

Counterfeit Drugs: Coming to a Pharmacy Near You

with an Update for 2009



Counterfeit Drugs: Coming to a Pharmacy Near You with an Update for 2009

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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 of countries 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 with drugs that are unlawfully imported or bought 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 Pharmacy (see the sidebar in the section “Internet Drug Stores” in Part III, below).

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

Definition of Counterfeit

Although a variety of definitions exist for what constitutes counterfeit medicine, the most comprehensive is that of the World Health Organization:

Counterfeit medicine is one which is deliberately and fraudulently mislabeled with respect to identity, composition and/or source...Counterfeit products may include products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient active ingredients or with fake packaging.²

It should be noted that 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. This broad definition reflects the fact that adulterated or substandard drugs can be as dangerous as fake drugs, and that all represent a fraudulent misrepresentation of the manufacturer’s trademark.

Substandard drugs are genuine products that are produced by legitimate or illicit manufacturers, which, due usually to poor manufacturing practice or improper storage conditions, do not meet agreed-upon standards for quality, purity, strength or packaging.³ If substandard drugs are knowingly produced to make unlawful profit (produced cheaply and then sold as if full quality) they are considered to be counterfeit. Substandard drugs pose as serious a problem as counterfeiting because substandard drugs can cause treatment failure and contribute to the emergence of drug-resistant diseases.

A Global Problem

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, although the percentage is much higher in developing countries.⁴ 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.⁵ The counterfeit drug industry’s sales are estimated to be \$39 billion or 11% of global pharmaceutical commerce.⁶ However, a study from the Center for Medicine in the Public Interest cited by the WHO estimates that number will climb to \$75 billion by 2010, representing a 92% increase from 2005.⁷

Contributing to this growth is the increasing size and sophistication of drug counterfeiting rings and the widening involvement of organized crime. Groups such as the “Russian mafia,” Chinese triads, Colombian drug cartels and Mexican gangs have all become heavily involved in producing and trafficking counterfeit drugs in the past decade.⁸ Many were driven by the U.S. “War on Drugs” from narcotics trafficking to a trade that offers similar huge profits at a much lower risk.⁹ At the same time, following the break-up of the Soviet Union, the privatization of many state-run pharmaceutical plants in Eastern Europe allowed advanced drug-making technology to fall into the hands of organized crime groups, giving them the ability to produce near-perfect fakes that are indistinguishable to all except well-trained experts (see Figures 1 and 2).¹⁰

Also disturbing is the growing involvement of terrorist organizations in the counterfeit drug trade. There is documented evidence of groups including the IRA, ETA, Chechen rebels and North African guerillas using drug counterfeiting as a source of funding.¹¹ There has been one reported case of al Qaeda involvement in a counterfeiting operation, and the Justice Department recently discovered a multi-national counterfeiting ring that smuggled counterfeit drugs into the United States and funneled its profits to the terrorist group Hezbollah.^{12 13} The use of counterfeiting by terrorists has increased in the past decade as the



Figure 1 and Figure 2: Comparisons of Counterfeit vs. Real Drugs

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

War on Terror has cut off many other more traditional sources of revenue. According to the head of Interpol, counterfeiting “is becoming the preferred method of funding for a number of terrorist groups.”¹⁴ Beyond the dangers posed by counterfeiting of drugs and the use of the revenues to fund terrorist activities is the potential for terrorists to use counterfeit drugs to introduce poisons or biological agents into the American drug supply.

Counterfeits in Developing Countries

Whereas counterfeiting of materials other than drugs is usually unlikely to cause death, drug counterfeiting is a murderous trade that targets the world’s most vulnerable groups, especially in developing countries. Counterfeiting thrives in developing countries because of supply shortages caused by high costs and limited resources, price controls, weak rule of law, lax regulations and oversight, and corruption.¹⁵ Indeed, about half of the countries in sub-Saharan Africa admit to having very limited or no capacity to control their domestic market in pharmaceuticals, and the regulatory authorities are weak in countries where they do exist.¹⁶ 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.¹⁷ 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.^{18 19} Counterfeit ingredients have included cement, gypsum, talcum powder, sawdust, industrial solvents and even yellow highway paint.²⁰ There are countless horror stories to be told of the tragedies caused by counterfeit drugs in developing nations; here are a few stark examples:

- During an outbreak of meningitis in 1995, the government of Niger inoculated 60,000 with a vaccine that turned out to be nothing but saltwater, resulting in 2,500 deaths.²¹
- In Haiti, Nigeria, Bangladesh and Argentina in the early 1990’s, over 500 people, mostly children, died of renal failure after taking cough syrup made with antifreeze.²²
- In 1998, over 200 women in Brazil became pregnant as a result of oral contraceptive pills made of nothing but wheat flour.²³

It is a tragedy that people in developing nations, who have so few resources to spend on medicines that they need so desperately, are forced into situations where

they are, in some cases, more likely to receive fake drugs than real ones.

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 counterfeit, substandard or degraded medicines that contain incorrect levels of a drug's active ingredient (as an estimated 68% of counterfeit antimalarials do; see Figure 3), cause 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.²⁴ The percentages are even worse in Africa (as shown in Figure 4), where in many countries more than half the chloroquinine tablets are ineffective; it is estimated that as much as 85% of Nigeria's malaria drugs are ineffective.²⁵ 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 more rapidly become resistant to a succession of drugs – possibly even artemisinin, the most recent and promising antimalarial.²⁶ According to Dr. Dora Akunyili, head of Nigeria's drug control agency, artemisinin is the last remaining effective antimalarial, and "when [this is] faked, any hopes the world once had of beating this disease can be forgotten. Reducing the strength of such drugs is tantamount to mass murder."²⁷

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, as

much as 20 times more costly and may require hospitalization, all of which significantly reduce access to these desperately-needed medicines.²⁸ Moreover, Southeast Asia has seen an emergence of multidrug-resistant tuberculosis, which officials at the U.S. Pharmacopeia believes can be linked to widespread counterfeiting of anti-TB drugs.²⁹

Beyond the serious direct costs of counterfeit and substandard drugs (i.e. the immediate health consequences of drug-resistant disease strains) are the long-term indirect costs, which can have serious macroeconomic consequences. Substandard and counterfeit drugs place a macroeconomic burden on a society because they accelerate drug resistance in patients, thereby contributing to increased morbidity, lost productivity and increased health care costs. This can seriously strain a nation's insurance system and social safety nets, especially in already-vulnerable developing countries.

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- Chris Hansen, "Inside the world of counterfeit drugs," Dateline NBC, June 4, 2006.

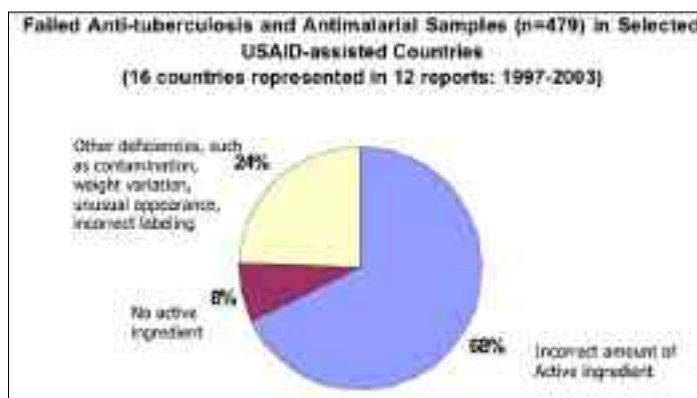


Figure 3: Deficiencies of Failed Antimalarials

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

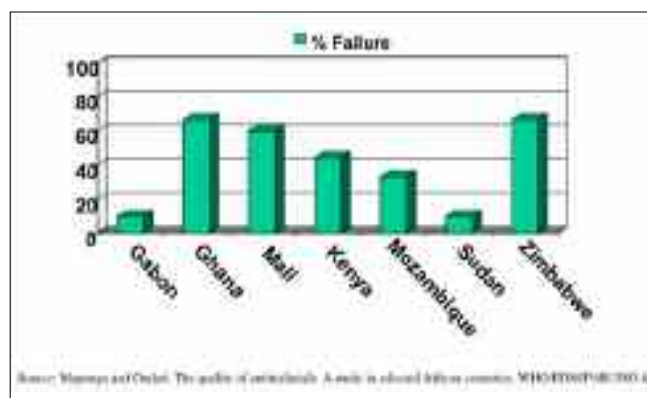


Figure 4: Percentage Failure of Chloroquinine – African Countries

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

9. Francis Burnett, "Pharmaceutical Counterfeiting: A General Perspective," In: Pharmaceutical Counterfeiting Conference; April 26-27, 2004; Caribbean Industrial Research Institute, Trinidad and Tobago.
10. Douglas W. Stearn, "Deterring the Importation of Counterfeit Pharmaceutical Products," *Food & Drug Law Journal*, Vol. 59 (2004): 550; In fact, such advanced pharmaceutical manufacturing machinery is available to anyone with a computer and a credit card: eBay.com openly sells laboratory equipment including pharmaceutical tablet presses, crystallizers, sifters and centrifuges on its website with a "no questions asked" policy.
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27. Olenka Frenkiel, "Bad Medicine" CBC News Report, December 11, 2005.
28. 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.
29. Daniel Seyoum and Nancy Blum, *Identification of Counterfeit and Sub-Standard Fixed-dose Combination Anti-Tuberculosis Drugs*, U.S. Pharmacopeia, June 2003. USP is a non-governmental organization that establishes safety and quality standards for pharmaceutical products.

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, including the United States, whose drug supply is among the most secure in the world. One problem is that despite the ultra-rigorous safety standards established by the FDA for the approval and production of prescription drugs, there is insufficient oversight to ensure safety farther downstream in the supply chain. Americans can no longer ignore the threat posed by counterfeit drugs, as they are starting to turn up in our neighborhood pharmacies.

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 5).³⁰ We can be certain that the number of detected incidents of counterfeits is a mere fraction of the actual number of cases.³¹ Although there is no way to know the true degree to which counterfeits have contaminated our drug supply, the FDA estimates that the frequency is 1% or less, while a 2003 article in the *Journal of the American Medical Association* cited a WHO estimate that "5% to 7% of all drugs sold in the United States have been tampered with, mislabeled, or are otherwise fraudulent."³² Even if we accept the FDA's more conservative estimate, 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.³³ It also means that out of the 4 billion prescriptions that were filled in this country last year, as many as 40 million may have been filled with counterfeits. Most of these incidents go undetected, as the evidence is usually destroyed when the drug is consumed, and the counterfeit's results are blamed on other causes, such as incorrect diagnosis.

