New Vendor Grabs Address*, 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); see also *Options for Safe and Effective Prescription Drug Importation: Hearing Before the S. Comm. on Commerce, Science & Transportation*, 108th Cong. (2004) (statement of Mark McClellan, Comm’r of the Federal Drug Administration), *available at* http://commerce.senate.gov/hearings/testimony.cfm?id=1105&wit_id=3132 (discussing “unapproved, imported pharmaceuticals,” “unsafe and illegal drugs,” and “ineffective, counterfeit drugs”) [hereinafter Mark McClellan]; COUNTERFEIT DRUG TASK FORCE INTERIM REPORT, *supra* note 27 (“Counterfeit drugs pose significant public health and safety concerns. They may contain only inactive ingredients, incorrect ingredients, improper dosages, sub-potent or super-potent ingredients, or be contaminated.”); Position Paper, Eur. Fed’n of Pharm. Indus. & Ass’ns, *International Exhaustion of Trade Mark Rights* (Apr. 2001), *available at* http://www.efpia.org/4_pos/legal/protecpatients.pdf [hereinafter EFPIA] (describing the range of products that may be considered counterfeit by

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

A. *The Good*

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

the WHO and the European Pharmaceutical Trade Association and those groups' corresponding concerns).

³⁰ See Paul N. Newton et al., Editorial, *Murder by Fake Drugs: Time for International Action*, 324 BRIT. MED. J. 800, 801 (2002), available at <http://bmj.bmjournals.com/cgi/content/full/324/7341/800>; Carmen Catizone & Peter Wyckoff, *Should Consumers be Allowed to Buy Drugs From Canada?*, AARP BULLETIN, May 2003, available at <http://www.aarp.org/bulletin/faceoff/a2003-06-25-shouldconsumers.html>.

³¹ 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.

³² 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.

³³ 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).

brick and mortar pharmacies in Canada.³⁴ The purchase is legal, but the FDA states that bringing these drugs back into the United States violates federal law.³⁵ 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.³⁶

In many important respects these drugs should not be confused with contaminated products peddled by criminal gangs. The first difference is safety and efficacy.³⁷ Canadian drugs are just as safe and effective as drugs sold in the U.S. market.³⁸ In fact, they are cheaper which makes them more effective because patient compliance with prescription drug regimes is higher when the drugs are affordable.³⁹

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

³⁴ Donna Young, *FDA Clarifies Importation Law As Internet Pharmacies Proliferate*, AM. SOC'Y OF HEALTH-SYS. PHARMACISTS, April 15, 2003, available at <http://www.ashp.org/news/ShowArticle.cfm?id=3365> (last visited Oct. 30, 2006).

³⁵ *Id.*; 21 U.S.C. § 331(a), (d), (t) (2000 & Supp. III 2004); 21 U.S.C. § 381(d)(1) (2000 & Supp. III 2004).

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.

³⁷ See Patricia Barry, *Prescription Drugs: The Rush to Buy Canadian*, AARP BULLETIN, May 2004, available at <http://www.aarp.org/bulletin/prescription/a2004-05-12-buycanadian.html> (reporting that a recent study revealed no difference in the active ingredients in drugs purchased from a Canadian Internet pharmacy and those purchased in the U.S.).

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. DEP'T 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).

³⁹ See *In re Petition: to Provide Certification to Congress Under Section 804(l) of Chapter VII of the Federal Food, Drug and Cosmetics Act, and to Authorize a Pilot Program for Importation of Prescription Drugs in the State of Illinois: Before the Dep't of Health and Human Services*, 108th Cong. (2004) (aff. of Alan Sager, Ph.D.).

drug trade.⁴⁰ This leads to the second distinction: this trade is not driven by criminals.⁴¹ United States residents fill prescriptions in Canada because the products appear fungible with a transparent price differential.⁴²

The primary negative effect of Canadian cross-border foot traffic is the lost pharmaceutical patent rents.⁴³ The patent-based pharmaceutical companies make a smaller profit when the prices are lower.⁴⁴ 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.⁴⁵ The dynamic effects may be positive if indeed current U.S. prices are supra-optimal.⁴⁶ Social welfare is improved if the market expands by selling therapeutically-equivalent drugs to lower-income populations with highly elastic demand curves.⁴⁷ Whether parallel trade is a net gain is

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).

