

NOTE

**THE R.F.I.D. ACT OF 2006 AND E-PEDIGREES:
TACKLING THE PROBLEM OF COUNTERFEIT
DRUGS IN THE UNITED STATES
WHOLESALE INDUSTRY**

*Suchira Ghosh**

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The U.S. Food and Drug Administration (FDA) regulates the drug distribution system within the country and is responsible for protecting public health by promoting access to safe and effective medicines. Ensuring safety of the drug supply is clearly important in achieving this goal, but drug distribution channels in the United States remain insecure. Gaps within the drug distribution system make it increasingly vulnerable to bad actors, such as counterfeiters and terrorists.

* J.D., expected May 2007, the University of Michigan Law School; B.S., Chemical Engineering, Columbia University. Many thanks to Professor Rebecca Eisenberg and the students in the University of Michigan Law School Student Scholarship Workshop.

Congress intended the Prescription Drug Marketing Act (PDMA) of 1987 to close these gaps, but the PDMA has not fully succeeded. Important PDMA provisions that require tracking of drugs throughout the distribution chain in the form of “pedigrees”¹ were set to be implemented as of Dec. 1, 2006, although a recent court order has stayed complete implementation. However, these PDMA requirements do not apply uniformly to all drug distributors in the United States. Moreover, since paper pedigrees can be forged, the pedigree system might not be sufficient to prevent the introduction of counterfeit drugs into the U.S. distribution system. Proposed bipartisan legislation in Congress, the Reducing Fraudulent and Imitation Drugs Act of 2006 (abbreviated hereinafter as “R.F.I.D. Act”) addresses some of these concerns, but the legislation has not yet been enacted and it is unclear whether it will be. Thus, many loopholes remain in current FDA regulations.

Electronic pedigree (“e-pedigree”) technology can alleviate some of the problems inherent in paper pedigrees. Radio frequency identification (RFID)² remains the most promising e-pedigree solution, although some have argued that use of this technology raises cost and privacy concerns. These challenges are not insurmountable, however, and RFID offers many benefits over other technologies in drug tracking. An alternative technology, barcodes, is immediately available to supplement use of paper pedigrees in drug tracking. Barcodes are an older, reliable technology, but they have limited uses and are inefficient. Both of these technologies have a place in drug tracking, and they can be used together to offer an immediate and comprehensive e-pedigree solution. The FDA has a strong interest in securing the drug distribution system, and e-pedigrees are the best way to do this.

This Note argues for immediate enactment of the R.F.I.D. Act or its equivalent (or alternatively, for Congress to amend the PDMA directly) to mandate the use of e-pedigrees by all distributors and manufacturers. This is not an impossible requirement to fulfill given the immediate availability of e-pedigree technology. The Note also encourages continued industry movement towards RFID as an e-pedigree solution, as well as implementation of the R.F.I.D. Act or its equivalent to protect consumer privacy.

Part I of this Note discusses threats facing the U.S. drug supply from counterfeit drugs. Part II describes how counterfeits are introduced into U.S. drug supply chains. Part III discusses problems with the PDMA,

1. A pedigree is a statement that records all transactions of the drug all the way back to the manufacturer. Pedigrees are discussed *infra* Part III.

2. RFID systems transmit information wirelessly, from an RFID tag to an RFID reader, using radio waves. RFID technology is discussed *infra* Part IV.

and introduces the R.F.I.D. Act as a potential solution. Part IV describes use of RFID to secure the drug supply and current challenges facing its implementation. Part V discusses current use of barcodes within the pharmaceutical industry and the potential use of barcodes as a supplement to paper pedigrees.

I. COUNTERFEIT DRUGS POSE THREATS TO THE U.S. DRUG SUPPLY

The U.S. drug system is highly controlled, but counterfeit drugs still enter the U.S. supply chain. Counterfeit drugs are defined by statute as those sold under a trademark or trade name without proper authorization from the manufacturer.³ They can be made in the United States or abroad. Drugs are counterfeit if the identity of the source is fraudulently mislabeled in a way that suggests it is actually the authentic approved product.⁴ Counterfeit drugs that reach patients through regulated supply chains can create a serious safety threat because they might contain the wrong active ingredient, dangerous ingredients, no active ingredient, or the correct ingredient in sub-potent or super-potent quantities.⁵ Counterfeit drugs sold in the United States might also originate from terrorist organizations, and sales from counterfeit drugs might go to fund terrorist groups.⁶

3. "The term 'counterfeit drug' means 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). This definition is broad, in part, because it is intended to protect the intellectual property rights of brand drug manufacturers, and not to simply restrict the sale of dangerous counterfeits. Thus, some drugs fall under this definition but might not pose health risks. For example, some unauthorized entities might create replicas of brand name drugs with the correct ingredients in the correct quantities ("copycat drugs"), and these drugs are still considered counterfeit in the United States if they bear the trademark or trade name of the authentic branded drug. Though certain types of counterfeit drugs will pose a greater health risk than others, copycat drugs should still be eliminated from regulated, legitimate U.S. distribution channels because we cannot be sure which actors are profiting from the sales of copycat drugs. For example, sales of copycat drugs could go to fund terrorist groups or other bad actors.

4. *Id.*

5. See World Health Organization—Counterfeit Medicines, <http://www.who.int/mediacentre/factsheets/fs275/en/> (last visited Feb. 16, 2007) (counterfeit Procrit contained bacteria-tainted water, posing a risk of infection in already severely weakened patients); FDA Counterfeit Drugs Questions & Answers, <http://www.fda.gov/oc/initiatives/counterfeit/qa.html> (last visited Feb. 16, 2007).

6. See U.S. DEP'T OF JUSTICE, PROGRESS REPORT OF THE DEPARTMENT OF JUSTICE'S TASK FORCE ON INTELLECTUAL PROPERTY (June 2006), available at <http://www.usdoj.gov/opa/documents/ipreport61906.pdf> (discussing how individuals used counterfeit drug sales to

The high retail prices of drugs create attractive opportunities for criminals to introduce counterfeit drugs into the U.S. drug distribution system. Profits from counterfeit sales can be large because counterfeit drugs are cheap to make⁷ but can be sold at the retail price of the authentic drug. Gross margins on counterfeit drugs are very high, and earnings from sales of counterfeit drugs are estimated to reach over \$75 billion globally by 2010.⁸ Expensive drugs are not the only counterfeit targets: internationally, the most commonly counterfeit drugs are ones that treat common diseases, like antibiotics.⁹ Thus, as counterfeiting increases, both expensive and high-demand drugs are likely targets.

The indictment of Douglas Albers, owner of Albers Medical Distributors, demonstrates the lucrative nature of counterfeit drug trafficking. In one of the largest criminal investigations of counterfeit medicines, the U.S. Department of Justice alleged that Albers' company conspired to sell \$42 million worth of counterfeit drugs,¹⁰ including Lipitor and Neupogen, to which Albers pled guilty in 2006.¹¹ The *Albers* case highlights an important point about the counterfeit drug trade—drugs with high sales volumes or expensive drugs are attractive targets. Drugs with high sales, like Lipitor, are particularly susceptible to counterfeiting or diversion.¹² Common targets also include expensive products intended

finance Hezbollah efforts); *see also* GRAHAM SATCHWELL, A SICK BUSINESS 51-64 (Stockholm Network 2004) (discussing the link between counterfeit drugs and terrorism and organized crime); GIULIANI PARTNERS LLC, INTERIM ASSESSMENT REPORT TO FDA (May 11, 2004), *available at* http://www.fda.gov/ohrms/dockets/dockets/04n0115/04N-0115_emc-000013-02.pdf; *see generally* *Links Between Intellectual Property Crime and Terrorist Financing: Before the H. Comm. on International Relations*, 108th Cong. (Jul. 16, 2003) (testimony of Ronald K. Noble, Secretary General of Interpol), *available at* <http://www.interpol.int/Public/ICPO/speeches/SG20030716.asp>.