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 drugs treating critically-ill patients, made their way into legitimate pharmacies across the country and were distributed to hundreds of thousands of unwitting

Sidebar 1: Counterfeit Drug Cases in U.S. – 2001-2006

(Source: Verbatim from Katherine Eban, "Counterfeit Medicine in America's Drug Supply," <http://www.dangerousdoses.com/html/facts.html>)

Pills and Tablets:

- Celebrex – One of nation's most popular drugs for arthritis – Replaced with vitamins
- Combivir – Prolongs life of HIV/AIDS patients by preventing virus from reproducing – Replaced with another HIV medicine that can cause fatal allergic reactions
- Lipitor – America's best selling medicine that lowers cholesterol and reduces risk of heart disease – Bitter-tasting counterfeit versions contained mixture of placebos, unapproved generic and some authentic ingredients
- Viagra – Taken to treat impotence – American counterfeiters manufactured over 700,000 fake pills
- Zyprexa – Helps prevent hallucinations and delusions in schizophrenic and bipolar patients – Replaced with aspirin

Liquid Biotechnology Medicines (injectables):

- Epogen, Procrit – Boosts red blood cell count of patients undergoing chemotherapy, organ transplant or kidney failure – Relabeled 110,000 vials to appear 20 times stronger
- Gammimune – Blood plasma to help patients with disorders of immune system fight infections – Diluted with bacteria-contaminated liquid
- Neupogen – Boosts immune system of cancer patients – Replaced with saline
- Nutropin AQ – Growth hormone for children with kidney problems or genetic disorders – Replaced with insulin
- Retrovir – Anti-viral drug for patients with HIV – Counterfeits sold by secondary wholesaler to AmerisourceBergen
- Serostim – Human growth hormone to prevent HIV/AIDS patients from wasting – Replaced with dangerous levels of a fertility drug

patients (see Sidebar 1). Moreover, there have now been multiple incidents of counterfeit versions of Tamiflu, which is being used to treat avian flu, being imported into the United States, raising the potential that treatment from sub-potent counterfeits could cause the virus to develop a resistance to this critically important drug.³⁴

Diverters 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 pathway from manufacturer to distributor to pharmacy. Out of the \$172 billion worth of prescription drugs manufactured annually for the U.S. market, 54% goes to wholesale distributors. About 90% of this passes through the presumably secure channel that flows from the pharmaceutical manufacturers to the "Big Three" primary drug wholesalers – AmerisourceBergen, Cardinal Health, Inc. and McKesson Corp. – to pharmacies and then to the consumer.³⁵ However, the rest 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. Most often, the drugs that flow through this network to consumers are legitimate drugs, although perhaps outdated or degraded by conditions in storage or transport, and these distribution networks can serve the legitimate purpose of evening out surpluses and shortages within the supply chain. However, as Figure 6 illustrates, because of their connections with the Big Three wholesalers, this network of intermediaries and "gray market" distributors also represents an open door into the legitimate U.S. drug supply that counterfeiters are all too willing and able to exploit.³⁶

The driving force behind the gray market lies in the profit opportunity created by the vastly differing prices at which pharmaceutical manufacturers sell drugs. Pharmacies pay a "direct" (the highest) price; wholesalers receive the discounted "wholesaler acquisition cost" or WAC; foreign countries receive cheaper drugs due to negotiated price controls; and groups such as Medicaid patients, hospitals, nursing homes and so-called "closed-door" pharmacies can receive drugs at discounts of up to 80% off the direct price. 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.³⁷

In order to "buy low, sell high," drug diverters employ a wide array of fraudulent, criminal or otherwise illegitimate methods for acquiring their discounted medicines.³⁸ One popular source is "closed-door" pharmacies, which operate within institutions such as nursing homes, hospices and AIDS clinics, and receive drugs at huge discounts on the contractual promise not to resell the drugs on the open market.³⁹ However, the National Association of Boards of Pharmacy (NABP) estimates that four out of five closed-door pharmacies have resold at least some of their medicine to diverters.⁴⁰

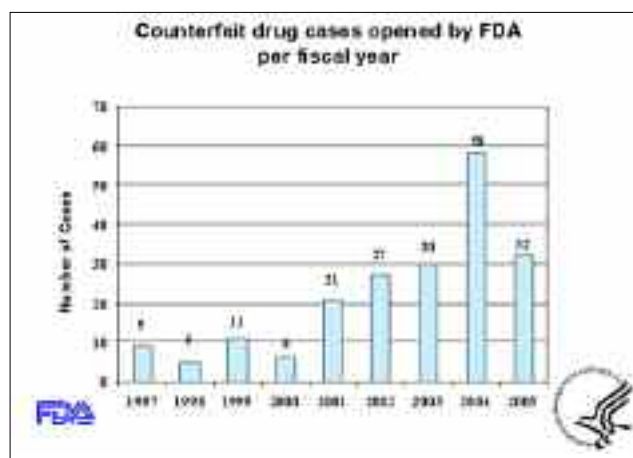
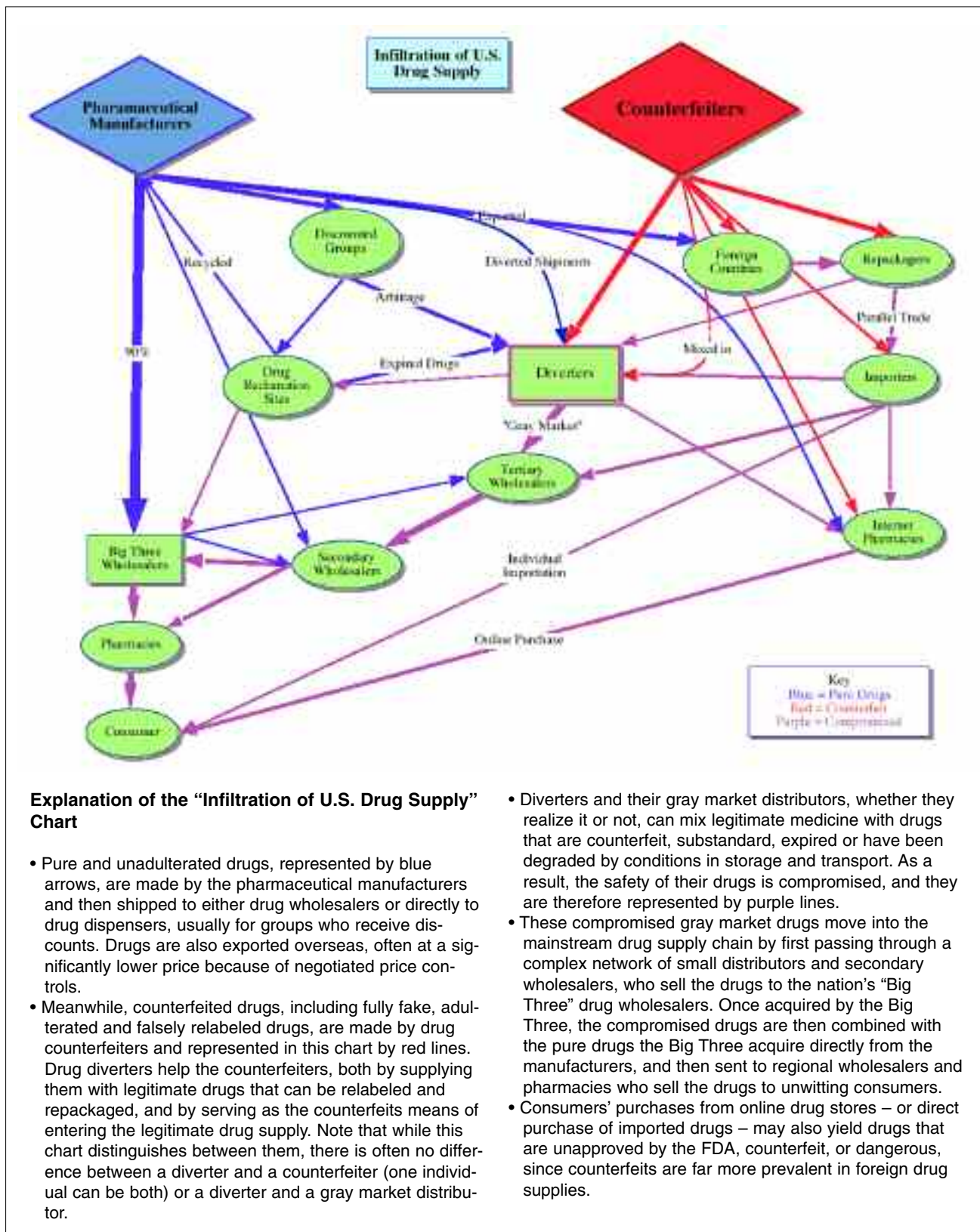


Figure 5: FDA Counterfeit Drug Cases, FY 1997-2005

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

Figure 6: Infiltration of U.S. Drug Supply



Explanation of the “Infiltration of U.S. Drug Supply” Chart

- Pure and unadulterated drugs, represented by blue 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. Drugs are also exported overseas, often at a significantly lower price because of negotiated price controls.
- Meanwhile, counterfeited drugs, including fully fake, adulterated and falsely relabeled drugs, are made by drug counterfeiters and represented in this chart by red 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. Note that while this chart distinguishes between them, there is often no difference between a diverter and a counterfeiter (one individual can be both) or a diverter and a gray market distributor.

- 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 purple lines.
- These compromised gray market drugs move into the mainstream drug supply chain by first passing through a complex network of small distributors and secondary wholesalers, who sell the drugs to the nation’s “Big Three” drug wholesalers. Once acquired by the Big Three, the compromised drugs are then combined with the pure drugs the Big Three acquire directly from the manufacturers, and then sent to regional wholesalers and pharmacies who sell the drugs to unwitting consumers.
- Consumers’ purchases from online drug stores – or direct purchase of imported drugs – may also yield drugs that are unapproved by the FDA, counterfeit, or dangerous, since counterfeits are far more prevalent in foreign drug supplies.

