

Counterfeit Drugs: Coming to a Pharmacy Near You (Condensed Version)

Prepared for
The American Council on Science and Health

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Part I: Executive Summary

Counterfeit drugs, including fake, substandard, adulterated or falsely labeled (“misbranded”) medicines, have become a real and growing threat to global health. Increasingly sophisticated counterfeiting rings, often involving organized crime, are slipping their fakes into the legitimate drug supply around the world. The problem is especially serious in developing countries, where hundreds of thousands die from ineffective medicines, and millions more from the drug-resistant strains of pathogens such as malaria, HIV/AIDS and tuberculosis that have been promoted by counterfeits’ suboptimal dosing of antibiotics and anti-viral agents.

Even the U.S. drug supply, among the most secure in the world, is increasingly threatened by counterfeit or substandard drugs. The last few years have seen a rising number of cases of counterfeits turning up in neighborhood pharmacies, including fake versions of some of the nation’s most popular drugs. The main point of entry for the counterfeits has been the “gray market,” a loose and complex network of drug diverters and secondary wholesalers that makes it possible for distributors to introduce diverted and sometimes counterfeit drugs into the legitimate drug supply chain. The risk of counterfeits is even greater when individuals import drugs or purchase from unregulated online sites.¹

Efforts to secure the system have focused on the pedigree provisions of the Prescription Drug Marketing Act (PDMA), which after two decades of delay, the FDA will soon begin to enforce. However, to be effective, the pedigree requirement must be combined in a multi-layered strategy with new emerging anti-counterfeit technology, such as RFID, and the reform of the wholesale industry. Moreover, because regulations are meaningless without effective enforcement, state and federal officials must be given the authority and resources they need to enforce the laws, and penalties must be increased for those who violate them.

How can consumers protect themselves? By paying attention to the drugs they take and their effects and reporting anything suspicious or unusual to appropriate authorities. Online drug shoppers should only use those legitimate Internet pharmacies that have been approved by the National Association of Boards of Pharmacies (see V.I.P.P.S. list on page 8).

1. See Part III of report: pharmacy drugs are, at most, 5-7% substandard, compared to estimates of more than 80% for imported drugs or those bought from online drug stores.

Part II: Overview of Counterfeit Drugs

According to the World Health Organization, a “counterfeit medicine is one which is deliberately and fraudulently mislabeled with respect to identity, composition and/or source.” This definition of counterfeits includes not only completely fake drugs, but also those that have been tampered with, adulterated, diluted, repackaged or relabeled so as to misrepresent the dosage, origin or expiration date, as well as substandard drugs that were cheaply produced in order to make unlawful profit.

Counterfeit drugs represent a real and growing danger to global health. The most widely-cited estimate is that 10% of the world’s drug supply is counterfeit and the counterfeit drug industry’s sales are expected to reach \$75 billion by 2010, representing a 92% increase from 2005.² The world’s largest producers of counterfeits are believed to be China and India, as well as Southeast Asia, Nigeria, Russia, Mexico, Brazil and Latin America.³

Contributing to this growth has been the increasing size and sophistication of drug counterfeiting rings and the widening involvement of organized crime groups, including the “Russian mafia,” Chinese triads, Colombian drug cartels, Mexican gangs, and even terrorist groups such as Hezbollah, IRA and ETA.⁴ Counterfeiters now have the ability to produce near-perfect fakes that are indistinguishable to all except well-trained experts (see Figure 1).⁵

Counterfeits in Developing Countries

Counterfeiting is an especially serious problem in developing countries, where supply shortages, lax regulations and oversight, and corruption allow the trade to thrive. According to the WHO, 60% of counterfeit drug cases take place in less-developed countries, where it is estimated that more than 25% of the drug supply is counterfeit.⁶ The percentages are worse in certain areas: 38% in Southeast Asia, 48% in Africa. Indeed, a recent study of pharmaceuticals on sale in Nigeria’s capital found that 80% were fake and 7% contained dangerous ingredients.^{7 8} Such dangerous counterfeits kill thousands each year in developing countries, in incidents such as the hundreds of children who died in Haiti



Figure 1: Comparisons of Counterfeit v. Real Drugs

(Source: Howard Zucker, “Combating Counterfeit Drugs: Building Effective Collaboration” WHO Presentation at Conference of Rome, February 2006)