7. Counterfeit drugs are often very cheap to produce because cheap ingredient substitutes might be used, ingredients might be omitted, and quality controls and Good Manufacturing Practices are not implemented during manufacture. *See* World Health Organization, *supra* note 5.

8. *Id.*

9. *Id.*

10. 2001-2006 U.S. ATT'Y W. DISTRICT FOR MO. PROGRESS REP. 32, *available at* http://www.usdoj.gov/usao/mow/progress_report.pdf.

11. News Release, *U.S. Att'y W. Dist. Mo. Pharmaceutical Distributor Pleads Guilty to Selling Counterfeit Drugs*, Oct. 18, 2006, *available at* <http://www.usdoj.gov/usao/mow/news2006/albers.ple.htm>.

12. Diverted drugs, also known as "gray market" drugs, are authentic drugs that are sold outside of intended distribution channels. They bear the trademark of the genuine good with the approval of the trademark holder, but the trademark holder has not approved these drugs for sale in the United States. Counterfeit drugs and drug diversion are closely associated, because parties who trade in diverted drugs often introduce counterfeit drugs into distribution channels. Drugs may be diverted from their legitimate ends or drugs from a cheaper market can be diverted to a market where the drug price is higher. *See* FDA, COUNTERFEIT DRUG TASK FORCE INTERIM REP. 9 (Oct. 2003) [hereinafter INTERIM REP.]. Even drugs that are diverted to the United States from overseas sales can be considered a patient

for extremely sick patients. Counterfeit Procrit, an anti-anemia drug used in patients severely ill with cancer or AIDS, posed serious risks of underdosing to these patients.¹³ Counterfeit Epogen, another anti-anemia drug, caused serious complications for organ transplant recipients and patients with end-stage kidney disease.¹⁴

American patients should be concerned about risks presented by counterfeit drugs. These drugs, when introduced into the supply chain, present a considerable health and safety threat.

II. HOW ARE COUNTERFEITS INTRODUCED INTO THE U.S. DRUG SUPPLY?

According to the Department of Health and Human Services (HHS), the drug distribution system within the United States is supposed to be a “closed system that involves several players (e.g., manufacturers, wholesalers, retailers) who move drug products from the point of manufacturing to the end user who dispenses the drug to the patient.”¹⁵ In theory, outside actors should not be able to infiltrate this closed system and introduce fake drugs. Yet counterfeit drugs *do* enter the system, because the system is not truly secure.

Challenges to policing U.S. borders permit counterfeit drugs to enter the country, and gaps in U.S. drug distribution routes allow these drugs to be distributed domestically. The FDA has witnessed an increase in counterfeiting activities and the introduction of counterfeits into legitimate drug distribution channels.¹⁶ Though counterfeit drugs can be manufactured within the United States, it is very common for counterfeit drugs to be manufactured abroad and then imported into the country.¹⁷ Customs and Border Patrol (CBP) and the FDA work together to

risk if the drug is not approved in the U.S. or the labeling is considered inadequate. *See* United States v. Rx Depot, Inc. 290 F. Supp. 2d 1238, 1243-44 (D. Okla. 2003). Rx Depot sold a generic Canadian version of antidepressant Serzone to U.S. customers through an internet pharmacy, which increased the risk of serious adverse events because the insert did not include descriptive warnings about serious liver damage, did not mention drugs that should be avoided while taking the generic, and did not convey the same sense of urgency as the U.S. insert.

13. Drug Warning Letter from Ortho Biotech Products to Healthcare Professionals (June 6, 2002), *available at* <http://www.fda.gov/medwatch/SAFETY/2002/procrit.htm>.

14. Bette Hileman, *Counterfeit Drugs*, CHEMICAL AND ENGINEERING NEWS, Nov. 10, 2003, at 36-43.

15. DEP'T OF HEALTH & HUMAN SERVICES, TASK FORCE ON DRUG IMPORTATION, PRESCRIPTION DRUG IMPORTATION REP. 38 (Dec. 2004) [hereinafter PRESCRIPTION DRUG IMPORTATION REP.].

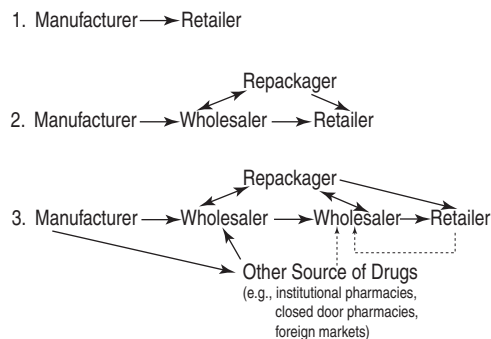
16. Randall Lutter, Associate Commissioner, Address at the NACDS/ HDMA RFID Healthcare Adoption Summit (Nov. 14, 2005).

17. *See* Kerry Capell, *What's in That Pill?*, BUSINESSWEEK ONLINE, June 18, 2001, http://www.businessweek.com/magazine/content/01_25/b3737153.htm.

monitor and prevent illegal importation of drugs into the country, including the import of counterfeit and diverted drugs,¹⁸ but it seems impossible to completely stem the influx of counterfeit drugs. There are 355 points of entry into the United States,¹⁹ including ports and mail facilities, and the volume of counterfeit drugs arriving at these points of entry is staggering.²⁰ While the volume of imported drugs has increased dramatically, FDA and CBP resources to police imports have not.²¹ Thus, the safety of the U.S. drug supply is compromised, in part, because of an insufficient amount of funding allocated to policing imports. Because it is very difficult to eliminate the influx of counterfeit drugs moving through U.S. ports of entry, it becomes even more important that these counterfeit drugs are not circulated through U.S. drug distribution channels.

U.S. drug distribution channels are difficult to monitor. As shown in Figure 1,²² these distribution routes can be simple or very complicated. These routes are linear or cyclical depending on whether intermediaries, such as wholesalers or repackagers, buy the drug before it reaches the retailer. Counterfeit drugs might be introduced at multiple points along these routes, especially when drugs change hands many times. The presence of intermediaries increases opportunities to introduce counterfeits. The *Albers* case demonstrates that the introduction of counterfeit drugs can occur during transactions between various distributors and wholesalers.

FIGURE I
DRUG DISTRIBUTION MODELS



18. CUSTOMS AND BORDER PATROL, CUSTOMS DIRECTIVE NO. 2310-008A, TRADEMARK AND TRADENAME PROTECTION (April 7, 2000) (discussing the difference between counterfeit goods and gray market goods and how importation of each type of good is handled by CBP).

19. PRESCRIPTION DRUG IMPORTATION REP., *supra* note 15, at 12.

20. *Id.* at 12. During an unannounced examination by the FDA and CBP in 2003 at various international mail facilities and airports, the agencies examined imported products and 88% of the drug products were “violative” of U.S. drug laws. *Id.* at 13.

21. *Id.* at 32.