Diverters also offer Medicaid patients cash in exchange for their medicines, which are often over-ordered on the diverters' behalf, thereby defrauding Medicaid of billions of dollars.⁴¹ In other cases, diverters bribe hospital or nursing home workers to sell their discounted medicines, divert or fraudulently acquire shipments for government institutions such as VA hospitals, prisons, the military or facilities covered under the government's Section 340b program, divert shipments bound for foreign countries, collude with corrupt pharmaceutical company employees and even break into warehouses and snatch shipments of drugs from loading docks.^{42 43}

While most diverters are still trafficking legitimate drugs through illegitimate means, an ever-increasing number realize that they can make even greater profits if they sell counterfeited drugs rather than merely diverted ones. As the examples of Sidebar 1 above demonstrated, counterfeiters' methods can involve re-labeling expired drugs or "up-labeling" low-dose drugs as much more expensive higher-dose versions (as was done in the Epogen and Procrit cases), importing and repackaging compromised foreign-market drugs (Lipitor), and making or buying completely fake drugs (Serostim and Viagra). As an illustration of the potential 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 \$4,570.⁴⁴ 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 involve drug diverters.

Drug Wholesalers and the Diversion Market

The primary channel for diverted drugs leads from gray market distributors to small secondary wholesalers, to the Big Three wholesalers and then to consumers, and is driven by the wholesalers' constant demand for discounted drugs. 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.⁴⁵ As a result, wholesalers – including the Big Three – are always seeking to buy cheaper drugs in order to increase their resale profit. This profit motive drives many secondary wholesalers to buy drugs from less-than-credible sources because of the discounts being offered. Wholesalers have even been accused of practicing "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.⁴⁶ Despite attempts by wholesalers in recent years to change these practices, the secondary wholesale market continues to represent a vulnerable point in our drug supply chain.

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."⁴⁷ In one infamous case, a convicted cocaine dealer named William Walker was able to open a wholesale distribution company named Reckus, Inc. ("Sucker" spelled backwards), and use it as a front for a diversion operation. Meanwhile, the state's Bureau of Statewide Pharmacy Services had only nine field inspectors to inspect the state's 422 wholesalers (as well as 1,500 retail distributors and 446 manufacturers of various medical products), a regulatory environment that allowed the state to become a haven for diverters and counterfeiters.⁴⁸

After passing among as many as a dozen different wholesalers, diverted drugs are then sold to one of the nation's 15 regional wholesalers, or to the Big Three national wholesalers, all of whom have operated trading divisions that monitor the secondary market looking for good discounts in order to improve their profit margins. 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. She quotes a letter from the general counsel of Bergen Brunswig, a subsidiary of AmerisourceBergen, that asserts that verifying whether their suppliers are properly licensed would be "unfair, impractical, administratively burdensome and costly."⁴⁹ The Big Three's discount-hunting policies, combined with the willful blindness and in some cases active collusion of some secondary wholesalers, have allowed diverted and, increasingly, counterfeited drugs to enter the legitimate American drug supply and threaten public health.

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.⁵⁰ However, some see loopholes in these declarations, and earlier claims of this nature have proven untrue; for instance, AmerisourceBergen claimed in 2001 that it bought all drugs vulnerable to counterfeiting straight from the manufacturer, but it was found to have continued buying from the secondary market for several more years.⁵¹ According to Eban, “they’ve closed one of their back doors – the back door that’s marked ‘back door.’ But there are other, unmarked back doors that are still open.”⁵²

Indeed, demonstrating their ability to adapt, counterfeiters have begun using Internet-based direct-to-consumer smuggling schemes that cut out the wholesalers entirely and enter the drug supply at the consumer level. According to U.S. Immigration and Customs Enforcement, “the Internet has become the primary tool used by organizations engaged in the trafficking of counterfeit pharmaceuticals, whether for advertisement, direct sales or communications. Individuals who previously would have purchased controlled or prescription pharmaceuticals through an underground supplier now use the Internet to locate a source for these drugs, place orders, arrange shipments and make payments.”⁵³ We can be sure that these well-organized and determined criminal organizations will continue to adapt their drug counterfeiting operations in response to our efforts to control the trade, as the potential profits offered by this trade are simply too large to be ignored.

Drug Importation

Just as the counterfeiters’ desire to make a profit drives them to produce, and many wholesalers’ desire to widen a profit margin drives many of them to purchase drugs of dubious origin, 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.⁵⁴ Many “consumer groups” and politicians strongly advocate opening up our domestic drug supply to drug importation by individuals (as opposed to the lawful importation of FDA-approved foreign-made drugs by wholesalers and pharmaceutical companies), which they see as an easy way to get cheap drugs. These same advocates dismiss the unmistakable and serious safety issues, claiming that because most of the drugs were actually produced in the United States and then

exported, “only safe, effective FDA-approved prescription drugs are imported.”⁵⁵

However, this claim is misleading because once a drug is exported, there is no way to tell whether it is still safe when it is re-imported, nor is there any way to know that what is being re-imported was actually made in the United States. According to the Congressional testimony of John M. Taylor III, Associate Commissioner for Regulatory Affairs of the FDA:

Many drugs obtained from foreign sources that either purport to be or appear to be the same as U.S.-approved prescription drugs are, in fact, of unknown quality...These outlets may dispense expired, sub-potent, contaminated or counterfeit product, the wrong or a contraindicated product, an incorrect dose, or medication unaccompanied by adequate directions for use...FDA has only limited ability to take action against these foreign operators.⁵⁶

The FDA has said repeatedly that it cannot verify the safety of re-imported drugs, and therefore none of them are FDA-sanctioned. Moreover, drugs manufactured for export are manufactured according to the regulatory specifications of their intended country, and therefore do not have to meet FDA standards.⁵⁷ In addition, the Canadian government has repeatedly gone on record saying that it cannot guarantee “the safety and effectiveness of drugs not legally exported into the United States.”⁵⁸

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.⁵⁹ Unfortunately, Customs officials are routinely able to check less than 1% of the 2,000,000 packages of drugs shipped into the United States each year.⁶⁰ In fact, under FDA regulations the importation of almost any volume of pharmaceuticals into the United States is by itself illegal.⁶¹ The FDA is well aware of the volume of illegal shipments but lacks the resources to intercept them. This problem is only going to get worse: according to one expert, the amount of pharmaceuticals entering the United States has grown ten-fold since 2002.⁶²

If importation were legalized, the countries exporting their drugs to the United States would jeopardize their

own drug supplies because of the shortages created in those countries by supplying the American market. Drug companies would likely respond to re-importation by limiting the amount exported to those countries to what was required for those countries' domestic consumption. As a result, for the population of Canada, for instance, "exportation of their prescription drugs jeopardizes patient access to drugs as supplies are diverted to the U.S. market [and] encourages unethical practices by pharmacists and physicians who prescribe and dispense prescription drugs to patients they have never seen."⁶³ Americans' insatiable demand for cheap drugs would quickly devour the limited drug supply of countries like Canada, and diverters and counterfeiters would rush to fill that gap by offering substandard or adulterated drugs for domestic use or export. As neither the FDA nor Canadian health officials are willing to guarantee the safety of drugs re-imported to the United States there would be no way to stop importation of these counterfeits. In fact, the Hezbollah-supporting counterfeiting

ring used precisely this channel to smuggle counterfeits into the United States, importing the drugs into Canada from overseas and then selling them directly to American consumers looking for cheap drugs.⁶⁴

However, because re-importation remains a popular measure in an aging population (three-quarters of whom support re-importation, according to a 2005 poll by the Kaiser Family Foundation) politicians have continued to advocate its approval.⁶⁶ As a result, in July 2006, the U.S. Senate, led by Senators Vitter (R-LA) and Dorgan (D-ND), voted 68-32 to prevent U.S. Customs agents from being able to seize individual imports of prescription drugs, in effect codifying an enforcement impotence hitherto caused by lack of resources.⁶⁷ Such politicians fail to heed the warning of then-Health and Human Services Secretary Tommy Thompson, who reported to Congress that it would be a flawed policy to "sacrifice public safety for uncertain and speculative cost savings."⁶⁸

Internet Drug Stores

The dangers involved in drug importation are even greater for direct consumer purchases from Internet drug stores. These drug store 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 mechanism for consumers to find, order and make payments for counterfeit pharmaceuticals."⁶⁹

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. The drugs were supposedly "Canadian generics" of brand-name drugs (Viagra, Lipitor and Ambien) for which there is no approved generic version, meaning all of them were unapproved. Analysis of the purchased drugs showed that the website had "shipped drugs that were the wrong strength, including some that were substantially super-potent and that pose real health risks as a result, drugs that didn't dissolve properly, drugs that contained contaminants, and drugs that should not have been given because of potentially dangerous drug interactions."⁷⁰ 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.⁷¹ 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 2), no sites have been verified as legitimate pharmacies dispensing genuine product.

Sidebar 2: V.I.P.P.S. Online Pharmacies⁷⁴

- 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.welldynex.com

Based on testimony from numerous government agencies, industry associations, non-governmental 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, all previous efforts in Congress to legalize importation have been defeated.⁶⁵ Moreover, numerous economists have questioned whether importation would be able to produce significant savings for consumers, particularly since drugs account for less than 10% of health care spending.

In 2003, *The Washington Post* wrote a series of articles on counterfeit drugs, one of which focused on Internet pharmacies. Their investigation found sites that employed doctors who wrote prescriptions on the basis of a brief phone interview or even less interaction. Many of these doctors were driven to the unethical practice by substance abuse, legal problems or financial woes. In many cases, the drugs sold were controlled substances such as OxyContin and Xanax, which fed customers' addictions.⁷²

Any Internet drug store that does not require a prescription is immediately suspect because a pharmacy unethical enough to dispense drugs without a prescription will probably have few qualms about selling substandard or counterfeit drugs or selling their customers' credit card information to identity thieves. Indeed, many of these "online pharmacies" are complete scams, featuring "Terms and Conditions" that explain that the site is not actually obligated to ship anything to the customer but will charge the customer's credit card each month for a "membership" to the site. Ironically, in some cases, such as the selling of controlled substances like OxyContin, the penalties are higher for sending the customer legitimate product (in this case a felony) than for defrauding the customer by sending a fake product (misdemeanor).⁷³ In such a circumstance, what reason would an informed seller have for providing the customer with the real product?