⁴³ See Kevin Outtersson, *Nonrival Access to Pharmaceutical Knowledge*, Submission to the WHO Commission on Intellectual Property Rights, Innovation & Public Health, (Jan. 3, 2005), available at <http://www.who.int/intellectualproperty/submissions/KevinOuttersson3january.pdf> (indicating that patents allow drugs to be priced above the marginal cost of production).

⁴⁴ See Marcia Angell, *Excess in the Pharmaceutical Industry*, 171 CAN. MED. ASS'N J. 1451 (2004) available at <http://www.cmaj.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.”).

⁴⁵ See *Drug Importation: Would the Price Be Right?: Hearing Before the S. Comm. on Health, Education, Labor and Pensions*, 109th Cong. (2005) (statement of Kevin Outtersson, Associate Professor, West Virginia University College of Law), available at http://help.senate.gov/Hearings/2005_02_17/outtersson.pdf (last visited Oct. 1, 2006).

⁴⁶ *Pharmaceutical Arbitrage*, *supra* note 25, at 197.

⁴⁷ *Id.* at 195; see generally Outtersson, *supra* note 43 (explaining how charging higher prices to low-income populations often results in mortality for those unable to afford the drugs).

unknown.⁴⁸ Most studies ignore the effect of lower prices in improving access,⁴⁹ as well as the larger question of global optimality of pharmaceutical patent rents.⁵⁰

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.⁵¹ US trade officials responded with quite intemperate language. A compromise was reached before the compulsory license was issued.⁵² 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.⁵³ Many of these drugs were pre-qualified by the WHO.⁵⁴ Some have now even been approved by the FDA,⁵⁵ and yet they violate intellectual property (IP) law. These drugs provide affordable access to millions of people with AIDS.⁵⁶

B. *The Bad*

Bad drugs include blatant attempts to defraud consumers by selling placebos lacking the correct active ingredient and drugs

⁴⁸ Pharmaceutical Arbitrage, *supra* note 25, at 195–96, 206.

⁴⁹ PETER WEST & JAMES MAHON, YORK HEALTH ECON. CONSORTIUM, BENEFITS TO PAYERS AND PATIENTS FROM PARALLEL TRADE (May 2003), at http://www.york.ac.uk/inst/yhec/downloads/ParallelTrade_ExecSumm.pdf (estimating direct savings of 631 million in 2002 from legal pharmaceutical arbitrage (parallel trade) within the EU); 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. Political Sci., Special Research Paper, Jan. 2004), available at <http://www.lse.ac.uk/collections/LSEHealthAndSocialCare/pdf/Workingpapers/Paper.pdf>.

⁵⁰ See Outtersson, *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.

⁵³ See Kevin Outtersson, *The Vanishing Public Domain: Antibiotic Resistance, Pharmaceutical Innovation and Intellectual Property Law*, 67 U. PITT. L. REV. 67, 74 (2005) [hereinafter *Vanishing Public Domain*]; Ben Hirschler, *Generic Drugs Key to Uphill AIDS Fight, WHO Says*, REUTERS NEWMEDIA, June 21, 2005, available at <http://www.aegis.org/news/re/2005/RE050646.html>.

⁵⁴ See *Vanishing Public Domain*, *supra* note 53, at 73; Hirschler, *supra* note 53.

⁵⁵ Hirschler, *supra* note 53.

⁵⁶ *Vanishing Public Domain*, *supra* note 53, at 73–74.

containing negligent or deliberate contaminants or poisons.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.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.

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.⁵⁹ 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.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.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.⁶² For limited English proficiency (LEP) populations, receiving a prescription with the proper U.S. FDA labels is practically useless.⁶³ For example, it

⁵⁷ Bryan A. Liang, *Fade to Black: Importation and Counterfeit Drugs*, 32 AM. J.L. & MED. (forthcoming 2006).

⁵⁸ *Id.*

⁵⁹ See William K. Hubbard, *supra* note 29.

⁶⁰ See Press Release, U.S. Food and Drug Admin., Recent FDA/U.S. Customs Import Blitz Exams Continue to Reveal Potentially Dangerous Illegally Imported Drug Shipments (Jan. 27, 2004) available at <http://www.fda.gov/bbs/topics/NEWS/2004/NEW01011.html> [hereinafter FDA Press Release].

