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STRUCTURALLY SOPHISTICATED OR LAMENTABLY LIMITED? MECHANISMS TO ENSURE SAFETY OF THE MEDICINE SUPPLY

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TABLE OF CONTENTS

I.	INTRODUCTION	485
II.	THE PROBLEM: TAINTED, FAKE, AND INEFFECTIVE DRUGS.....	486
	A. The Billion Dollar International Problem.....	486
	B. Harm	491
III.	LEGAL, MEDICAL, AND TECHNOLOGICAL WEAKNESSES.....	494
	A. Legal Weaknesses	494
	B. Medical Weaknesses	497
	C. Technological Weaknesses.....	499
	1. 2D Seriological Bar Codes and RIFD.....	500
	2. Simplistic Sophistication	503
	3. Chemical Testing in the Field	505
	4. Bulk Property Testing	511
	5. Full Laboratory Analysis	512
IV.	AN INTERDISCIPLINARY APPROACH	514
	A. Technology Investment	516
	B. Penalties	517
	C. Raising Awareness	517
	D. Reporting Systems	520
V.	CONCLUSION.....	523

I. INTRODUCTION

The use of medicines is ubiquitous. The benefits of pharmaceuticals are sought by virtually all citizens around the world to assist in sustaining life, treating illness, and preventing disease. As such, they represent a significant tool in promoting the quality of human existence.

Because of this extensive demand for drugs for these purposes, there is money to be made in developing, producing, and selling medications. The costs for producing effective medicines are high, and concomitantly, producers expect high remuneration for their investments.¹ And the world is often ready to pay these costs; it is estimated that U.S. drug sales will hit \$279 billion, and global drug sales will be \$650 billion in 2006.²

Yet because of the tremendous resources allocated by governments and citizens to medicines, and due to the inelastic demand for them, sordid elements are attracted to this industry.³ They sell tainted, fake, and ineffective drugs to the unsuspecting patients, and they make a lot of money at it.⁴

However, counterfeit or tainted drug sales have come a long way since Graham Greene's *The Third Man*, where ne'er do well Harry Lime, known as "the worst racketeer who ever made a dirty living[,]” sold fake penicillin in occupied Vienna.⁵ Yes, there are still dirty racketeers, and yes, they are still selling fake drugs. But these drug sellers are now sophisticated, technologically savvy, talented, and organized⁶ in a way that allows them to take advantage of legal, medical, and technological weaknesses—and evade detection.

¹ Bringing a molecule from the laboratory bench to the market by pharmaceutical companies is estimated to cost \$800–\$900 million. See FDA, FY 2003 PERFORMANCE REPORT TO THE PRESIDENT AND THE CONGRESS, available at <http://www.fda.gov/oc/pdufa/report2003/default.htm>; Tufts Center for the Study of Drug Development, *Total Cost to Develop a New Prescription Drug, Including Cost of Post-Approval Research, is \$897 Million*, May 13, 2003, <http://csdd.tufts.edu/NewsEvents/RecentNews.asp?newsid=29>.

² See Nicole Ostrow, *Global Drug Sales May Rise 7% in 2006 to \$650 Billion*, Oct. 25, 2005, available at <http://www.bloomberg.com/apps/news?pid=10000085&sid=a0W4sS3UreSc&refer=europe>.

³ See *infra* Part II.

⁴ *Id.*

⁵ THE THIRD MAN (British Lion Film Corporation 1949) (script available at http://www.aellea.com/script/the_third_man.txt).

⁶ See, e.g., Nicholas Zamiska & Heather Won Tesoriero, *Companies Battle Counterfeit Drugs in China*, PITTSBURGH POST-GAZETTE, Jan. 24, 2006, available at <http://www.post-gazette.com/pg/06024/643429.stm>.

In Part II, this article reviews the problem of tainted, fake, and ineffective drugs being sold around the world. It outlines a dismal picture: an epidemiology of fakes that show a presence in virtually every continent around the world and an associated set of harms that affect patients. In Part III, the legal, medical, and technological weaknesses that thwart stemming and addressing this worldwide scourge are recounted. Here, an equally dismal picture of low penalties, limited index of suspicion, and underdeveloped and impractical technology creates the environment for the perfect crime of peddling fake and tainted medicines. An interdisciplinary approach to address some of the issues raised is presented in Part IV. Finally, in Part V, the paper concludes.

II. THE PROBLEM: TAINTED, FAKE, AND INEFFECTIVE DRUGS

A. *The Billion Dollar International Problem*

Sales of fake drugs are a multi-billion dollar a year industry.⁷ The World Health Organization (WHO) estimates that fake drug sales represent \$40 billion annually—\$110 million in sales *per day*—and that ten to fifteen percent of all drugs in the world are fake.⁸

The costs of making these drugs are low, particularly in comparison to making illicit drugs such as cocaine and heroin.⁹ For example, manufacturing illegal drugs such as cocaine and heroin, getting them sold, and getting the proceeds into relevant drug lord hands is expensive, technologically complex, and associated with significant risk of severe penalties.¹⁰ These drugs have to work and these products must evade the efforts of government investigation and enforcement efforts to crack down

⁷ Frances Williams, *Taskforce Set Up to Tackle Counterfeit Drugs*, FIN. TIMES, Feb. 15, 2006, <http://news.ft.com/cms/s/1424e002-9e51-11da-b641-0000779e2340.html>; Robert Cockburn et al., *The Global Threat of Counterfeit Drugs: Why Industry and Governments Must Communicate the Dangers*, 2 PLOS MEDICINE 302, Apr. 2005, http://medicine.plosjournals.org/archive/1549-1676/2/4/pdf/10.1371_journal.pmed.0020100-S.pdf (estimating greater than \$35 billion in fake drug sales annually).

⁸ Williams, *supra* note 7; Cockburn et al., *supra* note 7, at 302.

⁹ Kerry Capell et al., *What's in That Pill? In Latin America, Fake Drugs are as Lucrative as Cocaine*, BUS. WK., June 18, 2001, available at http://www.businessweek.com/magazine/content/01_25/b3737153.htm.

¹⁰ See *id.* (describing the vast difference in time served for manufacturing counterfeit drugs juxtaposed with heroine and cocaine).

on illicit drug trade.¹¹

Yet making licit, fake drugs has few of these concerns. They are cheap to make—the product only needs to appear genuine rather than have any therapeutic effect.¹² Labor can be unskilled; no complex formulas or highly sensitive product manufacturing conditions are required.¹³ And there is very limited attention to focusing scarce enforcement resources on detecting and prosecuting makers of counterfeit licit drugs.¹⁴ It has been estimated that fake drugs can be made for as little as less than \$0.01 per tablet.¹⁵

Fakes have been detected in continents and countries throughout the world.¹⁶ Here in the United States, for example, 130,000 bottles of Lipitor, a cholesterol drug and one of the world's best selling medicines, were discovered to be counterfeit and recalled in 2003.¹⁷ These drugs were a mixture of fake drugs manufactured in Central America salted¹⁸ with South American versions of the actual drug, with both illegally imported and sold in the United States.¹⁹ Also in 2003, inspections by government

¹¹ See *id.* (noting the “two-decade” war waged by Latin American authorities against the cartels).

¹² See *id.*

¹³ *Id.*

¹⁴ See *id.* (highlighting the need for better regulation and stiffer penalties with respect to counterfeit drugs).

¹⁵ See Capell et al., *supra* note 9.

¹⁶ *Id.*

¹⁷ See *Lipitor Counterfeits Abound*, CBS NEWS, June 5, 2003, available at <http://www.cbsnews.com/stories/2003/06/04/earlyshow/health/main557016.shtml>.

¹⁸ See *infra* notes 66, 67 and accompanying text.

¹⁹ Press Release, FDA, Federal Authorities Cease Sale and Distribution of Counterfeit Lipitor (Aug. 31, 2005), available at <http://www.fda.gov/bbs/topics/news/2005/NEW01228.html>. Note that Latin America is itself awash in counterfeit drugs. For example, Peru's Ministry of Health (Minsa) estimates fifteen to twenty percent of medicines sold there are fake, stolen, or expired. See Encarna Nunez-Diaz, *Minsa Reports that 20% of Medicines Sold in Peru Are Counterfeit*, WORLD MARKETS ANALYSIS, Apr. 14, 2005; *World Update, Peru*, WEEKLY NEWS UPDATE (P'ship for Safe Meds., Vienna, Va.), Jan. 20, 2006 (summarizing *Health Ministry to Curb Illegal Drug Trade in Peru*, WORLD MARKETS ANALYSIS, JAN. 19, 2006) (on file with author). Indeed, because of the limited enforcement budget, it is estimated that thirty percent of the 6,000 pharmacies in Lima, the capital, are unlicensed. Nunez-Diaz, *supra* note 19. Compounding the problem is that one-fifth of the medicines trade occurs in the “informal sector,” such as night markets and other non-standard, non-pharmacy locations. *Id.* The notorious “triple frontier” area between Argentina, Brazil, and Paraguay is infamous for its counterfeiting activities in pharmaceutical and other products. See Martin Krause, *A New Balance on Counterfeit Goods*, TCS DAILY, Aug. 22, 2005,

officials of foreign drug imports at U.S. international mail facilities found that almost nine out of ten were unapproved, may have been stored improperly, and/or had safety issues.²⁰ According to one estimate, sales of counterfeit or tainted prescription drugs sold in the United States that year alone were \$200 million, which was “a seven-fold increase over the previous year.”²¹

In 2004 and 2005, FDA officials warned about counterfeit drugs purchased in Mexico and imported by U.S. citizens,²² including warnings of fake Lipitor, Viagra, and an unapproved osteoporosis drug being imported over the Mexican border.²³ The Pharmaceutical Security Institute, a nonprofit trade association group, reported in 2005 that the United States experienced the greatest number of problems in counterfeiting, theft, and drug

<http://www.tcsdaily.com/article.aspx?id=082105C>.

²⁰ U.S. DEP'T OF HEALTH & HUMAN SERVS., HHS TASK FORCE ON DRUG IMPORTATION: REPORT ON PRESCRIPTION DRUG IMPORTATION 13 (2004), *available at* <http://www.hhs.gov/importtaskforce/Report1220.pdf>.

²¹ Don Oldenburg, *Raising the Alarm on Rise in Counterfeit Drugs*, WASH. POST, Apr. 5, 2005, at C9 (quoting most recent figures from the Pharmaceutical Security Institute).

²² FDA Talk Paper, FDA Warns Consumers About Counterfeit Drugs Purchased in Mexico (July 30, 2004), *available at* <http://www.fda.gov/bbs/topics/ANSWERS/2004/ANS01303.html>. Drug purchases by U.S. citizens from Mexico are particularly insidious. The focus over the border is now on pharmaceutical sales to U.S. customers; virtually all medicines are available, and the appearance of those selling the product lends confidence to the transaction. *See* Matt Taibbi, *Pill City*, ROLLING STONE, Feb. 24, 2005, at 47, 49 (describing journalist's experience in obtaining medicines, including morphine derivatives, Ritalin, and other drugs, and experiencing “being ripped off . . . my battering average for counterfeits is about .350 . . .”). As well, one can purchase “medicines” that do not exist: the author of this article traveled to Tijuana, Mexico in February 2005, and asked for “generic Viagra.” All six pharmacies were able to sell this product. However, there is no such thing as “generic Viagra.” Pfizer, *Types of Fake Viagra*, <https://www.viagra.com/buyRealViagra/avoidingFakeViagra2.asp> (last visited Nov. 25, 2006). Further, medicines such as flu vaccine were also available. Upon purchase, the vaccine was at room temperature; yet flu vaccine must be kept refrigerated to maintain activity. *See* CTRS. FOR DISEASE CONTROL & PREVENTION, U.S. DEP'T OF HEALTH & HUMAN SERVS., VACCINE MANAGEMENT: RECOMMENDATIONS FOR STORAGE AND HANDLING OF SELECTED BIOLOGICALS 6 (2005), *available at* http://www.cdc.gov/Nip/publications/vac_mgt_book.pdf (specifying that Trivalent Inactivated Influenza Vaccine, for example, must be refrigerated “at 35° to 46°F (2° to 8°C)”).

²³ FDA Talk Paper, FDA Warns Consumers About Counterfeit Drugs Purchased in Mexico (May 10, 2005), *available at* <http://www.fda.gov/bbs/topics/ANSWERS/2005/ANS01357.html>.

diversion—for a second year in a row.²⁴ Also, Senator Charles Schumer (D-N.Y.) recently indicated that in New York alone in 2004, there may have been nearly 100,000 instances of fake drugs used to fill prescriptions.²⁵

In Europe, the United Kingdom recently uncovered one of the largest counterfeiting operations ever discovered.²⁶ The operation was capable of fabricating 500,000 counterfeit tablets *each day*, and disseminated those products throughout Europe.²⁷ Further, Dutch wholesalers were found to have inadvertently supplied counterfeits into the legitimate supply chain, such as was the case in 2004.²⁸ In Italy, a licensed medicines seller was discovered to be distributing counterfeit gastrointestinal drugs.²⁹ In France, “customs agents reported seizing 542,000 fake drugs” in 2004.³⁰ In Spain, authorities raided six laboratories producing counterfeit drugs, including steroids, “hormone-boosting substances,” and cancer treatments.³¹ The venture was capable of producing *20,000 fake doses per hour*.³² The scope of the operation was astounding: 30 million doses and 10 tons of high

²⁴ Julie Appleby, *Stolen, Counterfeit Drug Problems Rise*, USA TODAY, May 10, 2005, http://www.usatoday.com/news/health/2005-05-10-counterfeit-drugs-usat_x.htm.