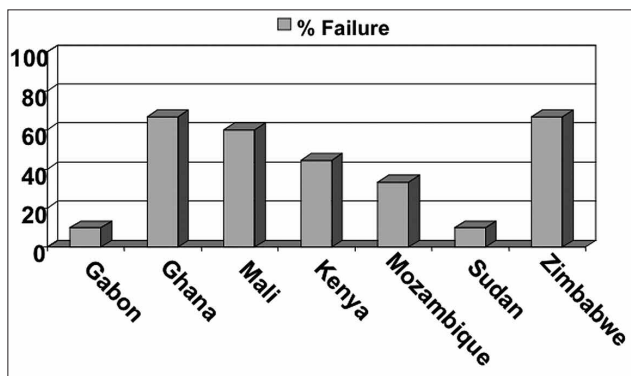


Figure 2:
Percentage Failure of
Chloroquine –
African Countries

(Source: Nancy Blum, "Quality Control Approaches for Essential Medicines," U.S. Pharmacopeia presentation at World Bank conference "Good Intentions – Bad Drugs," March 10, 2005)

in the early 1990's after taking cough syrup made with antifreeze.

Even worse, the trade in counterfeit drugs is responsible for increasing drug-resistance among some of the world's most deadly infectious diseases, including malaria, tuberculosis and HIV/AIDS. The reason is that most counterfeit, substandard or degraded medicines contain incorrect levels of a drug's active ingredient, which causes the weaker strains of the causal agent to be killed off while allowing the drug-resistant strains to multiply and adapt. A 2004 study found that 53% of the antimalarials being sold in Southeast Asia contained incorrect levels of the active ingredient, while it is estimated that as much as 85% of the malaria drugs in Nigeria are ineffective (see Figure 2).^{9 10} This has contributed to a doubling of malaria deaths over the last 20 years (to more than 1.5 million people per year, 90% of them children) as substandard therapy has caused the disease to become more quickly resistant to a succession of drugs.¹¹

In addition to antimalarials, a growing trade in counterfeit antiretroviral drugs for HIV/AIDs in Africa has caused the virus to become increasingly resistant to first-line therapies, forcing health officials to resort to second-line antiretrovirals, which are more toxic than first-lines, can cost over 20 times more and require hospitalization, significantly reducing access to these desperately-needed medicines.¹²

2. WHO Fact Sheet No. 275: "Counterfeit medicines," February 2006.

3. U.S. Immigration and Customs Enforcement, "ICE Efforts to Combat Counterfeit Pharmaceuticals," July 11, 2006.

4. Graham Satchwell, *Sick Business: counterfeit medicines and organized crime* (London: Stockholm Network, 2004), 60.

5. Douglas W. Stearn, "Deterring the Importation of Counterfeit Pharmaceutical Products," *Food & Drug Law Journal*, Vol. 59 (2004): 550

6. Julian Morris and Philip Stevens, *Counterfeit medicines in less developed countries* (London: International Policy Network, May 3, 2006).

7. Lew Kontnik, "Counterfeits: the cost of combat," *Pharmaceutical Executive*, November 1, 2003.

8. Joyce Primo-Carpenter, *Matrix of Drug Quality Reports on USAID-assisted Countries*, U.S.

Pharmacopeia Drug Quality and Information Program, April 4, 2006.

9. A.M. Dondorp et. al., "Fake antimalarials in Southeast Asia are a major impediment to malaria control," *Tropical Medicine and International Health*, Vol. 9 No. 12 (December 2004): 1241.

10. Robert Cockburn, "Counterfeit drug racket" report on Science Show on ABC Radio National, February 4, 2006.

11. Paul Newton et. al., "Manslaughter by Fake Artesunate in Africa – Will Africa be Next?" *PLoS Medicine*, Volume 3, Issue 6, e197 (June 2006): 0003.

12. Carol C. Adelman, Jeremiah Norris and S. Jean Weicher, *Access to Medicine: The Full Cost of HIV/AIDS Treatment*, Hudson Institute White Paper, 2nd ed., May 2005.

Part III. Counterfeits and the U.S. drug supply

A Growing Danger to the United States

Counterfeit drugs are by no means solely a problem of the developing world, or of those who obtain their drugs through unregulated channels. The growing size and sophistication of counterfeit drug rings has allowed them to penetrate the legitimate drug supplies of developed Western nations, even the United States, which has possibly the most secure drug supply in the world.