⁶¹ See *id.*

⁶² US CENSUS BUREAU, LANGUAGE USE AND ENGLISH-SPEAKING ABILITY: 2000 (Oct. 2003). A linguistically isolated person is one who lives in a household in which no person over age 14 speaks English "very well." *Id.*

⁶³ See 21 C.F.R. § 201.15(c) (2004) (requiring labels to appear in English); see also Leighton Ku & Glenn Flores, *Pay Now Or Pay Later: Providing Interpreter Services In Health Care*, 24 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.⁶⁴

Ugly drugs might also include products imported from legitimate Internet pharmacies.⁶⁵ 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.⁶⁶ Instead, most of the non-functional counterfeit drugs in the United States appear to have domestic origins or domestic networks.⁶⁷ The cause of this trade is simply the price differentials across borders.⁶⁸ The preferred solution of the FDA is to shut the trade down.⁶⁹ 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 Congress⁷⁰ and State-based

& Sheetal Matani, *Left Out: Immigrants' Access to Health Care and Insurance*, 20 HEALTH AFF. 247, 254 (Jan./Feb. 2001) (noting that language problems are "the leading barrier to child health services" by Latino parents and this may increase medical errors due to "misdiagnosis and misunderstanding of physicians' orders").

⁶⁴ See Ku & Flores, *supra* note 63, at 437 (pointing out that LEP patients with interpreters or bilingual providers are better informed and, sometimes, have less pain and better physical functioning).

⁶⁵ See National Association of Boards of Pharmacy, VIPPS, <http://www.nabp.net/vipps/intro.asp> (last visited Oct. 1, 2006) (providing certification for legitimate pharmacy practices on the Internet).

⁶⁶ See, e.g., FDA Press Release, *supra* note 60 (mentioning many categories of unapproved drugs but never indicating that any of them contained no active ingredient); COUNTERFEIT DRUG TASK FORCE INTERIM REPORT, *supra* note 27 (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."); EFPIA, *supra* note 29 (describing the range of products that may be considered counterfeit by the WHO and the European pharmaceutical trade association and corresponding concerns).

⁶⁷ 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.

⁶⁸ See Pharmaceutical Arbitrage, *supra* note 25, at 277-80.

⁶⁹ See William K. Hubbard, *supra* note 29.

⁷⁰ Pharmaceutical Market Access and Drug Safety Act of 2005, S. 334, 109th

importation plans, such as I-Save Rx,⁷¹ 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.⁷² Criminals follow the money. They typically counterfeit expensive patented drugs rather than generics.⁷³ The IP system creates the opportunity that counterfeiters exploit.⁷⁴

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 \$12,000.⁷⁵ 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.⁷⁶ These drugs are sold at 60 times their marginal

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).

⁷¹ See 29 Ill. Reg. 7108 (2005) (discussing the I-Save Rx program).

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).

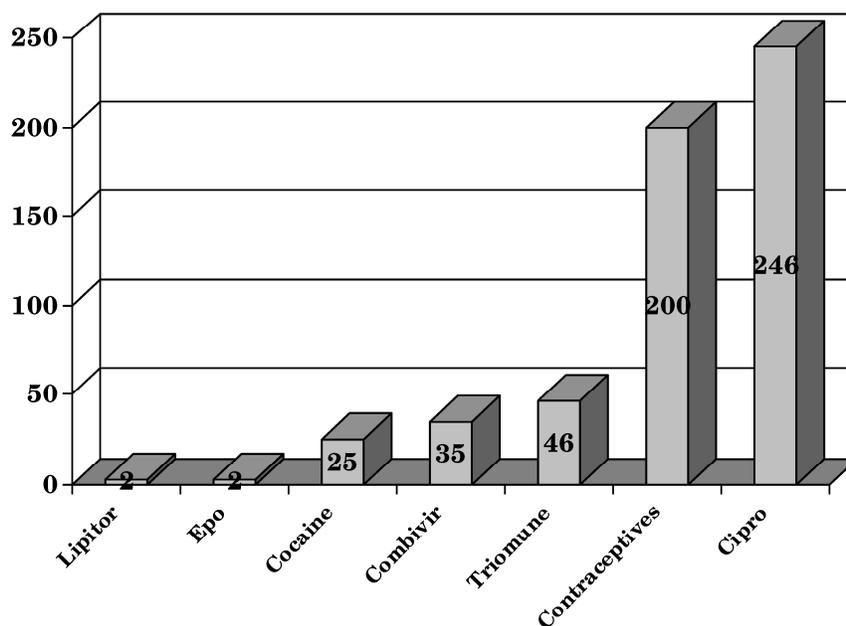
⁷⁵ Drugstore.com, Trizivir, <http://www.drugstore.com/pharmacy/prices/drugprice.asp?ndc=00173069100&trx=1Z5006> (last visited Oct. 1, 2006) (listing the price of the antiviral anti-HIV medication Trizivir® based on a two pill per day dosage as \$12,773.56).