²⁵ Press Release, Senator Charles E. Schumer, *Schumer Reveals: Millions of NY'ers at Risk as Gaping Holes in Rx Regulations Allow Criminals to Introduce Counterfeits into Drug Supply Chain* (Aug. 7, 2005), *available at* http://www.senate.gov/~schumer/SchumerWebsite/pressroom/press_releases/2005/PR41799.NYC%20Counterfeit%20Drugs.080705.html.

²⁶ Sam Lister, *The £6m Secret Factory that Churned Out Thousands of Fake Viagra Tablets*, TIMES (London), Nov. 27, 2004, <http://www.timesonline.co.uk/newspaper/0,,175-1376406,00.html>.

²⁷ *Id.* More recently, the U.K. authorities have seized counterfeit Tamiflu. *See* Steven Swinford & Jonathan Leake, *Black-Market Bird Flu Drugs Seized in Raids*, SUNDAY TIMES 7 (London), Jan. 15, 2006, *available at* <http://www.timesonline.co.uk/article/0,,2087-1986255.html>. Joining the United Kingdom is the United States; fake Tamiflu has been discovered and seized here. *See* Press Release, FDA, *FDA Statement on Fraudulent, Unapproved Influenza-Related Products* (Jan. 20, 2006), *available at* <http://www.fda.gov/bbs/topics/news/2006/NEW01301.html>.

²⁸ P'SHIP FOR SAFE MEDS., COUNTERFEIT DRUGS IN EUROPE FACT SHEET 1 (2005), *available at* <http://www.safemedicines.org/resources/europe.pdf> [hereinafter EUROPE FACT SHEET] (quoting Julian Mount, *Safer Pharmaceutical Distribution in Europe*, PROGRESSIONS 2005: THE ERNST & YOUNG GLOBAL PHARMACEUTICAL REPORT 15 (2005)).

²⁹ *See* GRAHAM SATCHWELL, *A SICK BUSINESS: COUNTERFEIT MEDICINES AND ORGANISED CRIME* 49 (The Stockholm Network 2004).

³⁰ EUROPE FACT SHEET, *supra* note 28, at 1 (citing Claude Fouquet, *Increase in Counterfeit Goods Seized in France*, LES ECHOS, March 22, 2005, at 23).

³¹ *Id.* at 2.

³² *Id.*

quality counterfeits were found, including fake drugs in vials, capsules, tablets, and syringes.³³ These fake medicines were sold throughout Europe to customers in Italy, France, Portugal, and beyond through health food stores and the Internet.³⁴

Africa has been particularly hard hit with fake and tainted medicines.³⁵ The director of Nigeria's National Agency for Drug and Food Administration has made it her mission to eradicate the extensive problem of counterfeits; her sister died from what she believes to be fake insulin and antibiotics.³⁶ Counterfeit drugs are reported to represent more than fifty percent of all medicines on the market in Kenya,³⁷ and one of every three patients in Kenya who purchases drugs—even from state-run hospitals—gets fakes.³⁸

Asia has not escaped the scourge of counterfeits.³⁹ Huge percentages of drugs have been discovered to be fake, particularly in Southeast Asian countries in the Mekong Delta region such as China, Thailand, Indonesia, Vietnam, Cambodia, and Laos.⁴⁰ Up to ninety percent of anti-malarial drugs in these

³³ *Id.*

³⁴ *Id.* (citing Memorandum from the Pharmaceutical Sec. Inst. (June 24, 2005)).

³⁵ See, e.g., *BBC News: Bad Medicine: One Woman's War with Fake Drugs* (BBC television broadcast July 12, 2005), available at http://news.bbc.co.uk/1/hi/programmes/this_world/4656627.stm (reporting on Nigeria's Dr. Dora Akunyili, whose country is filled with fake and sub-standard medicines that have killed adult and pediatric patients, and noting the United Kingdom and United States are not immune).

³⁶ *Id.*

³⁷ Wandera Ojanji, *Weak Medicine*, KENYA TIMES, Aug. 17, 2005 (reporting that "over 50 per cent of all medicines in the Kenyan market are counterfeits") (abstract of article available at <http://www.safemedicines.org/resources/002938.php>).

³⁸ Erick Wamanji, *The \$10 Billion Fake Drugs Rip-Off*, ALLAFRICA, Aug. 24, 2005 (reporting that "[a]lmost one out of every three people buying drugs from private pharmacies—even Government hospitals—are walking away with no more than plain water or chalk") (abstract of article available at <http://www.safemedicines.org/resources/002951.php>).

³⁹ See, e.g., A. M. Dondorp et al., *Fake Antimalarials in Southeast Asia Are a Major Impediment to Malaria Control: Multinational Cross-sectional Survey on the Prevalence of Fake Antimalarials*, 9 TROPICAL MED. & INT'L HEALTH 1241, 1242 (2004), available at <http://www.blackwell-synergy.com/links/doi/10.1111/j.1365-3156.2004.01342.x/abs>.

⁴⁰ Jane Parry, *WHO Combats Counterfeit Malaria Drugs in Asia*, 330 BRIT. MED. J. 1044 (2005), abstract available at <http://bmj.bmjournals.com/cgi/content/extract/330/7499/1044-d>; see Dondorp et al., *supra* note 39. Unfortunately, China itself is a major source of counterfeits whose government has not aggressively sought out and punished fake drug makers. See, e.g., Zamiska & Tesoriero, *supra* note 6.

countries have been found to be fake.⁴¹ As well, developed Asian countries such as Taiwan have also experienced the problem of fake drugs, with up to thirty percent of drugs discovered to be tainted or fake.⁴²

WHO believes that a significant portion of the world's drug supply is counterfeit.⁴³ Although absolute figures are difficult to come by—counterfeiters do not issue annual reports—WHO estimates that up to sixty percent of drugs in some developing countries and up to forty percent in industrialized countries are fake.⁴⁴ Such activities put a tremendous strain on the health care systems of affected countries and puts at risk the welfare of vulnerable patients.⁴⁵

B. Harm

Harm to patients occurs in three general ways. A patient may get the wrong drug, get the wrong dose, or intake fake materials that leave him or her untreated, maimed or killed.⁴⁶

If the fake medicine contains the wrong drug, the patient is not treated for the disease he or she has. This can occur when, for example, antibiotic containers (in some cases purchased on online auction sites like eBay)⁴⁷ are relabeled with a fake label as

⁴¹ Dr. Shigeru Omi, Regional Director for the Western Pacific, WHO, Address at the Fifty-Sixth Session of the Regional Committee (Sept. 19, 2005) (transcript available at <http://www.prnewswire.com/cgi-bin/stories.pl?ACCT=104&STORY=/www/story/09-19-2005/0004109770&EDATE=>).

⁴² Gavin Phipps, *Counterfeit Pills are Not Placebos*, TAIPEI TIMES, Aug. 21, 2005, at 17, available at <http://www.taipetimes.com/News/feat/archives/2005/08/21/2003268655> (describing Taiwan's counterfeit drug problem as having a counterfeit infiltration rate of up to thirty percent of some drugs, and heavy involvement of organized crime in smuggling, manufacturing, and selling counterfeit drugs).

⁴³ WHO, FACT SHEET NO. 275: SUBSTANDARD AND COUNTERFEIT MEDICINES (2003), <http://www.who.int/mediacentre/factsheets/2003/fs275/en> [hereinafter FACT SHEET NO. 275].

⁴⁴ *Id.* Overall, it is estimated that approximately ten to fifteen percent of all drugs sold in the world are counterfeit. *Id.* (estimating that more than ten percent of the world's drugs are counterfeit); Cockburn et al., *supra* note 7, at 302 (estimating that as much as fifteen percent of the world's drugs are counterfeit).

⁴⁵ See Omi, *supra* note 41.

⁴⁶ CTR. FOR DRUG EVALUATION & RESEARCH, FDA, COUNTERFEIT MEDICINES—FILLED WITH EMPTY PROMISES, available at <http://www.fda.gov/cder/consumerinfo/counterfeitDrugsNAPS.pdf> (last visited Nov. 25, 2006) [hereinafter FDA COUNTERFEIT].

⁴⁷ See LEW KONTRNIK, PHARMACEUTICAL COUNTERFEITING: PREVENTING THE PERFECT CRIME 2 (2004), available at <http://www.fffenterprises.com/>

another, more expensive antibiotic with different bacterial coverage than the one the physician prescribed, or when the drug has become inactive due to expiration⁴⁸ or poor storage. Wrong or ineffective drugs not only fail to help the patient get better but also contribute to the increase in antibiotic resistance, making infections harder to fight.⁴⁹ In addition, fake drugs also contribute to the mistaken impression that antibiotic resistant strains are present in the population due to apparent lack of effect of first-line therapies, resulting in use of stronger therapies.⁵⁰ This also contributes to creating pathogen resistance to antibiotics.⁵¹

The counterfeit or tainted drug may result in the patient getting the wrong concentration or dose.⁵² One such situation has occurred with Botox treatments.⁵³ A physician purchased a research version of Botox—a much more highly concentrated form than that utilized for anti-wrinkle treatment and not intended for human use.⁵⁴ Its use resulted in respiratory paralysis and near death for several patients, including the physician who was using it.⁵⁵ Another example is a cancer patient who needs red blood cell-promoting erythropoietin, which virtually all patients require after chemotherapy to counter the

web_files/fff_wht_ppr_111804.pdf. Note that pharmaceutical manufacturing and labeling equipment is also available on eBay. *See, e.g.*, GLOBALOPTIONS INC., AN ANALYSIS OF TERRORIST THREATS TO THE AMERICAN MEDICINE SUPPLY 29 (2003) (on file with the ALBANY LAW JOURNAL OF SCIENCE & TECHNOLOGY). EBay has admitted the difficulty in discerning between legitimate and counterfeit goods; drugs such as steroids and Viagra have found their way onto eBay. *See The £4 Billion Car Boot Sale*, NEWS & STAR (U.K.), Aug. 30, 2005, available at <http://www.newsandstar.co.uk/familylife/viewarticle.aspx?id=277293>.

⁴⁸ Labels are faked with a new expiration date in this circumstance. *See* KONTNIK, *supra* note 47, at 6.

⁴⁹ *See* WHO, FACT SHEET NO. 194: ANTIMICROBIAL RESISTANCE (2002), available at <http://www.who.int/mediacentre/factsheets/fs194/en/>.

⁵⁰ *See id.* (explaining that, if the failure of the first-line therapies is due to inadequate amounts of active drug, a common problem with counterfeits, treatment could be “switched to second- or third-line drugs, which are nearly always much more expensive and sometimes more toxic as well”).

⁵¹ *See id.*

⁵² *See* FDA COUNTERFEIT, *supra* note 46 (stating that counterfeit medicines may “be made with the wrong amount of ingredients”).

⁵³ *See, e.g., Husband, Wife Admit Selling Knockoff Botox*, THE ARIZ. REPUBLIC, Nov. 15, 2005, at 3B.

⁵⁴ *Id.*

⁵⁵ *Id.*

side effect of severe anemia.⁵⁶ Criminals have sold a form of this drug—intended for injection directly into the patient—that was apparently nothing more than bacterially contaminated water.⁵⁷

Another nefarious way that counterfeiters prey upon vulnerable patients is by making the fake drugs without any active ingredients and using harmful ingredients to make the drug more realistic.⁵⁸ In these circumstances, patients are not only harmed by the lack of treatment, but they are sometimes killed by materials used to make the fake drug.⁵⁹ As noted above, counterfeiters have introduced bacteria-laced water into drugs, used colored dye, powdered cement,⁶⁰ toxic yellow road paint, floor wax, boric acid⁶¹ (the latter used commonly to kill cockroaches), and antifreeze. In the latter situation, over 120 children died from ingesting what their parents thought was cough syrup but was instead counterfeit medicine tainted with diethylene glycol⁶² before the deadly chemical was discovered.⁶³

⁵⁶ Hawazin Faruki & Joseph E. Kiss, *Erythropoietin*, TRANSFUSION MED. UPDATE, July 1995, <http://www.itxmdiagnosics.com/tmu1995/tmu7-95.htm>.

⁵⁷ Sally Kestin & Bob LaMendola, *3 Men Plead Guilty in Drug Fraud; Tainted Water was Packaged and Sold as Medication*, SUN-SENTINEL (FT. LAUDERDALE, FL), June 12, 2003, at 1B.

⁵⁸ See Charles W. Schmidt, *Phony Pharm*, MODERN DRUG DISCOVERY, Nov. 2002, at 27.