In the last five years, counterfeit drug investigations by the FDA have increased almost ten-fold: from 6 in 2000 to 58 in 2004 (Figure 3).¹³ We can be certain that the number of detected incidents of counterfeits is a mere fraction of the real number of cases.¹⁴ Although there is no way to know the true degree to which counterfeits have contaminated our drugs, the FDA estimates that they are 1% or less of our drug supply, while the WHO estimated in 2003 that “5% to 7% of all drugs sold in the United States have been tampered with, mislabeled, or are otherwise fraudulent.”¹⁵ Even if we accept the FDA’s more conservative number, that could still mean that there is as much as a 1-in-100 chance that the drugs you get from your pharmacy are counterfeit. In the last few years we have seen a number of high-profile counterfeiting incidents, in which counterfeits of some of the nation’s most popular brands, including Lipitor, Celebrex and Viagra, as well as drugs treating critically-ill patients, made their way into legitimate pharmacies across the country and were distributed to hundreds of thousands of unwitting patients.

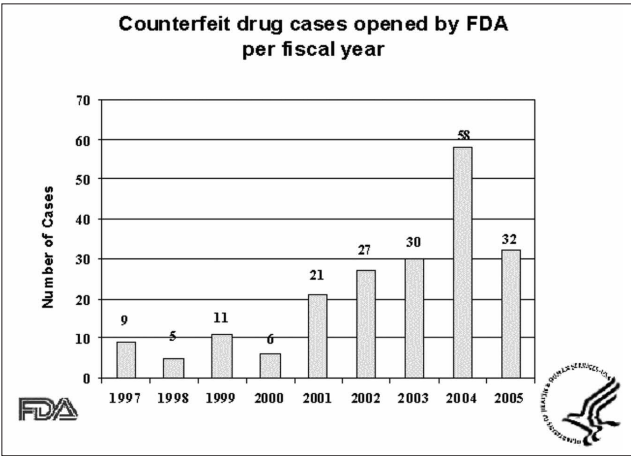


Figure 3: FDA Counterfeit Drug Cases, FY 1997-2005

(Source: Randall Lutter, Speech before NACDS/HDMA RFID Healthcare Adoption Summit, November 14, 2005, <http://www.fda.gov/oc/speeches/2005/radiofrequencyid1114.html>)

Diversifiers and the Gray Market

How could this happen? The answer lies in the nature of our nation's pharmaceutical manufacturing and distribution system, which is, contrary to widespread belief, not a single secure channel from manufacturer to distributor to pharmacy. While most drugs pass through the presumably secure channel that flows from the pharmaceutical manufacturers to the "Big Three" wholesalers, to pharmacies and then to the consumer, as much as 10% of the nation's wholesale drug supply travels through a complex and confusing network of distributors, intermediaries and secondary wholesalers, a vast array of businesses, most legitimate, many semi-legitimate and some outright criminal. As Figure 4 illustrates, this network of intermediaries, known as the "gray market," represents an open door into the U.S. drug supply which counterfeiters are all too willing and able to exploit.