22. INTERIM REPORT, *supra* note 12, at 8.

Wholesalers, both primary and secondary, play a major role in drug distribution: manufacturers sell most of their drugs to wholesalers.²³ A majority of sales from manufacturers are made to primary wholesalers,²⁴ who then move these drugs into their own warehouses and resell them to retailers, other wholesalers, or other entities.²⁵ A few primary wholesalers dominate this market: AmerisourceBergen, Cardinal Health, and McKesson.²⁶ Secondary wholesalers also play an important role in drug distribution (as well as in drug pricing), but secondary wholesaler sales make up only 5-10% of the \$100 billion wholesaler market,²⁷ and the secondary companies are much smaller. Secondary wholesalers usually specialize in purchasing and reselling select discounted drug products and base their business on a rapid turnover of discounted drugs. Secondary wholesalers buy discounted drugs from manufacturers who are selling these drugs for a short time at a discounted price, perhaps to meet quarterly sales goals or to reduce inventory overstock.²⁸ Secondary wholesalers might later sell these drugs to other wholesalers at a markup, but at prices lower than what the manufacturer then offers.²⁹ In this way, the secondary wholesaler market performs an arbitrage function.³⁰ Secondary wholesalers are important players in drug distribution because they often deal in smaller volumes of drugs, and can readily serve smaller and independent pharmacies. They can also offer quick turn-arounds on drug inventories, meet needs for specialized drugs, or focus on regional or rural areas.³¹

In practice, wholesalers often engage in multiple transactions in a drug. The cost differential between the price that wholesalers pay for drugs and the market price (based on the manufacturer's usual list price and paid by end users like retailers or patients) makes it possible for the drug to be resold multiple times at a profit, increasing the likelihood that multiple transactions occur during distribution. Each transaction

23. Approximately 80% of sales from innovator drug companies are made to wholesalers. FDA, FINAL REPORT ON PROFILE OF THE PRESCRIPTION DRUG WHOLESALING INDUSTRY (Feb. 12, 2001), available at <http://www.fda.gov/oc/pdma/report2001/attachment/1.html>.

24. FDA, THE PRESCRIPTION DRUG MARKETING ACT REPORT TO CONGRESS 5 (June 2001) [hereinafter REPORT TO CONGRESS].

25. Hileman, *supra* note 14.

26. REPORT TO CONGRESS, *supra* note 24. The market capitalizations of these 3 primary wholesalers are 9.27B, 26.76B, and 14.49B, respectively. See Google Finance, <http://www.google.com/finance> (last visited Dec. 9, 2006).

27. REPORT TO CONGRESS, *supra* note 24.

28. *Id.* at 7.

29. *Id.*

30. *Id.*

31. INTERIM REPORT, *supra* note 12, at 8.

provides another opportunity for bad actors, like Albers' company, to introduce counterfeit drugs into the legitimate supply chain.³²

Finally, counterfeit drugs enter the United States through personal importation and Internet pharmacies. These counterfeits can enter regulated distribution channels if wholesalers buy counterfeit goods via the Internet.³³ Gray market drugs (i.e., genuine drugs that have been licensed for sale abroad but not in the United States) are often diverted into the United States, and while these drugs pose less of a safety threat to Americans than drugs that are manufactured by counterfeiters, traffic in gray market goods is illegal. Gray market goods present special issues that are beyond the scope of this paper. Nonetheless, many of the remedies suggested in this paper, such as electronic pedigrees, will also help reduce the influx of gray market goods into legitimate distribution channels.

The inherent difficulties in policing the U.S. borders highlight the need for more secure drug distribution channels within the country. Securing drug distribution routes will limit the possibility that any counterfeit drugs that enter the country will find their way onto the shelves of legitimate pharmacies.

III. LEGISLATION TO PREVENT INTRODUCTION OF COUNTERFEITS INTO THE U.S. DRUG SUPPLY

Congress recognized that the prescription drug distribution system lacked sufficient safeguards to prevent the introduction and sale of counterfeit drugs, and that a wholesale drug market had developed which made it very difficult to determine the original source of drugs.³⁴ Congress attempted to address these health concerns through PDMA legislation enacted in 1988, which amended several sections of the Fed-

32. *See id.*

33. This paper focuses on regulated drug distribution channels and does not address regulation of personal importation or Internet pharmacies. A truly comprehensive approach to eliminating counterfeit drugs in the United States must address the major issues of illegitimate Internet pharmacies and personal importation of drugs. FDA issues cyber warning letters to shady Internet pharmacies, but the United States does not have jurisdiction to enforce these warnings in certain countries. Foreign governments do not always assist in tracking down counterfeit operations in their own countries. These rogue operations are fluid, often closing down quickly and re-opening elsewhere. The notice requirement for seizure of personal imports is also hampering federal enforcement efforts. *Enhanced Efforts and Better Agency Coordination Needed to Address Illegal Importation: Hearing before Subcomm. On Oversight and Investigations*, GAO-06 175T (Dec. 2005) (statement of Richard M. Stana, Director, Homeland Security and Justice Issues).

34. *See* H.R. REP. NO. 100-76, at 6 (1987).

eral Food Drug and Cosmetic Act (FDCA).³⁵ The PDMA is intended to ensure that drug products purchased by consumers are safe and effective, and to limit the risk that counterfeit, adulterated, misbranded, subpotent, or expired drugs are sold to American consumers.³⁶ In 1999, the FDA published regulations implementing provisions of the PDMA.³⁷ The 1999 regulations were to take effect in 2000, but the FDA received many objections to key provisions, leading it to stay the effective date of these provisions repeatedly.³⁸

The regulations establish a “pedigree” requirement for prescription drugs. A drug pedigree is a statement that identifies each prior sale, purchase, or transaction of the drug, for each transaction all the way back to the manufacturer, including the names and addresses of all parties engaged in the transaction.³⁹ Each person engaged in the wholesale distribution of a prescription drug in interstate commerce—except an authorized distributor of record (ADR) for that drug or the manufacturer—must supply a pedigree to the person who receives the drug in a transaction. The regulations define an ADR as a wholesaler that has an “ongoing relationship” with a manufacturer to distribute that manufacturer’s drug.⁴⁰ “Ongoing relationship” is defined to include a *written agreement* between manufacturer and wholesaler.⁴¹

The FDA delayed these provisions until Dec. 1, 2006⁴² in an effort to deal with various stakeholders’ concerns with the PDMA provisions, discussed below in Part III.A, and to consider requiring use of certain e-pedigree technologies, discussed below in Part III.B. As this date was about to expire, a Federal District Court recently entered a preliminary injunction prohibiting implementation of some of these regulations at the behest of secondary wholesalers, discussed below in Part III.A.

A. PDMA Pedigree Requirements Do Not Mandate Drug Tracking by All Wholesalers

The FDA delayed implementation of the PDMA pedigree provisions, in part, to deal with concerns of secondary wholesalers. Secondary wholesalers object to the definition of ADR described in the regulations for a number of reasons. First, secondary wholesalers claim that manufacturers

35. The FDCA protects public health and safety in a number of ways, including prohibiting commerce of misbranded or adulterated drug products. *See* 21 U.S.C. § 331.

36. REPORT TO CONGRESS, *supra* note 24, at 2.

37. 21 C.F.R. § 203 (2006).

38. REPORT TO CONGRESS, *supra* note 24, at II–III.

39. 21 C.F.R. § 203.50 (2006).

40. 21 C.F.R. § 203.3(b) (2006).

41. 21 C.F.R. § 203.3(u) (2006).

42. Prescription Drug Marketing Act Policies Delay of Effective Date, 69 Fed. Reg. 12,792 (Mar. 18, 2004) (to be codified at 21 C.F.R. pt. 203).

are unwilling to enter into written agreements with them; thus, they cannot be considered an ADR and would have to provide pedigrees.⁴³ In effect, the PDMA gives manufacturers the control in deciding which wholesalers can be considered ADRs. Second, secondary wholesalers insist that they will not be able to provide pedigrees showing *all* prior sales, because a large portion of their drugs are purchased from ADRs who are not required to provide pedigrees and will not voluntarily provide them.⁴⁴ Third, secondary wholesalers believe pedigree requirements will be financially burdensome and will eat into their already narrow profit margins.⁴⁵ A pedigree exemption for ADRs would thus put non-ADR wholesalers at a disadvantage, both financially and in terms of obtaining complete pedigrees as required by the PDMA.