⁵⁹ *Id.*

⁶⁰ *Id.*

⁶¹ See *Continuing Concerns over Imported Pharmaceuticals: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce*, 107th Cong. (2001) (statement of James Christian, Vice President and Head of Global Corporate Security, Novartis Int'l AG), available at <http://energycommerce.house.gov/107/hearings/06072001Hearing267/Christian404.htm> [hereinafter *Continuing Concerns*] (discussing additional deaths)

⁶² Ethylene glycol and diethylene glycol are chemical names for antifreeze; the substances are sweet so detection of their presence in artificially sweetened cough syrup is almost impossible. AGENCY FOR TOXIC SUBSTANCES AND DISEASE REGISTRY, U.S. DEPT OF HEALTH & HUMAN SERVS., *Medical Management Guidelines for Ethylene Glycol*, <http://www.atsdr.cdc.gov/MHMI/mmg96.html> (last visited Nov. 25, 2006); *Fatalities Associated with Ingestion of Diethylene Glycol-Contaminated Glycerin Used to Manufacture Acetaminophen Syrup — Haiti, November 1995–June 1996*, 45 MORBIDITY AND MORTALITY WEEKLY REPORT (Centers for Disease Control & Prevention) August 2, 1996, at 2, available at <http://www.cdc.gov/mmwr/PDF/wk/mm4530.pdf>; see also Brendan I. Koerner, *Why Is Antifreeze So Delicious?*, SLATE, July 13, 2004, <http://www.slate.com/id/2103821>.

⁶³ FACT SHEET NO. 275, *supra* note 43; see also Hridyesh Pandey, *Counterfeit Drugs: A Major Problem for Asia*, FOOD AND BEVERAGE IN ASIA PACIFIC (Decision News Media SAS, Montpellier, France), July 15, 2005, http://www.ap-foodtechnology.com/nl/arc/APw_2005-07-11.htm (reporting over 500 deaths in Haiti, Nigeria, Bangladesh, India and Argentina from ingestion of diethylene

Other shocking cases include counterfeit inhalers for pediatric cystic fibrosis patients contaminated with bacteria that would be directly introduced into the children's lungs,⁶⁴ and injected cancer drugs that were only vials filled with tap water.⁶⁵

One of the most sinister ways of facilitating the sale of counterfeits is "salting." Salting occurs when legitimate drugs or fakes with some active ingredient—which are often expired or imported from other countries—are mixed or "salted" with entirely fake versions of the drug.⁶⁶ In this way, even if patients, pharmacists, or government authorities are searching and sampling in an effort to detect fake drugs, counterfeits may avoid detection because a legitimate sample or fake with the active molecule is being pulled for testing.⁶⁷ This elevated level of sophistication creates innumerable challenges to finding fake or tainted drugs.

III. LEGAL, MEDICAL, AND TECHNOLOGICAL WEAKNESSES

A. Legal Weakness

It would seem that those who would exploit vulnerable patients by purveying counterfeit and tainted medications would

glycol).

⁶⁴ See Richard Danielson, *Pharmacy Sold Fake Meds*, ST. PETERSBURG TIMES (Florida), Apr. 9, 2005, at 3.

⁶⁵ See Todd Wright, *Man Faces Long Prison Term over Bogus Prescription Drugs*, THE MIAMI HERALD, Mar. 28, 2006. Further examples include an AIDS patient who discovered his growth hormone treatment was fake after the injection left a burning sensation. Oldenburg, *supra* note 21, at C9; see also Elizabeth Cady Brown, *Pharmaceutical Fakery: Counterfeit Drugs Threaten Patients' Health*, LONG ISLAND PRESS, June 9, 2005, available at http://www.longislandpress.com/?cp=188&show=article&a_id=4250 (describing how a liver transplant patient was given counterfeit Epogen for his anemia, which caused severe cramps and pain). Small markets have also been found to sell tainted and counterfeit drugs, particularly in minority communities. See, e.g., Lisa Reyes, *Prescription drugs sold illegally*, NEWS 14 CAROLINA, July 20, 2005, available at <http://www.news14charlotte.com/content/headlines/?SecID=41&ArID=98239>; see Paul M. Rudolf & Ilisa B.G. Bernstein, *Counterfeit Drugs*, 350 NEW ENGL. J. MED. 1384, 1384 (2004). This article also indicates that recent examples of drugs that have been counterfeited include Lipitor, Procrit, Neupogen, Viagra, and Zyprexa. Packaging and materials were of high quality. *Id.* at 1385.

⁶⁶ Kontnik, *supra* note 47, at 3.

⁶⁷ See *id.* at 2–3; see, e.g., Susan Todd, *Florida Man Admits Sale of Fake Lipitor*, THE STAR-LEDGER (Newark), Feb. 10, 2005 (describing Lipitor salting by convicted cocaine traffickers).

be severely punished if caught. The crime and harm certainly deserve such punishment. Yet throughout the world, the punishment for manufacturing, producing, and selling counterfeit medicines is light at best.⁶⁸

For example, in the United States, penalties are weak for drug counterfeiting.⁶⁹ Counterfeiting a *trademark* may result in a decade in jail, but counterfeiting a *drug* may only lead to at most three years in prison,⁷⁰ and in many cases, no jail time at all.⁷¹ Hence, our legal system apparently protects trademarks more than the public's health.⁷²

We are not alone in this peculiar emphasis. In the European Union, similar penalty structures are extant.⁷³ In a case that one might have expected to garner heavy penalties, Allen Valentine, the architect and instigator of a U.K. counterfeit operation that was producing and selling counterfeit products across Europe, and who had been convicted on *14 previous occasions* on charges of medication fraud, only received a sentence of five and a half years.⁷⁴ Like in the United States, his sentence was based largely on infringement of intellectual property rights, rather than any threat that peddling fake drugs had on the public's health.⁷⁵ Even more outrageous, it is likely that he will serve less than half of his sentence, since he is eligible for release in a mere two years.⁷⁶ The Valentine case follows several previous United Kingdom counterfeit discoveries⁷⁷ with similar light

⁶⁸ See WHO, General Information on Counterfeit Medicine, <http://www.who.int/medicines/services/counterfeit/overview/en/index1.html> (last visited Nov. 25, 2006).

⁶⁹ See *Protecting Consumers from Counterfeit Drugs*, FDA CONSUMER MAG., May–June 2004, http://www.fda.gov/fdac/features/2004/304_drug.html.

⁷⁰ *Id.*; see also Douglas W. Stearn, *Deterring the Importation of Counterfeit Pharmaceutical Products*, 59 FOOD DRUG L.J. 537, 550 (2004) (discussing limited criminal penalties and the extensive complexity involved in prosecuting illegal importers).

⁷¹ See, e.g., *Upland Man Sentenced in Fake Viagra Case*, INLAND VALLEY DAILY BULLETIN (Ontario, CA), May 17, 2005 (perpetrator caught smuggling and manufacturing counterfeit Viagra sentenced to six months home detention and 2500 hours community service).

⁷² See FDA, FDA COUNTERFEIT DRUG TASK FORCE INTERIM REPORT 16 (2003), available at http://www.fda.gov/oc/initiatives/counterfeit/report/interim_report.pdf.

⁷³ See Lister, *supra* note 26.

⁷⁴ *Id.*

⁷⁵ See *id.*

⁷⁶ See *id.*

⁷⁷ Counterfeit Zantac obtained from Greece was found in the U.K. in 1994. SATCHWELL, *supra* note 29, at 49. Counterfeit Cialis and Reductil were also

penalties for its perpetrators, including no prison time at all.⁷⁸

In Latin America, which is, of course, known historically for its cocaine and heroin production,⁷⁹ governments have passed increasingly stringent laws to penalize and deter these illicit substances' manufacture and sale.⁸⁰ Thus, drug lords engaging in such activities may be imprisoned—in a Latin American jail—for ten to fifteen years if caught.⁸¹ Yet the Latin American laws regulating production of fake *licit* drugs are akin to those in the United States and Europe.⁸² Penalties are again light, including less than six months in jail, and perpetrators are out in days after obtaining bail.⁸³

detected in the United Kingdom in August 2004 and September 2004, respectively. Drug Alert: Counterfeit Cialis 20 mg Tablets, Medicines and Healthcare Products Regulatory Agency (Aug. 24, 2004), *available at* <http://www.info.doh.gov.uk/doh/embroadcast.nsf/> (follow "All by Date" hyperlink); Drug Alert: Counterfeit Reductil 15 mg Capsules, Medicines and Healthcare Products Regulatory Agency (Sept. 2, 2004), *available at* <http://www.info.doh.gov.uk/doh/embroadcast.nsf/> (follow "All by Date" hyperlink).

⁷⁸ For example, an individual found guilty of selling 22,000 tablets of counterfeit Viagra in the United Kingdom was sentenced to 150 hours of community service and £1,250 in costs by Isleworth Crown Court. Press Release, Medicines and Healthcare Products Regulatory Agency, Reading Estate Agent Punished for Illegal Sale of Counterfeit (June 28, 2005), *available at* http://www.mhra.gov.uk/home/idcplg?IdcService=SS_GET_PAGE&useSecondary=true&ssDocName=CON2014953&ssTargetNodeId=389.

⁷⁹ See Donald J. Mabry, *The Latin American Narcotics Trade and Hemispheric Security*, Oct. 21, 1988, <http://historicaltextarchive.com/sections.php?op=viewarticle&artid=746>.

⁸⁰ See Capell et al., *supra* note 9.

⁸¹ See *id.*

⁸² See *id.*

⁸³ See *id.* Asia is also not immune to the light penalties in counterfeiting drugs. In a recent analysis of counterfeit penalties, Taiwan assessed how many cases of counterfeiting were brought to public prosecution and their attendant penalties. From 2003 to 2004, 137 cases of counterfeit drug importation and sale were actually tried in the country. Of all those cases, eighty-two resulted in sentences of less than six months, and only one resulted in a penalty of greater than two years. Li-Ling Liu, Deputy Director General, Bureau of Pharmaceutical Affairs, Taiwan Department of Health, The 2005 Symposium of APEC Network on Pharmaceutical Regulatory Science: Current Status of Anti-Counterfeiting in Chinese Taipei (Nov. 14, 2005). It should also be noted that in Taiwan, sentences can often be exchanged for payments to the government in lieu of incarceration, with the result that no prison time is required. Personal Communication with Oliver Yoa-Pu Hu, Ph.D., Dean of Research & Dev., Nat'l Def. Med. Ctr., in Taipei, Taiwan (Nov. 14, 2005).

B. Medical Weaknesses

Medical professionals act to promote patient welfare through disease diagnosis and patient treatment. Yet their detection of counterfeit medicines is sorely lacking.⁸⁴ Passing off counterfeit drugs has been described as “the perfect crime.”⁸⁵ Several interacting medical factors contribute to this reality. First, health care providers have little, if any, suspicion that a fake drug may be causing therapeutic failure associated with medical treatment.⁸⁶ Physicians and nurses often attribute poor clinical responses to human variation.⁸⁷ Related to this lack of suspicion, providers rarely ask where drugs were purchased to identify potentially problematic sources such as foreign countries or the

⁸⁴ See Harvey E. Bale, Jr., President, Pharma. Sec. Inst., Dir. Gen., Int'l Fed'n of Pharma. Mfrs. & Ass'ns, Counterfeit Medicines: The Role of Industry and Pharmacists, (May 17, 2002), <http://www.ifpma.org/News/SpeechDetail.aspx?nID=25> (describing the difficulty practitioners face in identifying counterfeit drugs).

⁸⁵ See Joel B. Finkelstein, *Drug Reimportation Situation is Shifting as Canada Could Cut Availability*, AMERICAN MED. NEWS, January 24, 2005, available at <http://www.ama-assn.org/amednews/2005/01/24/gvsa0124.htm>. Note that counterfeiters are also entering into the medical device market, including surgical supplies. In one case, a company was convicted for introducing counterfeit surgical mesh which it had purchased overseas and then resold to a domestic distributor, a process virtually identical to problematic counterfeit pharmaceutical transactions. Bob LaMendola, *Hollywood-Area Firms Pleads Guilty; Surgical Mesh that Company Sold is Not Sterile, Testing Finds*, SUN-SENTINEL (Fort Lauderdale, Fla.), April 28, 2005, at 2B; see also *Medical Device Importer to Pay \$10K Fine*, SOUTH FLORIDA BUSINESS JOURNAL, July 18, 2005, available at <http://southflorida.bizjournals.com/southflorida/stories/2005/07/18/daily50.html>.

⁸⁶ A case from China illustrates this tragically well. A six year-old girl died after receiving a fake hepatitis A vaccine; physicians “repeatedly assured” her father that she was fine even though she exhibited clinically worsening signs, turned purple and blue, and foamed at the mouth. See *Father Was Told Dying Daughter Was Fine After Illegal Vaccination*, RADIO FREE ASIA, July 29, 2005, available at http://www.rfa.org/english/news/social/2005/06/29/china_vaccinations.

