



Progress Report: A Comprehensive Evaluation of the FDA's Battle against Counterfeit Drugs

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**Progress report:
A comprehensive evaluation of the FDA’s Battle
against counterfeit drugs**

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Class of 2006
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Submitted in Fulfillment of Course Requirement and Third-Year Written Work Requirement

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ABSTRACT

Although drug counterfeiting is a major issue in many regions of the world, the U.S. drug supply is generally safe due to extensive federal and state oversight and steps taken by drug manufactures, distributors, and pharmacies to prevent drug counterfeiting. The U.S., however, now faces an increasing counterfeit drug threat due to advances in counterfeiting technology and increased financial incentives for criminals to introduce counterfeit drugs into the U.S. drug supply. The first half of this paper describes the threat posed by counterfeit drugs, discusses the scope of the counterfeit drug problem, explains how counterfeit drugs may be introduced into the U.S. drug supply, and discusses past efforts taken by U.S. authorities to secure the drug supply. The second half of this paper analyzes the FDA's 2004 recommendations on how to best fight the counterfeit drug threat, addressing the merits of the FDA's recommendations as well as the FDA's

success in implementing such recommendations thus far.

I. INTRODUCCION

When we walk into a pharmacy today, we are not terribly concerned with the possibility that the medication we receive will be counterfeit. We are confident that the prescription drugs we receive are legitimate. This is not the case in much of the world. In certain countries, the chance of receiving a fake drug is roughly equal to that of receiving an authentic medication. In such countries, an individual suffering from AIDS must worry about the possibility that he will be killed by the counterfeit medicine he inadvertently takes to treat the disease rather than AIDS itself. The FDA and other stakeholders must continue to take steps to insure that this is never a significant problem in the U.S. The U.S. should work with the World Health Organization and other nations to alleviate this issue globally as well.

II. BACKGROUND

A. The Prevalence of Counterfeiting Globally

The counterfeiting of currency and consumer products has historically been an immensely profitable enterprise for criminal organizations. It is estimated that the yearly global trade of counterfeit goods is in excess of \$450 billion dollars.¹ As criminals have made a fortune from counterfeiting, however, the world has bared a heavy burden. The United States Federal Bureau of Investigation (“FBI”) estimates that businesses in the United States lose between \$200 and \$250 billion dollars a year as a result of counterfeiting activities.² There is concern that much of this money ends up in the hands of terrorist organizations. It has been documented that Al Qaeda and other terrorist organizations have financially benefited from counterfeiting.³ In fact, it is estimated by some that terrorist organizations receive between one and two percent of the yearly income generated from counterfeiting.⁴ This figure puts the yearly income of terrorist organizations from counterfeiting at somewhere in the billions of dollars. This is all the more troubling as the United States is engaged in a global “war on terrorism.”

B. What are Counterfeit Drugs?

¹*Intellectual Property Crimes: Are Proceeds From Counterfeited Goods Funding Terrorism: Hearing Before The H. Comm. on Int’l Relations*, 108th Cong. 21 (2003) (statement of Ronald K. Noble, Secretary General, The International Criminal Police Organization (“Interpol”)), available at <http://commdocs.house.gov/committees/intlrel/hfa88392.000/hfa88392.0f.htm>.

²*Id.* at 26.

³*Id.* at 31-34.

⁴Commentary, *Michael D. Langan: Counterfeit Goods Make Real Terrorism*, *Pittsburg Post-Gazette*, July 24, 2003, available at <http://www.post-gazette.com/forum/comm/20030724edlang0724p1.asp>.

“Counterfeit drugs”⁵ are “those sold under a product name without proper authorization. Counterfeiting can apply to both brand name and generic products.”

Counterfeit drugs may contain “only inactive ingredients, incorrect ingredients, improper dosages, sub-potent or super-potent ingredients, or be contaminated.”⁷

Consumers face numerous risks as a result of taking counterfeit drugs. In certain cases, the drug may be lethal. For instance, 2,500 people died in Niger in 1995 after being inoculated with counterfeit meningitis vaccines.⁸ Even if a counterfeit drug is not inherently dangerous, it may still impose tremendous risks upon patients. If a drug does not possess the correct ingredients or the correct dosages, a patient may experience treatment failure.⁹ For many diseases, including cancer and HIV, treatment failure will lead to death. Thus, the counterfeiting of drugs is a particularly egregious form of counterfeiting.

C. The Scope of the Counterfeit Drug Problem Globally

Counterfeit drugs are a problem in every country throughout the world.¹⁰ The prevalence rates of counterfeit drugs in the global community are alarming. Fake drugs plague from the most affluent to the poorest of nations. In fact, it is estimated that 10% of the drugs sold worldwide are counterfeit.¹¹ The World Health

⁵The Federal Food, Drug, and Cosmetic Act defines counterfeit drugs as:

A drug which, or the container or labeling of which, without authorization, bears the trademark, trade name, or other identifying mark, imprint, or device, or any likeness thereof, of a drug manufacturer, processor, packer, or distributor other than the person or persons who in fact manufactured, processed, packed, or distributed such drug and which thereby falsely purports or is represented to be the product of, or to have been packed or distributed by, such other drug manufacturer, processor, packer, or distributor. 21 U.S.C. 321(g)(2) (2005).

⁶Counterfeit Drugs Questions and Answers, FDA, July 16, 2003, available at <http://www.fda.gov/oc/initiatives/counterfeit/qa.html>.

⁷*Combating Counterfeit Drugs, A Report of the Food and Drug Administration*, February 18, 2004, 1, available at <http://www.fda.gov/oc/initiatives/counterfeit/report02.04.html>.

⁸50,000 thousand people in Niger were inoculated with counterfeit vaccines during a meningitis epidemic. The vaccines were a gift from a country which they considered safe.

Substandard and Counterfeit Medicines, World Health Organization, Fact Sheet Number 275, November, 2003, available at <http://www.who.int/mediacentre/factsheets/fs275/en/>.

⁹Counterfeit version of Serostim, a growth hormone taken by patients suffering from AIDS was found to have no active ingredient.

New FDA Initiative to Combat Counterfeit Drugs, July 16, 2003, available at <http://www.fda.gov/oc/initiatives/counterfeit/background.html>.

¹⁰“In virtually all countries, counterfeit drug problems have been uncovered in recent years.” *Combating Counterfeit Drugs, A Report of the Food and Drug Administration*, at 2.

¹¹*Counterfeit Drugs Questions and Answers*, FDA, *supra* note 6.

Organization (“WHO”) predicted, in 2003, that \$32 billion is spent annually on counterfeit drugs.¹² This already astronomical figure is predicted to dramatically increase over the next few years. The Center for Medicines in the Public Interest estimates that counterfeit drug sales will reach \$75 billion by the year 2010. The prevalence rates of counterfeit drugs differ globally, however. The FDA estimates that in underdeveloped countries such as Columbia, Argentina, and Mexico, nearly 40% of the prescription drugs may be counterfeit.¹³ This figure may worry persons from the United States who travel into Mexican border towns to purchase medications. In certain regions in Africa and Asia, it is estimated that over 50% of drugs are counterfeit.¹⁴ Pakistan’s *Daily Times* reported that “Pakistanis spend 77% of their household health budgets on medicines half of which may be fake or unfit for human consumption.”¹⁵ According to these figures, Pakistanis are spending over one third of their household health budgets on counterfeit medicines. The types of drugs counterfeited also vary globally. In wealthy nations, the medications most often counterfeited are “new, expensive lifestyle medicines, such as hormones, steroids, and antihistamines.”¹⁶ One of the most often counterfeited medicines in industrialized nations is Viagra, which is widely sold on the internet.¹⁷ In poorer countries, however, the most widely counterfeited drugs are those that treat life threatening diseases such as malaria, HIV/AIDS and tuberculosis.¹⁸ Thus, the effects of drug counterfeiting in the third world are particularly devastating. About 1 million people die annually as a result of malaria. The WHO reports, however, that up to 20% of such fatalities could be avoided if the drugs available “were effective, of good quality and used correctly.”¹⁹

¹²*Substandard and Counterfeit Medicines*, WHO, *supra* note 8.

¹³*FDA’S Counterfeit Drug Task Force Interim Report*, FDA, October 2003, available at http://www.fda.gov/oc/initiatives/counterfeit/report/interim_report.html.

¹⁴Robert Cockburn, Paul N. Newton, E. Kyremateng Agyarko, Dora Akunyili, Nicholas J. White, *The Global Threat of Drugs: Why Industry and Governments Must Communicate the Dangers*, Public Library of Science (PLOS): Medicine, Vol. 2, Issue 4, April 2004, available at <http://medicine.plosjournals.org/perlserv?request=get-document&doi=10.1371/journal.pmed.0020100>.

¹⁵*40% of All Medicines Are Fake*, Daily Times (Pakistan), March 9, 2006, available at http://www.dailytimes.com.pk/default.asp?page=2006\03\09\story_9-3-2006_pg7_60.

¹⁶*Substandard and Counterfeit Medicines*, WHO, *supra* note 8.

¹⁷*Id.*

¹⁸*Id.*

¹⁹*Id.*

Although drug counterfeiting cannot be completely obliterated, nations can reduce the amount of counterfeit drugs within their borders through enhanced regulation and enhanced vigilance. Counterfeit drugs are “more prevalent in countries with weak drug regulation, control, and enforcement, scarcity and/or erratic supply of basic medicines, unregulated markets and unaffordable prices.”²⁰ The prevalence rates of counterfeit drugs are not, however, fully dependent upon government action or inaction. Poverty also stems the development of counterfeit medicines.²¹ In countries where consumers cannot afford drug prices, consumers are more likely to purchase drugs from less conventional and more affordable sources.