Any consumer who buys medication at an online drug store (other than V.I.P.P.S. sites) is taking a foolish risk and endangering his health.

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30. 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.
 31. Donald deKieffer, "Trojan Drugs," *American Journal of Law & Medicine*, 32 (2006): 325.
 32. Brian Vastag, "Alarm Sounded on Fake, Tainted Drugs," *JAMA*, Vol. 290 No. 8, August 27, 2003.
 33. The percentage is not evenly distributed through all categories of drugs or store outlets: Counterfeiters like to focus on high-cost drugs for diseases such as cancer and HIV, as well as widely used drugs or those for "lifestyle" problems such as Viagra; however, counterfeits can turn up in even the most legitimate of pharmacies because they can unwittingly be distributed by the Big Three wholesalers.
 34. Philip Stevens, "Counterfeit Drugs: Getting to the root of the problem," *MedicalProgressToday.com*, March 24, 2006.
 35. Florida Supreme Court Case No. SC02-2645, *Interim Report of the Seventeenth Statewide Grand Jury*, 7, Out of \$172 billion worth of drugs manufactured for U.S. market in 2001, 46% shipped directly to dispensers and 54% went to wholesalers. The secondary channel can then contaminate the secure primary channel when the Big Three buy from secondary wholesalers. Almost every counterfeit discovered in the U.S. retail supply moved through one of the Big Three.
 36. The term "gray market" refers to the loosely regulated buying and selling of discounted drugs, so-named because it exists in the gray area between the illegal black market and legitimate pharmaceutical trade.
 37. If the drugs are legitimately acquired and resold in another region for a profit, this is a legal form of arbitrage known as "parallel trade," which is often practiced in Europe. Diversion involves the acquisition of discounted drugs by misrepresenting themselves as someone entitled to the discount, paying someone else to commit fraud in acquiring them, or other illegal or illegitimate means. For more on the difference between the two, see Peter J. Pitts, ed., *Coincidence or Crisis?: Prescription medicine counterfeiting* (London: Stockholm Network, 2006), 17.
 38. 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.
 39. Gilbert Gaul and M.P. Flaherty, "U.S. Prescription Drug System Under Attack; Multi-billion Dollar Shadow Market is Growing Stronger," *The Washington Post*, October 19, 2003, A15.
 40. Katherine Eban, *Dangerous Doses* (New York: Harcourt, 2005), 91.
 41. Mary Pat Flaherty and Gilbert Gaul, "Medicaid is start of drug resale trade," *The Washington Post*, October 22, 2003, A17.
 42. Under the Section 340b program, manufacturers provide discounts on covered outpatient drugs for specified government-supported facilities that serve the nation's most vulnerable patient populations. An increasingly popular diversion scheme involves getting 340b certification for questionable patients who then pass the drugs on to the diverters.
 43. A particularly despicable practice involves diverting shipments of aid drugs being donated to Africa by American drug companies, more than half of which according to one estimate never reach their intended recipients, but are instead resold for a profit in Western Europe and the United States. Donald deKieffer, "Trojan Drugs," *American Journal of Law & Medicine*, 32 (2006): 334.
 44. Lew Kontnik, *Pharmaceutical Counterfeiting: Preventing the Perfect Crime*, Lew Kontnik Associates, 2003.
 45. Gilbert Gaul and M.P. Flaherty, "U.S. Prescription Drug System Under Attack," *The Washington Post*. Wholesalers have never been able to provide studies to actually substantiate this claim.
 46. Katherine Eban, *Dangerous Doses*, 213, 321; see also Florida Grand Jury Report, 25, 29.
 47. Martin Downs, *Counterfeit Drugs: Victims and Villains*, WebMD Feature Archive, October 18, 2004.
 48. Florida Supreme Court Case No. SC02-2645 Grand Jury Report, 2; Gilbert Gaul and M.P. Flaherty, "U.S. Prescription Drug System Under Attack," *Washington Post*. "Nationwide, there are an estimated 6,500 small wholesalers, yet most states have only a handful of inspectors. In some states, amusement park rides, elevators and even dog kennels are inspected more frequently than drug wholesalers."
 49. Katherine Eban, *Dangerous Doses*, 215. Wholesaler groups claim that changes to their compensation model from a profit-margin model to a fee-for-service model has made discount-hunting on the secondary market less necessary.
 50. James Frederick, "Cardinal latest wholesaler to curb secondary dealing," *Drug Store News*, May 23, 2005. The decision came

- less than two weeks after the Big Three wholesalers were subpoenaed by NY Attorney General Elliot Spitzer to testify regarding their trading practices.
51. Katherine Eban, *Dangerous Doses*, 226.
 52. Melissa Davis, "AmerisourceBergen Dims Gray Market for Drugs," *TheStreet.com*, September 25, 2005.
 53. Kevin Delli-Colli, Testimony before House Subcommittee on Criminal Justice, Drug Policy and Human Resources hearing on "Pharmaceutical Supply Chain Security," July 11, 2006.
 54. 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.
 55. "Pharmaceutical Market Access Act of 2005 Bill Summary," *FairDrugPrices.org*, February 2005, http://www.fair-drugprices.org/Pharmaceutical%20Market_Access_Act.htm.
 56. Testimony of John M. Taylor III before Permanent Subcommittee on Investigations, Committee on Governmental Affairs, July 22, 2004.
 57. House Committee on Energy and Commerce Staff, "Memorandum: Imported Pharmaceutical Safety," June 24, 2003.
 58. M. Kaufman, "FDA: Canadian drug position misinterpreted," *The Washington Post*, May, 26 2003: A11.
 59. FDA Press Release: "FDA/U.S. customs import blitz exams reveal hundreds of potentially dangerous imported drug shipments," Sept. 29, 2003.
 60. Mary Pat Flaherty and Gilbert Gaul, "Millions of Americans Look Outside U.S. for Drugs," *The Washington Post*, October 23, 2003, A01.
 61. Current law does allow for the importation of a 90-day supply for "personal use" under certain specific conditions.
 62. Peter Lowe, "Fighting the Problem," Presentation at CARIRI Conference on Pharmaceutical Counterfeiting, Trinidad and Tobago, April 27, 2004.
 63. Christopher Ward, "Economic and Policy Implications of Reimportation: A Canadian Perspective," *Managed Care*, Vol. 13, No. 3, March 2004.
 64. "Editorial: Counterfeit drugs and border security," *The Washington Times*, July 19, 2006.
 65. John A. Marcille, ed., "Reimportation of Pharmaceuticals: Economic and Policy Implications," Supplement to *Managed Care*, Vol. 13, No. 3 (March 2004). Organizations included the FDA, Canadian Health Products and Food Branch, Immigration and Customs Enforcement, DEA, PhRMA, NABP, AMA, National Alliance for the Mentally Ill, Kidney Cancer Association, U.S. Chamber of Commerce, National Association of Manufacturers, Generic Pharmaceutical Association, National Association of Wholesaler-Distributors and many others. Even the AARP no longer actively advocates drug importation.
 66. Kaiser Family Foundation, "Americans Favor Malpractice Reform and Drug Importation, but rank them low on health priority list for the Congress and President," January 11, 2005, <http://www.kff.org/kaiserpolls/pomr011105nr.cfm>. "Almost three quarters (73%) say they favor changing the law to allow Americans to buy prescription drugs imported from Canada if they think they can get a lower price, with nearly as many (69%) agreeing that the change would make medicines more affordable without sacrificing safety or quality."
 67. Lara Jakes Jordan, "Senate OKs Import Prescription Drug Plan," *The Washington Post*, July 11, 2006. The vote came in response to an effort by Immigrations and Customs Enforcement to begin aggressively enforcing the laws regarding individual importation.
 68. 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.
 69. U.S. Immigration and Customs Enforcement [ICE], "ICE Efforts to Combat Counterfeit Pharmaceuticals," ICE Fact Sheet, July 11, 2006.
 70. FDA Press Release, "FDA Test Results of Prescription Drugs from Bogus Canadian Website Show All Products Are Fake and Substandard," July, 13 2004.
 71. FDA Press Release, "FDA Operation Reveals Many Drugs Promoted as 'Canadian' Products Really Originate From Other Countries," December 16, 2005, P05-102.
 72. Gilbert Gaul and Mary Pat Flaherty, "Internet Trafficking in Narcotics Has Surged," *The Washington Post*, October 20, 2003, A01.
 73. "DEA Warning – Buying drugs online may be illegal and dangerous!" BuySafeDrugs Consumer Alerts, 2005, <http://www.buysafe-drugs.info/Reports/DEAalert.htm>.
 74. 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

Counterfeiting is a particularly insidious threat in the United States because the FDA's rigorous pre-market drug approval process may breed a false sense of security in the overall safety of the drugs that we take. The reality is that once a drug leaves the manufacturer, there are few effective regulatory safeguards in place to prevent the drugs from being adulterated or replaced with counterfeits downstream.⁷⁵

The most significant attempt to respond to the emerging threat of counterfeit drugs is the Prescription Drug Marketing Act (PDMA). Passed by Congress in 1988, it outlines various regulations meant to secure the U.S. drug supply against substandard medicine.⁷⁶ An essential part of the law, known as the pedigree provision, mandated that:

Each person who is engaged in the wholesale distribution of a drug – who is not the manufacturer or authorized distributor of record of such drug – provide to the person who receives such drug a statement (in such form and containing such information as the Secretary may require) identifying each prior sale, purchase or trade of such drug.⁷⁷

This regulation was meant to control the problems of diverted drugs by requiring 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, defined as a wholesaler with an “ongoing relationship” with a manufacturer for the sale of that particular drug. 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 essentially never been enforced largely because lobbying from wholesaler industry groups has repeatedly convinced the FDA to delay its enforcement. When the FDA tried in 1999 to enforce the requirement, secondary wholesalers objected, claiming that the pedigree requirement would drive them out of business because having to “reveal the sources of our products to our customers...would permit them...to buy directly from our vendors, effectively putting us and other wholesale distributors out of business.”⁷⁸ In 2004, the FDA

was convinced by stakeholders that the paper pedigrees originally called for by PDMA would be too expensive and offer incomplete protection. Instead, the FDA thought 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 (which are discussed further in the next section). The FDA issued another stay on PDMA enforcement and staked all of its hopes on the voluntary adoption of RFID track-and-trace.