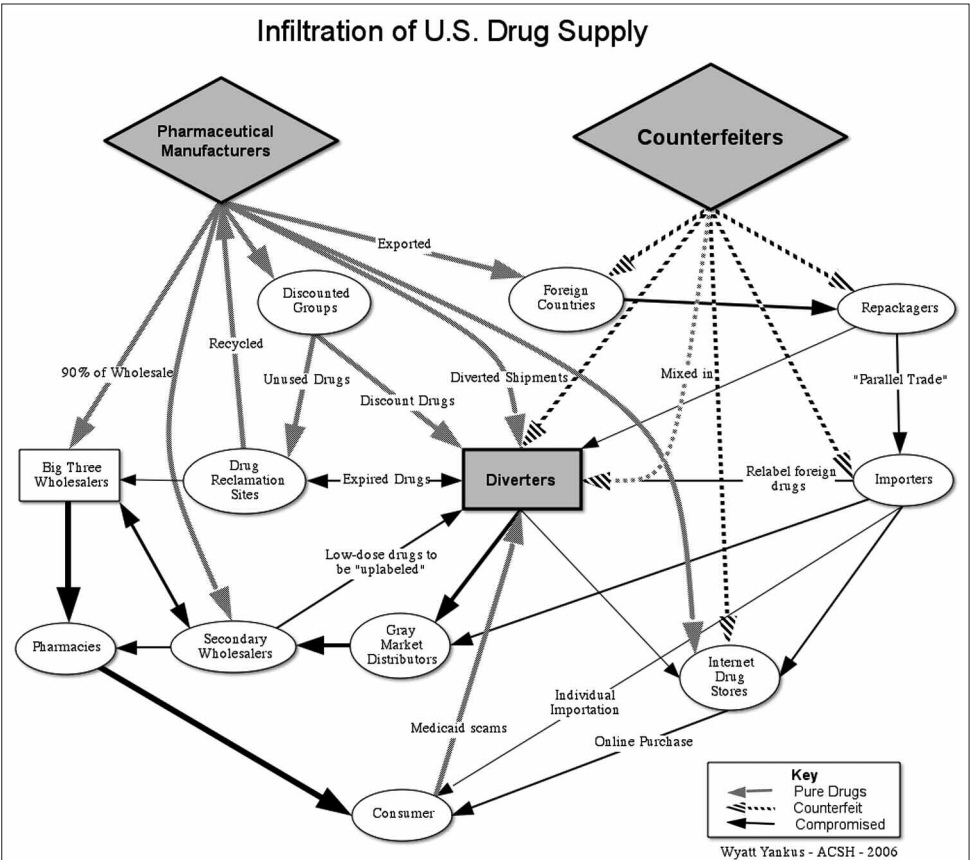
The driving force behind the gray market lies in the profit opportunity created by the vastly differing prices at which pharmaceutical manufacturers sell drugs. Gray marketeers known as "diverters" take advantage of this price differential, buying or otherwise acquiring discounted medicine and then reselling the drugs at a marked-up price to other distributors, wholesalers and other regions. Diversifiers employ a wide array of illegitimate methods for acquiring these discounted medicines.¹⁶ One popular source is "closed-door" pharmacies, dispensaries for institutions such as nursing homes, hospices and AIDS clinics, four out of five of which have resold at least some of their medicine to diversifiers according to the National Association of Boards of Pharmacy.¹⁷ In other cases, diversifiers pay hospital or nursing home workers to sell their discounted medicines, divert or fraudulently acquire shipments for government institutions or foreign countries, offer Medicaid patients cash in exchange for their medicines, collude with corrupt pharmaceutical company employees or break into warehouses and snatch shipments of drugs from loading docks.

Counterfeiters are increasingly taking advantage of this diversion channel to distribute their products. Counterfeiters' methods include relabeling expired drugs or "up-labeling" low-dose drugs, importing and repackaging compromised foreign-market drugs, and making or buying completely fake drugs.¹⁸ These potentially dangerous counterfeits are then passed through the same gray market channels that lead into the legitimate drug supply. Drug regulators claim they have never seen a case of counterfeits infiltrating the drug supply that didn't also involve drug diversifiers.

Drug Wholesalers and the Diversion Market

Diverted drugs move through gray market distributors to small secondary

Figure 4: Infiltration of U.S. Drug Supply



Explanation of the "Infiltration of U.S. Drug Supply" Chart

- Pure and unadulterated drugs, represented by gray arrows, are made by the pharmaceutical manufacturers and then shipped to either drug wholesalers or directly to drug dispensers, usually for groups who receive discounts.
- Meanwhile, counterfeited drugs, including fully fake, adulterated and falsely relabeled drugs, are made by drug counterfeiters and represented in this chart by dotted lines. Drug diverters help the counterfeiters, both by supplying them with legitimate drugs that can be relabeled and repackaged, and by serving as the counterfeits means of entering the legitimate drug supply.
- Diverters and their gray market distributors, whether they realize it or not, can mix legitimate medicine with drugs that are counterfeit, substandard, expired or have been degraded by conditions in storage and transport. As a result, the safety of their drugs is compromised, and they are therefore represented by black lines.

wholesalers and then to the Big Three wholesalers. Drug wholesaling is a highly competitive industry, characterized by razor-thin profit margins of 1% or less of revenue and by the constant pressure to offer drugs at a lower price than competitors.¹⁹ This profit motive drives many secondary wholesalers to buy drugs from less-than-credible sources because of the discounts being offered, in some cases to the point of “willful blindness” as far as the source and quality of the medicine, caring only about its low price and the profit that can be made from reselling it.²⁰ In her book *Dangerous Doses*, investigative reporter Katherine Eban documents this practice and the fact that the wholesalers appear to consider the possibility of receiving counterfeit drugs to be an acceptable risk.²¹ Despite recent attempts to change these business practices, the secondary wholesale market remains a vulnerable point in the system and an opportunity for the infiltration of counterfeit drugs.