D. The Scope of the Counterfeit Drug Problem in the United States

Drug counterfeiting has, thus far, not been as prevalent within the United States as in other parts of the world. According to the FDA, counterfeit drugs are not widespread within the United States “as a result of an extensive system of federal and state regulatory oversight and steps to prevent counterfeiting undertaken by drug manufacturers, distributors and pharmacies.”²²

Certain evidence may suggest, however, that the quantity of counterfeit drugs available in United has increased in recent years. The number of newly initiated counterfeit drug cases by the FDA’s Office of Criminal Investigations (OCI)²³ has multiplied in the past decade. Between the 1997-2000, the OCI initiated between four to six new counterfeit drug cases yearly.²⁴ This figure increased to 20 cases in 2001, 22 cases in 2002, and 30 cases in 2003. In 2004, the number of newly initiated counterfeit drug cases jumped again to 58, almost doubling in one year.

²⁰ *Id.*

²¹ *Id.*

²² *Combating Counterfeit Drugs, A Report of the Food and Drug Administration*, *supra* note 7 at 1.

²³ The OCI is responsible for the conduct and coordination of criminal investigations within the FDA. It also serves as the liaison to other intelligence and law enforcement agencies, including the Central Intelligence Agency (CIA), the FBI, and the National Counter Terrorism Center. The OCI also works with state and foreign law enforcement agencies to assess terror threats and to respond to any threats against the U.S. drug supply. 60 Food Drug L.J. 117, 124-125 (2005).

²⁴ *New FDA Initiative to Combat Counterfeit Drugs*, *supra* note 9.

1.

What is the significance of the increase in newly opened counterfeit drug cases?

Although the FDA believes that the United States is facing an increasing counterfeit drug problem, the number of newly opened counterfeit drug cases does not necessarily mean that the counterfeit drug problem in the United States has drastically worsened. The increase in the number of new drug investigations may be a result of increased “awareness and vigilance at all levels of the drug distribution chain” and from better coordination between the FDA and other law enforcement agencies.²⁵ Nevertheless, the increasing number of counterfeit drug investigations is not completely a result of increased FDA and law enforcement action. The FDA reports that the amount of counterfeit drugs available in the U.S. has in fact increased in recent years. In recent years, the FDA “has witnessed an increase in counterfeiting activities and a greater capacity to introduce finished dosage form counterfeits into legitimate drug distribution channels.”²⁶

2.

What has caused drug counterfeiting activities in the United States to increase in recent years?

Drug counterfeiting has increased in recent years for several reasons. First, improved technology has allowed counterfeiters to manufacture fake drugs that look more and more genuine. Counterfeiters are now able to construct labels, packages, and products that closely resemble authentic medications.²⁷ With readily avail-

²⁵Randall Lutter, PhD, Co-chair, FDA Counterfeit Drug Task Force, Speech before RFID World Conference, March 1, 2006, available at <http://www.fda.gov/oc/speeches/2006/rfid0301.html>.

²⁶*Id.*

²⁷60 FOOD AND DRUG LAW JOURNAL 117, 123, remarks by Steven M. Niedelman, Commissioner for Regulatory Affairs, Office of Regulatory Affairs, FDA, (July, 2005).

able technology, counterfeiters can now “copy drug products and their labeling and packaging to such an exact degree that even the manufacturer of the authentic product cannot tell if it is real or fake.”²⁸ Second, the criminal organizations that manufacture and distribute counterfeit drugs have become better organized and are more effectively run.²⁹ Criminal organizations have become more and more drawn to drug counterfeiting in recent years as the price of pharmaceuticals has increased and lucrative financial opportunities have been created. The increase in drug prices has allowed counterfeiters to make an increased profit without incurring much additional costs. Thus, drug counterfeiting has become more attractive as the price of prescription drugs has risen.

The advent of the Internet has also given counterfeiters an opportunity to distribute drugs to on-line consumers through unlicensed pharmacies and foreign websites.³⁰ In fact, most of the suspect counterfeit drugs discovered in 2004 were heading towards the black market or internet sales.³¹

3.

There is some evidence to suggest that the tide is turning and that drug counterfeiting activity is starting to decline.

Preliminary data for the FDA’s 2005 fiscal year suggests that the number of newly initiated counterfeit drug investigations peaked in 2004.³² There were 30 new cases in 2005, as compared to 58 in 2004.³³ It is not clear why the number of new cases declined in 2005. One reason for the decrease may be the deterrent effect of the large number of newly initiated counterfeit drug cases in 2004.³⁴ Another explanation for the decrease

²⁸ *FDA’S Counterfeit Drug Task Force Interim Report*, FDA, *supra* note 13.

²⁹ 60 FOOD AND DRUG LAW JOURNAL 117, *supra* note 27 at 123.

³⁰ *Id.*

³¹ *Combating Counterfeit Drugs, A Report of the Food and Drug Administration*, *supra* note 7 at 1.

³² Randall Lutter, *supra* note 25.

³³ *Id.*

³⁴ *Id.*

in the number of newly initiated cases in 2004 may be that because of the high number of cases opened in 2004, many new investigations in 2005 may have related to already opened cases.³⁵ It is too early to determine exactly what caused the decrease in newly initiated cases. We must wait for new data to emerge.

³⁵ *Id.*

III. THE ENTRY OF COUNTERFEIT DRUGS

INTO THE U.S DRUG SUPPLY

A. The U.S. Drug Distribution System

In order to properly understand where the vulnerabilities lie in the U.S. drug distribution system, it is important to first understand the drug distribution system itself. At the top of the distribution system are drug manufacturers such as Pfizer and Johnson & Johnson. Once a drug manufacturer fashions a pharmaceutical product into its final form, it may either decide to sell the finished product to a wholesaler or directly to a retailer.³⁶ Pharmaceuticals companies usually sell to both wholesalers and retailers. If the drug is sold to a wholesaler, that “primary” wholesaler may then sell the drugs to a retailer or to a secondary wholesaler. The secondary wholesaler may even sell the drug to a third wholesaler. Thus, a drug may pass through several wholesalers before it reaches its final destination.³⁷ Wholesalers may benefit from these transactions due to changes in drug prices. Drug prices frequently fluctuate as a result of short term overstocks or increase demands for certain drugs.³⁸

Drugs may also pass through “repackagers” before reaching retail pharmacies. This is a common practice in the U.S. drug distribution system. Manufacturers will distribute bulk amounts of wholesale drugs, which are later repackaged into smaller containers prior to sale.³⁹ The repackaging may be conducted by independent entities or by pharmacies themselves.⁴⁰ The practice of repackaging does not exist in Europe, as European

³⁶90% of the primary wholesale pharmaceutical market is controlled by three companies.
FDA’S Counterfeit Drug Task Force Interim Report, *supra* note 13.

³⁷*Id.*

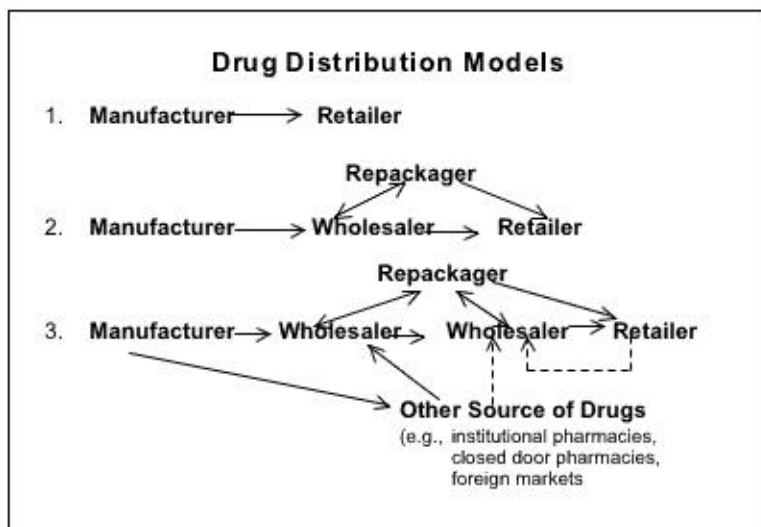
³⁸*Id.*

³⁹*Id.*

⁴⁰*Id.*

drugs are originally packaged into amounts that equal a course of treatment.

The practice of repackaging within the U.S. drug distribution system is concerning. As drugs pass through more and more hands, the risk of drug counterfeiting unquestionably increases. The government should thus give greater thought to terminating the practice of repackaging drugs, as European countries have done. Repackaging drugs is not illegal in the U.S. because it is argued that repackaging lowers drug prices.⁴¹ This does not appear to be a compelling argument, however. Even in the United States, most drugs are not repackaged once they are distributed by manufacturers. It is not clear why a drug manufacturer would expend much greater cost to package a product in its final form as compared to an independent repackager. Unless there are shown to be significant cost savings from repackaging, this practice should be ceased. The burden should be placed upon the pharmaceutical industry to prove that its costs will actually increase more than incrementally as a result of such action.



⁴¹ *Id.*

B. Illegal Drug Diversion

Not all prescription drugs are distributed in the prototypical manner described above. Authentic drugs are often diverted from their originally intended destinations when opportunities for financial gain exist.⁴³ For instance, drugs given to doctors or other health care providers as free samples may be diverted and sold to retailers.⁴⁴ Drugs may also be diverted from foreign markets, where products are donated or sold for lower prices back into the U.S. drug supply.⁴⁵ Anytime certain parties or entities receive drugs at below market prices, there is a possibility such parties or entities will divert such drugs in order to make a financial profit. Although it is often beneficial to sell drugs at a discount to certain groups, there is a risk that discounted drugs will be diverted to other markets.