The pedigree exemption for an ADR would erase the chain of custody on a pedigree each time the drug passes through an ADR's hands during distribution because ADRs are not required to provide pedigrees. Since most of the drugs moving through the distribution channel today pass through an ADR at least once,⁴⁶ the ADR exemption creates gaps in the distribution history of drugs.⁴⁷ Bad actors could exploit such a gap by selling counterfeit drugs to ADRs because ADRs do not request pedigrees before a sale and do not need to pass on pedigrees to their purchasers.⁴⁸ Broadening and relaxing the definition of ADR to include more secondary wholesalers might help more wholesalers stay in business (which is desirable since secondary wholesalers play an important role in distribution and reduced drug pricing as discussed *supra* Part II), but will reduce the extent to which pedigrees are maintained and passed

43. Usually primary wholesalers are considered ADRs because they have ongoing relationships with the drug manufacturers that have been codified in writing, as PDMA requires. This Note uses ADR and primary wholesalers interchangeably.

44. REPORT TO CONGRESS, *supra* note 24, at 9.

45. “[P]rice and competitive conditions dictate that [wholesalers] operate on narrow profit margins. In general, the wholesale markup is modest . . . for every dollar of prescription drugs sold in 1997, 76 cents went to the manufacturer, 20 cents went to the dispenser (i.e., pharmacy), and 4 cents went to the wholesale distributor . . . The [National Wholesale Distributors Association] reported that the after-tax net profit expressed as a percent of sales, was only 0.62 percent for 1998 . . . [R]egional wholesalers . . . are at least an order of magnitude smaller than [primary wholesalers, and] generate revenues of approximately \$500 million to \$900 million per year.” EASTERN RESEARCH GROUP INC., PROFILE OF THE PRESCRIPTION DRUG WHOLESALING INDUSTRY, FINAL REPORT 1–12, 1–13 (2001), *reprinted in* REPORT TO CONGRESS, *supra* note 24, at Attachment G.

46. REPORT TO CONGRESS, *supra* note 24, at IX.

47. When Congress passed the PDMA, they envisioned a linear drug distribution chain where an ADR would buy drugs directly from the manufacturer. In reality, as discussed *supra* Part II, drug distribution can be cyclical, and ADR can buy drugs from wholesalers as well as manufacturers. REPORT TO CONGRESS, *supra* note 24, at VIII.

48. *Id.* at X. Though it is not clear whether this has happened or will happen, counterfeiting is a real threat to the U.S. drug supply and a comprehensive approach to securing the distribution system includes acknowledging and addressing potential gaps.

on in distribution channels (conflicting with Congress' goal of thoroughly tracking drug movement). In November 2006, after weighing these conflicting considerations, the FDA decided to implement the PDMA pedigree provisions for all prescription drugs,⁴⁹ over the objections of secondary wholesalers.

The FDA issued a non-binding guidance in November 2006 in an effort to address these concerns of secondary wholesalers,⁵⁰ but it is unlikely this guidance will help secondary wholesalers. In the guidance, the FDA strongly recommends that *all* parties in the distribution chain, including ADRs, maintain and pass on pedigrees. Since the PDMA only gives the FDA authority to enforce pedigree requirements against non-ADR, the FDA cannot enforce this recommendation against ADRs. It remains to be seen whether ADRs will comply with these recommendations all the same, but it seems unlikely. By not complying, an ADR can effectively drive secondary wholesalers out of business, or at the very least, reduce profits of secondary wholesalers by reducing the number and types of sales they can make. Compliance is costly, and it is unlikely that ADRs will comply with merely hortatory recommendations out of beneficence. In fact, one major primary wholesaler, AmerisourceBergen, offers a pedigree service where, for \$5,000 or more, the company will offer pedigrees to secondary wholesalers.⁵¹ AmerisourceBergen claims this fee will help the company recover its cost of providing the pedigrees and is not a money-making scheme, but very few secondary wholesalers have participated. In all likelihood, most secondary wholesalers will not be able to afford to pay such high fees to primary wholesalers.

Though the FDA decided to fully implement these pedigree provisions as of December 1, 2006, the Agency has recently faced a major setback, making the future of the PDMA pedigree provisions uncertain. In September 2006, secondary wholesalers fought back against the discriminatory treatment under the PDMA by filing suit against HHS.⁵² The secondary wholesalers claimed that the pedigree provisions violate the Equal Protection and Due Process clauses of the U.S. Constitution,⁵³ and sought an injunction against the FDA to delay their implementation. On

49. Prescription Drug Marketing Act Pedigree Requirements, 71 Fed. Reg. 66,448 (Nov. 15, 2006) (to be codified at 21 C.F.R. pt. 203 and 205).

50. OFFICE OF REGULATORY AFFAIRS, GUIDANCE FOR INDUSTRY, PRESCRIPTION DRUG MARKETING ACT (PDMA) REQUIREMENTS 6 (2006).

51. Press Release, IMDA Update, Pedigree Issue Dog Distributors (Oct. 2006), <http://www.imda.org/news/update/200610.htm> (last visited Dec. 8, 2006); See Press Release, AmerisourceBergen Announces Innovative Track and Trace Program for the Pharmaceutical Supply Channel, <http://www.amerisourcebergen.com> (last visited Dec. 8, 2006).

52. The FDA is an agency within Health and Human Services (HHS).

53. RxUSA Wholesale, Inc. v. Dep't of Health and Human Serv., No. 06-CV-5086 (JS) (AKT) (E.D.N.Y. Dec. 8, 2006).

December 8, 2006, a federal district court judge in the Eastern District of New York issued a preliminary injunction effectively staying implementation of the pedigree provisions.⁵⁴ The FDA recognizes that limiting the injunction to the plaintiffs or to the EDNY would be confusing and unfair,⁵⁵ so it appears that the FDA will apply the terms of the injunction uniformly to all non-ADR wholesalers. Both the FDA and RxUSA have made clear that they will continue to litigate this issue,⁵⁶ but for the moment, the Agency's attempts to enforce inconsistent pedigree provisions upon the industry have been thwarted. The decision was a major blow to the Agency's reliance upon the PDMA to secure drug tracking, leaving drug tracking status quo and the drug supply vulnerable.

Uniform pedigree requirements are necessary to ensure comprehensive safety of the U.S. drug supply. To achieve this goal, Congress and the FDA should enact legislation to require pedigrees by all wholesalers and manufacturers. It remains to be seen how the secondary wholesaler litigation plays into this scenario, but hopefully the injunction will accelerate Congressional interest in making legislative changes to impose uniform pedigree requirements. An outcome favorable to the secondary wholesaler plaintiffs will almost certainly spur legislative changes, whereas the opposite outcome could drive secondary wholesalers out of business.

B. *The PDMA Does Not Mandate E-Pedigrees*

Though uniform paper pedigree requirements can help secure drug distribution chains, these pedigrees are only a partial solution. The FDA stayed PDMA pedigree provisions, in part, to consider alternatives to paper pedigrees.⁵⁷ Under the PDMA, however, the FDA does not have

54. RxUSA Wholesale, Inc. v. Dep't of Health and Human Serv., No. 06-CV-5086 (JS) (AKT) (E.D.N.Y. Dec. 8, 2006), Order Adopting Report and Recommendation, filed Dec. 11, 2006; Heather Won Tesoriero, *Federal Injunction Will Delay Part of Drug-Tracking Law*, WALL STREET JOURNAL ONLINE, Dec 4., 2006, <http://online.wsj.com> (last visited Feb. 15, 2007). Specifically, the decision enjoins provision 21 C.F.R. § 203.50(a) and its subparts. This provision requires non-ADR wholesalers to pass on pedigrees documenting each prior transaction of the drug, including the lot number of the drug and other identifying information. 21 C.F.R. § 203.50(a) (2004). FDA claims, however, that other subparts of Section 203 and its related guidance documents still require wholesalers to maintain pedigree statements showing prior transactions up to the last ADR. FDA, ADDENDUM TO FDA'S GUIDANCE FOR INDUSTRY: PDMA PEDIGREE REQUIREMENTS—QUESTIONS AND ANSWERS RELATED TO THE PRELIMINARY INJUNCTION ORDERED 12/5/06 IN RXUSA WHOLESALERS, INC. v. HHS (Dec. 15, 2006) [hereinafter ADDENDUM]. Based on the statutory language within § 203, however, this claim seems weak.