⁸⁷ See Finkelstein, *supra* note 85. For example, in one counterfeit drug case, only ten percent of the fake drug was ever recovered; hence ninety percent of the counterfeit drug may have gone undetected to 25,000 cancer and HIV patients. See Mary Pat Flaherty & Gilbert M. Gaul, *Lax System Allows Criminals to Invade the Supply Chain*, WASHINGTON POST, October 22, 2003, at A1, available at <http://www.washingtonpost.com/ac2/wp-dyn/A61473-2003Oct21>. Further, in some cases, the provider may believe that the patient is not being truthful when asked whether he or she is taking the drug appropriately, and attribute therapeutic failure to patient noncompliance. See *Health Pages, Just What the Doctor Ordered*, <http://www.thehealthpages.com/articles/ar-drord.html> (last visited Nov. 25, 2006) (describing the problem of patient noncompliance).

Internet.⁸⁸ Even in the unlikely event that providers actually do ask, patients may be reluctant to disclose that medicines were bought from these sources.⁸⁹

Similarly, patients and their families, like their health care providers, may not know that they have been harmed by a fake drug.⁹⁰ This is akin to the large percentage of patients dying without knowing they had a treatable illness, which is only detected upon autopsy.⁹¹ Further, silent diseases such as hypertension and other clinical circumstances may not provide any clinical symptoms that result in clues that the medications prescribed may not be what they purport to be.⁹²

Of course, the patient's clinical condition itself may mask any suspicion of a counterfeit drug or drugs.⁹³ Patients may be frail, elderly, and/or very ill, limiting any consideration that a faulty or counterfeit drug is the cause of the patient's condition.

Even if there is suspicion of a fake drug, forensic evidence may be unavailable. For example: medication packaging is often thrown away;⁹⁴ the "drug" is metabolized by the patient's body

⁸⁸ See, e.g., Sid Kirchheimer, *Docs Should Warn Patients About Online Drugs*, WEBMD, Feb. 18, 2004, available at <http://www.webmd.com/content/Article/82/97237.htm> (quoting Bernard Bloom, Ph.D., professor of medicine at the University of Pennsylvania Medical School as stating that "most doctors don't know anything about Internet pharmacies . . . doctors never ask, and I don't expect they will start doing it anytime soon").

⁸⁹ This may be due to embarrassment or stigma associated with a particular disease or frustration with access to the care desired. See Jim Thomson, *Stigma? What Stigma?*, E-HEALTH INSIDER PRIMARY CARE, Sept. 6, 2005, http://www.ehprimarycare.com/comment_and_analysis/index.cfm?ID=100.

⁹⁰ Oldenburg, *supra* note 21, at C9.

⁹¹ See generally Joel S. Gross et al., *Autopsy Study of the Elderly Institutionalized Patient: Review of 234 Autopsies*, 148 ARCHIVES INTERNAL MED. 173 (1988) (describing findings that treatable illnesses are underdiagnosed); see also B. Szende et al., *Accuracy of Admission and Clinical Diagnosis of Tumours as Revealed by 2000 Autopsies*, 32A EUR. J. CANCER 1102 (1996) (describing diagnostic error rate in tumor-related deaths verified by autopsy).

⁹² Marv Shepherd, *Drug Quality, Safety Issues and Threats of Drug Importation*, 36 CAL. W. INT'L L.J. 77, 83-84 (2005).

⁹³ See, e.g. Interview by Renee Giachino with Al Cors, Dir. of Gov't Affairs, RetireSafe, on WEBY 1330AM (transcript posted on Apr. 28, 2005), available at http://www.cfif.org/htdocs/freedomline/current/in_our_opinion/drug-importation-interview.htm (noting the possibility that someone could unwittingly take fake Lipitor to lower their cholesterol and suffer a heart attack without the true cause ever being identified).

⁹⁴ See, e.g., News Release, N.C. State University, *Users Rarely Keep Over-the-Counter Medication Instructions, Study Finds* (Nov. 6, 2002), available at http://www.ncsu.edu/news/press_releases/02_11/292.htm (finding that 85% of people threw out over-the-counter medicine packaging after the first use).

once taken;⁹⁵ and there are few lab tests normally available to detect the thousands of drugs that patients could be taking, hence drug levels are not easily obtained.⁹⁶

Overall, providers do not suspect, patients do not tell of the source, and evidence of fakes does not get saved because it is discarded or digested.⁹⁷ This situation results in barriers to effective forensic investigation of the presence of and factors associated with harm that may have been the result of a fake medicine.⁹⁸ This is exactly the circumstance that has blocked effective investigations of recent counterfeit drug deaths in Canada.⁹⁹

C. Technological Weaknesses

Many technological fixes have been proposed to address the issue of counterfeit drugs in an effort to protect the drug supply and, of course, the patient.¹⁰⁰ Yet all have significant weaknesses that make them unsuitable as “the” solution to the problem of fake or tainted drugs.¹⁰¹

⁹⁵ See Oldenburg *supra* note 21, at C9.

⁹⁶ Note that there are two problems in testing whether an ingested drug is a fake; first, drug levels to test for the legitimate drug may not be available and second, if attempting to determine if a fake material was used, one has to know what to test for—a daunting task with the plethora of substances used to create counterfeits. See *id.* (discussing an increasing danger to consumers, as well as citing this author regarding the widening range of drugs being counterfeited).

⁹⁷ Even well-known cases where information and the fake materials are available present challenges to any investigation and prosecution. Governments may also attempt to suppress information about counterfeit drugs, including through false certification of these drugs, which also creates significant barriers to detection. See Cockburn et al., *supra* note 7, at 303. Industry, because of fears that legitimate drug sales would be adversely affected, also does not provide broad information about detection and scope of counterfeits. *Id.* Further, physicians and government officials may actually be compromised and become part of the illegal activity. See *12 Doctors Involved in Spreading of Fake Drugs: Health Office*, SUNSTAR PANGASINAN (Philippines), Aug. 21, 2005, available at <http://www.sunstar.com.ph/static/pan/2005/08/21/news/12.doctors.involved.in.spreading.of.fake.drugs.health.office.html>.

⁹⁸ See Luma Muhtadie, *Fake-Drug Case: Huge Forensic Challenge*, THE HAMILTON SPECTATOR (Ontario), July 16, 2005, at A1 (describing investigation into seven deaths associated with suspected counterfeit drugs, which “is definitely going to be a major forensic challenge”).

⁹⁹ *Id.*

¹⁰⁰ See discussion *infra* Parts III.C.1, III.C.2.

¹⁰¹ See discussion *infra* Parts III.C.1, III.C.2.

1. 2D Serialized Bar Codes and RFID

2D Serialized Bar Codes, or two dimensional bar codes, and RFID, or radio-frequency identification tags, have been touted by the FDA and others as major contenders for ensuring the security of the medicine supply.¹⁰² These technologies rely upon electronic product codes, or EPCs, that use a unique identification number to mark items they are affixed to.¹⁰³ Theoretically, the EPC then travels with and identifies the legitimate product or item, hence allowing those who handle the product to authenticate it through the supply chain.¹⁰⁴

2D bar codes, like the familiar linear, or one dimensional bar codes used on grocery and consumer products, use EPCs.¹⁰⁵ However, 2D bar codes can hold a great deal more information, including product-specific information such as lot numbers, expiration dates, serial numbers, and, most importantly for drug sales, the FDA's National Drug Code (NDC) number.¹⁰⁶ Tracking and tracing the product for authenticity purposes using 2D bar codes would require assignment of the code, placement on commercial units that are distributed, technology for and the procedure of scanning at each level of supply, and updating database storage.¹⁰⁷

RFID represents another effort at track and trace technology.¹⁰⁸ RFID is made up of electronic tags composed of electronic circuits and an antenna.¹⁰⁹ This tag emanates electromagnetic waves, which are then read by an external reader, which interprets the information and electronically converts it to useable data for supplier and distributor use.¹¹⁰ Like 2D bar codes, information on the tag could include the NDC

¹⁰² FDA, COMBATING COUNTERFEIT DRUGS: A REPORT OF THE FOOD AND DRUG ADMINISTRATION 9–10 (2004), *available at* http://www.fda.gov/oc/initiatives/counterfeit/report02_04.pdf [hereinafter COMBATING COUNTERFEIT DRUGS REPORT]; FDA, COMBATING COUNTERFEIT DRUGS: A REPORT OF THE FOOD AND DRUG ADMINISTRATION ANNUAL UPDATE (2005), *available at* <http://www.fda.gov/oc/initiatives/counterfeit/update2005.html> [hereinafter COMBATING COUNTERFEIT DRUGS 2005 UPDATE].

¹⁰³ *See* COMBATING COUNTERFEIT DRUGS REPORT, *supra* note 102, at 9–10.

¹⁰⁴ *See id.*; COMBATING COUNTERFEIT DRUGS 2005 UPDATE, *supra* note 102.

¹⁰⁵ *See* Robert P. Giacalone, *Drug Wholesaling and Importation: Challenges and Opportunities*, 36 Cal. W. Int'l L.J. 65, 70–71 (2005).

¹⁰⁶ *Id.* at 71.

¹⁰⁷ *See id.*

¹⁰⁸ *See* COMBATING COUNTERFEIT DRUGS REPORT, *supra* note 102, at 9.

¹⁰⁹ *See id.* at 10.

¹¹⁰ *See id.*

number, a unique identifier or number, as well as other customized information. An advantage of RFID over 2D bar codes is that this technology theoretically “does not require line-of-sight scanning since radio waves are transmitting information to [the RFID] readers.”¹¹¹

Although both 2D bar codes and RFID appear to be robust technologies and have great potential for track and trace as well as authentication goals, they are severely limited in practice.¹¹² There is a broad array of issues that have not yet been addressed, placing these technologies squarely within the “potential” category, rather than ready for prime time.¹¹³

First, 2D bar codes will require that all who employ their use must agree upon “the same data standard.”¹¹⁴ Hence, cross-industry negotiations and protocols must be harmonized. Differing data standards used by different members of the supply chain will make the usefulness of this strategy negligible as well as inefficient and costly.¹¹⁵ Clearly, given the various interests of stakeholders, an agreement as to the specific data form across all who use the technology—from the manufacturers, to the wholesalers, to distributors, to providers, and to the pharmacists—makes this a daunting task. Unfortunately, this issue is made more complex in that such an agreement must also cross international and hemispheric lines for current manufacturer parallel trade as well as potential future commercial importation.¹¹⁶

Further, 2D bar codes presently require physical scanning of each affixed label for data input purposes.¹¹⁷ This will be an onerous and expensive process. For example, for distributors of medicines, “each item would have to be removed from [cases received from the manufacturer] at the warehouse, physically scanned, and then [re-]stored.”¹¹⁸ This is particularly problematic because wholesalers generally do not open cases until the product is to be delivered, and automated systems that retrieve products within a warehouse are not designed or able to

¹¹¹ Giacalone, *supra* note 106, at 72.

¹¹² *See id.* at 71–73.

¹¹³ *See id.*

¹¹⁴ *Id.* at 71.

¹¹⁵ *See id.*

¹¹⁶ *See id.* at 75–76.

¹¹⁷ *See* Giacalone, *supra* note 105, at 71.

¹¹⁸ *Id.* at 71.

scan 2D bar codes.¹¹⁹

Finally, of critical import is the unanswered question as to who owns the data obtained through the use of 2D bar codes. A related question is who would be responsible for “develop[ing] and maintain[ing] a single database” with “millions of records of all pharmaceuticals manufactured and distributed” throughout the country.¹²⁰ Alone, this is an issue that creates a significant barrier that must be addressed for any chance at success using 2D bar code technology.

RFID suffers from similar weaknesses.¹²¹ One large wholesaler engaged in a pilot study with several manufacturers, other wholesalers, and retail pharmacies to determine the usefulness of RFID for use in the medicine supply chain.¹²² The results were disappointing. Only 73 percent of the RFID tags were readable even before affixing them to the product containers by the manufacturer,¹²³ and “of those . . . that were readable,” wholesalers had a failure-to-read rate of between 3.5 percent and 21 percent.¹²⁴ Finally, “it took between three and fifteen minutes to read a full case of RFID labeled drugs, due to radio wave interference,” *some of which emanated from the RFID tags themselves*.¹²⁵

Finally, similar to 2D bar codes, RFID suffers from issues such as: additional time and labor costs, the costs of scanners and readers, who owns the data, the compatibility of different supply chain members, international data standards, the development of databases, and the actual implementation of the technology by all members of the supply chain.¹²⁶ These factors indicate a technological approach not yet able to be broadly applied to ensure the safety of the drug supply.¹²⁷ The thousands of manufacturers, wholesalers, distributors, providers, chain stores,¹²⁸ and independent pharmacies must all agree to work

¹¹⁹ *Id.* at 71–72.

¹²⁰ *Id.* at 72.

¹²¹ *See id.* at 73.

¹²² *Id.* at 72 (discussing “Project Jumpstart”).

¹²³ Giacalone, *supra* note 105, at 73.

¹²⁴ *Id.*

¹²⁵ *Id.* (emphasis added). RFID tags have also been shown to be adversely affected by other technology, such as wireless telephones. *Id.*

¹²⁶ *See id.*

¹²⁷ *See id.*

¹²⁸ *See id.* A whole host of other issues are also brought into play with efforts to unify a track and trace system. At the recent FDA meeting with industry leaders regarding RFID, several issues arose showing the complexity of

together to implement a unified system before this technology can even begin to address safety issues including the detection of fake or tainted drugs.¹²⁹

2. Simplistic Sophistication

There are other technology-oriented methods beyond RFID and 2D bar codes that represent strategies to ensure the safety of the drug supplies, such as tamper-proof labels, label embossing, holograms, bottle etching, thermo-reactive ink, and DNA markers.¹³⁰ Although these are very sophisticated and

integrating a single usable infrastructure:

Pfizer is using RFID for tracking bottles of Viagra, but is not including item serialization.