Compounding this problem is the lax oversight and loose licensing requirements within the wholesale industry that have allowed the proliferation of small wholesaling operations that serve as front companies for criminals and diverters. For instance, a grand jury in Florida discovered in 2003 that because of the state’s lax licensing requirements, “uneducated, inexperienced, ill-informed rank amateurs with no pharmaceutical experience, many with criminal records, make up a sizeable portion of Florida’s drug wholesalers.”²² Moreover, because of limited resources, there is insufficient enforcement of those regulations that are in place.

The Big Three have long maintained that they buy only a small fraction of their drugs from the secondary market, and within the last year or so, under tremendous pressure from lawmakers and regulators, have declared that they will no longer buy any of their drugs from secondary wholesalers.²³ However, loopholes remain and only time will tell what effect these changes may have. Meanwhile, the counterfeiters have adapted, increasingly using Internet-based smuggling operations to sell counterfeits directly to consumers.²⁴

Drug Importation

Just as the counterfeiters’ desire to make a profit drives them, and as many wholesalers’ desire to widen a profit margin drives them to purchase questionable drugs, so too has the consumers’ desire to find low-price prescription drugs driven many to purchase cheaper drugs from overseas, despite the very real safety risks involved.²⁵ Many “consumer groups” and politicians advocate strongly for opening up our domestic drug supply to drug importation, which they see as an easy way to get cheap drugs and, they claim, a safe practice because most of the drugs were actually produced in the United States.

However, once a drug is exported, there is no way to tell whether it is still safe, nor is there anyway to know that what is being re-imported was actually made in the United States. Neither the FDA nor Canadian health officials have any ability to guarantee the safety of re-imported drugs or to prevent the introduction of counterfeit drugs.²⁶ Indeed, in an operation in 2003, the FDA and U.S. Customs Service conducted spot-checks of drugs being imported into the country and found that 88% of them violated FDA safety standards because they contained unapproved and potentially dangerous drugs.²⁷ In fact, under FDA regulations, the shipment of any volume of pharmaceuticals into the United States is by itself illegal. The FDA is well aware of the volume of illegal shipments, but it lacks the resources to intercept them.²⁸

Previous efforts in Congress to legalize importation have been defeated based on testimony from numerous government agencies, industry associations, non-government health organizations and health officials from around the world that re-importation was a dangerous practice that would increase the vulnerability of the American drug supply.²⁹ However, because re-importation remains a popular measure among an aging population, politicians have continued to advocate its approval.³⁰ Such politicians fail to heed the warning of Health and Human Services Secretary Tommy Thompson, who reported to Congress that the policy would “sacrifice public safety for uncertain and speculative cost savings.”³¹

Sidebar 1: V.I.P.P.S. Online Pharmacies³⁴

- Anthem Prescription – www.anthemprescription.com
- Caremark.com – www.caremark.com
- DrugSource, Inc. – www.drugsourceinc.com
- DrugStore.com – www.drugstore.com
- Familymeds.com – www.familymeds.com
- Hook Superx, Inc. dba CVS/pharmacy – www.cvs.com
- Medco Health Solutions, Inc. – www.medcohealth.com
- Omnicare, Inc. dba Care for Life – www.careforlife.com
- Prescription Solutions – www.rxsolutions.com
- Tel-Drug, Inc./CIGNA – www.teldrug.com
- Walgreen, Co. – www.walgreens.com
- WellDyneRx – www.welldynernx.com

Internet Drug Stores

The same dangers that exist with drug importation are found to an even greater extent in Internet drug stores. These websites, most of which purport to be based in Canada, are, in reality, a vast unregulated conduit through which unapproved and often substandard drugs can flow to the U.S. consumer. Indeed, according to U.S. Immigration and Customs Enforcement, “the Internet has become the primary tool for criminal organizations to advertise, communicate and conduct sales of counterfeit pharmaceuticals.”³²

In July 2004, the FDA conducted a study of drugs purchased from a “Canadian website” and determined that *all* of the drugs were substandard

or fake, and potentially dangerous. A separate study in August 2005 showed that 85% of Internet drugs purported to be from Canada actually came from any of 27 other countries, including India, Costa Rica and Vanuatu.³³ There is no effective government regulation of Internet drug sellers, and other than those on the NABP's Verified Internet Pharmacy Practices Site (V.I.P.P.S.) list (See Sidebar 1), no sites have been verified as legitimate pharmacies dispensing genuine product. Any Internet drug store that does not require a prescription is immediately suspect because any pharmacy unethical enough to dispense drugs without a prescription will probably have few qualms about selling substandard or counterfeit drugs or selling credit card information to identity thieves. Any consumer who buys medication at an online drug store (other than V.I.P.P.S. sites) is taking an unacceptable risk and endangering his or her health.