55. ADDENDUM, *supra* note 54, at 3.

56. Backgrounder re: RxUSA Wholesalers, Inc. v. HHS (Dec. 18, 2006), http://www.fda.gov/cder/regulatory/PDMA/PDMA_backgrounder.pdf; RxUSA Pro Consumer Litigation Files and Information, <http://www.rxusa.com/litigation/> (last visited Jan. 29, 2006).

57. Lutter, *supra* note 16.

the authority to compel use of electronic pedigrees (“e-pedigrees”). As a result, various states have adopted their own legislation requiring use of e-pedigrees⁵⁸ to improve security in statewide drug distribution and to reduce inefficiencies associated with paper tracking, but most states do not have e-pedigree legislation in place.

Until very recently, the FDA had been pressuring stakeholders aggressively to adopt electronic pedigrees, particularly RFID technology, by 2007.⁵⁹ In November 2006, the FDA acknowledged that industry-wide adoption of RFID would be unfeasible by its previously announced goal of 2007.⁶⁰ The FDA acknowledged in its November 2006 guidance letter that e-pedigrees could be used as an alternative or supplement to paper pedigrees, but the Agency refused to back any particular e-pedigree technology, noting instead that a variety of technologies were available, including barcodes. Though the FDA withdrew some of its pressure upon stakeholders to adopt RFID, RFID remains the most promising e-pedigree solution within the pharmaceutical industry. Despite the FDA’s recent hedging about which e-pedigree technology is best, some pharmaceutical companies have already invested in and implemented programs to use RFID to track highly counterfeit drugs,⁶¹ and some primary wholesalers have done the same.⁶² It seems that many of these industry players recognize current deficiencies in paper tracking and are gradually moving toward alternative solutions.

Since paper pedigrees alone are insufficient to deter introduction of counterfeit drugs, e-pedigrees should be utilized as a replacement or supplement to paper pedigrees. Congress could require the use of e-pedigrees, in order to improve drug tracking, by revising the PDMA. Alternatively, Congress could enact the R.F.I.D. Act, discussed in the next section, which mandates e-pedigrees.

58. See, e.g., CAL. BUS. & PROF. CODE § 4034 (2007); IND. CODE ANN. § 25-26-14 (2006).

59. FDA, COMBATING COUNTERFEIT DRUGS REPORT, February 18, 2004, at II, available at http://www.fda.gov/oc/initiatives/counterfeit/report02_04.html [hereinafter COUNTERFEIT DRUGS REPORT].

60. 71 Fed. Reg. 66448 (Nov. 15, 2006).

61. Susannah Patton, *Cracks in the Pharmaceutical Supply Chain*, CIO MAG., Jan. 15, 2006, available at <http://www.cio.com/archive/011506/pharma.html> (discussing RFID pilot programs by Purdue Pharma, Pfizer, GlaxoSmithKline); Jonathan Collins, *Novartis Trial Shows RFID Can Boost Patient Compliance*, RFID J., June 20, 2006, available at <http://www.rfidjournal.com/article/articleview/2438/>.

62. Claire Swedberg, *AmerisourceBergen to Conduct HF/UHF RFID Pilot*, RFID J., Nov. 14, 2006, available at <http://www.rfidjournal.com/article/articleview/2820/>; Press Release, Cardinal Health, Cardinal Health Announces Next Phase of RFID Pilot (May 9, 2006), available at http://www.cardinal.com/content/news/592006_13829.asp.

C. Solutions Within the Reducing Fraudulent and Imitation Drugs Act of 2006

Current bills in Congress, if enacted, would address inconsistent pedigree requirements, problems with paper pedigrees, and overall, help secure the safety of the U.S. drug supply. In 2006, Representative Dan Burton (R-IN) and Senator David Vitter (R-LA) introduced the Reducing Fraudulent and Imitation Drugs Act of 2006 in the House and Senate, respectively.⁶³ Both bills have been referred to subcommittees,⁶⁴ but neither has yet passed. This Act, which has bipartisan support, gives HHS the authority to require pedigree tracking by *all* manufacturers and distributors of prescription drugs. ADRs would no longer be exempt from the pedigree requirement. Furthermore, the Act recognizes the need for a federal mandate to bring about national e-pedigree compliance. The proposed legislation establishes e-pedigree requirements, and states that “radio frequency identification (RFID) tagging technology, or similar trace and track technologies that have an equivalent function” are required for all prescription drug packaging to authenticate the pedigrees of these drugs.⁶⁵

The R.F.I.D. Act goes beyond the PDMA to require a more multi-layered approach to securing drug distribution. The Act requires that the drug’s packaging incorporate “tamper-indicating technologies.”⁶⁶ Without tamper-evident packaging, the original container could be reused for counterfeit drugs and could be more easily passed off as genuine product.⁶⁷ The Act also requires use of “blister security packaging when possible.”⁶⁸ A blister pack is a pack consisting of indentations (blisters) into which a pill is placed, before being sealed with a plastic covering. A blister pack might be safer than pill bottles because removal of pills is more obvious from a blister pack than from a pill bottle, and it might be more expensive to make counterfeit blister packs than it is to put counterfeit pills in bottles.⁶⁹ The Act also recommends incorporating overt and covert technologies into drug packaging.⁷⁰ Overt technologies, such

63. Reducing Fraudulent and Imitation Drugs Act of 2006, H.R. 4829, 109th Cong. (2006); S. 2668, 109th Cong. (2006).

64. In March 2006, H.R. 4829 was referred to the Subcommittee on Health, and in April 2006, S. 2668 was referred to the Committee on Health, Education, Labor, and Pensions, where they remain currently. See Bill Summary & Status, <http://thomas.loc.gov/> (follow “Bills, Resolutions” hyperlink; follow “Search Bill and Summary & Status” hyperlink; search for bill numbers) (last visited Dec. 8, 2006).

65. H.R. 4829 § 2(a)(1).

66. *Id.* at § 2(a)(2).

67. See INTERIM REPORT, *supra* note 12, at 13.

68. H.R. 4829 § 2(a)(3).

69. COUNTERFEIT DRUGS REPORT, *supra* note 59.

70. H.R. 4829 § 2(c).

as colors or holograms, are visible to the eye, and covert technologies, such as invisible bar codes, chemical markers, and fluorescent inks, are not visible to the eye and require special equipment to read.⁷¹ Under a multi-layered approach, counterfeiters must overcome multiple technological barriers, which might prove impossible or, at the very least, expensive.

The R.F.I.D. Act also recommends phased-in implementation of e-pedigree requirements. Congress intends for these provisions to apply first to drugs that are most commonly counterfeit beginning December 31, 2007 at the latest, and finally to all prescription drugs no later than December 31, 2010.⁷² Phased-in implementation helps address some of the challenges still facing widespread RFID deployment, discussed *infra* Part IV.

The R.F.I.D. Act offers a more comprehensive solution to the counterfeit drug problem in wholesale distribution than does the PDMA. It is imperative that Congress enact the R.F.I.D. Act, or its equivalent, to give the FDA authority to require e-pedigrees by all distributors and to encourage a multi-layered approach to combating drug counterfeiting. Parts IV and V discuss e-pedigree technology that is currently available.