The diversion of drugs from the normal drug distribution system poses a great threat to the U.S. drug supply. In fact, the FDA reports that “counterfeit drugs generally are associated with the practice of diversion.”⁴⁶ The “current [U.S.] regulatory system does not have legitimate, regulated channels for such diverted drugs (even if authentic) to re-enter the drug distribution system. Consequently, there is no reliable mechanism in place to distinguish effective authentic lower-cost drugs from drugs that simply appear to be so, but are not legitimate and may be harmful.”⁴⁷ Thus, a drug wholesaler or pharmacy may inadvertently purchase a counterfeit drug, erroneously believing that it is simply obtaining a legitimate drug at a bargain price.

C. Penetration of Counterfeits into the U.S. Drug Distribution System

⁴² *Id.*

⁴³ *Id.*

⁴⁴ *Id.*

⁴⁵ *Id.*

⁴⁶ *Id.*

⁴⁷ *Id.*

As discussed above, the practice of drug diversion and of repackaging are both major vulnerabilities in the U.S. drug distribution system. As authentic drugs are diverted back in to the system, harmful counterfeit drugs may also make their way into the U.S. drug supply. Counterfeited drugs may be combined with diverted drugs, repackaged, and sold to retailers.⁴⁸ Expired or unadulterated drugs may also be repackaged and passed off as authentic drugs.⁴⁹

Not maintaining complete “pedigrees” on drugs also increases the risk of drug counterfeiting. A pedigree “is a statement of origin that traces the drug from the point of manufacture and contains information about all transactions that the product undergoes until it reaches the end user.”⁵⁰ Where drugs lack complete pedigrees, it is not clear exactly where the drugs have been. Thus, there is a higher risk that such drugs are counterfeit, as it is not clear that they have moved through legitimate distribution channels.

Drug importation also elevates the counterfeit drug threat to the U.S. drug supply. U.S. drug regulations are amongst the toughest, if not the toughest in the world. In certain areas outside the United States, however, there is little regulation of pharmaceuticals or of the drug industry. As discussed above, in some countries, a consumer’s chances of buying a fake drug are roughly equal to his chances of buying an authentic drug.⁵¹ Thus, there is considerable risk that imported drugs may be counterfeited. This risk varies, depending on what the country of origin is and who is distributing the drug.

The sale of drugs via the internet renders it impossible to completely terminate the importation of drugs from foreign countries.⁵² Drug counterfeiters are able to make numerous small purchases of drugs over the internet, which will be virtually undetectable by the FDA.⁵³ The counterfeiter may then successfully combine these purchases together into a bulk amount and sell such drugs to a wholesaler, introducing the counterfeit

⁴⁸ *Id.*

⁴⁹ *Id.*

⁵⁰ *Id.*

⁵¹ See *supra* note 14.

⁵² *FDA’S Counterfeit Drug Task Force Interim Report*, *supra* note 13.

⁵³ *Id.*

drug into the U.S. drug supply. It is not practical for the FDA or other government agencies to allocate enough resources to completely eviscerate internet sales of drugs.

IV. THE FIGHT AGAINST COUNTERFEIT DRUGS

A. Drug Abuse Control Amendments of 1965

The fight against counterfeit drugs is not a completely new phenomenon. The U.S. Congress has been strongly concerned with the introduction of counterfeit drugs into the U.S. drug supply since it passed the Drug Abuse Control Amendments of 1965 (“1965 Amendments”).⁵⁴ In this legislation, Congress included provisions that were aimed at deterring the spread of counterfeit drugs.⁵⁵ The stated purpose of the 1965 Amendments was to “protect the public health and safety by amending the Federal Food, Drug, and Cosmetic Act to establish special controls for depressant and stimulant drugs and counterfeit drugs, and for other purposes.”⁵⁶

As a result of the 1965 Amendments, counterfeit drugs, counterfeit drug packaging, and devices used to develop counterfeit drugs became subject to seizure.⁵⁷

The sale of counterfeit drugs and possession of counterfeit drugs with intent to sell were also specifically prohibited under the 1965 Amendments.⁵⁸ Violations of these provisions carried criminal penalties.

Counterfeited drugs were prohibited before 1965 because they were “deemed misbranded within the meaning of section 502(i) of the Federal Food, Drug, and Cosmetic Act.”⁵⁹ For a variety of reasons, however, this provision was not very effective in combating counterfeit drugs.⁶⁰

B. Prescription Drug Marketing Act

⁵⁴ The Congress finds and declares that there is a substantial traffic in counterfeit drugs simulating the brand or other identifying mark or device of the manufacturer of the genuine article; that such traffic poses a serious hazard to the health of innocent consumers of such drugs because of the lack of proper qualifications, facilities, and manufacturing controls on the part of the counterfeiter, whose operations are clandestine.

PUBLIC LAW 89-74-JULY 15, 1965, available at http://www.erowid.org/psychoactives/law/law_fed_daca1.shtml.

⁵⁵ Douglas W. Stearn, 59 Food Drug L.J. 537, 541 (2004).

⁵⁶ See PUBLIC LAW 89-74, *supra* note 54.

⁵⁷ *Id.*

⁵⁸ *Id.*

⁵⁹ *Id.*

⁶⁰ *Id.*

Since the passage of the 1965 Amendments, Congress has been forced to revisit the issue of counterfeit drugs time and time again. The next major counterfeit drug regulation, the Prescription Drug Marketing Act (“PDMA”), was passed in 1987 and enacted in 1988.⁶¹ In its findings, Congress reported that “consumers [could not] purchase prescription drugs with the certainty that the products [were] safe and effective.”⁶² It also found that “integrity of the distribution system for prescription drugs [was] insufficient to prevent the introduction and eventual retail sale of substandard, ineffective, or even counterfeit drugs.” In its findings, Congress was also very critical of drug importation into the U.S. drug supply. As a result of these and other concerns, including the resale of sample and discount medications, Congress concluded that there was “an unacceptable risk that counterfeit, adulterated, misbranded, subpotent, or expired drugs [would] be sold to American consumers.”

The PDMA was partly passed in response to two high profile cases of counterfeit drug importation into the U.S. drug supply. In 1985, over 2 million fake tablets of Ovulen-21, a birth control pill, were distributed throughout the country.⁶³ The counterfeit pills were reportedly introduced into the United States from Panama.⁶⁴ In that same year, counterfeit Ceclor was imported into the U.S. drug supply from another foreign country.⁶⁵ Ceclor was an extremely popular antibiotic at the time.

Under the PDMA, the reimportation of drugs into the U.S. drug distribution system by anyone other than the manufacturer of the original drug is expressly prohibited.⁶⁶ There is an exception for emergency medical situations, if approved by the Secretary of the Department of Health and Human Services (“DHHS”). The PDMA also requires drug wholesalers to maintain and exchange a written “pedigree” on drugs, each time the drug is bought, sold or exchanged.⁶⁷ A “pedigree” is a statement of origin which tracks each prior purchase,

⁶¹The Prescription Drug Marketing Act of 1987, Publ. L. No. 100-293, 102 Stat 95 (1988).

⁶²*Id.*

⁶³*FDA’S Counterfeit Drug Task Force Interim Report*, *supra* note 13.

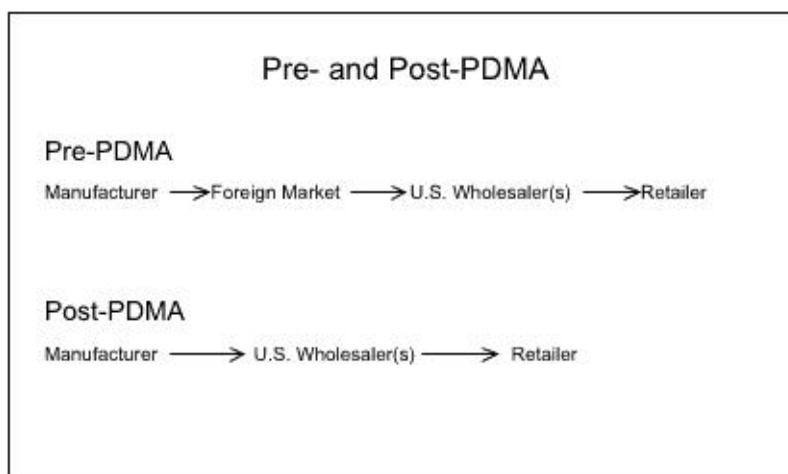
⁶⁴*Id.*

⁶⁵*Id.*

⁶⁶The Prescription Drug Marketing Act of 1987, *supra* note 61.

⁶⁷*Id.*

trade, or sale of the drug. Thus, an accurate and complete pedigree serves to decrease the chances that a drug has passed through unscrupulous hands. The written pedigree requirement has never gone into effect, however, as it has continuously been stayed by the FDA due to concerns over the costs and the usefulness of written pedigrees.⁶⁸



FDA FIGURE⁶⁹

Also under the PDMA, health care entities and charitable organizations that have been sold medications at discounted prices or have received free medications are prohibited from selling or reselling such medications, except under limited circumstances.⁷⁰

There are many criticisms of the PDMA. The PDMA's great reliance on written drug pedigrees is particularly

⁶⁸*FDA'S Counterfeit Drug Task Force Interim Report*, *supra* note 13.

⁶⁹*FDA'S Counterfeit Drug Task Force Interim Report*, *supra* note 13.

⁷⁰PDMA, *supra* note 61.

worrisome. Just as drugs and drug packaging can be counterfeited, written drug pedigrees can be faked as well. Thus, the written pedigree requirement does not go far enough in preventing the public from the counterfeit drug risk.