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.”⁷⁹ The FDA refused to mandate RFID adoption or set a new target date for its adoption. Instead, the pedigree rule will be enforced first through paper pedigrees, originally dismissed as too costly and vulnerable to forgery, and then gradually move towards an electronic pedigree as the necessary technology emerges. The report also indicates that the FDA has finally decided to look past the objections of the secondary-wholesaler lobbying groups regarding the impact of PDMA. Belatedly, the FDA has realized that “the secondary wholesale market is where much of the illegal activity occurs... [C]ontinuing the stay would perpetuate the current confusion and further allow opportunities for counterfeit and diversionary practices to occur.”⁸⁰

Unfortunately, the FDA's latest decision alone will not create a secure drug supply chain overnight. Under PDMA's pedigree provision, any wholesaler who is an authorized distributor of record (ADR) does not need to provide a pedigree for its products, meaning that whenever a drug goes through an ADR, such as the Big Three, all record of its prior history is lost.⁸¹ As the Florida Grand Jury explained, in theory this means that “even if a wholesaler purchases Procrit out of a car trunk, they believe that they are not obligated to provide a pedigree paper in any subsequent sale of that product as long as they are an ADR of that manufacturer for that product.”⁸² 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, usually through state boards of pharmacy. Moreover, the FDA must share its regulatory authority with more than 20 other federal

agencies, most notably the Drug Enforcement Administration (DEA) and Federal Trade Commission.⁸³ With regards to PDMA, each state has its own regulations regarding what information a drug pedigree must contain and many have varying requirements regarding electronic pedigrees, yet “under existing law, FDA lacks statutory authority to implement a universal and nationally uniform pedigree.”⁸⁴ In addition, there is continuing confusion on the exact definition of an authorized distributor of record, an essential element of PDMA enforcement. Unless Congress takes action, the split jurisdictions, different pedigree requirements and confusion over ADR definitions will create chaos in the drug supply, perpetuating the conditions that allow diversion and counterfeiting to occur.

Furthermore, 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 (and in some cases primary) wholesalers that they are under no obligation to verify the legitimacy of a supplier is as arrogant and irresponsible as it is dangerous. The only attempt at reforming these practices was a set of voluntary due-diligence guidelines issued by the Healthcare Distribution Management Association (HDMA), the trade association of the larger wholesalers, which focused on buyers’ verification of the legitimacy of a potential vendor through physical inspection of the business and validation of all credentials before doing business with them.⁸⁵ Given that the secondary wholesale market is a nationwide and fast-moving network of thousands of businesses, there is little if any chance of businesses deciding on their own to follow these guidelines, because rather than go through time-consuming verification measures, potential customers would prefer to do business with someone else. Tighter licensing requirements and mandatory due-diligence practices for secondary wholesalers, such as those contained in the NABP’s “Model Rules for the Licensure of Wholesale Distributors,” will help to strengthen this weakest link of our drug supply chain. To date, 16 states have enacted such tougher licensing standards, but a concerted nationwide effort will be needed if the criminal element is going to be permanently purged from the industry and not merely driven from one state to another.⁸⁶

However, increased regulations alone will do nothing to prevent counterfeiting if it is not accompanied by more aggressive enforcement of these laws. The FDA’s regulatory regime is based upon the notion that all stakeholders will play by the rules, following prop-

er manufacturing practices and honestly reporting their drug sources.⁸⁷ It is wholly insufficient for dealing with criminals who are determined to deceive regulators and exploit the weaknesses of the system.⁸⁸ Such criminals must be detected, arrested and prosecuted by badge-carrying law enforcement officials, such as those in the Drug Enforcement Agency or state-level pharmaceutical enforcement bureaus, which must be given the resources and authority needed to track down drug counterfeiters and bring them to justice.

Moreover, the punishments for drug counterfeiting and the liabilities for distributing dangerous materials need to be strengthened significantly: under current law, the criminal penalty for drug counterfeiting is three years in prison, an insignificant deterrent given the millions of dollars that can potentially be made. Proposals such as those contained in the “Counterfeit Drug Prevention Act” (HR 5156), which would increase penalties for drug counterfeiting to 20 years, and life in prison if the counterfeiting causes a death, would help to reduce the incentives that currently exist for committing such crimes.⁸⁹

Anti-Counterfeiting Technology

Many believe that emerging anti-counterfeiting technological advances will solve the problem of counterfeit drugs in the legitimate drug supply. However, many of these technologies have yet to be proven effective, most are far from industry-wide implementation, and none can ever be a “silver bullet” that alone will prevent counterfeiting. Rather, these technologies allow drugs to be more “counterfeit resistant,” and, if they are part of a multi-layered strategy, may be able to make drug counterfeiting less economically attractive to criminals.

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. Fake drugs, or drugs that have been relabeled or diverted, could be detected and removed from the drug supply. Thus, industry-wide adoption of RFID “would ‘wipe out’ a significant number of ‘gray market’ wholesalers [because] the smaller wholesalers will no longer be able to sell drugs they have purchased ille-

gally.⁹⁰ RFID would have benefits beyond supply chain security, allowing distributors to save money through better inventory management, reduction in theft and product loss, improved recall efficiency and reduced paperwork burdens.

There have been some encouraging accomplishments in the adoption of RFID technology. For instance, Wal-Mart has recently developed an RFID system for the tracking of “class 2 narcotics,” such as OxyContin in its supply chain.⁹¹ Moreover, there have been successful tests of RFID systems for the tracking of drugs along a single wholesaler’s distribution system, but not yet any successful application in tracking transfers between distributors.⁹²

However, after two years of FDA efforts promoting its use, “the pharmaceutical industry is still barely even employing the technology.”⁹³ There are many barriers to widespread RFID adoption that will delay its industry-wide use for many years, perhaps as much as a decade. These barriers 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.⁹⁴ Also, groups such as the ACLU and Consumers Against Supermarket Privacy Invasion and Numbering, or CASPIAN, have raised concerns over the potential invasions of privacy created by the potential for a centralized database with information on an individual’s pharmaceutical use.⁹⁵

Another potential track-and-trace technology would place a barcode on each drug package with a unique

electronic product code that could then be scanned at each stage of the distribution system, similar to packages sent by UPS and FedEx.⁹⁶ Barcode technology would be cheaper to implement than RFID but more expensive to operate, as it would require manual scanning of the barcode rather than the passive reading of the RFID signal. Unlike barcodes, RFID has potential uses beyond track-and-trace, such as maintaining a log of temperatures during the package’s transportation.

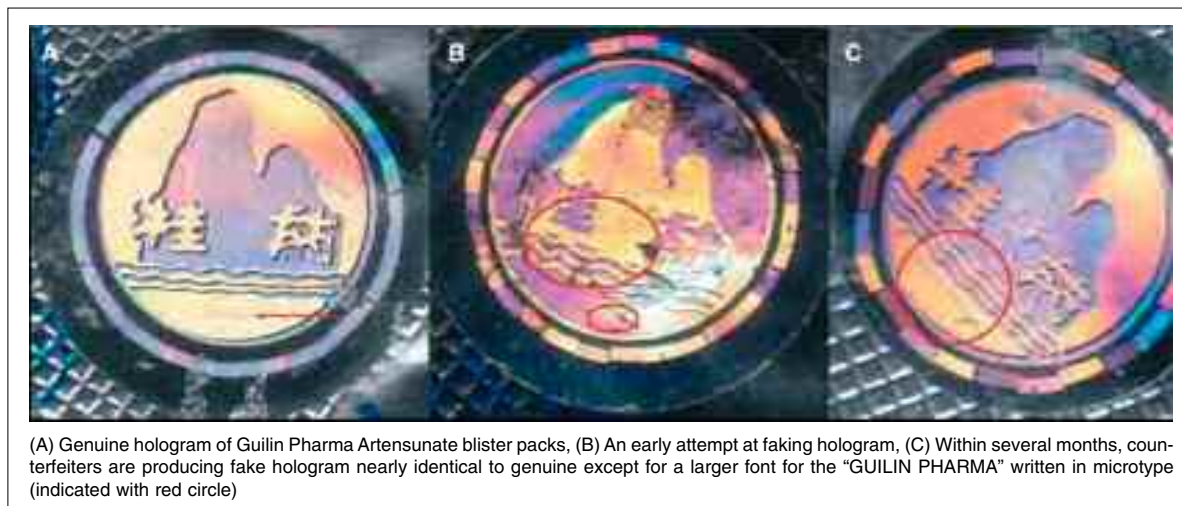
In addition to track-and-trace technology, new authentication technologies could make it more difficult for counterfeiters to replicate pharmaceuticals. These authentication technologies can be broken up into the following categories:⁹⁷

- Overt – Visible and immediately apparent security features on the packaging or components, such as holograms, color-shifting ink or tamper-evident features.
- Covert – Visible but not immediately apparent security measures, often hidden features such as UV markers or micro batch codes.
- Forensic – Extremely covert security measures that require special equipment to detect. These include imbedded chemical tags that can be tested for, and elemental analysis to verify composition.

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, as demonstrated by Figure 7, which shows how counterfeiting evolved

Figure 7: Genuine and Fake Antimalarial Security Holograms

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



to replicate a security hologram. Given the technical expertise of today's counterfeiters, even RFID tags could conceivably be faked or the information they contain altered, demonstrating the need for a multi-layered strategy that does not rely too heavily on one technology.

Prospects for the Future

The prospects for maintaining a safe and secure U.S. drug supply ultimately depend on the decisions that America makes in balancing the conflicting goals of drug cost and drug safety. By lowering standards of drug safety, through drug importation and widespread use of the secondary market, some contend that you could reduce the average cost of drugs to the consumer. Meanwhile, ensuring drug safety by creating a completely closed system would require expensive technology, ultra-strict regulation and enforcement, effectively closing down the secondary wholesaler industry. This might well drive the price of drugs even higher, which would create more incentive for counterfeiters to find a way in.

Thus, there is no easy answer, but 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 authority to create a uniform pedigree standard, and law enforcement agencies at the federal and state level must be given the resources needed to make sure these laws are followed. Although some counterfeiting will continue to take place no matter what we do, these reforms, if enforced energetically, can make it more difficult for those counterfeiters to reach – and harm – American consumers.