IV. RFID E-PEDIGREES

Legislation mandating e-pedigrees might stall in Congress if stakeholders object that the available e-pedigree technology cannot be feasibly deployed. Certainly, available e-pedigree technology must be sufficiently developed if Congress intends to mandate its use throughout the pharmaceutical industry. RFID deployment throughout the industry currently faces cost and privacy challenges. These challenges are not insurmountable, however, and the R.F.I.D. Act's goal of widespread RFID adoption for all prescription drugs by 2010 is attainable.

RFID can serve as a complete replacement to paper pedigrees. RFID systems consist of three components: a tag, a reader, and a database.⁷³ The tag consists of a tiny silicon chip and antenna. Mobile or stationary readers scan the tag using radio frequency ("RF") waves and the information is then stored in a central database.⁷⁴ The RFID tag can be encoded with a unique serial number, also known as an electronic prod-

71. PRESCRIPTION DRUG IMPORTATION REP., *supra* note 15, at 47.

72. To determine which drugs are most commonly counterfeit, the Act requires HHS to publish in the Federal Register a list of no less than 30 prescription drugs that are frequent counterfeit targets, and to annually update the list. H.R. 4829 § 2(f)(1).

73. FED. TRADE COMM'N, RADIO FREQUENCY IDENTIFICATION: APPLICATIONS AND IMPLICATIONS FOR CONSUMERS 3 (2005).

74. *Id.* at 1.

uct code (“EPC”). The RFID tag can be affixed to a pharmaceutical package (on the bottle or package itself, or on a bottle seal⁷⁵) and as the package moves through the distribution chain, distributors can use RFID readers to scan the EPC on the package and generate a record of the drug’s movement (an e-pedigree). Since certain types of RFID tags can have new information “written” upon them, the pedigree of the drug can be updated every time the drug changes hands by those having access to the RFID database. Paper tracking becomes unnecessary. RFID tags are most effective in preventing introduction of counterfeit drugs when used on an individual drug package instead of placed on a case of drug packages; that way even if the case of drugs is subdivided and sold by distributors, each drug unit can be individually tracked. RFID is also highly efficient; multiple RFID tags can be read instantly by a strategically placed reader, without the need for humans to scan products.⁷⁶ In this manner, large inventories of RFID tagged drugs can be read and authenticated rapidly.

RFID use in pharmaceutical tracking is relatively new, however the technology has already been put to use in other industries. Many government agencies and private companies are using RFID tags. RFID is used in EZ-Pass toll payment,⁷⁷ and the Department of Defense uses tags to track supply chain and military items all over the world.⁷⁸ The Department of Homeland Security has issued final rules on implementation of RFID chips in passports,⁷⁹ and diplomats have already been issued such passports.⁸⁰ The Federal Aviation Administration has conducted studies on RFID interference with flight communications,⁸¹ the U.S. Postal Service has begun implementing RFID in tracking certain shipments,⁸² and the USDA plans to use RFID in tracking animals.⁸³ Major

75. Pharmaceutical Online, *Tagsys RFID Technology to be Used In Helping Combat Drug Counterfeiting*, Apr. 11, 2005, <http://www.pharmaceuticalonline.com/Content/> (discussing collaboration to develop RFID tagged packaging seals between major pharmaceutical packager and RFID hardware provider).

76. Lori Chordas, *Tag, You’re It*, BEST’S REVIEW 50 (June 2006).

77. FED. TRADE COMM’N, *supra* note 73, at 5.

78. See Mark Roberti, *DOD Releases Final RFID Policy*, RFID J., Aug. 9, 2004, available at <http://www.rfidjournal.com/article/articleview/1080/1/14/>.

79. 22 C.F.R. § 51 (2006).

80. *U.S. Government Issues 300 RFID Passports*, RFID UPDATE, Mar. 14, 2006, available at <http://www.rfidupdate.com/articles/index.php?id=1073>.

81. Anthony Cerino & William Walsh, *Research and Application of RFID Technology to Enhance Aviation Security*, PROC. OF THE IEEE 2000 NAT’L AEROSPACE AND ELECS. CONF. 127 (2007).

82. See Laurie Sullivan, *Global Mail Services Seen as New Frontier for RFID*, INFORMATION WEEK, Nov. 10, 2005, <http://informationweek.com/story/showArticle.jhtml?articleID=173601751&tid=5978>.

83. See Marsha Walton, *USDA Steps Up Efforts to Track Livestock*, CNN.COM, May 28, 2004, <http://edition.cnn.com/2004/TECH/science/05/24/animalidentification/>.

retailers like Marks & Spencer and Wal-Mart already use RFID in inventory and supply-chain management.⁸⁴

In addition to use as an e-pedigree, RFID has broader applications within pharmaceutical distribution. RFID tags with batteries can measure environmental conditions and confirm that transported drugs have been held at the appropriate temperature and humidity conditions, which is important to a drug's safety and efficacy. RFID can also be used to track drug shipments internationally and prevent international drug diversion.⁸⁵ RFID-tagged drugs can also be identified in the event of a manufacturer recall, so that only specific lots of drugs that were contaminated could be identified and recalled.⁸⁶ RFID-tagged drugs can be read by Customs and Border Patrol enforcement at ports of entry, potentially reducing illegal reimportation or diversion of drugs into the United States.

If RFID has significant advantages over paper pedigrees and offers added benefits as well, why is it not widely used by all manufacturers and wholesalers to track drugs during distribution? Cost and privacy concerns are barriers to immediate widespread adoption of RFID as an e-pedigree solution for all drugs. As discussed in Part IV.A, as RFID costs decrease over time, stakeholders can eventually deploy RFID as an e-pedigree for all drugs. This is desirable since RFID systems offer a complete pedigree solution and other benefits to pharmaceutical distribution. But before item-level RFID drug tagging can occur, Congress and the FDA must address privacy concerns by swiftly enacting and implementing the R.F.I.D. Act, or its equivalent, as discussed in Part IV.B.

A. Cost

Costs associated with RFID use are a major concern throughout the industry.⁸⁷ Even for major companies, the costs of implementing enterprise-wide RFID systems are not trivial. Some analysts predict that "typical, large-scale manufacturers in the consumer goods industry will

84. See Background to Marks & Spencer's Business Trial of RFID in its Clothing Supply Chain, <http://www2.marksandspencer.com/thecompany/mediacentre/pressreleases/2005/com2005-02-18-00.shtml> (last visited Dec. 2, 2005); Jonathan Birchall, *WalMart Toughens Push on Wireless Tagging*, MSNBC.COM, Dec. 20, 2005, <http://msnbc.msn.com/id/10536693/>.

85. See Cristen Bolan, *Is RFID's Tag Too Pricey?*, GLOBAL COSMETIC INDUSTRY 28 (Jan. 2005) (discussing use of e-seals to track products over long international routes).

86. Chordas, *supra* note 76.

87. See Todd Zwillich, *Breaking News in Depth: FDA Relaxing Packaging Rules to Ease RFID Use*, DRUG TOPICS, Dec. 13, 2004, <http://www.drugtopics.com/drugtopics/article/articleDetail.jsp?id=137453&&pageID=2> (last visited Mar. 9, 2007); Burt Moore, *Hidden Costs of Implementing RFID*, MATERIAL HANDLING MANAGEMENT 62 (Nov. 2004).

spend from \$9 million to \$25 million” to become RFID-compliant,⁸⁸ but that number could be larger for pharmaceutical companies to tag their product lines. A Pfizer RFID pilot for Viagra cost several million dollars to tag retail packages and cases of the drug.⁸⁹ Presumably costs will be far greater to tag unit packages. Costs vary for each part of the RFID system. The price for RFID tags have been quoted from anywhere between 20 cents per tag⁹⁰ to 20 dollars or more.⁹¹ Reader costs vary based on frequency and can range from a few hundred to a few thousand dollars.⁹² Installation, connectivity, and database management costs vary based on a number of factors, but can run from thousands to millions of dollars.