States have passed pedigree bills requiring some form of electronic track and trace pedigree; yet one bill does not require RFID use or serialization (Florida) while another bill (California), which has not yet been implemented, may include an item-level serialization requirement using RFID.

Wal-mart has mandated shipment tracking of drugs using ultrahigh-frequency tags, but manufacturers such as Pfizer have found that high-frequency tags work better.

The read range of tags and the antenna placement of RFID tags need testing. Different frequency tags for ultra-high frequency tags versus high frequency tags require multiprotocol interrogators, i.e., tag readers; yet some companies have already invested in single protocol readers, making any switch expensive.

See Mary Catherine O'Conner, *FDA to Update Its RFID Vision*, RFID J., Feb. 10, 2006, <http://www.rfidjournal.com/article/view/2148/1/1>.

¹²⁹ Industry representatives apparently are confused about electronic pedigree requirements for RFID. For example, "[t]here are . . . questions about how radio frequency will affect biological products [Specifically,] the industry still needs to be reassured that their liquid and biological medications won't be affected by RFID tags" Susannah Patton, *Cracks in the Pharmaceutical Supply Chain*, CIO MAG., Jan. 15, 2006, available at <http://www.cio.com/archive/011506/pharma.html>. "[P]rivacy could be the killer issue that seriously limits the potential value of RFID in product tracking." *Id.* (quoting Forrester Research Vice President Laura Ramos); see also Thomas Wailgum, *Tag, You're Late*, CIO MAG., Nov. 15, 2004, available at <http://www.cio.com/archive/111504/rfid.html> (noting that Wal-Mart's requirement for RFID tags are not cost-effective for companies due to lack of standards; many industry suppliers of consumer goods will not be able to comply; many companies will merely "slap and ship" by sticking a tag on only a fraction of cases and pallets closest to Wal-Mart distribution centers that do not track product movement; there are multiple vendors who sell RFID tags which will require different reading equipment; radio frequencies act abnormally near certain materials such as liquids, metals, and porous objects; and many tags are of poor quality with up to 30 percent unusable).

¹³⁰ *Product Counterfeiting: How Fakes Are Undermining U.S. Jobs*,

fascinating technologies, all of these efforts suffer from a fundamental defect, regardless of their inherent sophistication: they merely track packaging, not product.¹³¹ Hence, if it is cardboard we wish to authenticate, these technological solutions are apt—yet if it is the medicines that we want to ensure are authentic, these technologies, like RFID and 2D bar codes, are still far from the ideal.

Industry spokespersons strongly echo this concern. James Christian, Vice President and Head of Global Corporate Security at Novartis International, testified in front of the House Subcommittee on Commerce, Trade, and Consumer Protection on this subject.¹³² He explained:

New anti-counterfeiting technologies have numerous shortcomings . . . :

- In almost every case, the technology, be it a hologram, tamper-proof labels, embossing, thermo-reactive ink, RFID tags, DNA markers, and the like, enable companies to track cardboard, not product. It is not unusual to find genuine product in counterfeit packaging and counterfeit product in genuine packaging.
- In the United States and in the European Union, the two largest pharmaceutical markets in the world, repackaging is legal; thus, without violation of any law, packaging, with all types of expensive, state of the art secure devices, can end up in the trash or worse, in the hands of a counterfeiter, while genuine product is legally distributed in packaging with no security features.
- RFID technology which was featured in a FDA task force report is more of an inventory management tool than an anti-counterfeiting device.
- A counterfeiter or diverter could purchase RFID tags and attempt to mimic manufacturers' RFID codes.
- Industries which have and are using RFID products have noted that when their products enter the "grey market", their RFID tags are often "zapped" rendering them unreadable.
- Counterfeiters generally deal, not only with counterfeit product,

*Innovation, and Consumer Safety: Hearing Before the Subcomm. on Commerce, Trade and Consumer Protection of the H. Comm. on Energy and Commerce, 109th Cong. 7 (2005) (statement of James Christian, Vice President and Head of Global Corporate Security, Novartis Int'l AG), available at <http://energycommerce.house.gov/108/Hearings/06152005hearing1551/Christian.pdf> [hereinafter *Product Counterfeiting*].*

¹³¹ *Id.*

¹³² *Id.* at 1.

but with diverted, expired, and stolen product as well. Envision the scenario where a counterfeiter steals product, removes genuine product from the “secure packages”, and then puts the counterfeit product in these packages, and then reinserts the counterfeit product back into the system. The counterfeit product would pass through all the readers successfully. What then happens to the genuine product? The irony is that the genuine product would most likely be repackaged in counterfeit packaging with unreadable tags and entered into the distribution system. If the RFID system works correctly, the genuine product would be kicked out of then [sic] system, but later determined to be genuine, undermining any confidence in the system.¹³³

This is a cogent, practical observation as well as a damning indictment for those who would place their hopes on packaging technology to ensure safety of the drug supply.

3. Chemical Testing in the Field

If high level, manufacturing technology is not yet ready for mainstream detection, ground level assessment may be a more promising means to detect counterfeit or tainted drugs. Yet a review of the international experience may not lead one to be too sanguine about its potential.

¹³³ *Id.* at 7 (emphasis in original); see also J. Alan Cates, Consulting Fraud Prevention Specialist, Fraud Prevention Institute, FDA’s Placebo for Counterfeit Drugs, <http://www.fraudpreventioninstitute.org/pdf/FDAsPlacebo.pdf> (last visited Nov. 25, 2006) (“The FDA’s recent decision to use radio tags to track drug shipments from manufacturer to major wholesalers may dampen diversion of legitimate drugs. However, the real threat is not *legitimate* – but *counterfeit* drugs.”) (emphasis added). Note also that many in the industry still question the business case for RFID and the manufacturing benefits, and that Europe lags in adoption. See Rick Lingle, *Survey: What’s the Value of RFID/EPC?*, PACKAGING WORLD MAG., Sept. 2004, at 37, available at <http://www.packworld.com/view-17930> (indicating that a survey of manufacturing representatives reveals two-thirds think the benefits of RFID/EPC technology remain unclear); see also News Release, Accenture, Half of Manufacturing Executives Expect High Return on RFID Investment, Finds Accenture Survey (June 7, 2004), http://www.accenture.com/Countries/Canada/About_Accenture/Newsroom/HalfSurvey.htm (finding that only “one in three (34 percent) [of participating executives] reported that they will implement RFID by 2005”). Further, countries such as Russia, with a large counterfeit problem, note that security systems will have little effect on piracy due to the ability of counterfeiters to mimic security systems as well. See *Fake Medications Inundate the Russian Pharmaceutical Market*, PRAVDA, May 4, 2005 (Russ.), <http://english.Pravda.ru/russia/economics/8180-medicine-0>.

Rapid chemical screening tests for drugs are available.¹³⁴ A common approach is the use of thin-layer chromatography (TLC).¹³⁵ To perform TLC, the tester simply “plac[es] a spot of drug sample” that has been dissolved in a solvent “on a thin layer of [silica-coated] glass, aluminum, or plastic.”¹³⁶ The tester also generally places a verified sample of the drug dissolved in the solvent onto the plate as well.¹³⁷ A combined sample is often also created and placed on the plate.¹³⁸

The Centers for Disease Control & Prevention (CDC) summarize the subsequent steps as follows:

The plate is then inserted into a vessel containing a solvent mixture. By capillary action, the solvent mixture creeps up the silica material and dissolves the sample. . . . [C]ompounds [in the sample] will have various affinities to the silica matrix and will migrate [up the plate] with the solvent at various speeds. This characteristic effectively separates out a mixture of compounds. . . . The distance that the components migrate is characteristic for each compound; therefore the active ingredient can be recognized by comparison with a known drug standard.¹³⁹

Although theoretically TLC is very helpful to identify a sample drug in comparison to the known one, there are complexities.¹⁴⁰ First, one must know what drug one wants to test for because different forms of the drug may have different migration patterns on the TLC plate, and one must secure a sample of the actual drug’s active ingredient for reliable validation of the results.¹⁴¹ Further, the plates are small, often only several centimeters

¹³⁴ CTRS. FOR DISEASE CONTROL & PREVENTION, U.S. DEP’T OF HEALTH & HUMAN SERVS., COUNTERFEIT AND SUBSTANDARD ANTIMALARIAL DRUGS (2005), http://www.cdc.gov/malaria/travel/counterfeit_drugs.htm [hereinafter “CDC WARNING”]; A.S. KENYON & T.P. LAYLOFF, FDA, DIV. OF TESTING & APPLIED ANALYTICAL DEV., A COMPENDIUM OF UNOFFICIAL METHODS FOR RAPID SCREENING OF PHARMACEUTICALS BY THIN-LAYER CHROMATOGRAPHY 4 (1999), <http://www.pharmweb.net/pwmirror/library/tlc/TLC.pdf>.

¹³⁵ See CDC WARNING, *supra* note 134.

¹³⁶ *Id.*

¹³⁷ See *id.* (describing how the active ingredient can be determined by comparing migration characteristics of a sample with “a known drug standard”).

¹³⁸ See *id.*

¹³⁹ *Id.*

¹⁴⁰ See 2 MARSHALL HOUTS ET AL., COURTROOM TOXICOLOGY, §§ 21.09–21.10 (2005) (explaining the disadvantages and advantages of the TLC method).

¹⁴¹ See CDC WARNING, *supra* note 134.

long.¹⁴² Hence, discerning different lengths of sample migration may require an observer to differentiate fractions of a millimeter.¹⁴³ In addition, the process of creating the sample appropriately for testing may be challenging at best, requiring materials not easily available and skills not within the competencies of the ground level tester.¹⁴⁴ For example, to test for the validity of aspirin¹⁴⁵ in the field:

Acetylsalicylic acid

300 mg tablet

Molecular formula and mass: $C_9H_8O_4$ – 180.15

Category: Analgesic

Sample:

Dissolve 1 tablet in 49 mL of methanol and 1 mL of glacial acetic acid. Concentration of the solution = 300 mg/50 mL = 6 mg/mL. The required concentration of the sample solution for analysis is 2 mg/mL. Dilute 1 mL of the 6 mg/mL solution to 3 mL by adding 2 mL of methanol. This solution will represent 100% sample.

Standards:

High standard:

The high limit is 115%; therefore the concentration of the high standard = (2 mg/mL) X 1.15 = 2.30 mg/mL. Weigh approximately 10 mg of the standard. If you weighed 8 mg of standard, dissolve it in: 8 mg X 2.30 mg/mL [sic] = 18.4 mL of methanol. This makes the high standard solution concentration equal to 2.30 mg/mL.

Low standard:

¹⁴² R.J. FLANAGAN ET AL., BASIC ANALYTICAL TOXICOLOGY § 4.4.1 (1995), http://www.who.int/ipcs/publications/training_poisons/basic_analytical_tox/en/ (noting that plates are usually only twenty centimeters long, and that “smaller sizes can also be used”).

¹⁴³ See Carlton E. Turner, *Drug Testing in the Workplace: Essay on Mechanics of Drug Testing*, 33 WM. & MARY L. REV. 147, 149 (1991) (stating that “[i]f a drug is present in the sample, it will be identified by the distance it migrated from the bottom of the plate toward the top of the plate.”); FLANAGAN ET AL., *supra* note 142, § 4.4.5 (discussing the distance migrated as measured in millimeters).

¹⁴⁴ 2 HOUTS ET AL., *supra* note 140, § 21.10 (“Accurate interpretation of thin-layer chromatograms is considered by many to be an art which few people can fully master; much of the ultimate value of a test depends upon the personal skills of the technician.”)

¹⁴⁵ Aspirin, once a trade name, is the generic term for acetylsalicylic acid. Lawrence E. Evans, Jr., *A Primer on Trademarks and Service Marks*, 18 ST. MARY'S L.J. 137, 149 (1986).

The low limit is 85%; therefore the concentration of the low standard = (2 mg/mL) X 0.85 = 1.70 mg/mL. Dilute 1 mL of high standard solution to 1.35 mL by adding 0.35 mL of methanol (2.30/1.70 = 1.35).

Spotting:

Spot on the TLC plate as follows:

Left spot low standard (85%)

Center spot 100% sample

Right spot high standard (115%)

Development:

Mix 17 mL of toluene, 13 mL of ethyl acetate, and 1 mL of acetic acid. Add approximately 20 mL of this mixture to the TLC development bag. Develop until the solvent front reaches within 1 cm of the top of the TLC plate.

Detection:UV:

Dry the plate and observe under UV light (254 nm).

Iodine stain:

Dip the plate in the iodine-KI solution in the detection bag. Allow the plate to dry and observe the size and intensity of the spots.¹⁴⁶

Here, it is apparent that the tester may need a wide array of materials, including vials, weighing apparatus, UV light source, organic and nonorganic solvents, plates, and sample holders. However, even if the material is present in the sample, one cannot tell whether the other materials in the sample are toxic or nontoxic. Of course, such a test will also not reveal whether the medicine is legitimate and from the actual manufacturer and distributed through a regulated chain with concomitant assurance of appropriate environmental controls and other critical situational factors.