The PDMA also requires that wholesale drug distributors are licensed by the state in which they have a wholesale distribution facility.⁷¹ Under the PDMA, state licensing facilities are required to follow federally issued guidelines for the state licensing of wholesale drug distributors.⁷² The guidelines pertain to the “requirements for the storage and handling” of drugs as well as for “the establishment and maintenance of records of the distributions of such drugs.”⁷³ The guidelines are minimum standards that states must meet; states are free to go beyond such minimum standards.

The minimum guidelines include the “Model Regulations for Wholesale Drug Distribution” (“Model Rules”), which were formulated by the National Association of the Boards of Pharmacy (“NABP”).⁷⁴ The Model Rules were originally drafted by the NABP as a model for states to follow, but were later incorporated as minimum guidelines by the FDA.⁷⁵ All 50 states have now enacted legislation to comply with the PDMA.⁷⁶

Certain states, such as Florida and Nevada have passed laws that are stricter than those required by the

⁷¹*Id.*

⁷²At the time, President Reagan had “grave reservation” about the PDMA. He believed that the new legislation represented a “substantial intrusion into traditional State responsibilities and prerogatives.” Reagan also expressed concern that the PDMA would have an unfavorable impact on competition and would ultimately hurt consumers.

law firm

Robert T. Angarola, *The Prescription Drug Marketing Act: A Solution in Search of a Problem*, 51 Food Drug L.J. 21 (1996), available at <http://www.fdli.org/pubs/Journal%20online/51.1/art2.pdf#search='PDMA%20reagan'>.

⁷³PDMA, *supra* note 61.

⁷⁴The NABP is a professional association that represents the state boards of pharmacy in all 50 United States. It is an “independent, international, and impartial association that assists its member boards and jurisdictions in developing, implementing, and enforcing uniform standards for the purpose of protecting the public health.”

NABP mission statement, available at <http://www.nabp.net/>.

⁷⁵*FDA’S Counterfeit Drug Task Force Interim Report*, *supra* note 13

⁷⁶*Id.*

PDMA.

C. The FDA Counterfeit Drug Task Force

In July of 2003, the Commissioner of the FDA, Mark McClellan established the FDA Counterfeit Drug Task Force (“Task Force”) in response to the growing counterfeit drug threat.⁷⁷ The Task Force was established to “develop recommendations for steps FDA, other government agencies, and the private sector [could] take to minimize the risks to the public from counterfeit drugs...getting into the U.S. drug distribution.”⁷⁸ The Task Force was charged with establishing recommendations to achieve four specific goals:

(1) preventing the introduction of counterfeit drugs, (2) facilitating the identification of counterfeit drugs, (3) minimizing the risk and exposure of consumers to counterfeit drugs, and (4) avoiding the addition of unnecessary costs on the prescription drug distribution system, or unnecessary restrictions on lower-cost sources of drugs.⁷⁹

The Task Force was made up of senior staff from several FDA offices including the Office of the Commissioner, the Office of Regulatory Affairs, the Office of Policy and Planning, the Office of External Affairs, and the Office of the Chief Counsel. Also included on the Task Force was staff from the Center for Drug Evaluation and Research (“CDER”) and the Center for Biologics Evaluation and Research (“CBER”).

In October of 2003, three months after it was formed, the Task Force issued the FDA’s Counterfeit Drug Task Force Interim Report (“Interim Report”). The Interim Report included the Task Force’s initial recommendations on how to best counter the counterfeit drug threat and its initial conclusions.

The Task Force recommended that the FDA, other government agencies, and the pharmaceutical industry develop a “multi-pronged strategy” to combat the threat of counterfeit drugs.⁸⁰ The Interim Report explained that a “multi-pronged strategy” is necessary as no single “magic bullet approach” would be successful in effectively stopping the counterfeit drug threat.⁸¹ It would be too easy for counterfeit drug distributors

⁷⁷ *Id.*

⁷⁸ *Id.*

⁸⁰ *Id.*

⁸¹ *Id.*

to adapt to any “one-size-fits-all approach” through advances in technology and through changes to their operations.⁸²

The Interim Report lays out several options that may be implemented as part of a comprehensive anti-counterfeit drug strategy. The Interim Report discusses the development and implementation of new anti-counterfeit drug technologies, including “authentication technologies,” and “track and trace” technologies. Other options discussed include: (1) adopting more stringent regulatory requirements for the licensure of wholesale drug distributors; (2) implementing more “secure business practices” for entities involved in the U.S. drug distribution system; (3) strengthening counterfeit drug reporting systems; and (4) increasing awareness on the counterfeit drug threat both among the public and among health care officials.⁸³

The Task Force met with several government agencies, including the Secret Service, the U.S. Customs and Border Protection, the Bureau of Engraving and Printing, and the Department of Justice in order to produce the Interim Report. It also consulted with state governments, pharmaceutical manufacturers, wholesale distributors, pharmacy associations, consumer groups, academics, independent consultants, and manufacturers of anti-counterfeiting technologies. In the conclusion of the Interim Report, the FDA requests comments on the potential options presented in the Interim Report. The FDA planned to issue a final report in January of 2004.

⁸² *Id.*

⁸³ *Id.*

V. The Recommendations of the FDA as presented in the 2004 Final Report

The FDA released its final report on the counterfeit drug threat on February 18, 2004, one month after the originally planned January release date.⁸⁴ The report was entitled *Combating Counterfeit Drugs, A Report of the Food and Drug Administration* (“2004 Report”). In the 2004 Report, the FDA offered several recommendations that government agencies, states, and the private sector should follow in order to fight the counterfeit drug threat. In this section, I will outline the specific recommendations made by the FDA.

A. Adoption of Track and Trace Technology

The FDA sees “track and trace technology” or “mass serialization” of drug products as the most promising and the most powerful tool available in the fight against counterfeit drugs.⁸⁵ Mass serialization would involve assigning every individual drug product a unique tracking number, which would be used to record the origin of each drug product as well as every transaction each product is involved in, from the time the product is manufactured until the time it reaches the retailer.⁸⁶ The unique number assigned to each drug is also an electronic product code (“EPC”) that is attached to each product.⁸⁷ Thus, drug purchasers would have the capacity to instantly determine who manufactured each drug product, when the drug product was manufactured, and exactly who has had possession of the product since the time of manufacture.⁸⁸

The availability of such a tool would make it much more difficult for counterfeiters to introduce illegitimate drugs into the U.S. drug distribution system as it would be much harder to disguise the true origin of

⁸⁴ *Combating Counterfeit Drugs, A Report of the Food and Drug Administration*, *supra* note 7.

⁸⁵ *Id.* at 9.

⁸⁶ *Id.* at 9-10.

⁸⁷ *Id.* at 9-10.

⁸⁸ *Id.* at 10.

pharmaceuticals. Track and trace technology is already being used to authenticate the identity of several products, including livestock, software, and electronics.

Although many issues remain to be worked out, the FDA believes that adoption of track and trace technology by the pharmaceutical industry is inevitable.⁸⁹ There was also near unanimous support for the adoption of such technology by those who responded to the Interim Report.⁹⁰

It is widely believed that radio-frequency identification (“RFID”) technology is the most promising form of track and trace technology currently available.⁹¹ RFID technologies utilize radio waves to instantly and uniquely identify individual drug products.⁹² The most prevalent method of RFID involves storing a unique serial number that is assigned to a specific product to a microchip; the microchip is then attached to an antenna.⁹³ Together, the microchip and the antenna form what is known as an RFID transporter or an RFID tag.⁹⁴ The information on the chip can then be broadcast through the antenna to an RFID reader, where the information is digitized and passed on to a computer.⁹⁵

RFID technology itself is not entirely new. In fact, such technology has been utilized since at least 1970.⁹⁶ Currently, thousands of companies throughout the world employ RFID technology to improve the efficiency of their production lines and in numerous other ways.⁹⁷ Although RFID technology is superior to standard bar code technology, it has not been embraced to a greater extent because of the large financial costs involved in making commercial use of such technology; barcode technology is much more affordable and is suitable for most purposes.⁹⁸

⁸⁹*Id.*

⁹⁰*Id.* at 9.

⁹¹*Id.*

⁹²RFID technology can be used to track people and pets as well as any object. RFID Journal, *Frequently Asked Questions: General RFID Information, What is RFID?*, available at <http://www.rfidjournal.com/faq/16/49>.

⁹³*Id.*

⁹⁴*Id.*

⁹⁵*Id.*

⁹⁶RFID Journal, *Frequently Asked Questions: General RFID Information, Is RFID New?*, available at <http://www.rfidjournal.com/faq/16/52>.

⁹⁷RFID Journal, *Frequently Asked Questions: General RFID Information, Are any companies using RFID today?*, available at <http://www.rfidjournal.com/faq/16/55>.

⁹⁸RFID Journal, *Frequently Asked Questions: General RFID Information, Is RFID New?*, available at

In the 2004 Report, the FDA concluded that the use of RFID technology would be feasible by 2007, and would provide significant protection.⁹⁹ The FDA recommended, however, that the government did not yet enact any regulations relating to RFID.¹⁰⁰ At the time, the FDA felt that the pharmaceutical industry should be left to experiment with RFID technology before the FDA or other government agencies adopt any specific policies or regulations relating to such technology.¹⁰¹ The FDA believed, that in the interim, its role would be to assist stakeholders, to “the extent necessary and appropriate,” to facilitate the “rapid widespread adoption of RFID” technology.¹⁰² The FDA also encouraged the pharmaceutical industry to take several steps to successfully implement RFID technology. Such steps included: (1) creating an internal team to focus on RFID issues; (2) performing external RFID studies to coordinate technology with other business; and (3) adopting standard minimum information requirements that would be required under each serial number.