⁷⁶ MEDECINS SANS FRONTIERES, UNTANGLING THE WEB OF PRICE REDUCTIONS: A PRICING GUIDE FOR THE PURCHASE OF ARVs FOR DEVELOPING COUNTRIES 9 (8th ed. 2005), available at <http://www.accessmed-msf.org/documents/untanglingtheweb%208.pdf>.

cost (a “pricing ratio” of 60:1).⁷⁷ 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,⁷⁸ 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 264:1.⁷⁹ Others have found pricing ratios of 200:1 in global markets for vaccines and contraceptives.⁸⁰

Table 1. Rx Pricing Ratios



Outtersson, Pharmaceutical Arbitrage, 5 Yale J H Pol’y, L & Ethics 193 (2005).

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).

⁷⁸ Tomas J. Philipson & Anupam B. Jena, *Dividing the Benefits from Medical Breakthroughs: The Case of HIV/AIDS Drugs*, THE MILIKEN INSTIT. REV. 46, 51 (2006).

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.accessmed->

By way of comparison, one of us (KO) has previously estimated the pricing ratio for cocaine at 25:1.⁸¹ The potential returns from parallel importation of some patented drugs are higher than cocaine by an order of magnitude.⁸² Patented drugs are especially attractive if the markets are less crowded and law enforcement is less diligent.⁸³

The story gets worse. These ratios are built by comparing safe and effective versions of a drug sold in different markets.⁸⁴ All of these pricing ratios assume that the criminal intends to deliver actual functional pharmaceuticals.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.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.⁸⁷ Some commentators reluctantly acknowledge that

msf.org/prod/publications.asp?scentid=20920021811218&contenttype=PARA&
(last visited Oct. 1, 2006).

⁸¹ See Pharmaceutical Arbitrage, *supra* note 25, at 262 (comparing the street price in producing countries and the street price in the US).

⁸² See *id.* at 254 (showing that the Cipro pricing ratio is 246:1 as opposed to cocaine at a ratio of 25:1).

⁸³ Liang, *supra* note 57. Brian Liang and others have decried the poor law enforcement resources dedicated to pharmaceutical counterfeiting.

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).

⁸⁵ Liang, *supra* note 57.

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.

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).

counterfeit drugs are something of a “perfect crime.”⁸⁸

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.⁸⁹ Criminal enterprises may be increasingly involved in pharmaceutical counterfeiting.⁹⁰

At this point the reader may complain that blaming the IP system for counterfeiting is akin to blaming the law for crime.⁹¹ 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”⁹² 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.’”⁹³ 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.⁹⁴ This is especially true if alternatives are available which fund R&D without creating the pricing ratios found attractive by counterfeiters.

⁸⁸ LEW KONTNIK, PHARMACEUTICAL COUNTERFEITING: PREVENTING THE PERFECT CRIME 1, available at http://www.fffenterprises.com/web_pages/anticounterfeiting.html, at 1 (last visited Oct. 1, 2006).

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).

⁹⁰ *FDA Eyes New Tactics Against Fakes*, CBS NEWS, Oct. 3, 2003, available at <http://www.cbsnews.com/stories/2003/09/26/health/main575354.shtml> (last visited Oct. 1, 2006) (indicating that organized crime groups are attracted to the sale of counterfeit pharmaceuticals because of financial incentive).

⁹¹ ALLIANCE AGAINST COUNTERFEITING & PIRACY, PROVING THE CONNECTION 7, available at <http://www.allianceagainstiptheft.co.uk/Proving-the-Connection.pdf> (last visited Oct. 1, 2006) (noting various incentives for selling counterfeit products).