Though initial roll-out costs might be high, companies are seeking better returns on investment in these RFID expenditures. RFID can save a pharmaceutical company billions of dollars in long-term management and inventory control costs.⁹³ Counterfeit drug sales represent lost profits that a drug company can prevent through use of RFID. Pharmaceutical companies can also recover these initial cost expenditures through the value RFID tracking returns in production planning and marketing, through sales and distribution data based on region or retailer.

To date, however, most pharmaceutical companies have rolled out RFID pilot programs only for their most highly counterfeit drugs, and not all of their product lines.⁹⁴ At present, it may not be feasible to use RFID enterprise-wide: RFID may only be justifiable for products that represent a high value in lost profits and products that have a higher retail price.⁹⁵ Similarly, generic prescription drug makers might find the costs of rolling out RFID harder to justify because the profit margins on generic drug sales are much lower than those on brand-name drug

88. Larry Shutzberg, *Scoping Out the Real Costs of RFID*, INFORMATION WEEK, Nov. 1, 2004, available at <http://www.informationweek.com/story/showArticle.jhtml?articleID=51201525>.

89. Pfizer News Release, http://www.pfizer.com/pfizer/are/news_releases/2004pr/mn_2004_1115.jsp (Nov. 15, 2004).

90. RFID Journal, *Frequently Asked Questions*, <http://www.rfidjournal.com/faq/20> (last visited Mar. 8, 2007).

91. FED. TRADE COMM’N, *supra* note 73, at 6.

92. RFID Journal, *supra* note 90.

93. Estimates project cost savings of \$2 billion worldwide for pharmaceuticals through RFID use due to improved inventory management. Chris Paddison, *Busting the Myths of Pharma RFID*, ATKEARNEY EXECUTIVE AGENDA, vol. VIII, no. 2, 40, 41–42 (2005), available at http://www.atkearney.sk/shared_res/pdf/Busting_the_Myths_of_Pharma_RFID.pdf.

94. Zwillich, *supra* note 87 (discussing Pfizer, Purdue Pharma, and GlaxoSmithKline’s RFID tagging pilots for highly counterfeit products, including Viagra, OxyContin, and anti-HIV drugs).

95. Bolan, *supra* note 85, at 24–25 (discussing an IBM business study concluding that manufacturers can see a return on investment by RFID tagging “high value goods that are often stolen or counterfeit.”)

sales.⁹⁶ However, as demand for RFID increases, perhaps spurred by e-pedigree federal mandates,⁹⁷ RFID production will increase and associated costs will drop.⁹⁸

As drug manufacturers move towards using RFID to track all of their products, all wholesalers will eventually have to pass on pedigrees using RFID. Secondary wholesalers, who operate on narrow profit margins, might find RFID costs prohibitive. However, secondary wholesalers do not need to implement full RFID systems to track drugs. The costs that secondary wholesalers will incur include the costs of readers, and the costs of verifying authenticity of the EPC by connecting (often via secure means online)⁹⁹ to the RFID database. Subscription fees for this connection can be high, but they appear to vary based on the dollar sales of the subscribing company.¹⁰⁰ Subscription costs might be substantially lower for small secondary wholesalers and reader costs might be as low as a few hundred dollars, but the exact costs incurred by secondary wholesalers for partial RFID adoption are unknown.

Cost remains a barrier to immediate implementation of RFID as an e-pedigree solution for *all* prescription drug products, but RFID costs will drop as use increases. Pharmaceutical companies can justify RFID costs because the technology offers companies a positive return on investment and meaningful benefits. Additionally, RFID use might not drive secondary wholesalers out of business. Federal e-pedigree legislation, like the R.F.I.D. Act, will encourage pharmaceutical companies to gradually utilize RFID for all of their drug products, increase RFID use throughout the industry, and drive down hardware costs.

96. See *id.* at 25–27 (discussing IBM business study concluding that companies who sell high volumes of low priced goods will not realize a return on investment for RFID at present.)

97. David Hannon, *What You Need to Know About RFID for Inbound Logistics*, PURCHASING, vol. 134, no. 4, Mar. 3, 2005, at 46 (discussing the link between mandates, increased adoption, and cheaper technology).

98. Charles J. Murray, *RFID: Beyond the Drive for Five*, DESIGN NEWS, Apr. 24, 2006 (discussing that RFID technologies will become widespread when RFID production volume reaches a “tipping point” and drives down costs low enough so that it becomes feasible to use RFID for everyday items), available at <http://www.designnews.com/article/CA6324161.html?industryid=22204>.

99. See, e.g., SupplyScape, *Nation’s First Authentication Service*, http://www.supplyscape.com/spotlight/2005_authentication.html (last visited Dec. 15, 2006).

100. Shutzberg, *supra* note 88.

B. Privacy

Consumer privacy groups, including CASPIAN¹⁰¹ and EPIC,¹⁰² as well as government agencies,¹⁰³ have raised a number of privacy issues in response to growing RFID use. RFID-tagging at a pill or bottle level could reveal information about a consumer's whereabouts, tastes, purchases, and medical information. A variety of solutions have been proposed to deal with potential privacy threats.¹⁰⁴ One solution would be to disable RFID tags in the pharmacy so that the tag stops tracking, and drug and patient cannot be linked by anyone having access to the associated RFID database. This is known as "killing" the tag, and can be accomplished when a reader gives the tag a "kill" command, usually upon purchase of the tagged object, deactivating it permanently.¹⁰⁵ The FDA believes that, for privacy reasons, it is not necessary for a tag to remain active once the drug is sold to a consumer¹⁰⁶ though this limits the benefits of RFID in product recalls if the drug has already been sold by the pharmacy. Another approach to protecting privacy is use of blocker tags that contain a "privacy bit" which prohibits unauthorized scanning.¹⁰⁷ So far, agency regulations have failed to address privacy issues in RFID drug tracking.

If enacted, the R.F.I.D. Act would offer the FDA a way to address e-pedigree privacy issues in rulemaking. Specifically, the Act prohibits e-pedigree technologies from "containing or transmitting any information that may be used to identify a health care practitioner or the prescription drug consumer."¹⁰⁸ Enforcement of this provision would help allay privacy concerns. The Act would still allow RFID use, but RFID tags might

101. Consumers Against Supermarket Privacy Invasion and Numbering (CASPIAN) began a website opposing use of RFID chips. *See*, RFID Nineteen Eighty-Four, <http://www.spychips.com/> (last visited Mar. 4, 2007).

102. Electronic Privacy Information Center (EPIC) has a website devoted to RFID privacy issues. *See*, EPIC RFID Systems, <http://www.epic.org/privacy/rfid/> (last visited Mar. 4, 2007).

103. *See, e.g.*, U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-05-551, INFORMATION SECURITY RADIO FREQUENCY IDENTIFICATION TECHNOLOGY IN THE FEDERAL GOVERNMENT 18 (May 2005).

104. *See, e.g.*, Hyangjin Kim & Jeeyon Kim, *Privacy Threats and Issues in Mobile RFID*, 2006 IEEE PROC. OF FIRST INT'L CONF. ON AVAILABILITY, RELIABILITY, AND SECURITY (discussing sleeping, killing, blocking, passwords, and encryption to address RFID privacy threats); Zhang et al., *An Improved Approach to Security and Privacy of RFID Application System*, IEEE 1149-52 (2005) (discussing read access control solutions and ways to prevent eavesdropping and interception of RFID messages).

105. Kim, *supra* note 104.

106. FDA, COUNTERFEIT DRUG TASK FORCE 2006 UPDATE 20 (June 2006).

107. Zhang et al., *supra* note 104.

108. H.R. 4829, 109th Cong. at §2(b)(2) (2006).

need to be killed or blocked when a consumer purchases the drug in the pharmacy to protect the consumer's privacy.