The 2004 Report also included a timeline which laid out FDA’s expectations on how quickly mass serialization or RFID technology would be implemented by drug manufacturers, drug wholesalers, health facilities, and drug retailers. At the time, the FDA predicted that RFID technology would be widely utilized in the U.S. drug distribution system by sometime in 2007.¹⁰³

<http://www.rfidjournal.com/faq/16/52>.

⁹⁹ *Combating Counterfeit Drugs, A Report of the Food and Drug Administration*, *supra* note 7 at 11.

¹⁰⁰ *Id.*

¹⁰¹ *Id.*

¹⁰² *Id.* at 12.

¹⁰³ **January - December 2004**

- Performances of mass specialization feasibility studies using RFID on pallets, cases, and packages of pharmaceuticals;

January – December 2005

- Mass serialization of some pallets and cases of pharmaceuticals likely to be counterfeited.
- Mass sterilization of some packages of pharmaceuticals likely to be counterfeited; and
- Acquisition and use of RFID technology (i.e., ability to read and use the information contained in the RFID tags and the associated database) by some manufacturers, large wholesalers, some large chain drug stores, and some hospitals.

January – December 2006

- Mass serialization of most pallets and cases of pharmaceuticals likely to be counterfeited and some pallets and cases of other pharmaceuticals;
- Mass serialization of most packages of pharmaceuticals likely to be counterfeited; and
- Acquisition and use of RFID technology by most manufacturers, most wholesalers, most chain drug stores, most hospitals, and some small retailers.

January – December 2007

- Mass serialization of all pallets and cases of pharmaceuticals;

B. Authentication Technology

There are several types of available authentication technology, both overt and covert. Covert authentication technologies refer to authentication measures that are not public information and require special knowledge or special machinery to decipher.¹⁰⁴ Several types of authentication technology are currently used to distinguish genuine money from counterfeit money. Security features included in U.S. currency include magnetic inks and threads, “precise dimensions that can be optically measured, and markings that are designed to be seen under IR and UV light.”¹⁰⁵ Special devices have the ability to authenticate each of these variables. These or similar security features may be instituted in the context of prescription drugs to ensure the safety of the U.S. drug supply.

In the 2004 Report, the FDA concluded that authentication technology is “sufficiently perfected” to be effective and that the utilization of such authentication technology is a “critical component” of any comprehensive anti-counterfeit drug strategy.¹⁰⁶ The FDA, however, declined to regulate or mandate the use of authentication technology, fearing that such regulations may do more harm than good.¹⁰⁷ There was concern among the FDA and other stakeholders that requiring specific authentication technologies would aid counterfeiters by allowing them to adopt such technologies themselves.¹⁰⁸ The FDA also feared that stringent requirements would stifle the development of new and evolving authentication technologies that would be more effective. The FDA sees its main role in this area as easing any regulatory burdens that may interfere with the adoption of authentication technologies.

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- Mass serialization of most packages of pharmaceuticals; and
 - Acquisition and use of RFID technology by all manufacturers, all wholesalers, all chain drug stores, all hospitals, and most small retailers

Id. at 11-12.

¹⁰⁴*Id.* at 5.

¹⁰⁵Samuel J. Kassey, *Laser Technology Identifies Counterfeit Currency* (August 2005), available at <http://www.photonics.com/content/spectra/2005/August/applications/65824.aspx>.

¹⁰⁶*Combating Counterfeit Drugs, A Report of the Food and Drug Administration*, *supra* note 7 at 6.

¹⁰⁷*Id.* at 5-6.

¹⁰⁸*Id.* at 6-7.

C. Increased Penalties for Drug Counterfeiters

In the 2004 Report, the FDA recommended that penalties for drug counterfeiting be increased to reflect the seriousness of the crime. Such a measure was overwhelmingly supported. In responses to the FDA, there was unanimous agreement that penalties for drug counterfeiting were too lax and should be increased.¹⁰⁹ The FDA, other law enforcement agencies, and the pharmaceutical industry were each concerned that existing criminal penalties did not adequately deter drug counterfeiters.¹¹⁰

The FDA explained that sentencing guidelines for purely economic crimes were much harsher than the sentencing guidelines for drug counterfeiting. A person convicted on a charge of drug counterfeiting could only be punished by a maximum of three years of prison.¹¹¹ In contrast, an individual could spend up to 10 years in prison for counterfeiting a prescription drug label.

Prior to the release of the 2004 Report, the FDA requested that the United States Sentencing Commission amend its sentencing guidelines to substantially increase penalties for those who manufacture and distribute counterfeit drugs.¹¹² The FDA also recommended that drug counterfeiters receive increased penalties, dependent upon the level of risk their behavior imposes on the public health. In the 2004 Report, the FDA reiterated that it would continue to lobby for harsher criminal penalties for drug counterfeiting.

D. Adoption and Implementation of Secure Business Practices

The 2004 Report also listed the adoption of secure business practices by companies involved in the U.S. drug distribution system as a key component in any comprehensive counterfeit drug strategy.¹¹³ The FDA found that although many companies had already adopted and implemented heightened security measures in response to the counterfeit drug threat, the security measures at a number of U.S. companies remained

¹⁰⁹*Id.* at 18.

¹¹⁰*Id.*

¹¹¹*Id.*

¹¹²*Id.*

¹¹³*Id.* at 24.

unsatisfactory.¹¹⁴ Drug companies often engaged in business transactions with parties they did not know well or maintained insufficient physical security. The FDA was especially concerned with companies involved in repackaging activities.¹¹⁵

Prior to the release of the 2004 Report, drug wholesalers drafted a list of secure business practices.¹¹⁶ The FDA made it a priority to work with other companies involved in the U.S. drug distribution system to develop similar standards.¹¹⁷ The FDA outlined the key steps involved in developing secure business practices: (1) designating a team that reports directly to senior management, to coordinate all security and anti-counterfeiting activities; (2) confirming that all business partners are legitimate and are not of unknown or questionable background; (3) securing physical facilities against counterfeit drugs.¹¹⁸ The FDA also announced that it would expand its oversight of re-packagers, as such companies posed a substantial risk to the U.S. drug distribution system.¹¹⁹

E. Increased Education for Consumers and Healthcare Professionals

The FDA recommended that greater efforts be put forward to alert the public of the risks posed by counterfeit drugs and to provide consumers with information on how to avoid illegitimate drugs.¹²⁰ The FDA discussed educating consumers on “safe purchasing methods.”¹²¹ Specifically, the FDA planned to increase public awareness on the risks posed by purchasing drugs from internet pharmacies and to encourage consumers to look for the Verified Internet Pharmacy Practice (VIPPS) seal when making online purchases.¹²² The FDA further elaborated that it was preferable to focus public education on areas where consumer awareness

¹¹⁴*Id.*

¹¹⁵*Id.*

¹¹⁶*Id.* at iv.

¹¹⁷*Id.* at 25.

¹¹⁸The FDA planned to introduce a list of steps that companies involved in the U.S. drug distribution should take to insure physical site security.

Id. at 24-25.

¹¹⁹*Id.* at 25.

¹²⁰*Id.* at 27.

¹²¹*Id.*

¹²²*Id.*

could make an impact, rather than on unnecessarily inundating consumers with frightening information that would not prove useful to them.¹²³

The FDA also found that it was essential to educate healthcare professionals, including physicians, nurses, and pharmacist on how to identify, avoid, and report counterfeit drugs.¹²⁴ Thus, the FDA planned to take to several steps to increase education for healthcare officials. Such steps included: (1) developing clear protocols and delivery mechanisms to educate health professionals on the counterfeit drugs threat; (2) encouraging health professionals to join the Counterfeit Alert Network; and (3) participating in conferences and publishing articles in professional journals that target healthcare professionals.¹²⁵

F. Promoting Heightened Vigilance and Awareness

1. Encouraging Health Professional Reporting via MedWatch

The FDA decided to encourage health professional to utilize the MedWatch system as an avenue to report and receive timely information on any possible outbreak of counterfeit drugs.¹²⁶ MedWatch is the FDA's "Safety Information and Adverse Event Reporting Program."¹²⁷ It was developed in 1996, with the goal of providing "important and timely clinical information about safety issues involving medical products, including prescription and over-the-counter drugs, biologics, medical and radiation-emitting devices, and special nutritional products."¹²⁸ FDA regularly communicates information on medical product safety alerts, recalls, and withdrawals to health care professionals and consumers via the MedWatch system.

The FDA believed that using the MedWatch System to report counterfeit drug use would prove to be an

¹²³ *Id.*

¹²⁴ *Id.* at 29.

¹²⁵ *Id.*

¹²⁶ *Id.* at 22.

¹²⁷ *What is MedWatch?*, FDA, available at <http://www.fda.gov/medwatch/What.htm>.

¹²⁸ *Id.*

effective tool in battling the threat of counterfeit drugs. It argued that healthcare professionals already used the MedWatch system and were accustomed to it, and could thus utilize the system aptly. MedWatch is not used as a system for consumers to report counterfeit drugs. Rather, consumers should report suspicious drugs to healthcare professionals, who can then report such drugs to MedWatch if there is reason for genuine concern.¹²⁹

2. Creation of the Counterfeit Alert Network

In the 2004 Report, the FDA also announced the creation of a Counterfeit Alert Network (“CAN”), which would link up “national [healthcare] organizations, consumer groups, and industry representatives.”¹³⁰ The aim of the newly created network was to deliver specific timely information regarding counterfeit drugs and to provide general educational information on counterfeit drugs to members of partnering organizations. Member organizations could also use the network to relate important information on counterfeit drugs to members of other organizations partnered in the Counterfeit Alert Network.¹³¹

The 2004 Report contains a “Co-Sponsorship Agreement” that members of the Counterfeit Alert Network must abide by.¹³² The agreement includes the goals of the Counterfeit Alert Network as well as the responsibilities of individual members.¹³³ Among these is the responsibility to “distribute in a timely manner FDA’s notifications about specific counterfeit incidents as an alert through an active messaging system (separate e-mail or fax alert correspondence).” Participating organizations are also required to “facilitate the ability of their members/subscribers/website visitors to report suspect counterfeit drug products to FDA” through the use of a link to FDA’s MedWatch webpage or the FDA Counterfeit Drugs webpage.