⁹² *Romans* 4:15 (New International Version).

⁹³ *Id.* at 7:7.

⁹⁴ See Carsten Fink & Patrick Reichenmiller, *Tightening TRIPS: The Intellectual Property Provisions of Recent US Free Trade Agreements*, TRADE NOTE 20 (World Bank Group/Int’l Trade Dep’t) Feb. 7, 2005, at 9, available at <http://siteresources.worldbank.org/INTRANET/TRADE/Resources/Pubs/TradeNote20.pdf> (explaining that the lack of flexibility when attempting to overcome drug patents “can have a detrimental impact on public health.”).

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.

⁹⁶ The FDA estimates that pharmaceutical counterfeiting has increased in the past few years. *See, e.g.*, Mary Pat Flaherty & Gilbert M. Gaul, *Anti-Counterfeit Steps by 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. Anna Wilde Mathews & Heather Won Tesoriero, *Bogus Medicines Put Spotlight on World of Drug Distributors*, WALL ST. J., Sept. 29, 2003, at A1.

⁹⁷ Pharmaceutical Arbitrage, *supra* note 25, at 269–70.

⁹⁸ THE ANTI-COUNTERFEITING GROUP, WHY YOU SHOULD CARE ABOUT COUNTERFEITING 14 (2003), available at http://www.a-cg.com/guest_frames.html.

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).

¹⁰⁰ *See* David Greising & Bruce Japsen, *Pharmaceutical Companies Feeling Potent Effect of Fakes*, CHICAGO TRIB., Nov. 20, 2005, available at <http://www.chicagotribune.com/business/chi-0511200306nov20,1,2099145.story?coll=chi-business-utl> (last visited Oct. 1, 2006) (citing a World Health Organization study finding that counterfeit drugs cost the pharmaceutical industry \$32 billion a year; *Global Pharmaceutical Market Grew 7% in 2005 to \$602 Billion; Emerging Markets in Asia, Latin America and Eastern Europe Gain Strength*, FINFACTS IRELAND, Mar. 22, 2006, available at http://www.finfacts.com/irelandbusinessnews/publish/printer_1000article_10005271.shtml).

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.¹⁰¹ 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.”¹⁰² 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.¹⁰³ The sum of the allegedly lost patent rents equals no more than \$7.5 billion per year,¹⁰⁴ and is likely to be much smaller, as low as \$355 million.¹⁰⁵ In any case, these numbers are much smaller than the pharmaceutical patent rents lost to counterfeiting.¹⁰⁶

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.¹⁰⁷ Broadly similar

¹⁰¹ See innovation.org, Preserving Incentives for Innovation, http://www.innovation.org/index.cfm/InnovationToday/KeyIssues/Preserving_Incentives_for_Innovation (last visited Oct. 1, 2006).

¹⁰² INT’L TRADE ADMIN., U.S. DEP’T OF COMMERCE, PHARMACEUTICAL PRICE CONTROLS IN OECD COUNTRIES: IMPLICATIONS FOR U.S. CONSUMERS, PRICING, RESEARCH AND DEVELOPMENT, AND INNOVATION viii (2004), available at <http://trade.gov/td/chemicals/drugpricingstudy.pdf>.

¹⁰³ Kevin Outtersson, *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 ¼ 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 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.

http://www.earthinstitute.columbia.edu/cgsd/accesstomedicines_papers.html; James Love, Remarks at Colombia Univ.: 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 subjects was done by Peter Drahos. Peter Drahos, *An Alternative Framework for the Global Regulation of Intellectual Property Rights*, AUSTRIAN J. OF DEV. STUDIES (forthcoming 2006) *available at* <http://cgkd.anu.edu.au/menus/workingpapers.php>.

¹⁰⁸ WORLD HEALTH ORG., GLOBAL FRAMEWORK ON ESSENTIAL HEALTH RESEARCH AND DEVELOPMENT, EXECUTIVE BD. RES. 13 (Jan. 27, 2006) *available at* http://www.who.int/gb/ebwha/pdf_files/EB117/B117_R13-en.pdf (last visited Oct. 1, 2006).

¹⁰⁹ *Id.*