Colorimetry is another field test used to attempt to verify medicine authenticity.¹⁴⁷ It employs certain "chemical reactions or characteristic acidity . . . properties to evaluate drug quality."¹⁴⁸ Through reactions with certain added chemicals, a color change occurs if the drug is present.¹⁴⁹ The relative

¹⁴⁶ A. S. KENYON & T. P. LAYLOFF, *supra* note 134, at 11–12.

¹⁴⁷ CDC WARNING, *supra* note 134.

¹⁴⁸ *Id.*

¹⁴⁹ *See id.*

intensity of the color reaction is usually proportional to its concentration; hence colorimetry has the potential to provide some information on the relative amount of active ingredient present.¹⁵⁰ This intensity can be assessed using a portable filter photometer.¹⁵¹ Colorimetry has been used for the assessment of artesunate, a standard anti-malarial drug.¹⁵²

Colorimetry suffers from several weaknesses similar to TLC. A colorimetric test only determines if the ingredient in question is present; there is no ability to detect what other materials or toxins are accompanying the purported active ingredient.¹⁵³ Finally, the testing process is not necessarily easily performed:

Test For Checking The Authenticity Of Artesunate Tablets

Items Required

100 mg Fast Red TR salt

20 ml sodium hydroxide (NaOH) 1 N

40 ml acetic acid 1.1 M

20 ml distilled water

Scalpel blades and gloves

Clean tubes, 5–10 ml volume

Droppers or pipettes for dispensing 0.5–1.0 ml

Test tube rack

Genuine artesunate tablet for positive control

Prior to testing, dissolve 100 mg Fast Red TR salt in 20 ml of distilled water. The above reagents are sufficient to do ~40 tests.

Reagents can be stored at room temperature. Wrap the tubes containing Fast Red TR salt and solution in aluminum foil to protect from light.

Please note that the chemicals are potentially dangerous:

- Wear gloves
- Keep out of reach of children
- Fast Red TR salt is an irritant and potentially mutagenic
- Sodium hydroxide is a strong base and will cause burns

¹⁵⁰ See U.S. DEP'T OF HEALTH & HUMAN SERVS., ANALYTICAL TESTING METHODS 3 (2005), available at <http://dwp.samhsa.gov/drugtesting/DTesting.aspx> (follow "Analytical Testing Methods [pdf]" hyperlink).

¹⁵¹ CDC WARNING, *supra* note 134.

¹⁵² See *id.*; Michael D. Green et al., *A Colorimetric Field Method to Assess the Authenticity of Drugs Sold as the Antimalarial Artesunate*, 24 J. PHARM. & BIOMED. ANAL. 65, 65–66 (2000) [hereinafter *Colorimetric Field Method*].

¹⁵³ 2 HOUTS ET AL., *supra* note 140, § 25.06.

- Dispose of the used chemicals safely after each test

Method

Test a positive control, using a known genuine artesunate tablet, and a negative control (blank, no artesunate) at each session. This is to check that the test is working correctly.

Scrape ~ 1% of the test 'artesunate' tablet into a clean tube and label with test number.

Scrape ~ 1% of the positive control artesunate tablet into a clean test tube and label as '+ control'.

Leave a third clean tube empty and label as '- control'.

Add 0.5 ml 1N NaOH to all tubes and shake gently (you should at least have 3 tubes, more if you are testing more than one suspect tablet).

Wait for at least 5 minutes. Some fragments of the tablets may not dissolve—this does not matter.

Add 1 ml of 1.1M acetic acid to all tubes and shake gently.

Add 0.5 ml of the Fast Red TR salt solution to all tubes and shake gently.

Wait 5 minutes.

If the solution turns yellow the tablet contains artesunate. If the solution remains colorless the tablet does not contain artesunate.

In order to interpret the test of the suspicious tablet, the positive control must turn yellow and the negative control **MUST** remain colorless. If this does not occur, repeat test.¹⁵⁴

Also note that beyond the materials needed, the process has the potential to take a significant amount of time per sample tested.¹⁵⁵ This characteristic will make broad-based testing using colorimetry cumbersome and labor intensive. Further, the test will depend upon an observer's determination that the appropriate color change is present.¹⁵⁶ Without training, there may be variations on observer interpretations that, in turn, would lead to potential inconsistency of results for the same sample.¹⁵⁷

¹⁵⁴ See *Colorimetric Field Method*, *supra* note 152, at 66–68.

¹⁵⁵ See 2 HOUTS ET.AL, *supra* note 140, § 25.04 (detailing the process of the colorimetric test for Serum Acetaminophen including the waiting periods of several minutes between steps)

¹⁵⁶ See *id.*

¹⁵⁷ Scientists have recognized the need for computer enhancement to improve human perceptions of color, for example in DNA testing. See Caryl Goodyear-Bruch, et al., *Comparison of a Visual to a Computer Assisted-Technique for Detecting Apoptosis*, 6 BIOL. RESEARCH FOR NURS. 180, 184–85 (2005) (finding

Kits have been developed to try and make testing in the field more convenient for an end user with limited scientific training.¹⁵⁸ The German Pharma Health Fund (GPHF), an industry-formed group, has worked with academic institutions to create the GPHF Mini-Lab for field-based identification of pharmaceutical products.¹⁵⁹ The Mini-Lab has reagents and capacity for testing up to 3000 samples using colorimetry and 1000 samples using TLC for forty different compounds.¹⁶⁰ The Mini-Lab is contained in two suitcase-sized containers weighing forty kilograms total.¹⁶¹

The Mini-Lab is one of the most advanced, convenient medicine field testing kits available.¹⁶² However, again, it suffers from its focused methodology: colorimetry and TLC.¹⁶³ Hence, it can only detect active ingredients, and not the presence of toxic materials, and is limited to the 40 compounds it can test.¹⁶⁴ Further, even though it is meant to be easily used, the Mini-Lab does take training to be able to use the kit effectively, with its concomitant costs.¹⁶⁵ Importantly, although GPHF has attempted to disseminate the Mini-Lab at a reasonable price, its cost still represents a barrier: approximately 4000 € (\$5000) for the kit, with an approximate two year shelf life.¹⁶⁶

4. Bulk Property Testing

Between field testing and full laboratory analysis is bulk property testing (BPT). BPT attempts to assess the authenticity of drugs using a variety of tests that discern whether the product

both intra- and interrater unreliability in detecting DNA using human visual perception of color).

¹⁵⁸ PHARM. RES. & MFRS. OF AMERICA, GLOBAL PARTNERSHIPS: HUMANITARIAN PROGRAMS OF THE PHARMACEUTICAL INDUSTRY IN DEVELOPING NATIONS 5, 8 (2003), available at <http://world.pharma.org/global.partnership.2003.pdf>.

¹⁵⁹ See German Pharma Health Fund, The GPHF-Minilab® — Protection Against Counterfeited and Substandard Pharmaceuticals, http://www.gphf.org/web_en/projekte/minilab (last visited Nov. 25, 2006).

¹⁶⁰ *Id.*

¹⁶¹ *Id.*

¹⁶² See Richard W. O. Jähnke et al., *Low-Cost Quality Assurance of Medicines Using the GPHF-Minilab®*, 35 DRUG INFO. J. 941, 943 (2001), available at <http://www.diahome.org/content/abstract/2001/dij1666.pdf>.

¹⁶³ See German Pharma Health Fund, GPHF-Minilab® Fact Sheet, http://www.gphf.org/web_en/projekte/minilab/factsheet.htm (last visited Oct. 15, 2006).

¹⁶⁴ *Id.*

¹⁶⁵ *Id.*

¹⁶⁶ *Id.*

at hand is authentic.¹⁶⁷ In general, the properties covered by BPT include the material's molecular weight, density, solubility, refractive index and optical rotation characteristics, viscosity, and gross description.¹⁶⁸

However, similar to colorimetry, bulk property testing has focused on artesunate and its derivatives, rather than broad-based application to detecting counterfeits generally.¹⁶⁹ Further, the complexity of testing requires significant skills and time. For example, for refractive index testing, one must weigh and pulverize the sample before suspending it in alcohol.¹⁷⁰ A light meter must be used, and assessment of light transmission through the sample by plotting the number of sample drops and light transmitted through the signal then provides the ability to assess actual artesunate.¹⁷¹ Other tests, such as crystal morphological studies, take hours and require an assessment of crystal shape.¹⁷² Even with extensive testing, BPT still missed seventeen percent of fake product and failed to identify actual product ten percent of the time.¹⁷³

5. Full Laboratory Analysis

Of course, full laboratory analysis is the gold standard through which actual drugs as well as fake drugs and potential toxic materials can be detected. Methods include gas chromatography (GC),¹⁷⁴ mass spectrometry (MS),¹⁷⁵ combination technologies such as GC-MS¹⁷⁶ and liquid chromatography-MS,¹⁷⁷ near-

¹⁶⁷ M. D. Green et al., Simple Low-Cost Strategies to Rapidly Identify Counterfeit Drugs in Developing Countries, Conference, Combating Pharmaceutical Fraud and Counterfeiting (2003) (unpublished paper, on file with author) [hereinafter Combating Fraud and Counterfeiting].

¹⁶⁸ *Id.*

¹⁶⁹ *Id.*

¹⁷⁰ *Id.*

¹⁷¹ *Id.*

¹⁷² *Id.*

¹⁷³ See Combating Fraud and Counterfeiting, *supra* note 167.

¹⁷⁴ 4 ENCYCLOPAEDIA BRITANNICA 565, 567 (15th ed. 1974). In essence, GC is simply TLC in gaseous form. See *id.*

¹⁷⁵ MS is an "analytic technique by which chemical substances are identified by the sorting of gaseous ions in electric and magnetic fields according to their mass-to-charge ratios." Encyclopaedia Britannica Online, Mass Spectrometry 1, <http://www.britannica.com/eb/article-9110406/mass-spectrometry> (last visited Nov. 25, 2006).

¹⁷⁶ GC-MS was used to detect fake Ritalin in California and the presence of oxycodone and dihydrocodeinone in its place. See U.S. Drug Enforcement Admin., *Intelligence Alert: Counterfeit Methylphenidate (Ritalin) Tablets*

infrared spectroscopy,¹⁷⁸ Raman spectroscopy,¹⁷⁹ tensiography,¹⁸⁰ and isotopic characterization.¹⁸¹ All can provide information on the sample that span from the contents of the sample—again,

containing *OxyCodone in Santa Rosa, California*, 37 MICROGRAM BULL., (April 2004), available at <http://www.usdoj.gov/dea/programs/forensicsci/microgram/mg0404/mg0404.html>.

¹⁷⁷ See 4 ENCYCLOPAEDIA BRITANNICA 568 (15th ed. 1974) (explaining liquid chromatography).

¹⁷⁸ Near-infrared spectroscopy measures “the wavelength and intensity of the absorption of near-infrared light by a sample.” Near-Infrared Absorption Spectroscopy (NIR), <http://elchem.kaist.ac.kr/vt/chem-ed/spec/vib/nir.htm> (last visited Nov. 25, 2006). As such, it creates a fingerprint of a material that can detect a broad range of materials. Near-infrared spectroscopy has been used to identify active pharmaceutical ingredients in raw form as well as finished products. See F. González & R. Pous, *Quality Control in Manufacturing Process by Near Infrared Spectroscopy*, 13 J. PHARM. & BIOMED. ANAL. 419, 419 (1995). The technique has also been able to detect fake versions of methyl dopa, norfloxacin, and acetametophin. See, e.g., Sérgio Henrique Frasson Scafi & Celio Pasquini, *Identification of Counterfeit Drugs Using Near-Infrared Spectroscopy*, 126 ANALYST 2218, 2218 (2001).

¹⁷⁹ Raman spectroscopy measures “the wavelength and intensity of inelastically scattered light from molecules. The Raman scattered light occurs at wavelengths that are shifted from the incident light by the energies of molecular vibrations.” Raman Spectroscopy, <http://elchem.kaist.ac.kr/vt/chem-ed/spec/vib/raman.htm> (last visited Nov. 25, 2006). This intensity is plotted and provides spectra giving a unique pattern for identification of materials within the sample. Raman spectroscopy has been used to distinguish between different Ecstasy (N-methyl-3,4-methylenedioxymethylamphetamine) tablets, their excipients, and their distribution. See Steven E. J. Bell, et al., *Tracking the Distribution of "Ecstasy" Tablets by Raman Composition Profiling: A Large Scale Feasibility Study*, 128 ANALYST 1331, 1331–32 (2003); Steven E. J. Bell et al., *Composition Profiling of Seized Ecstasy Tablets by Raman Spectroscopy*, 125 ANALYST 1811, 1815 (2000); Steven E. J. Bell, et al., *Rapid Analysis of Ecstasy and Related Phenethylamines in Seized Tablets by Raman Spectroscopy*, 125 ANALYST 541, 541 (2000).