Sidebar 3: Visit the following sites for more information:

- The Partnership for Safe Medicines: http://www.safemedicines.org/north_america/counterfeit.php
- Consumer Information for buying drugs online: <http://www.buysafedrugs.info/Resources/>
- Katherine Eban's Dangerous Doses drug safety page: <http://www.dangerousdoses.com/html/safety.html>
- National Consumer League's safety tips: <http://fraud.org/fakedrugs/>
- 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>
- WHO's Counterfeit Medicine News & Information page: <http://www.who.int/medicines/services/counterfeit/en/index.html>

75. Florida Grand Jury Report, 7.
76. Carmen Catizone, "Counterfeit Drugs and States' Efforts to Combat the Problem," Testimony before House Subcommittee on Criminal Justice, Drug Policy and Human Resources, July 11, 2006.
77. U.S. Food, Drug, and Cosmetic Act, as amended by PDMA, Section 503(e)(1)(A).
78. Katherine Eban, *Dangerous Doses*, 163, see also Donna Young, "Secondary Wholesalers oppose FDA Pedigree Regulation," ASHP News, American Society of Health-System Pharmacists, September 15, 2001.
79. U.S. Food and Drug Administration, *FDA Counterfeit Drug Task Force Report: 2006 Update*, June 8, 2006, 11.
80. *Ibid.*, 6.
81. Katherine Eban, *Dangerous Doses*, 164.
82. Florida Supreme Court Case No. SC02-2645 Grand Jury Report, 12.
83. Donald deKieffer, "Trojan Drugs," *American Journal of Medicine and Law*, 330.
84. *FDA Counterfeit Drug Task Force Report: 2006 Update*, 16; The FDA does claim a pre-emptive authority that allows it to establish a minimum amount of information, but a patchwork still exists among the states as far as what additional information is needed.
85. Health Distributors Management Association, *Recommended Guidelines for Pharmaceutical Distribution System Integrity*, November 5, 2003.
86. John M. Gray, "Statement of the Healthcare Distribution Management Association," Testimony before House Subcommittee on Criminal Justice, Drug Policy and Human Resources, July 11, 2006; Florida stands as a model of such reform efforts, having recently passed stringent licensing requirements that have dramatically reduced the number of licensed wholesalers in the state.
87. Donald deKieffer, "Counterfeit drugs in the supply chain," *Pharmaceutical Business Strategies*, September/October 2004.
88. Donald W. Stearn, "Deterring the Importation of Counterfeit Pharmaceutical Products," *Food & Drug Law Journal*, Vol. 59 (2004): 548, "Inspections cannot and should not be relied upon as the only mechanism to deal with all of the deceptive practices that exist in the industry...prosecutions are necessary to reach counterfeit operations that fall outside the regulatory system."
89. John Gray, "Statement of the Healthcare Distribution Management Association," July 11, 2006.
90. Susannah Patton, "Cracks in the Pharmaceutical Supply Chain," *CIO Magazine*, January 15, 2006.
91. Laurie Sullivan, "Could RFID Protect Prescription Drug Supply Chains?" *TechWeb Technology News*, June 13, 2006.
92. Susannah Patton, "Cracks in the Pharmaceutical Supply Chain," *CIO Magazine*, January 15, 2006.
93. Stacy Lawrence, "FDA to Pharma: Where's the RFID?," *eWeek*, May 30, 2006.
94. 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.
95. There are no plans for the creation of any such database, but privacy groups nevertheless insist that RFID tags somehow be deactivated before being sold to consumers.
96. Susannah Patton, "Cracks in the Pharmaceutical Supply Chain," *CIO Magazine*, January 15, 2006.
97. From presentation "Evaluating Security Technologies," by Richard Jotcham, AxBess Technologies at CARIRI Conference on Pharmaceutical Counterfeiting, April 27, 2004.

Part V: How to Protect Yourself⁹⁸

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. When you are first prescribed a new medicine by your doctor, ask him for a manufacturer’s sample of the drug, or failing that, look up a photo of the actual pill or capsule in the Physicians’ Desk Reference (your doctor’s office or the local library will have one).⁹⁹ Thereby, you’ll have a benchmark against which to compare the drugs you receive later. Be familiar with the shape, size and color of your medicine and try to quickly inspect these features before taking it for unusual variations. 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. If the drug is injectable, look for any unusual undissolved particles and be sure to note any stinging or rash at the injection site. During a course of treatment, be alert in case new or unusual side effects develop or the medicine stops being effective. Try to get a sense of the status of your condition: are you feeling better or worse? Talk to your doctor or pharmacist about how the drugs are supposed to work.

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. Your pharmacist could let you know about any changes in packaging or ingredients that might explain the differences that you are observing. 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. You can also check MedWatch and the manufacturer’s website for information on possible recalls or counterfeiting cases.

Internet Pharmacies

The best bet for ensuring drug safety is to buy your medicines only from reputable state-licensed pharmacies. Despite certain safety issues, the U.S. drug supply is still among the safest in the world. The risk of getting substandard medicine is exponentially higher when importing drugs or buying them through online drug stores. If you are going to buy drugs online, then the only safe choice is using one of the 14 NABP-approved V.I.P.P.S. sites listed in Sidebar 2.

When evaluating the safety of any online pharmacy, the most important indicator is whether they require a prescription to be mailed in. Any site that does not require a prescription or that dispenses drugs on the basis of a phone interview or online questionnaire is immediately suspect. Also, a legitimate online pharmacy will have a street address and a toll-free number that allows customers to contact a pharmacist with any questions or concerns. Beware of any site that focuses almost solely on “lifestyle” products (such as Viagra), that offers novel formulations (such as sub-lingual) or that offers generic versions of brand-name drugs for which no generic versions have yet been approved. Finally, before placing an order, be sure to check the site’s “Terms and Conditions” for any hidden provisions or conditions that may be a sign of a scam or identity theft operation. If at all possible, avoid giving a credit card number, using instead a cashier’s check or a money order.

98. 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>).

99. N.B. This won’t help for medicines that are available as generics, as it is not unusual for the same pharmacy to change suppliers of generics from time to time.

Part VI: Conclusion

Counterfeiting has been described by some as the world's second-oldest profession, because for as long as people have been coining or printing money, others have been trying to fake it. In the same way, as long as pharmaceutical manufacturing remains a lucrative and dynamic industry with large price differentials, there will be drug counterfeiters working to exploit the high demand, no matter what the human toll may be. While we can do little to remove the profit motive, we can and should work towards limiting their effect on global health – by reducing the opportunity for counterfeiters to infiltrate national drug supplies and by punishing transgressors severely.

Globally, controlling counterfeiting will require the emergence of adequate regulatory and quality-control regimes in developing countries, the application of the rule of law, the enforcement of contracts and intellectual property agreements, reduced corruption, a crackdown on counterfeiting operations in nations where counterfeit production is prevalent and stronger penalties for convicted counterfeiters.¹⁰⁰ 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. There have been encouraging signs of progress on the international stage recently, most notably the WHO International Conference on Combating Counterfeit Medicine, held in February 2006 to

promote “collaboration and harmonization” between international stakeholders. The result of this conference was 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, known as the International Medical Products Anti-Counterfeiting Taskforce or IMPACT.¹⁰¹

However, it remains to be seen how much impact the *Declaration of Rome* will have, and the United States cannot wait for an effective international framework to provide protection from counterfeiting. While supporting global reform efforts, we must take the steps necessary to close the loopholes within our own regulatory framework that allow counterfeiters to enter our drug supply. The American public must be made aware of the danger posed by counterfeiting so that consumers take it into account when considering such practices as drug importation and buying drugs online. In this way, we can begin to reduce the danger of this murderous trade.

100. Julian Morris and Phillip Stevens, “Counterfeit Medicine in less developed countries,” in *Coincidence or Crisis?*, 88.

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Part VII The View from 2009: Turning the Tide?

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A Burgeoning Problem

In the over two years since the first edition of *Counterfeit Drugs: Coming to a Pharmacy Near You* was published, how goes the war against fake pharmaceuticals? Unfortunately, the reports from the front are something less than reassuring. For example, nearly 100 people died from an imported blood-thinning medication that contained a contaminated active pharmaceutical ingredient (API) (see below). The contamination, which occurred at the Chinese manufacturing plant, may have been deliberate, according to the FDA (FDA Media March 2008). In the developing world, the death toll has been far greater, for as the WHO reports, up to one-third of its prescription medications are counterfeit, with many containing toxic ingredients, sub-therapeutic doses, or no API at all (WHO Counterfeit 2006). Other indices are also disturbing. For instance:

- Up to 50% of Americans who recently purchased prescription drugs imported from a foreign country (about 2.7 million people) did not have a valid prescription, according to a 2007 survey sponsored by the Pharmaceutical Research and Manufacturers of America, the Partnership for a Drug-Free America, the Men's Health Network, and the Center for Pharmacoeconomic Studies at the University of Texas College of Pharmacy.
- Challenging the assumption that most online drug purchasers are people of modest means who lack insurance coverage and thus must search for the best medication deals, the survey also found that 85% of those importing drugs over the Internet have prescription drug coverage and 25% earn more than \$100,000 a year (PhRMA Release 2007).
- These findings are supported by a contemporaneous FDA investigation, which examined more than 2000 drug packages shipped from overseas to American customers (FDA Release 2007). Nearly 90% were for prescription drugs available in the US, and more than half were for FDA-approved generic versions. "These data lead us to believe that many people are buying drugs online not to save money but to bypass the need for a prescription from their doctor since these Web sites typically do not require the purchaser to have a prescription," said Randall Lutter, the FDA's deputy commissioner for policy. "In essence, they seem to be getting and using prescription drugs without a prescription, an intrinsically risky practice."
- Demonstrating the extent of the risk, the European Alliance for Access to Safe Medicines (EAASM) showed that more than 60% of such online purchases contained fraudulent or substandard medicines (EAASM 2008). Their 2008 analysis, "The Counterfeiting Superhighway," investigated more than 100 popular European websites and discovered that 96% of Internet pharmacies operate illegally; 94% of these sites do not have a verifiable pharmacist; and 86% of online "pharmacy approval" stamps are phonies. Adding a potential injury to insult, many of these scam purchases contained free samples of unsolicited prescription drugs. In one notorious instance, free Viagra was supplied with cardiovascular drug Plavix. Patients with serious

coronary artery disease often use Plavix along with aspirin to prevent blood clots. Adding a medication to treat erectile dysfunction to an antithrombotic drug regimen could be a recipe for disaster; such a drug cocktail could cause a heart attack if used without medical supervision. Of course, no such warning accompanied the “gift.”