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13. Randall Lutter, Testimony before House Committee on Government Reform, July 11, 2006: The number of new cases dropped to 32 in (FY) 2005, while preliminary numbers for (FY) 2006 indicate an increase in line with the numbers for 2004. All parties admit that the number of FDA cases is a fairly poor indicator of the true prevalence of counterfeits in the U.S. because most cases are never reported and a single investigation can involve tens of thousands of counterfeit doses.
 14. Donald deKieffer, "Trojan Drugs," *American Journal of Law & Medicine*, 32 (2006): 325.
 15. Brian Vastag, "Alarm Sounded on Fake, Tainted Drugs," *JAMA*, Vol. 290 No. 8, August 27, 2003.
 16. For a thorough discussion of different sources of diverted drugs, see: Donald deKieffer, "Trojan Drugs: Counterfeit and Mislabeled Pharmaceuticals in the Legitimate Market," *American Journal of Law & Medicine*, 32 (2006): 334-339.
 17. Katherine Eban, *Dangerous Doses* (New York: Harcourt, 2005), 91.
 18. Lew Kontnik, *Pharmaceutical Counterfeiting: Preventing the Perfect Crime*, Lew Kontnik Associates, 2003. As an illustration of the profits involved in this practice, a single vial of Epogen at 2,000 unit strength costs \$258 but when up-labeled to 40,000 unit strength might sell for \$4,570.
 19. Gilbert Gaul and M.P. Flaherty, "U.S. Prescription Drug System Under Attack," *The Washington Post*, October 19, 2003.
 20. Florida Supreme Court Case No. SC02-2645 Grand Jury Report, 25, 29.
 21. Katherine Eban, *Dangerous Doses*, 213, 321
 22. Martin Downs, *Counterfeit Drugs: Victims and Villains*, WebMD Feature Archive, October 18, 2004.
 23. James Frederick, "Cardinal latest wholesaler to curb secondary dealing," *Drug Store News*, May 23, 2005.
 24. Kevin Delli-Colli, Testimony before House Subcommittee on Criminal Justice, Drug Policy and Human Resources hearing on "Pharmaceutical Supply Chain Security," July 11, 2006.
 25. The introduction of the Medicare Part D prescription drug benefit has reduced some of this pressure, as have pharmaceutical industry programs that increase the availability of drugs to low-income groups.
 26. Testimony of John M. Taylor III before Permanent Subcommittee on Investigations, Committee on Governmental Affairs, July 22, 2004.
 27. FDA Press Release: "FDA/U.S. customs import blitz exams reveal hundreds of potentially dangerous imported drug shipments," Sept. 29, 2003.
 28. Mary Pat Flaherty and Gilbert Gaul, "Millions of Americans Look Outside U.S. for Drugs," *The Washington Post*, October 23, 2003, A01.
 29. John A. Marcille, ed., "Reimportation of Pharmaceuticals: Economic and Policy Implications," Supplement to *Managed Care*, Vol. 13, No. 3 (March 2004).
 30. Jeff Siegel, "Re-importation: The Issue That Will Not Die," *Pharmaceutical Commerce*, January 30, 2006.
 31. Lori Reilly, "Imported Prescription Drugs Are Not the Answer," in "Reimportation of Pharmaceuticals," Supplement to *Managed Care*, Volume 13, No. 3, (March 2004): 34; Cites studies by the Department of HHS, Congressional Budget Office, Massachusetts Group Insurance Commission and National Taxpayers Unions all of which found the possible savings from importation, if any, to be negligible.
 32. U.S. Immigration and Customs Enforcement [ICE], "ICE Efforts to Combat Counterfeit Pharmaceuticals," ICE Fact Sheet, July 11, 2006.
 33. FDA Press Release, "FDA Operation Reveals Many Drugs Promoted as 'Canadian' Products Really Originate From Other Countries," December 16, 2005, P05-102.
 34. Accurate as of 8/2/06; National Board of Pharmacy, <http://www.nabp.net/vipps/consumer/listall.asp>.

Part IV: Fixing the system

The FDA and PDMA

The most significant attempt to respond to the emerging threat of counterfeit drugs is the Prescription Drug Marketing Act (PDMA), which was passed in 1988. An essential part of the law, known as the pedigree provision, requires that a seller provide, prior to sale, a “pedigree” demonstrating the chain of custody for the drug going back to an authorized distributor of record.³⁵ It was intended to remove the risk of stolen or diverted drugs entering the drug supply and to create a paper trail for investigators to follow if they located questionable drugs.