¹⁸⁰ Tensiography analyzes “a forming pendant drop . . . [which] is illuminated from within by an optic fibre generator and receiver. The technique provides complex fingerprinted traces whose profiles depend on surface tension, refractive index, colour and other parameters.” Brian O’Rourke, *Tensiography for Pharmaceutical, Biotechnological and Environmental Applications*, IR. SCIENTIST Y.B. (2002), <http://www.irishscientist.ie/2002/02toc.htm> (follow “Reports from Institutes of Technology” hyperlink, then follow hyperlink for article). With respect to detecting counterfeits, “[t]ensiography, by fingerprinting each product, is capable of accurately discerning not alone one supplier from another, but one batch from another — differences merely depending on the quality of the match.” *Id.*

¹⁸¹ Isotopic characterization focuses upon identifying and documenting the distribution of naturally occurring isotopes of key atoms to create fingerprints of drug samples and batches. In such a way, the unique combination of isotopes is exceedingly difficult to create, making counterfeiting virtually impossible. See, e.g., J.P. Jasper, et al., *Stable Isotopic Characterization of Active Pharmaceutical Ingredients*, 35 J. PHARM. & BIOMED. ANAL. 21, 29–30 (2004).

including toxicants—to specific non-active ingredient excipients, which can be used to determine whether the drug is the actual branded product and assist in tracing its source.¹⁸²

Of course the critical problem with scientific laboratory methods is just that—one needs to have all samples tested in a scientific laboratory. But one cannot simply transfer the laboratory building to the field. Further, the equipment is exceedingly expensive; experts must run it; and it takes time and resources to perform each test. Although each of these technologies is powerful to confirm suspicions with confidence and authority, these approaches are unlikely candidates for broad authentication use for the billions of prescriptions filled each year by U.S. as well as international consumers.

IV. AN INTERDISCIPLINARY APPROACH

It is apparent that the production of fake drugs is an international threat, and will continue to be for the foreseeable future.¹⁸³ Estimates are that the fake drug trade will grow worldwide to \$75 billion annually by 2010—more than \$205 million in sales each day.¹⁸⁴ Further, there is increasing concern that international crime and terrorist forces are becoming involved in this activity.¹⁸⁵ As noted by Harvey Bale, Director

¹⁸² See Thomas A. Wheatley, *What are Excipients?*, EXCIPIENT TOXICITY AND SAFETY 1, 1–2 (Myra L. Weiner & Lois A. Kotkoskie, eds. 1999). Excipients are the non-therapeutic materials within the drug. *Id.* Note that excipients themselves may cause toxic and allergic reactions, and hence need to be evaluated. The FDA has noted known reactions to excipients include renal failure, osmotic diarrhea, hypersensitivity reactions, cardiotoxicity, and death. See Robert E. Osterberg & Norman A. See, *Toxicity of Excipients—A Food and Drug Administration Perspective*, 22 INT'L J. TOXICOL. 377, 377–78 (2003).

¹⁸³ See, e.g., GLOBALOPTIONS INC., *supra* note 47, at 5 (describing potential terrorist threats to medicine supplies).

¹⁸⁴ WHO, *WHO Launches Task Force to Fight Counterfeit Drugs*, 84 BULLETIN WORLD HEALTH ORG. 689, 689 (2006) available at <http://www.who.int/bulletin/volumes/84/9/news.pdf>.

¹⁸⁵ The FDA and international government authorities have warned that counterfeit drug sales are linked to funding international criminal operations and terrorist activities, including those of Hezbollah and Al Qaeda. See GLOBALOPTIONS INC., *supra* note 47, at 163; Ben Hirschler, *Criminals Make Killing from Fake Drugs*, SAN DIEGO UNION TRIB., July 31, 2005, <http://www.signonsandiego.com/news/business/biotech/20050731-1802-health-medicines-counterfeit.html> (stating that “[g]iven the low production costs [counterfeit drug production] is a hugely lucrative trade and some criminals now prefer it to narcotics”); Andrew Zajac, *Cops Arrest 59, Say Ring Smuggled Goods from Asia*, CHI. HERALD, Aug. 23, 2005, at C8 (describing crime bust of counterfeit drugs, money, cigarettes, and consumer products); Phipps, *supra*

General of the International Federation of Pharmaceutical Manufacturers and Associations, "Organized crime is gravitating towards the industry because the risks are a lot less than forging currencies or trafficking heroin. You can make a fortune, at no risk."¹⁸⁶ As well, terrorist strategies may make the counterfeit drug production highly dangerous for US citizens:

In addition to providing a way for unscrupulous enterprises to obtain massive profits by distributing phony, high-priced drugs,

note 4, at 17 (describing Taiwan's fake drug problem with up to thirty percent of some drugs counterfeit, and the involvement of organized crime); Celia Hall, *Internet Fuels Boom in Counterfeit Drugs*, DAILY TELEGRAPH (U.K.), Aug. 16, 2005, at 9 ("Much of the [counterfeit drug] supply comes from India and Asia and there are signs that the counterfeit medicines trade is linking up with organised crime. 'If people buy these drugs, they should be aware of the risk they are taking as well as being aware they may be supporting organised crime or terrorism.'" [quoting Naeem Ahmed, Head of Medicines Intelligence for the U.K. Medicines and Healthcare Products Regulatory Agency]); Elizabeth Thompson, *Counterfeit Items Pose Real Threat to Public*, MONTREAL GAZETTE, Sept. 6, 2005, at A1 (discussing influx of counterfeits into Canada, including counterfeit drugs, leading the US to place Canada on its watch list "in large part because the United States believes [Canada] is not doing enough to stop counterfeits at the border and [Canada] is being used as a transit point for goods destined for the U.S. market"). Further, Canada Border Services Agency officials do not have the right to search shipments for goods bearing a counterfeit trademark, nor can it alert the holders of the intellectual property rights there is an actual or potential trademark infringement. *Id.*; see also INT'L ANTI-COUNTERFEITING COALITION, WHITE PAPER, THE NEGATIVE CONSEQUENCES OF INTERNATIONAL INTELLECTUAL PROPERTY THEFT: ECONOMIC HARM, THREATS TO THE PUBLIC HEALTH AND SAFETY, AND LINKS TO ORGANIZED CRIME AND TERRORIST ORGANIZATIONS 3-14 (2005), available at http://www.iacc.org/resources/IACC_WhitePaper.pdf (describing product piracy effects, including those of counterfeit drugs, on U.S. economy and public health). Counterfeiting has also been linked to countries that may sponsor these activities, such as North Korea. See Jay Solomon & Gordon Fairclough, *North Korea's Counterfeit Goods Targeted*, WALL ST. J., June 1 2005, at A4; *US Hardliners Seek NK Demise Through Counterfeiting Probe*, YONHAP NEWS (S. Korea), Jan. 19, 2006, <http://english.yna.co.kr/Engnews/20060119/30000000020060119091336E8.html> (noting that the White House has discovered that North Korea is making counterfeit pharmaceuticals). The drug supply has also been identified by the FDA as a target for terrorists. *FDA: Al-Qaida Could Poison Medicines*, MSNBC, Aug. 12, 2004, <http://www.msnbc.msn.com/id/5682351>; *Fake Drugs are Real Dangers for U.S. Consumers*, PR NEWswire, Aug. 13, 2004, <http://www.prnewswire.com/cgi-bin/stories.pl?ACCT=109&STORY=/www/story/08-13-2004/0002231340&EDATE>.

¹⁸⁶ Williams, *supra* note 7; see also Patton, *supra* note 129 (stating that "in 2004, the FDA reported that the number of its investigations of counterfeit drugs rose by 150 percent from the previous year as a growing number of criminal groups take advantage of high profits and penalties that are less severe than those for selling illegal narcotics such as heroin or cocaine").

the vulnerabilities in the system provide a way for terrorists to target our citizens. One frightening and widely discussed scenario, among dozens of possibilities of how terrorists might exploit our vulnerabilities in this area, involves a deliberate anthrax “scare” in order to trigger a run on Cipro[floxacin], the antibiotic used for fighting the anthrax poison. A phony, deadly version of this medicine, having already been injected without detection into the nation’s pharmaceutical stream by terrorists, would then cause thousands more deaths. Baz Mohammad, a Taliban-linked narco-terrorist who was recently extradited from Afghanistan, defends a “Jihad” of taking Americans’ money at the same time the drugs we are paying for kill us.¹⁸⁷

Since technology is not the answer to ensuring safety of the drug supply, nor are field testing systems in their current iteration, better means of detection, awareness, and cooperation are necessary to at least cover some of the gaping systemic holes allowing counterfeits to enter into the mainstream distribution system.

A. *Technology Investment*

The limited state of current technology for broad application to drug safety is exceedingly worrisome. This state of affairs thus highlights the absolute need for additional investment, both public and private, into moving these potentially helpful technologies into the realm of realistically useful.

Importantly, standardization must be a priority across industries involved in drug manufacture, distribution, and front line sales ensure appropriate identification of valid drugs and their pedigree. Just as important, such efforts should be developed internationally to harmonize their applicability across country and hemispheric lines.

It should be noted, however, that the two largest markets in the world—the United States and the European Union—allow repackaging of medicines.¹⁸⁸ Given this reality, and the limits of

¹⁸⁷ *Sick Crime: Counterfeit Drugs in the United States: Hearing Before the House Subcomm. on Criminal Justice, Drug Policy and Human Res. of the Comm. on Gov’t Reform, 109th Cong. (2005)* (statement of Rep. Mark Souder, Chairman, Subcomm. on Criminal Justice, Drug Policy and Human Res.); see also *Examining the Implications of Drug Importation: Hearing Before the Senate Judiciary Comm., 108th Cong. (2004)* (statement of Rudolph W. Giuliani, Former Mayor of N.Y., Chairman and CEO, Giuliani Partners LLC).

¹⁸⁸ See *Product Counterfeiting*, *supra* note 130, at 7.

packaging track and trace methods, the focus of research must be to have technology go beyond the function of an inventory device to a system that identifies pedigree or authenticity of the actual medicine itself.¹⁸⁹

Hence, an investment in research and development of authentication and pedigree of actual drugs (rather than its packaging) should be an emphasis of public and private efforts. But it should be emphasized that technology can only be a part of—not the entire—solution to the risks of fake medicines entering the drug supply. The talents of counterfeiters to keep up with technological advances to the detriment of patients is astounding and would be a source of admiration if not for the nefarious ends to which they apply their skills.

B. Penalties

Penalties for counterfeiting and selling around the world are uniformly light.¹⁹⁰ Such jurisprudential messages send a clear signal inviting the criminal element to enter into this activity. Such legal perversions should be immediately addressed through reform of current statutory provisions as well as international agreements to severely punish, in a consistent and common way, purveyors of counterfeit drugs.¹⁹¹

At a minimum, criminal penalties for sale and distribution of licit drugs should be similar to illicit drugs. Life imprisonment is an appropriate penalty, given the broad and significant harm these “products” impose upon the vulnerable.¹⁹² As well,

¹⁸⁹ Even then, there is significant error associated with technology use. See Giacalone, *supra* note 105, at 71–73.

¹⁹⁰ See 21 U.S.C. § 333(b)(1) (2000) (stating that violators of prescription drug marketing laws are fined “not more than \$250,000” and “shall be imprisoned for not more than 10 years”); see also *Continuing Concerns*, *supra* note 61.

¹⁹¹ Unfortunately, parallel trade locations such as Europe have not come forth with strong penalties or statements on the manufacture and sale of counterfeit drugs. Even reform efforts have been highly limited. See, e.g., Huw Jones, *EU to Crack Down on Peddlers of Fake Products*, REUTERS, July 12, 2005, <http://today.reuters.com/News/CrisesArticle.aspx?storyId=L12615140> (describing European Commission proposal that people that sell fakes that threaten the public health should be imprisoned for at least four years and fined up to \$365,000).

¹⁹² Some jurisdictions, such as Iowa, have considered such a bill. See David Pitt, *Iowa House Passes Law Against Making Counterfeit Drugs*, WATERLOO-CEDAR FALLS COURIER, April 22, 2005, http://www.wfcourier.com/articles/2005/04/22/news/breaking_news/doc4268d24b27870940659285.txt (reporting that a conviction of being involved in the sale of counterfeit drugs resulting in death can be penalized by life in prison).

forfeiture of all assets and treble damages may also be appropriate to disincentivize those who would consider entering into this activity.

C. Raising Awareness

Counterfeit and tainted drugs represent a public health concern. Public health awareness should therefore be part of a strategy to protect citizens from harm associated with tainted or fake medicines.

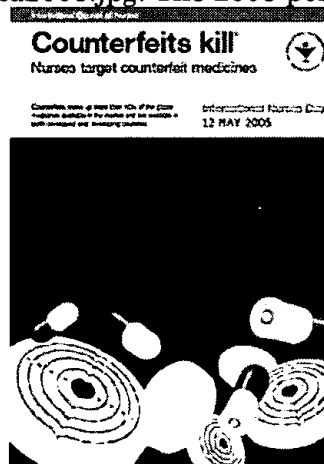
To be effective, public health strategies must be interdisciplinary and aggressive.¹⁹³ Raising patient awareness of the public health threat of counterfeit drugs is important. Dramatic advertisements and messages would be appropriate. The International Council of Nurses (ICN) recognized this approach; International Nurses Day 2005 was focused upon the problem of counterfeit drugs.¹⁹⁴

International Nurses Day 2005 included posters with “Counterfeits Kill” as its tagline, distributed to clinics and facilities around the world.¹⁹⁵ ICN represents the 12 million nurses worldwide, and these posters have a significant public health reach.¹⁹⁶

¹⁹³ See, e.g., Lisa Smith & Bryan A. Liang, *Childhood Obesity: A Public Health Problem Requiring a Policy Solution*, 9 MICH. ST. J. MED. & LAW 37 (2005) (proposing an example of a comprehensive and aggressive interdisciplinary approach to solving the problem of childhood obesity).