- Back in the States, in March 2008, the FDA issued warnings to six US companies and one foreign individual for the Internet marketing of unapproved and misbranded drugs to prevent and treat sexually transmitted infections, such as herpes, human papillomavirus, Chlamydia, and HIV/AIDS (FDA Release 2008). Some of the fake products that were discovered by investigators were fraudulently marked as “FDA Approved” and “more effective.” One such drug claimed, “Treatment Kills all Herpes Viruses WITHOUT having to use conventional drugs or medications” (sic), while another (OXI-MED) boasted, “The active ingredient in our product is FDA certified to destroy 99.9992 percent of all pathogenic organisms Chlamydia” (sic). FDA Deputy Commissioner Janet Woodcock warned consumers to stay away from these Web sites. “STDs are very serious diseases, and these [bogus] products give consumers a false sense of security.”
- Somewhat reassuring, perhaps, is the recent jump in counterfeit drug seizures. Law enforcement officers confiscated more than \$3 billion worth of bogus prescription medicines in 2007, an increase of more than 24% (Frank Bloomberg.com 2008). Counterfeit versions of 403 different compounds were nabbed in 1513 incidents in 99 countries. The fraudulent drugs included both brand-name and generic products, said the Pharmaceutical Security Institute, a counterfeit drugs monitoring group funded by 26 pharmaceutical manufacturers. Among those products seized by customs agents and police at ports of entry, in free-trade zones, and at illegal manufacturing and distribution centers, were copies of 19 of the world’s 25 best-selling medication, as well as treatments for heart disease, arthritis, asthma, cancer, and AIDS. The lost revenues have hit the industry hard. Pfizer, the world’s largest drug maker,

estimates a loss of \$2 billion in Viagra sales alone. Illegal copies of all of the company’s nine best-selling drugs, which account for more than half of Pfizer’s \$48 billion annual revenue, were picked up during the seizures. Other drug companies, including Lilly and Novartis, have reported similar losses.

- Despite the surge in the number of seizures, government officials indicate that their efforts barely put a dent in the traffic. “There are counterfeiters circulating all over the world,” Illsa Bernstein, the FDA’s director of pharmacy affairs, told Bloomberg.com (Frank Bloomberg 2008). “It’s hard to tell how many there are because the counterfeiters are just so good at what they do.” Moreover, the scale of the illegal activity is staggering, with millions of packages landing at global mailing centers each year. “It’s simply too difficult to find and catch all of these drugs,” she added. Many drug industry security experts and politicians such as US Reps. Bart Stupak (D-MI) and Steven Buyer (R-IN) dispute that claim. In their minds, law enforcement agencies simply don’t make counterfeit drugs a high enough priority (Frank Bloomberg 2008).

Taken together, the evidence suggests that both sides may be right. Today, the manufacturing and distribution of counterfeit drugs is a bull market*, and the risks of getting caught are slim. One of the few Americans who has done time for drug counterfeiting, Mark Kolowich, claims he sold more than \$20 million of fake Viagra and other products to more than 65,000 customers on a number of Web sites over a 6-year period before his arrest in 2004 (Frank Bloomberg.com 2008). He is now on probation after serving a three-year sentence. He himself used the Internet to acquire both packaged pills and APIs from sources in India, China, and other countries.

“If you are on the Internet, people can’t really tell if you’re a big operator or a reputable operator, who you are, as long as you make that website look impressive,” he said. In this Wild West environment, pharmaceutical companies, law enforcement agencies, health and medical providers, and consumers concerned about the security of the drug supply have much work yet to do.

*Just how profitable is drug counterfeiting? Consider that the fake chemical used in the adulterated heparin that killed nearly 100 Americans late in 2007 and early 2008 costs \$9 a pound, whereas real heparin is \$900 a pound. No wonder criminals are attracted to this relatively new cash cow—and the problem is likely to get worse!

The Safety of the Global Drug Supply: Recent Developments

The Problem of Free Trade Zones

Tracking the movement of counterfeit drugs in a global economy is, as Bernstein intimated, a singular challenge. Adding to the difficulty for law enforcement and customs officers is the emergence of free trade zones. These zones are ports of transit designed to encourage trade, in which countries waive tariffs and provide little in the way of regulatory or police oversight. These liberal customs policies can promote legitimate trade by easing paperwork and expediting the flow of goods. However, for individuals of a criminal bent, free trade zones are the ultimate safe harbors, havens where a drug's provenance can be forged or altered and where bogus products can be manufactured, sold, and distributed.

One of the key free trade zones is Dubai, the most populous city of the United Arab Emirates (UAE), located at the hub of global trade between Asia, Europe, and Africa. Dubai is the oldest and largest of 17 such zones in the UAE, and more are in development. These trade zones provide an economic bonanza for the government, which, naturally, is reluctant to exert a heavier regulatory hand and make the regions less attractive to manufacturers and distributors and thus less lucrative for themselves. Walt Bogdanich, whose dogged reporting for the *New York Times* has revealed much of what the public knows about the depth and breadth of drug counterfeiting, notes that nearly 33% of all of the bogus drugs seized in Europe in 2007 emerged from the UAE (Bogdanich NYT 2007). Drug security experts told him that Dubai is a particularly attractive location for counterfeiters because an enormous number of goods move through its free trade zone. Also, it is unclear which branch of the local government has jurisdiction over the zone. Dubai authorities have acted on tips from drug company investigators from time to time; indeed, one such call led to a massive 2007 raid that broke an intricate supply chain running from mainland China through Hong Kong, the UAE, England, and the Bahamas to an Internet pharmacy located in Canada that sold fraudulent "Canadian" drugs to Americans. Nevertheless, the chain of command over the zone remains uncertain most of the time (Bogdanich NYT 2007). As a consequence, large quantities of contraband still manage to slip out of the zone.

Yet Dubai is but one of a growing number of free trade zones popping up around the world, offering counter-

feiters a way to avoid normal customs checks and to take advantage of multiple shipping points to sanitize a product's origins and hide its ultimate destination. Ridding these trade zones of those who exploit the public's demand for inexpensive prescription drugs will not happen overnight. Experts believe that close cooperation between national and international law enforcement and regulatory agencies, drug manufacturers, and consumers will be essential if any real progress is to occur. The raid in Dubai is one such example of how collaboration between interested parties can work.

Parallel Pharmaceutical Trade: How Price Inequalities Threaten Safety

As in the case of free trade zones, the rationale for what is called "parallel trading" for many goods makes economic sense. Parallel trade in pharmaceuticals refers to the process in which a middle-man buys drugs available in one European country, say, Italy, and then exports them to and resells them in another, England, for a higher price. A different way to describe this activity is by the term arbitrage. As the health researcher Roger Bate points out in his insightful book *Making a Killing: The Deadly Implications of the Counterfeit Drug Trade*, arbitrage can increase the efficiency and equitability of an economic system by correcting for underlying market discrepancies (Bate p. 32 2008). But pharmaceutical markets are different from those for, say, DVDs, diamond earrings, or watches. Drugs have high front-end costs (i.e., research and development) but low manufacturing costs. Therefore, in the wealthy markets of the West, efficient pricing occurs at a level far above the marginal costs of production. This discrepancy can lead to price imbalances, which can create hardships for poor countries. Even more important, parallel trading practices take place outside the manufacturer's or licensed distributor's formal channels. This lack of oversight creates the opportunity for mischief, and for the entry of counterfeit drugs into regulated chains of supply and distribution.

Some justify parallel trade by saying that price shopping is always smart, according to Jonathan Harper, MD, author of a 2007 report on how the parallel pharmaceutical trade threatens public health (Harper 2008). But recent health economic studies of the benefits of parallel trade in drugs are mixed, with half indicating that the savings are outweighed by the direct (health and medical) and indirect (social and economic) costs to consumers and the respective national health services (West 2003, Szymanski 2004,

Kanavos 2004, Enemark 2006). In fact, the Harper report showed that the parallel pharmaceutical trade exploits inefficiencies within the pricing and distribution system that redound to the benefit of middlemen (Harper EAASM 2008). The system also increases regulatory and supervisory costs and, most important, compromises drug safety.

Parallel trading is a particular problem in Europe because the system is legal, and the various EU members have different drug pricing systems. Harper endorses the view that the idiosyncrasies of pharmaceutical pricing make it unlikely that the parallel trade will increase efficiency between national markets. Although it is possible that parallel trading provides savings to purchasers, at best the benefits are marginal, accruing largely to intermediary traders. Moreover, parallel trade creates unnecessary supply system stress. It also introduces additional regulatory costs and burdens, undermines the guarantee of continuous supply, reduces incentives to invest in R&D, provides only marginal health benefit, and, most important, puts patient safety in jeopardy (Harper EAASM 2007).

Europe Economics reached similar conclusions in its June 2008 report to the European Commission (EC)(Europe Economics 2008). The study found that the parallel pharmaceutical trade exacts a substantial social, economic, and environmental toll on society and recommended that the EC criminalize the repackaging and relabeling of prescription drugs. Although such a dramatic step would eliminate about 10,000 jobs, Europe Economics concluded it would improve patient safety, increase the ability of poorer countries to purchase a more diverse supply of medications, enhance drug regulation, and create a more competitive economy.

“It is high time to rationalize and simplify the European pharmaceutical distribution system,” Harper said. “We also need to strengthen regulation of the supply chain, imposing restrictions on freedom of movement of pharmaceuticals within the territories of the EU. These draconian measures may be necessary because patients are already at risk, and this risk will worsen if we do not act quickly.”

Drug Importation: An Idea Whose Time Has Come...and Gone

In the US, parallel pharmaceutical trade is called “drug importation” and so-called consumer rights groups and politicians on both sides of the aisle have

championed its cause for many years. The appeal is obvious. Americans pay more for their medicines than anyone else in the world, largely due to the rigid price controls in place overseas. So why shouldn’t US citizens have the opportunity to take advantage of those market inefficiencies by re-importing common prescription drugs from Canada? Or so the populists endorsing a parallel trade system for Americans argue, ignoring the fact that such a policy is a violation of FDA regulations. A number of states, both red and blue, have taken the bait in the past few years, establishing drug-importation plans for their citizens. How have they fared?