Yet, in the nearly two decades since its passage, the pedigree rule of PDMA has never been enforced, largely because lobbying from the wholesaler industry groups has repeatedly convinced the FDA to delay its enforcement.³⁶ In 2004, the FDA issued another stay on PDMA enforcement because it was convinced that within a few years, the pedigree requirement could be fulfilled using “e-pedigrees” provided by electronic track-and-trace technology, most notably radio frequency identification (RFID) tags.

However, in its June 2006 Update Report, the FDA decided that it “could no longer justify” delaying enforcement of PDMA and therefore declared that the pedigree would go into effect on December 1, 2006, but without a mandate for RFID technology, as the FDA was “disappointed with the lack of overall progress across the drug supply chain.”³⁷ The report also indicates that the FDA has realized that “the secondary wholesale market is where much of the illegal activity occurs [and] continuing the stay would perpetuate the current confusion and further allow opportunities for counterfeit and diversionary practices to occur.”³⁸

Unfortunately, the FDA’s latest decision alone will not create a secure drug supply chain overnight. Technicalities regarding the definition of an authorized distributor of record may reduce the effectiveness of pedigrees. A deeper problem involves the split jurisdiction over drug safety, in which the FDA oversees the approval and manufacture of drugs, while the states have jurisdiction over the distribution and dispensing of those drugs. Moreover, the FDA must share its regulatory authority with more than 20 other federal agencies, most notably the Drug Enforcement Agency and Federal Trade Commission.³⁹

Further, the wholesale industry suffers from deeper problems that pedigrees will not solve and which there has been no concerted effort to solve. The view

among secondary wholesalers that they are under no obligation to verify the legitimacy of a supplier is as arrogant as it is dangerous. There has yet to be a nationwide effort to tighten wholesale licensing standards, an essential step if the criminal element is going to be driven out of the industry. Tighter licensing requirements and mandatory due-diligence practices for secondary wholesalers will help to strengthen this weakest link of our drug supply chain. Moreover, criminal statutes against the counterfeiting of drugs and the liabilities for distributing dangerous materials need to be significantly strengthened in order to make the practice a riskier undertaking.

However, increased regulation will do nothing to prevent counterfeiting and diversion if it is not accompanied by aggressive enforcement of these laws. Law enforcement agencies such as the Drug Enforcement Agency and state-level pharmaceutical enforcement bureaus must therefore be given the resources and authority they need to track down and arrest the criminals involved.

Anti-Counterfeiting Technology

Many believe that emerging anti-counterfeiting technology will solve the problem of counterfeit drugs in the legitimate drug supply. However, many of these technologies have yet to be proven effective and most are far from industry-wide implementation. While none can ever be a “silver bullet” that will by itself prevent counterfeiting, if combined in a multi-layered strategy, they can work to make the system more resistant to counterfeiting.

The most discussed and, to many, most promising option for securing the drug supply is the electronic track-and-trace capability offered by radio-frequency identification (RFID) tags. These tiny radio transmitters, when affixed to a package of drugs, would emit a unique electronic product code, which would allow for each individual package of drugs to be tracked through each step of the supply chain, from manufacturer to distributors and wholesalers and finally to pharmacies. While there have been some encouraging accomplishments in the adoption of RFID technology, after two years of FDA efforts promoting its use, “the pharmaceutical industry is still barely even employing the technology.”⁴⁰ Barriers to widespread RFID adoption include the costly and complicated infrastructure required to track the drugs through the distribution system, as well as the lack of any agreed-upon industry-wide standards for RFID technology and unresolved questions regarding its possible effects on biological medicines.⁴¹

In addition to track-and-trace technology, new authentication technologies could make it more difficult for counterfeiters to replicate pharmaceuticals. These authentication technologies include overt (visible) features such as holo-

grams, covert (hidden) features such as UV markers and forensic tags.⁴² Although these authentication technologies can make it easier to tell real drugs from counterfeits, the increasing sophistication of counterfeit-production rings means that such anti-counterfeit features must constantly be improved and updated in order to stay one step ahead of the counterfeiters.

35. U.S. Food, Drug, and Cosmetic Act, as amended by PDMA, Section 503(e)(1)(A).

36. Donna Young, "Secondary Wholesalers oppose FDA Pedigree Regulation," *ASHP News*, American Society of Health-System Pharmacists, September 15, 2001.