¹⁹⁴ See Int’l Council of Nurses, International Nurses Day 2005 Resources, <http://www.icn.ch/indkit2005.htm> (last visited Nov. 25, 2006).

¹⁹⁵ See Int’l Council of Nurses, International Nurses Day 2005 Poster, <http://www.icn.ch/images/ind2005.jpg>. The 2005 poster is quite striking:



¹⁹⁶ INT’L COUNCIL OF NURSES, 2002–2003 BIENNIAL REPORT: TACKLING THE UN MILLENNIUM DEVELOPMENT GOALS 18 (2003). Unfortunately, although the ICN represents nurses from around the world, the United States contingent

Raising awareness through public media outlets is also an important part of any public health approach on counterfeit drugs. Public service messages disseminated through television and print media outlets, as with the Ad Council efforts as well as prominent displays in high circulation periodicals of general interest, would provide greater exposure of the risks and dangers of fake and tainted medications to the general public.

Any public health effort regarding counterfeit and fake drugs must specifically include health care providers such as physicians and nurses. These providers' lack of awareness should be addressed through use of professional society educational activities and focused information outlets. Some efforts have been made to do this already, as noted above with the International Council of Nurses, as well as a SAFE DRUG checklist that has been developed and distributed to nurses on a small scale in the United States to assist in their detection of potential fake or tainted drugs.¹⁹⁷ At a minimum, providers should be educated to ask where their patients obtained their medicines.

Beyond raising awareness, it should be noted that patients are the last barrier to harm. As such, if they are educated and have the relevant tools to participate in the detection and safety process, the effect fake or tainted drugs may be limited and avoided in at least some cases.

Patient tools such as simple consumer education cards with guided checklists for assessment of their medicines would be helpful. The SAFE DRUG checklist for consumers, available free from the Partnership for Safe Medicines, is an example of such an approach.¹⁹⁸ Broadly disseminating these cards or similar

generally does not participate. Telephone Interview with Linda Carrier-Walker, Dir. of Comm'ns and External Relations, Int'l Council of Nurses (Oct. 17, 2005). Indeed, International Nurses Day was not recognized or celebrated in the United States. *Id.*

¹⁹⁷ A prototype of the nursing SAFE DRUG checklist has been developed and disseminated to approximately 200 nurses in the San Diego area, and is being developed for dissemination by the International Council of Nurses in the future.

¹⁹⁸ The SAFE DRUG checklist is also available online. SafeMedicines.org, SAFE DRUG: An 8-Step Check List for Medicine Safety, <http://www.safemedicines.org/resources/SAFEDRUG.pdf> (last visited Nov. 25, 2006) (outlining that to protect oneself against the potential for counterfeit drugs, patients should consider: using samples; assess drug appearance; note the body's feeling after taking the drug; evaluating one's response; contacting one's doctor if a suspected fake drug is detected; reporting any potential fake

tools by organizations with significant medicine-dependent members such as AARP, the Consumers Union, as well as other disease-specific advocacy groups would be highly desirable.

Further, counterfeit and fake drug alert systems for consumers and providers should also be broadly employed to rapidly provide information on detected fakes. Currently, WHO has begun a rapid alert system.¹⁹⁹ When fully implemented, the WHO system may provide some benefit to governments who can, upon receiving a report, disseminate this information to its citizens.²⁰⁰ The Partnership for Safe Medicines has also created its SafeMeds email alert system, which allows individuals to sign up for email alerts notifying them of counterfeit medicine warnings from any government alert or announcement.²⁰¹ These programs, as well as existing programs such as the FDA Counterfeit Alert Network,²⁰² which warns organizational entities of counterfeit drugs who then are responsible for warning their members, should be coordinated and work with media to create an integrated network of information to provide early notification of fake or tainted drugs.

drug to the FDA and other regulatory agencies; make the drug unavailable so it will not be confused with legitimate forms; and gather relevant information about the suspect drug for investigation).

¹⁹⁹ *WHO Launches Web-based System to Track Fake Drugs*, CTV, May 3, 2005, http://www.ctv.ca/servlet/ArticleNews/story/CTVNews/1115117564266_14?hub=Health. The system is essentially an information clearinghouse; reports sent, emailed, faxed or otherwise communicated to it are then disseminated to national authorities. Note, however, that the system does not reach individual consumers, primarily because certain parts of the region to be served, Southeast Asia, have a technology deficit. For example, countries such as Burma only have 0.5 Internet users per 1000, Cambodia has 2.2 per 1000, and Laos has 2.7 per 1000, compared with Singapore with 504 per 1000 and Malaysia with 320 per 1000. See Marwaan Macan-Markar, *Fake Drugs in Poor Nations Worry Health Experts*, INTER PRESS NEWS AGENCY, May 9, 2005, available at <http://ipsnews.net/news.asp?idnews=28600> (last visited Nov. 25, 2006).

²⁰⁰ See *Web-based System*, *supra* note 199.

²⁰¹ The SafeMeds Alert System has been featured in the Healthy Ideas section of Consumer Reports. See *Healthy Ideas: Counterfeit Drugs Alert System*, 18 CONSUMER REP. ON HEALTH 3 (2006).

²⁰² See generally COMBATING COUNTERFEIT DRUGS 2005 UPDATE, *supra* note 102; see also *Sick Crime: Counterfeit Drugs in the United States: Hearing Before the House Subcomm. on Criminal Justice, Drug Policy, and Human Res. of the Comm. on Gov't Reform*, 109th Cong. 9 (2005) (statement of Randall W. Lutter, Ph.D., Acting Assoc. Comm'r for Policy & Planning, FDA).

D. Reporting Systems

To detect counterfeit and tainted drugs for consumer and law enforcement purposes, a broad-based reporting structure is essential. All stakeholders with treatment, investigation, and enforcement interests must be part of and privy to this system. This group would include patients, providers, public health staff, law enforcement, customs, intelligence, industry, and other stakeholders, including researchers.²⁰³

The goal of such a reporting system is dual: to provide information to outline the epidemiology of fake or tainted medicines that allow effective public health intervention, as well as to support law enforcement investigation and prosecution.²⁰⁴ A corollary is that an integrated reporting structure will raise joint awareness of the problem between stakeholders who may not have considered working together before.

These efforts would require information on the environment associated with a detected fake to determine the nature of the fake, appropriate warnings, and its targeted markets. Importantly, because counterfeit drugs are an international problem requiring an international solution, an effective reporting system must coordinate and permit international reporting of and access to the data.²⁰⁵

Effective reporting systems require simple forms. For example, information to be collected could include the reporter name and contact information for follow up; location and date of detection of suspected product; patient diagnosis; suspected drug name and description; drug source if known or reported by patient; whether a sample is available for testing or has been tested; patient harm; patient outcome; necessary treatment

²⁰³ See generally Bryan A. Liang, *Measuring the Impact of Counterfeit Drugs: Applying the Patient Safety Reporting System Approach*, Presentation at the Org. for Econ. Cooperation & Dev. and World Intellectual Prop. Org. Expert Meeting on Measurement of Counterfeiting and Piracy (Oct. 17–18, 2005) (presentation slides available at <http://www.oecd.org/dataoecd/43/17/35650095.pdf>) (explaining that there is a “[c]ritical need to detect counterfeit drugs from patient, provider, public, and private perspectives”) [hereinafter *Measuring Impact*].

²⁰⁴ See *id.*

²⁰⁵ See *id.* (asserting that a single site for data collection and coordination is necessary for a successful reporting system). Note that the United States and the European Union have pledged cooperation and a zero tolerance for counterfeits. See *EU, U.S. Pledge Zero Tolerance on Fakes*, ASSOC. PRESS GENERAL FINANCIAL/BUSINESS NEWS, Nov. 30, 2005. However, no concrete details or efforts to share information or a reporting structure are yet evident.

changes; and any additional information deemed appropriate for public health or law enforcement purposes. Critically, the form should be easily filled out and accessible for use and communication, including online, by fax, or by mail to allow broad-based participation.²⁰⁶

All reports should be sent to a single data repository site, at least regionally; this would allow ease of analysis and cross-party assessment.²⁰⁷ Indeed, a single data repository would allow integration of reports and avoid the potential disparate and fragmented nature of insulated stakeholder reporting systems that do not communicate.²⁰⁸ Drop down menus and other systems might be employed to further hone information by reporter or analyst.

It should be emphasized that a single reporting system gives a key public health benefit: rapid dissemination of identified suspect drugs by locale, and even individual facility, to relevant patients, providers, and public health staff.²⁰⁹ And because reporting is broadened to include industry and broader government stakeholders such as customs officials, more information can be provided more rapidly for the benefit of the public's health. Since it also integrates the significant industry efforts,²¹⁰ the intelligence gathered can be used for a wide array of public purposes.

A unified reporting infrastructure also provides other benefits.

²⁰⁶ *Measuring Impact*, *supra* note 203.

²⁰⁷ A single data repository site would also make it easier for subsequent analysis of data. The Aviation Safety Reporting System, which is a gold standard in reporting to improve aviation safety, is a national database available for public use, including research and government, which has improved safety tremendously since its inception. Its data has also been put in newsletter form for even broader application and dissemination. See Aviation Safety Reporting System, http://asrs.arc.nasa.gov/main_nf.htm (last visited Nov. 25, 2006).

²⁰⁸ It should be noted that fields on the data reporting form may be altered or expanded, depending upon the relevant stakeholder. For example, discovery of fake medicines by customs officials could allow for more detail in the drug source field.

²⁰⁹ See *Measuring Impact*, *supra* note 203 (explaining that such systems can integrate rapid alert systems from the WHO and e-mail alerts from Safemedicines.org, and that they can keep reporter identities confidential for security purposes).

²¹⁰ Industry efforts to detect counterfeit drugs are extensive in scope and discovery. See, e.g., Todd Datz, *Drug Busters*, CSO MAG., Nov. 2005, available at <http://www.csoonline.com/read/110105/counterfeit.html> (outlining the extensive efforts of James Christian at Novartis to detect counterfeit drugs around the world).

Reporting that provides information on the epidemiology of counterfeits and tainted drugs may also elicit the public economic burden faced by governments, as well as the private economic burden faced by providers, patients, and industries that must face the issue in their respective roles.²¹¹

Finally, for investigation and enforcement purposes, such a system will also allow much more effective tracing of fakes through database analysis, as well as effective application of geographic information systems (GIS).²¹² GIS analyses can perform thematic mapping for both public health and legal investigation purposes.²¹³

V. CONCLUSION

The answer to the question posed by the title of this piece is, of course, a little of both. There are sophisticated infrastructural and technological approaches on the horizon that may be beneficial in ensuring drug supply safety against counterfeits. Human ingenuity is astounding, and the development of increasingly complex methods to assess authenticity and trace products is a tribute to the creativity of a species that can look about it and wonder.

Yet much of the current effort misses the point. *Drugs* need to be tracked, verified, and authenticated, not cardboard. Hence, despite all our sophistication, we are indeed lamentably limited when it comes to the focused goal of making sure the drugs we take are, in fact, the real thing—in substance, and in oversight.

Clearly, there is no magic technological bullet that will slay the monster of counterfeit drugs, and its effect upon patients. As in most complex problems, the solutions are tough, will take resolve, and will necessitate multidisciplinary approaches to shore up the systemic weaknesses that allow fake products to enter into the supply chain.

What this means, ultimately, is that the problem must be attacked on several fronts. Technology development must occur, and problems associated with legal issues of standardization, protocols, data ownership, and information stewardship must be

²¹¹ *Measuring Impact*, *supra* note 203.

²¹² *Id.*

²¹³ *Id.* Note that, for example, recipients of the fake or tainted drugs can be tracked using GIS, which may allow for source identification and illicit transport pathways across country lines supporting investigation and law enforcement efforts.

addressed. Penalties must be strengthened to signal to those creatures who would trade upon a human's health that we will exact a very dear price of liberty and financial punishments for these activities. The general and health professional public must be educated on the problem, and on the means by which they may protect patients and themselves from harm associated with fake drugs. Finally, international cooperation in reporting, investigating, and prosecuting will be necessary amongst all stakeholder groups to detect, protect against, and punish the perpetrators of this most heinous crime.

Overall, the "worst racketeers" have come far in their production and sale of counterfeit medicines. We must go farther in detecting, punishing, and protecting against the harms associated with their "dirty living." This is no movie: this is the reality the world increasingly faces as humans become more and more dependent upon the benefits medicines can provide. We must act, and we must make the relevant investments now. The present and future public health depends upon it.