¹²⁹Reports can be made online at www.fda.gov/medwatch. The reports are confidential.

Combating Counterfeit Drugs, A Report of the Food and Drug Administration, *supra* note 7 at 22.

¹³⁰*Id.* at 21.

¹³¹*Id.*

¹³²*Id.* at 32-34.

¹³³*Id.* at 33.

G. Greater Global Cooperation

The FDA also recommended that the United States increase international cooperation in the fight against counterfeit drugs. The FDA promised that it would “collaborate with foreign stakeholders to develop strategies to deter and detect counterfeit drugs globally.”

H. Options Found to be Non-Essential

1. Unit of Use Packaging

The FDA considered whether it should mandate “unit of use” packaging to combat the counterfeit drug threat, but declined to take such action. Unit of use packaging is “any container closure system designed to hold a specific quantity of drug product for a specific use and dispensed to a patient without any modification except for the addition of appropriate labeling.”¹³⁴ The FDA opined that “unit of use” packaging could be effective as part of a multi-pronged effort to combat the counterfeit drug threat, however, it would not be able to serve as a stand-alone “anti-counterfeiting” measure.¹³⁵

The FDA decided to step back and allow the pharmaceutical industry to search for the proper resolution of this issue. The pharmaceutical industry argued that regulations mandating the implementation of “unit of use” packaging would entail significant costs upon drug companies. The concern was that drug manufacturers would need to drastically change their production lines in order to allow for such packaging, and that investments made by pharmacies in repackaging equipment would be sunk.¹³⁶

Thus, in the 2004 Report, the FDA decided that it would not require “unit of use” packaging as it was not clear how significant the costs from such regulation could be. The FDA proposed, however, that manufacturers and repackagers analyze the benefits and costs that would be realized by implementing “unit of use”

¹³⁴*Id.* at 4

¹³⁵*Id.*

¹³⁶Many additional costs are also involved.
See Id. at 36.

packaging and utilize such packaging where the benefits outweigh the costs.¹³⁷

2. Tamper Evident Packaging

The FDA found that the use of “tamper evident” packaging could be effective as part of a multi-pronged approach in stopping the distribution of counterfeit drugs.¹³⁸ The FDA felt, however, that it would not be terribly difficult for drug counterfeiters to design around “tamper evident” packaging. Thus, the FDA did consider the adoption of “tamper evident” packaging as an essential defense mechanism in the fight against counterfeit drugs.

The FDA’s stance on “tamper proof” packaging was almost identical to its stance on “unit of use” packaging. It recommended that it be left to the pharmaceutical industry on whether to adopt tamper proof packaging. There was again concern that the financial cost of tamper evident packaging would outweigh any benefits obtained. Thus, the FDA did not take any direct action on this front. The FDA did, however, prompt manufacturers and repackagers to “consider using tamper evident packaging for prescription product containers, starting with products likely to be counterfeited or newly approved products, where the benefits are equal to or outweigh the costs.”

¹³⁷ *Id.* at 4.

¹³⁸ *Id.*

VI. PROGRESS REPORT: AN EVALUATION OF THE FDA'S 2004 Recommendations and ITS implementation of the recommendations

The FDA is absolutely correct to recommend a multi-pronged strategy in dealing with counterfeit drug threat. It is not possible to solve the counterfeit drug problem through the adoption of any single solution. Drug counterfeiting is an immensely profitable crime. As prescription drug prices soar to new levels, criminals stand to make even greater profits from drug counterfeiting. Thus, such criminals have powerful financial incentives to work around any individual measure adopted to stop the introduction of counterfeit drugs into the U.S. distribution system. It is thus absolutely necessary that multiple security measures are instituted in this fight. In addition, parties involved in the U.S. drug distribution system must continue to change and upgrade their defenses against counterfeit drugs; otherwise, drug counterfeiters will slowly adapt to the measures adopted.

A. Track and Trace Technology

Although there is no single cure for the counterfeit drug problem, the adoption and implementation of track and trace technology, specifically RFID technology, by all companies involved in the U.S. drug distribution system would likely have a greater impact on securing the U.S. drug supply than any other option currently under consideration. The utilization of RFID technology would most effectively allow the pharmaceutical industry to meet the objectives behind the PDMA's written pedigree requirement. The implementation of RFID technology, with minimum information standards, throughout the drug distribution system would permit every drug to have an electronic pedigree, detailing exactly where each drug has been. Such in-

formation would be extremely useful in preventing the infiltration of counterfeit drugs into the U.S. drug supply. Companies would have the capability to more adequately ensure that the origin of a particular drug is the proper manufacturer for the drug and that the drug has not been compromised in any intervening time period. The implementation of such technology would also likely have a powerful deterrent effect on drug counterfeiters, as it will make it significantly more difficult to introduce counterfeit drugs into the drug distribution system.

An electronic pedigree is preferable to the written pedigree requirement contained in the PDMA. There exists a high possibility that counterfeiters could forge and alter written pedigrees. It would be much more expensive and more difficult to manipulate information contained on an RFID tag.

In the 2004 Report, the FDA encouraged companies to invest in and implement track and trace technology. The FDA, should, however urge companies to specifically focus on RFID technology. RFID technology has already been implemented in several sectors and has a proven track record. Encouraging companies to focus on RFID technology will insure that there is greater integration and compatibility throughout the U.S. drug distribution system.

In addition to enhancing the security of the drug supply, the adoption of RFID will generate numerous benefits for the pharmaceutical industry. Drug companies could better manage inventories and more easily institute efficient recalls.¹³⁹ RFID technology would also allow drug companies to more aptly deal with problems associated with drug diversion. It was earlier explained how the practice of drug diversion harms the security of the drug supply. Drug diversion, however, also imposes a different cost on the pharmaceutical industry. Drug companies may find themselves competing with parties who have diverted drugs from markets where the drugs are either discounted or donated. Each time a diverted drug is sold, the manufacturer of the authentic drug suffers financially, as its potential revenues decrease. If such diverted drugs were not sold,

¹³⁹ *Combating Counterfeit Drugs, A Report of the Food and Drug Administration*, *supra* note 7 at 9.

the legitimate manufacturer would have captured such revenues. In addition, the groups who the discounted or donated drugs are meant for suffer as such drugs are diverted away.

The FDA and the pharmaceutical industry have taken significant steps to adopt RFID technology since the FDA's 2004 Final Report. In November of 2004, the FDA issued public guidelines on implementing RFID feasibility studies and pilot programs.¹⁴⁰ Further steps taken by the FDA to encourage the implementation of RFID technology include: (1) creation of the "RFID Workgroup," an internal group responsible for monitoring the adoption of RFID technology among the drug distribution system and (2) investigation of the effects of radio frequency technology on specific medical products.¹⁴¹

Several pharmaceutical companies now have RFID technology in place, including Pfizer and Purdue Pharma.¹⁴²

There is concern, however, that some participants in the U.S. drug distribution system have not moved quickly enough to adopt RFID technology. In a November 2005 speech, a prominent FDA official explained:

[FDA] took an essentially voluntary approach toward widespread adoption of electronic track and trace. Supply chain stakeholders assured us that there would be considerable movement toward implementation of RFID and that widespread adoption could be done in 2007. We believed at that time regulatory intervention might stifle innovation and progress in adopting this emerging technology. Yet from our vantage point today, it appears a voluntary approach may not be enough.¹⁴³

Recently, members of Congress have also expressed frustration at the rate in which RFID technology has been implemented. A bipartisan group in the House of Representatives has introduced a bill that would mandate the use of RFID technology for certain drugs by 2007 and for all other drugs by the year 2010.¹⁴⁴ Legislation mandating the implementation of RFID technology would be wise. The voluntary recommendations proposed by the FDA in its 2004 Final Report do not go far enough. RFID cannot be fully effective

¹⁴⁰ *Combating Counterfeit Drugs: A Report of the Food and Drug Administration Annual Update*, FDA, May 18, 2005, available at <http://www.fda.gov/oc/initiatives/counterfeit/update2005.html>.

¹⁴¹ *Id.*

¹⁴² *Bill to Fight Counterfeiters would Require RFID TAGS for all Drugs*, FDA WEEK: Vol. 12, No 9: March 3, 2006, Inside Washington Publishers.

¹⁴⁴ Vol. 12 No 9. March 3, 2006: FDA Week: Inside Washington Publishers

unless such technology is adopted by all companies involved in the drug distribution system. Otherwise, drug counterfeiters may endanger the integrity of the drug supply by targeting vulnerable segments within the distribution system. The PDMA's written pedigree requirements should be permanently discarded and legislation should be passed to mandate the eventual implementation of RFID technology throughout the U.S. drug distribution system.