RFID remains one of the most promising technologies for securing drug distribution channels in the United States, and cost and privacy concerns should not prevent eventual adoption of this technology in e-pedigrees. Many pharmaceutical manufacturers and some wholesalers are moving towards RFID tracking, and in the long term, costs are likely to come down. Eventually, item level tagging of all prescription drugs could be justifiable by all generic and brand drug manufacturers. Furthermore, RFID systems do not necessarily have to compromise patient privacy.

V. BARCODES ARE AN E-PEDIGREE ALTERNATIVE

Though RFID offers a complete alternative to paper pedigrees, and has added advantages as well, RFID is not the only available e-pedigree option. The FDA has also suggested barcodes as an e-pedigree solution.¹⁰⁹ It is worth examining whether barcodes are a viable option. A barcode is "a way to encode data using a series of bars and spaces."¹¹⁰ Barcodes are most commonly available in 1-dimensional (1D) and 2-dimensional (2D) formats. 2D barcodes have the capacity to store more information.¹¹¹ Information about the drug can be stored on a barcode; for example, the manufacturer, drug name, and lot number. When drugs change hands, the buyer can use a barcode reader to authenticate the original source of the drug. Barcodes, however, are read-only and cannot be written upon. Each time a drug changes hands, the barcode cannot be updated with information to indicate that the drug has been sold to a new wholesaler. In this way, barcodes do not track the chain of custody of a drug. Thus, 1D or 2D barcodes cannot replace paper pedigrees entirely, and can only be used as a supplement to the paper pedigree system. Furthermore, barcodes are inefficient compared to RFID: they require "line of sight" to be read, large numbers of barcoded packages cannot be read instantly, and human intervention is still required to read barcoded packages.¹¹² But barcodes have been in use for a long time and are reliable. Barcodes are inexpensive, many industries already use barcodes, and

109. 71 Fed. Reg. 66448 (Nov. 15, 2006).

110. Fotel Inc. General Barcode Frequently Asked Questions, <http://www.fotel.com/resources/faqs/barcode.htm#Q005> (last visited Dec. 9, 2006).

111. Clyde E. Witt, *Playing Well Together: Bar Code & RFID*, 60 MATERIAL HANDLING MGMT. 12, 13 (2005).

112. See Charles J. Murray, *RFID: Beyond the Drive for Five*, 61 DESIGN NEWS 48, 48-50 (2006); Chordas, *supra* note 76, at 48.

transitioning a company to barcode systems should be less expensive than adoption of RFID.

Also, barcodes are already federally mandated for uses within the pharmaceutical industry, and are thus well-positioned to be used as a partial e-pedigree solution. In 2004, the FDA issued regulations requiring use of bar code labeling on the internal package and external packaging of most prescription drugs.¹¹³ The bar code must, at minimum, include the National Drug Code number for the drug.¹¹⁴ The regulations, which were made effective in April 2006, are intended to reduce administration errors in a hospital setting by allowing hospital staff to scan the barcode and verify that the correct drug is being administered, and the regulations apply only to drugs that may end up in hospital settings. Since manufacturers make most of their drug sales to wholesalers, and these wholesalers sell drugs to hospitals as well as other distributors and retailers, the bar code requirements will likely apply to the majority of a manufacturer's prescription drugs. Interestingly, the FDA does not allow use of any other identification technology in lieu of a barcode for this regulation, though they do allow manufacturers to encode any additional information upon the barcode.¹¹⁵ This regulation opens the door to use of barcodes as a supplement to paper pedigrees. Drug manufacturers will now need to barcode individual drug units, and wholesalers and retailers can read these barcodes to verify the identity and other information about the drug. The chain of custody will still need to be updated on paper in order to provide a complete pedigree with each transaction; however, item-level barcodes provide an additional deterrent to counterfeiters attempting to introduce false drugs into legitimate distribution.

Both RFID and barcode technologies will likely have a role in e-pedigrees since both can enhance drug distribution security and reduce the inefficiencies associated with sole reliance on paper forms.¹¹⁶ The widespread availability of barcodes also means that there is a comprehensive approach to drug tracking immediately available. It appears that barcodes will be widely used to authenticate all drug products while RFID use is limited, at present, to highly counterfeited drugs. Interestingly, RFID and barcode technology are interoperable: some RFID

113. 21 C.F.R. § 201.25 (2006); FDA, GUIDANCE FOR INDUSTRY: BAR CODE LABEL REQUIREMENTS QUESTIONS AND ANSWERS 7 (2006), available at <http://www.fda.gov/cber/gdlns/barcode.pdf> [hereinafter GUIDANCE FOR INDUSTRY].

114. GUIDANCE FOR INDUSTRY, *supra* note 113 at 1.

115. FDA said that it would consider accommodating new technologies by April 2006, but the Agency did not provide any new opinions or information on other technologies in its October 2006 guidance. *Id.* at 6.

116. Olin Thompson, *Mobile Computing*, 77 FOOD ENGINEERING 135, 135 (2005) (discussing how RFID or barcodes increase efficiency over paper forms).

vendors offer scanners that can read RFID tags as well as barcodes.¹¹⁷ The technologies are not mutually exclusive, so wholesalers will be able to authenticate either barcoded or RFID-tagged drug packages and pass on the pedigree. It remains to be seen whether manufacturers will continue to use a hybrid RFID and barcode system to generate e-pedigrees, or will move towards RFID as the sole e-pedigree solution. Though they are less efficient to use, barcodes are cheaper than RFID and might make sense to use on drugs that are of lower value or less frequently counterfeit until RFID tags become more affordable. Furthermore, barcodes are not precluded in the R.F.I.D. Act, since they can be considered a track and trace technology that has an equivalent function to RFID. In light of these e-pedigree options, Congress should enact the R.F.I.D. Act immediately to require e-pedigrees from manufacturers and wholesalers during drug distribution.

CONCLUSION

Counterfeit drugs are a health and safety threat to U.S. consumers. Counterfeit operations place consumers at risk and fund terrorist organizations. Congress and the FDA have an important interest in safeguarding the U.S. drug supply, and this interest is thwarted by the relative ease of importing counterfeit drugs into the country. In light of this, the safety of the drug supply can only be guaranteed by comprehensively securing domestic drug distribution routes, but the attempts of Congress and the FDA to do this have so far proved inadequate. The PDMA is insufficient in securing drug supply chains because it does not require all drug wholesalers to maintain effective and tamper-proof pedigrees, and a recent court decision has hampered the FDA's ability to enforce the PDMA pedigree provisions in a discriminatory fashion against only some distributors.

Congress needs to amend the PDMA or enact the R.F.I.D. Act to require e-pedigrees from all manufacturers and distributors. Though the R.F.I.D. Act alone cannot eliminate the problem of counterfeit drugs in the United States, the Act offers many benefits over the current PDMA. It addresses the problem of counterfeit drugs in a comprehensive and multi-faceted way and significantly decreases the likelihood that counterfeit drugs will enter legitimate drug distribution routes. Congress should not forestall mandating e-pedigrees: e-pedigree technology, in the form of RFID or barcodes, is immediately available for use. In fact, the FDA already mandates barcodes for other uses, and when barcodes are

117. Witt, *supra* note 111.

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used in conjunction with paper tracking, they can provide a stronger defense to counterfeiters than paper pedigrees alone. RFID is a newer technology that offers added benefits over barcodes, and the industry should continue to move towards broader RFID adoption. RFID costs are decreasing, and privacy concerns with RFID can be readily addressed through the R.F.I.D. Act, making RFID a feasible e-pedigree solution for manufacturers and wholesalers.