Not very well, according to Peter Pitts, president of the Center for Medicine in the Public Interest. It seems that once Americans learn that these discount plans do not access well-controlled Canadian drug sources but the European parallel trade or unregulated drug operations in Asia instead, interest in drug importation rapidly wanes. For example, the Minnesota RxConnect program, a project of Republican Governor Tim Pawlenty that was expected to include 700,000 people, is filling fewer than 150 prescriptions a month, Pitts said in a paper presented at the 2008 Global Forum on Pharmaceutical AntiCounterfeiting that drew on the reporting of the *Wall Street Journal’s* Kimberly Strassel (Pitts 2008). The experience in Illinois has been even worse. When Democratic Gov. Rod Blagojevich introduced his I-Save-Rx program in 2006, he claimed that nearly 13 million citizens would have the opportunity to purchase drugs at prices “25 to 50% less” than their cost in the US (Blagojevich 2008). The state expended about \$1 million developing I-Save-Rx, including the time (5600 hours) some 500 state workers spent promoting the program. After 19 months, only 3,689 residents of the state had signed up, 0.2% of the population (Pitts 2008). The four states that offered I-Save-Rx to their residents have seen a similar turnout:

- Wisconsin – 321 people out of a population of 5,411,196
- Kansas – 267 out of 2,764,075
- Missouri – 460 out of 5,842,713
- Vermont – 217 out of 623,908

Finally, there is the city of Portland, Maine, which in 2004 became the first US jurisdiction to flout federal law and set up its own Canadian drug importation program for city workers and their families. By 2007, the program attracted all of 350 participants, which, in comparison with the several extant state programs, makes Portland’s plan a rousing success (Strassel WSJ

2007). The FDA has not taken any regulatory enforcement action against these plants—possibly because of their unpopularity and the agency’s desire to avoid a political confrontation with lawmakers.

Clearly, the US experience with drug importation has been “dismal and a political embarrassment,” Pitts said. Program administrators admit that consumers are worried about drug safety and appreciate their relationship with local pharmacists. The public also demands the quality-checks that come with US drugs (Strassel WSJ 2007). After the events of the past year, it appears Americans were wise to worry.

The Heparin Calamity

Importing packaged drugs and the APIs used to make them could help lower the price of the product, and US pharmaceutical companies have taken advantage of the latter to reduce their manufacturing costs. The industry already imports 40% of its APIs from factories in India and China, and that figure is expected to double by 2020 (Bate NRO 2008). Regulatory oversight in both countries is notoriously haphazard, and the problem is compounded by the FDA’s failure to conduct mandated quality-control inspections. In fact, between 2000 and 2007, the agency carried out only 200 plant inspections in both countries, and only a few of those met the same quality standards set for US drug companies (Kaufman WaPo 2007). At that pace, the FDA would need at least 27 years to inspect every foreign medical-device plant that exports to America, 13 years for every drug plant, and 1900 years for every overseas food plant (Harris NYT 2008).

So it should have come as no surprise when, in January 2008, Illinois-based Baxter International recalled certain forms of its blood thinner heparin after hundreds of patients in the US developed allergic reactions, some of them fatal, from contaminated product eventually traced to China (Baxter Release 2008). As the death count at home rose—95 between November 2007 and February 2008 (Bate WaPo 2008)—the problem spread beyond US shores. The FDA identified 12 Chinese companies that supplied contaminated heparin to 10 other countries, including Australia, Canada, Denmark, France, Germany, Italy, Japan, the Netherlands, New Zealand, and, yes, China, eventually tracing the source of the impurity, a cheap, man-made chemical called oversulfated chondroitin sulfate, to the Changzhou SPL Company (Medline Plus Release 2008, Pharma AntiCounterfeiting News 2008). Although Changzhou is owned in part by Scientific Protein Laboratories, a Wisconsin firm, nei-

ther the FDA nor Chinese authorities licensed the plant for the production of APIs. A clerical error at FDA erroneously granted Changzhou certification, leading Baxter to believe its heparin source was legitimate (Pharma AntiCounterfeiting May 2008). The Chinese government denies any culpability.

In theory, this calamity could have been prevented if the FDA conducted its foreign plant inspections on a timely basis. Yet the agency has limited resources, a shrinking staff of inspectors, and on-site difficulties such as language barriers and prohibitions against unannounced inspections (Schweitzer NEJM 2008). If current economic and production trends continue, and there is no reason to believe they will not, the burden on the overstretched FDA is likely to grow even heavier in the future, suggesting another heparin-like disaster may be inevitable.

There are several ways to make the FDA’s job less daunting. First, the agency can increase efficiency by targeting those facilities that are least likely to comply with good manufacturing practices. Second, Congress can increase the FDA’s budget, either through funding increases or by revising the Prescription Drug User Fee Act (PDUFA) to charge US manufacturers for at least part of the cost of overseas inspections. Although expanding PDUFA would be popular in a political environment that has demonized the pharmaceutical industry, such a step would likely lead to higher drug prices. Finally, it may be necessary to reconsider whether the FDA can possibly meet its obligations of assuring the safety of all drugs and APIs made and shipped from foreign facilities. This means that the public must accept that no drug, even one that is FDA approved, is absolutely risk free and consider the benefits and risks when deciding whether to take it. It also means that consumers and drug manufacturers must weigh the desire for low-cost medicines and greater profits against the risk of serious adverse events and potential lawsuits. Not easy decisions, to be sure, but ones that are essential to make in the real world.

Meanwhile, the FDA is attempting to address the inefficiency issue. In June 2008, the agency asked Congress for an additional \$275 million to help pay for more inspections and develop new tracking and authentication systems (Favole WSJ 2008). The following month, Health and Human Services Secretary Mike Leavitt announced a new program, in which FDA inspectors will join with authorities from the European Union and Australia to conduct inspections of foreign plants making APIs (Favole WSJ 2008). If

the program is successful, Leavitt said, it will be expanded to include other manufacturing facilities. Exactly how much the collaboration will cost and whether the regulatory responsibilities will be shared remain to be determined.

Conclusion: What Is to Be Done?

Clearly, the globalization of pharmaceutical manufacturing and distribution dramatically increases the chance that fraudulent prescription medicines will slip into the drug supply. From the counterfeiters' perspective, trafficking in phony or substandard pharmaceuticals makes economic sense, the paltry penalties a mere cost of doing business. Close down one website or raid one factory here, and five minutes later another e-pharma.com or back-lot plant becomes active over there. As Jim Thomson, chair of the EAASM ruefully noted, "counterfeiters don't think like us." For them, threatening the public's health and wellbeing is just another day at the office.

Beyond increasing penalties to a point at which the risks are no longer worth the reward, anticounterfeiting experts agree that a number of steps should be taken to ensure drug safety. At the top of the list is the creation of public-private partnerships to develop transparent and verifiable systems to secure tracking and authentication throughout the supply chain. Although the FDA once heralded emerging radio frequency identification (RFID) systems as the preferred means to create electronic pedigrees for prescription drugs, the technology has yet to overcome substantial technical problems and has proven far more costly than originally promised—a penny a pill (Pharma AntiCounterfeiting May 2008). Glaxo SmithKline is but one of several big pharma companies to suspend its pilot RFID program due to such glitches as tags breaking during attachment, tracking technology that fails to read the tags, and a general disinclination on the part of wholesalers and retailers to adopt the technology (Pharma AntiCounterfeiting 2007). Other systems are in development; they include two-dimensional barcodes and holograms, digitally encrypted inks and printing systems, and on-tablet marking for film-coated tablets.

In the US, the recently-passed FDA Amendments Act of 2007 gives the FDA until 2010 to develop a standardized numerical identifier that would be applied at the point of manufacturing or repackaging such that it would allow "the identification, validation, authentication, and tracking and tracing of the prescription drug (Public Law 110-85, 2007)." Potential identifiers

include RFID, nanotechnology, encryption technologies, and other techniques still to be determined (Pharma AntiCounterfeiting May 2008). Some states, including Florida and California, have already passed their own laws requiring e-pedigrees, creating a potential conflict with the pending FDA requirements. However, the recently introduced H.R. 5839 (Safeguarding America's Pharmaceuticals Act), which requires, among other things, federal standards for tracking and authentication, would resolve any federal-state inconsistencies. Although circumspect about the details, the EU also announced plans to issue new regulations to document the pedigree of pharmaceutical products throughout the supply chain. "[Counterfeit drugs are] a huge threat to public health and can cost people's lives in some cases," EU Industry Commissioner Gerhard Verheugen told the European Parliament on October 22, 2008 (Jones Yahoo 2008). "The EC will come up with a legal act to tighten up the framework. The technical solutions...already exist."

In addition, Western nations should re-evaluate such risky practices as parallel trading and drug importation and carefully monitor or limit online drug sales. Closer regulatory and law enforcement cooperation between the US and China also will help contain the traffic in counterfeit and substandard drugs. Pharmaceutical companies, which have finally come around to acknowledging the threat of counterfeit drugs and have begun to beef up their quality assurance programs, should cease dealing with small traders and work directly with known distributors and wholesalers. Furthermore, the FDA, which spends most of its time and money verifying pre-market drug safety, should correct the imbalance by shifting at least some of its emphasis to the verification of post-market quality. To this end, agency Commissioner Andrew von Eschenbach revealed in October 2008 that more than 60 food and drug regulators would be posted abroad in China, the Middle East, and Latin America to monitor product safety. The agency also might consider outsourcing some of its surveillance work to accredited private organizations. Finally, the public and private sectors should work together to develop new programs to educate pharmacists and consumers about the dangers of counterfeit drugs and how to recognize them. For instance, the Partnership for Safe Medicines' SafeMeds Alert System allows individual to sign up for free, real-time e-mail warnings about newly discovered counterfeit drugs. The system, which is part of the FDA's Counterfeit Alert Network, is a major leap forward in improving consumer awareness. (More detailed recommendations can be found

in Roger Bate's *Making a Killing*, from which some of these proposals have been drawn.)

In short, the view from 2008 is guarded but optimistic. Progress in the fight against drug counterfeiting and diversion will surely continue, as stakeholders become more vigilant in their efforts to combat the scourge. But as Jim Thomson acknowledged, the counterfeiters are clever and, so far, have remained one step ahead of the authorities. For this reason, expect any progress to be slow and incremental.

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