B. Authentication Technology

The utilization of authentication technologies must be included in any comprehensive strategy developed to defend against the counterfeit drug threat. This view was shared by the FDA in its 2004 Report. The FDA, however, declined to regulate or mandate the use of authentication technologies at the time.¹⁴⁵ Since the release of the 2004 Report, the FDA has played a limited role in encouraging the adoption of such technologies. It has “provided advice and suggestions regarding application and use of authentication technologies” when asked to do so by drug manufacturers.¹⁴⁶ The FDA has also made efforts to address any regulatory issues that would render the adoption of authentication technologies more difficult.¹⁴⁷ The FDA, however, decided to delay publishing “draft guidance on notification procedures” for making changes to drug products, drug packaging, and drug labels.

While the FDA's decision not to mandate authentication technology is certainly understandable, I believe that the FDA's logic was partly flawed. The FDA was concerned that mandating the use of authentication technology could lead to more harm than good. It was feared that if rigid requirements are enacted, drug manufacturers would be slow in shifting the types of authentication technology they utilize for certain products. Also, drug counterfeiters could mimic such technologies as the precise anti-counterfeiting measures that pharmaceutical companies take would be laid out in regulations.

¹⁴⁵ *Combating Counterfeit Drugs, A Report of the Food and Drug Administration*, *supra* note 7 at 5-6.

¹⁴⁶ Annual Update 2005, *supra* note 140.

¹⁴⁷ *Id.*

This is a valid concern. Regulations dealing with authentication technologies should not be too rigid. Otherwise, drug counterfeiters may develop the capacity to counterfeit such authentication technologies themselves. Such regulations may provide too much information to drug counterfeiters. Counterfeiters would have the ability to determine exactly what authentication measures are mandated by law and would also receive advance information on when and how such standards may be changed. In order to minimize this risk, drug manufacturers should be left with the flexibility to change the specific authentication technologies employed on particular drugs as often as they deem appropriate. Also, there should be standards adopted on how drug manufactures can adequately communicate such information to drug retailers.

A compromise balance can be reached between rigid regulation and no regulation at all. It would have been wise for the FDA to mandate the use of a combination of authentication technologies for the drugs most likely to be counterfeited by a certain date. Such regulation seems to pose little risk. Drug manufacturers would be free to determine exactly what combination of authentication technologies to utilize and when to make changes to such technology. There is no reason to believe that such regulation would impede the development of new technologies or that such regulation would give any advantage to drug counterfeiters. Authentication technologies are now sufficiently ready to be utilized in the context of drug counterfeiting and have been extremely successful in fighting currency counterfeiting.

C. Increased Penalties for Drug Counterfeiters

Any effective anti-criminal strategy must contain a criminal penalty component that adequately deters potential perpetrators from committing the targeted crime. There is no adequate deterrent in place for the crime of counterfeiting. As indicated above, a criminal convicted on a drug counterfeiting charge would only be punished by a maximum of three years of prison.¹⁴⁸ It is unlikely that such a limited sentence achieves an adequate level of deterrence in the context of counterfeit drugs. Thus, the FDA should indeed push for

¹⁴⁸ *Combating Counterfeit Drugs, A Report of the Food and Drug Administration*, *supra* note 7 at 19.

tougher criminal penalties for such crimes.

The deterrent power of such limited punishment is miniscule for several reasons. First, drug counterfeiting is a particularly profitable crime. Counterfeiters have the capability to charge market level fees for prescription medicines without contributing to the billions of dollars of research and development costs that drug companies expend yearly. Also, patent holders for prescription medications set drug prices at monopoly prices because patent holders have the exclusive right, for a limited time, to prevent others from making, using, or selling their patented invention. Thus, the price of a patented drug can be significantly higher than the marginal cost required to manufacture an additional dosage of that drug. Drug counterfeiters have the capability to take advantage of this price disparity to capture enormous profits.

Second, it is often very difficult to apprehend individuals involved in manufacturing and distributing counterfeit drugs. Counterfeiting operations are usually conducted by underground criminal organizations and are often run from outside the U.S. Thus, it is difficult to deter drug counterfeiters. In order to adequately deter a potential criminal from breaking a specific law, the government must insure that his probability of being punished for the crime multiplied by his potential punishment exceeds the benefits he will receive from breaking the targeted law. The probability of a drug counterfeiter being apprehended and punished is relatively low and the expected payoff for drug counterfeiting is especially high; thus, the government must substantially increase the prison sentences for drug counterfeiting in order to effectively deter such behavior. Third, drug counterfeiting places tremendous risks upon public safety. It is difficult to morally differentiate an individual who provides a cancer patient with a fake drug that ultimately kills him from a more “common criminal” who shoots and murders a convenience store clerk in the process of a robbery. Thus, the FDA’s recommendation that drug counterfeiters receive increased penalties dependent upon the level of risk their behavior imposes on the public health is very sensible.¹⁴⁹ A person who exposes a cancer patient to an

¹⁴⁹*Id.*

inactive version of a life saving medication should receive a punishment that fits his crime.

It is important to recognize, however, that increasing criminal penalties for drug counterfeiters will only have a limited effect upon the problem. In many situations, it is almost impossible to apprehend and prosecute the perpetrators of such crimes in the United States. Much of the counterfeit drugs distributed throughout the world are manufactured in China, India, and Pakistan.¹⁵⁰ Thus, it is difficult for U.S. authorities to uncover the identities of those involved in such criminal activities. Even where the U.S. can determine who the culprits are, prosecutors must be able to: “1) gather evidence abroad, 2) gain the cooperation of [foreign] witnesses who may face possible prosecution in their own countries, 3) produce competent evidence gathered abroad in a U.S. trial that demonstrates culpability beyond a reasonable doubt, and 4) overcome the legal barriers of jurisdiction and extradition.”¹⁵¹ Under international law, the U.S. may assert jurisdiction over such individuals through the “protective principle.”¹⁵² Under this doctrine, a nation may exert jurisdiction over an individual where conduct outside its borders produces or is intended to produce a detrimental effect within its borders.¹⁵³

The 2004 Report did not discuss whether the existing penalties for drug diversion should be increased. This is an important topic that was overlooked by the FDA in its report. As discussed above, the practice of drug diversion significantly contributes to the introduction of counterfeit drugs into the U.S. drug supply. Thus, the penalties for drug diversion should also be set at a level that will adequately deter such activity. This objective may be reached through greater financial deterrents. Drug companies who purchase diverted drugs should be punished. If drug companies expect to pay large fines for engaging in or aiding drug diversion, they are unlikely to take part in such harmful activity.

D. Secure Business Practices

¹⁵⁰ *Detering the Importation of Counterfeit Pharmaceutical Products*, 59 Food Drug L.J. 537, 540 (2004).

¹⁵¹ *Id.* at 550.

¹⁵² *Id.* at 543.

¹⁵³ *Id.*

The FDA was correct to include the adoption of secure business practices by companies involved in the drug distribution system as a part of the overall U.S. strategy on dealing with counterfeit drugs. Entities that are involved with and profit from the production and distribution of prescription drugs have a responsibility to take steps to minimize risks to the drug supply. Such steps include knowing who they do business with and maintaining adequate physical security of their sites. Companies involved in the drug distribution system have an interest in protecting the legitimacy of the U.S. drug supply. Thus, such companies should contribute to maintaining such legitimacy.

The FDA's expansion of oversight activities with regard to re-packagers of perceptions drugs was also a positive development, as repackaging activities impose significant risks upon the U.S. drug distribution system.¹⁵⁴ Repackagers may have a motive as well as an opportunity to engage in deceptive practices, such as combing legitimate medications with expired medications.¹⁵⁵

As the FDA continues ongoing efforts to encourage drug companies to adopt secure business practices, many stakeholders have already upgraded the security of their business practices. After the release of the 2004 Report, several trade associations for wholesale drug distributors issued guidelines to their members regarding "best practices for drug distribution system integrity."¹⁵⁶ In addition, the Healthcare Management Association (HDMA),¹⁵⁷ released new membership rules "that require active members to adopt best practices

¹⁵⁴ *Combating Counterfeit Drugs, A Report of the Food and Drug Administration*, *supra* note 7 at 25.

¹⁵⁵ *FDA'S Counterfeit Drug Task Force Interim Report*, *supra* note 13.

¹⁵⁶ Annual Update 2005, *supra* note 140.

¹⁵⁷ "HDMA has worked with members to secure a safe, efficient and reliable healthcare distribution system that is able to provide life-saving health products and services. HDMA members are responsible for ensuring that billions of units of medication are safely delivered to tens of thousands of retail pharmacies, hospitals, nursing homes, clinics and other provider sites in all 50 states."

HDMA website, available at http://www.healthcaredistribution.org/about_hdma/vision_values.asp.

that include extensive regulatory, financial, security, and due diligence processes and procedures.”¹⁵⁸ The FDA should continue to encourage and assist all companies involved in the drug distribution system to adopt such secure business practices.

E. Increased Education for Consumers and Healthcare Professionals

As recognized by the FDA, educating the public as well as healthcare professionals about the risk of counterfeit drugs must be a central component in the battle against counterfeit drugs. The FDA has taken several steps to achieve this goal since the release of the 2004 Report. It developed two public service announcements regarding the counterfeit drug problem that were targeted towards consumers. In the year subsequent to the 2004 Report, the FDA ran these announcements in 4.5 million public magazines.¹⁵⁹ In the same time period, retail pharmacies distributed 4.6 million leaflets to consumers that carried the public service announcements developed by the FDA in addition to other information on the problem.¹⁶⁰ Other steps taken by the FDA to educate consumers about counterfeit drugs include: (1) publishing an article that was printed in local newspapers nationwide with an estimated readership of nearly 10 million consumers; (2) developing a website where consumers may learn about counterfeit drug issues;¹⁶¹ (3) teaming up with National Health Council (“NHC”) to develop and distribute informational messages on how to avoid counterfeit drugs; (4) initiating a campaign to educate consumers of the risks posed by internet pharmacies and how to buy medications safely on the Internet.¹⁶² The FDA also took steps to educate pharmacists on how to properly identify counterfeit drugs and on how to proceed once such drugs have been identified.¹⁶³

The FDA’s balanced approach towards educating the public on the counterfeit drug threat is exactly what is called for. Consumers should not be inundated with countless information about counterfeit drugs, but

¹⁵⁸Annual Update 2005, *supra* note 140.