37. U.S. Food and Drug Administration, *FDA Counterfeit Drug Task Force Report: 2006 Update*, June 8, 2006, 11.

38. *Ibid.*, 6.

39. Donald deKieffer, "Trojan Drugs," *American Journal of Medicine and Law*, 330.

40. Stacy Lawrence, "FDA to Pharma: Where's the

RFID?," *eWeek*, May 30, 2006.

41. Concerns regarding biological medicines, include questions of whether the liquid medicines and its metal packaging will interfere with the reading of the RFID signal, and whether the RF radiation might affect the biologicals in such a way that compromises its effectiveness.

42. From presentation "Evaluating Security Technologies," by Richard Jotcham, Axess Technologies at CARIRI Conference on Pharmaceutical Counterfeiting, April 27, 2004.

Part V: How to Protect Yourself⁴³

Pharmacy Drugs

The only honest response to the often-asked question, “How can I be sure that the drugs I receive at the pharmacy are legitimate?” is that you can’t be sure. However, there are steps that you can take as a consumer to reduce your risk of taking counterfeits.

First, you should be vigilant in monitoring the medicines that you take for anything unusual or different. Be familiar with the shape, size and color of your medicine and try to quickly inspect these features before taking it. Also, pay attention to the packaging of the drug for any damage or differences in design. When you take the medicine, try to take note of its feel and taste, and any unusual effects that you experience after taking it. During a course of treatment, be sure to observe your symptoms in case new or unusual side effects emerge or the medicine stops being effective.

If you suspect that your medicine may be counterfeit, keep it and make sure that you report it. Tell your pharmacist or doctor, or call the manufacturer. Also, try to gather all the information you can regarding the medicine you purchased and be sure to keep a sample of the suspect medicine as evidence, even if the manufacturer asks you to send it back. Reports of suspected counterfeits can be submitted to the FDA through a form on its MedWatch site.

Sidebar 2: Visit the following sites for more information:

- The Partnership for Safe Medicines:
http://www.safemedicines.org/north_america/counterfeit.php
- Katherine Eban’s *Dangerous Doses* website: <http://www.dangerousdoses.com>
- FDA’s Combating Counterfeit Drugs page: <http://www.fda.gov/oc/initiatives/counterfeit/>
- FDA’s MedWatch Counterfeit Alert site: <http://www.fda.gov/medwatch/report/consumer/consumer.htm>
- Consumer Information for buying drugs online: <http://www.buysafedrugs.info/Resources/>
- WHO’s Counterfeit Medicine News & Information page: <http://www.who.int/medicines/services/counterfeit/en/index.html>

43. Compiled with help from the National Consumer League (<http://fraud.org/fakedrugs/>), the Partnership for Safe Medicine’s SAFEDRUG checklist (http://www.safemedicines.org/north_america/index.php) and *Dangerous Doses* (<http://www.dangerousdoses.com/html/safety.html>).

Part VI: Conclusion

Globally, controlling counterfeiting will require the emergence of adequate regulatory and quality-control regimes in developing countries, reduced corruption, a crackdown on counterfeiting operations in nations where its production is prevalent and stronger penalties for convicted counterfeiters. This first requires that the international community become aware of the threat posed by counterfeit drugs and motivate various public and private stakeholders to work together towards a multi-layered anti-counterfeiting strategy that can begin to contain this threat. There have been encouraging signs of progress on the international stage recently, such as the Declaration of Rome, in which the international community recognized drug counterfeiting to be a “vile and serious criminal offense” and a threat to global health, and pledged to work together to address it through a new WHO task force.⁴⁴

However, it remains to be seen what effects the Declaration of Rome will have, and the United States cannot wait for an effective international framework to protect itself from counterfeiting. While supporting global reform efforts, we must take the steps necessary to close the loopholes within our own regulatory framework. The best solution is a multi-faceted one: to increase security features and develop electronic track-and-trace capability as quickly as possible while increasing oversight and regulation of the secondary wholesale market and establishing mandatory wholesaler due-diligence procedures. The FDA needs statutory power to create uniform pedigree standards, and law enforcement agencies at the state and federal level need the resources to enforce these provisions. The American public must also realize the danger posed by counterfeiting and take it into account when considering such practices as drug importation and buying drugs online.

44. World Health Organization [WHO] *The Declaration of Rome*, WHO International Conference on Combating Counterfeit Medicines, February 18, 2006, Rome, Italy.

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