¹⁵⁹*Id.*

¹⁶⁰*Id.*

¹⁶¹The FDA’s site is accessible at www.fda.gov/counterfeit.

¹⁶²Annual Update 2005, *supra* note 140.

¹⁶³*Id.*

should rather be given the information that will allow them to engage in safer behavior and make more informed choices. Thus, the FDA should focus on communicating information to the public on how to purchase medications safely on the Internet. This is where the highest risk to the public lies, as most drugs in the legitimate U.S. drug distribution are authentic. The FDA should continue efforts to educate consumers on the importance of looking for the VIPPS seal whenever purchasing medications on the Internet.¹⁶⁴

F. Promoting Heightened Vigilance and Awareness

1. Encouraging Health Professional Reporting Via MedWatch

As promised, subsequent to the 2004 Report, the FDA took steps to encourage health care professionals to report suspected counterfeit drugs to the FDA via the MedWatch form.¹⁶⁵ In several speeches to health care professionals, FDA staff advocated the utilization of the MedWatch system to report counterfeit drugs.¹⁶⁶ The FDA's decision not to create a separate system for reporting counterfeit drugs appears to be the prudent course of action. Health professionals are already familiar with the MedWatch system and are able to use it effectively. It does not make sense to have such officials report through different systems depending on whether medications are hazardous due to manufacturing errors or as a result of being counterfeited. The FDA reports that health professionals have started to use the MedWatch system to report suspect counterfeit medicines.¹⁶⁷

2. Creation of the Counterfeit Alert Network

¹⁶⁴ *Combating Counterfeit Drugs, A Report of the Food and Drug Administration*, *supra* note 7 at 27.

¹⁶⁵ Annual Update 2005, *supra* note 140.

¹⁶⁶ *Id.*

¹⁶⁷ *Id.*

The Counterfeit Alert Network (“CAN”) was initiated in February of 2004, one month after the release of the 2004 Report.¹⁶⁸ Thus far, 15 organizations have joined the CAN.¹⁶⁹ The FDA continues to encourage organizations to join the CAN and to sign the CAN co-sponsor agreement. The CAN is vital to protecting consumers from counterfeit drugs. The development of the CAN does not directly help stop the infiltration of counterfeit drugs into the U.S. drug distribution system; it performs a different, yet tremendously important function. The CAN helps to minimize the number of patients who are harmed by the potential penetration of such drugs into the U.S. drug supply. By teaming up with several prominent organizations, the FDA helps to insure that information on any potential outbreak of counterfeit drugs is disseminated quickly and widely. Such information is time sensitive and must be communicated as quickly as possible to be effective. Regardless of any other activities that the government and private companies take, it is likely that at least a small amount of counterfeit drugs will enter the U.S. drug supply; the FDA must be ready to disseminate such information quickly when they do.

3. Disclosure by Pharmaceutical Companies

Although the development of the CAN and the utilization of MedWatch for reporting counterfeit drugs are positive developments, the FDA should do more to increase vigilance and awareness in regards to counterfeit drugs. Specifically, the FDA should mandate that pharmaceutical companies quickly disclose the discovery of counterfeit versions of their products. Under a 2003 agreement between the FDA and the Pharmaceutical Research and Manufacturers of America (“PhRMA”), pharmaceutical companies are expected to report “within five working days of determining that there is a reasonable basis to believe that their product has

¹⁶⁸Counterfeit Alert Network webpage, FDA, available at <http://www.fda.gov/oc/initiatives/counterfeit/network.html>.

¹⁶⁹*Id.*

been counterfeited.”¹⁷⁰ Such disclosure is voluntary, however. Pharmaceutical companies should be required to disclose such information by law. Otherwise, companies may wait too long to disclose such information due to market concerns.¹⁷¹

G. Greater Global Cooperation

In order to effectively protect against the dangers of counterfeit drugs, there must be a worldwide sustained effort against drug counterfeiting activities. If nations are not able to cooperate in fighting this threat, they will place their citizens at a greater risk. Thus, nations should be encouraged to apprehend and punish drug counterfeiters operating within their borders even if the harm from the counterfeiting activity occurs outside the country. There is evidence that certain groups focus solely on exporting counterfeit drugs in order to avoid punishment.¹⁷² In 1997, an underground criminal network in Greece that was broken up was found to export counterfeit drugs to various countries, but distributed absolutely no drugs into the Greek drug supply.¹⁷³

The FDA has cooperated with the global community to stop the proliferation of counterfeit drugs. Subsequent to the release of the 2004 Report, it took several steps to increase such cooperation: (1) it has supported and participated in WHO meetings focused on counterfeit drug issues; (2) the OCI has trained foreign law enforcement agents and judicial officers on counterfeit drug issues and has worked with foreign law enforcement agencies on counterfeit drug cases; (3) the FDA has trained foreign nations on counterfeit drug issues.¹⁷⁴

The FDA has also cooperated with Mexico in battling the counterfeit drug threat. With Mexico just at

¹⁷⁰Robert Cockburn, Paul N. Newton, E. Kyremateng Agyarko, Dora Akunyili, Nicholas J. White, *The Global Threat of Drugs: Why Industry and Governments Must Communicate the Dangers*, Public Library of Science (PLOS): Medicine, Vol. 2, Issue 4, April 2004, available at <http://medicine.plosjournals.org/perlserv?request=get-document&doi=10.1371/journal.pmed.0020100>.

¹⁷¹*See Id.*

¹⁷²59 Food Drug L.J. 537, *supra* note 61 at 550.

¹⁷³*Id.*

¹⁷⁴Annual Update 2005, *supra* note 140.

the border of the U.S., it should receive special attention from the FDA and other U.S. authorities. It is reported that counterfeit drugs are prevalent in Tijuana, Juarez, Los Algodones, and Nogales, towns on the Mexican border.¹⁷⁵

As a result of U.S. and Mexican cooperation, 19 pharmacies were suspended and more than 105 tons of counterfeit drugs were seized.¹⁷⁶

It is also vital for the U.S. to cooperate with China and India on this issue, the origins of much of the counterfeit drugs found in the world. In October of 2005, Pfizer and Novartis¹⁷⁷ spoke out; explaining that it is imperative there is greater global cooperation on counterfeit drug issues.¹⁷⁸ At a pharmaceutical conference in Singapore, Ray Valez, an asset protection and compliance officer for Eli Lilly Asia reportedly explained that: “[Counterfeit drugs is a very, very big business. The competition today for us is not Viagra. It is counterfeit drugs.”¹⁷⁹ Eli Lilly is the maker of Cialis, a medication that competes directly with Viagra.

In the past few years, the WHO has also taken a more active role on counterfeit drug issues. In 2005, WHO developed the Rapid Alert System (“RAS”), a communications network in the Western Pacific Region that “alerts member countries and areas and relevant partner organizations...about cases of counterfeit medicine.”¹⁸⁰ It would be prudent for the RAS to be expanded to cover the rest of the world as well.

Although progress has been made in the last few years, cooperation between the global community must increase. It is unacceptable for 10% of prescription drugs to be counterfeits. Counterfeit drugs are different than imitation watches or stolen intellectual property; counterfeit drugs can and do kill. The U.S. and developed nations should work to bring affordable track and trace technologies as well as authentication tech-

¹⁷⁵ *WHO Pushes for Global Cooperation In War On Counterfeit Drugs*, February 16th, 2006, available at <http://www.newsinferno.com/archives/848>.

¹⁷⁶ *Id.*

¹⁷⁷ With a market capitalization of over \$130 billion, Novartis is the seventh largest prescription drug company in the world. *Id.*

¹⁷⁸ *Id.*

¹⁷⁹ *Id.*

¹⁸⁰ *Rapid Alert System for Combating Counterfeit Medicine*, WHO fact sheet, available at http://www.wpro.who.int/media_centre/fact_sheets/fs_20050503.htm.

nologies to the developing world, where the counterfeit drug problem is so severe. The United States cannot single-handedly eradicate the counterfeit drug threat. In order to succeed, the battle against counterfeit drugs must be a sustained and coordinated global effort.

VII. Conclusion

There is no single solution to the counterfeit drug threat. However, the implementation of the “multi-pronged strategy” recommended by the FDA should minimize the danger counterfeit drugs present. Although the recommendations propounded by the FDA in the 2004 Report are prudent, the FDA does not go far enough in ensuring that its recommendations will be implemented. The pharmaceutical industry’s slow pace in implementing RFID technologies is evidence of this. There exists a proper balance between too much regulation and no regulation at all. This balance has not been achieved here.

Most importantly, it should be mandated that drug manufacturers, drug distributors, and drug detailers adopt and implement RFID technology by a reasonable date. The failure of even a small number of stakeholders to adopt such technology will leave unnecessary vulnerabilities in the U.S. drug distribution system. It should also be required that drug manufactures implement authentication technologies in the drugs that are mostly likely to be counterfeited, including the most expensive and the newest drugs. It is important, however, that such regulation is not too rigid. Otherwise, such regulation may do more harm than good. It is also imperative that there is greater international cooperation in the battle against counterfeit drugs. A global problem of this magnitude must be met with a global response.