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Benchmark Legislation: 
A Measured Approach in the Fight Against Counterfeit Pharmaceuticals

ADAM POWELL*

Pharmaceutical counterfeiting is unique in the field of counterfeiting because criminals only attempt to copy the appearance of a drug, not its actual effect. Because such counterfeit drugs are cheap to make and ineffective or dangerous, counterfeiters see immense profits without regard for the potential for injury or death. Furthermore, the complexity of distribution channels and lax penalties result in little risk for criminals.

One potential tool to address this problem is an electronic pedigree system that would track shipments of drugs and reduce the opportunity for counterfeiters to infiltrate the supply chain. Unfortunately, such a system is years away from being effectively implemented. To compound the problem, soaring drug prices and a dwindling economy have led to calls for free importation from countries that have less expensive drugs. Yet many of those countries have counterfeit problems of their own.

Because of the risk to human life, safety must take priority over efforts to reduce costs. The best solution to pharmaceutical counterfeiting is a single bill that attacks the problem in steps that are implemented when certain objective criteria are met. First, criminal sanctions should be increased to at least match those of illicit drug trafficking. Next, e-pedigree should be implemented when technology advances to the point that it is affordable and reliable. Finally, once safety is assured, the bill should reconsider reimportation plans.

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INTRODUCTION

Counterfeiting has moved beyond unsophisticated attempts to replicate expensive brand-name jewelry or sunglasses; it has become a sophisticated criminal enterprise that poses a global threat to industry profits and health alike. Pharmaceutical counterfeiting is unique because counterfeiters often only attempt to copy the appearance of a drug, not
A MEASURED APPROACH

its actual effects. They do not try to copy the effect because it is much more profitable to copy the drug’s appearance and packaging using whatever materials are available, regardless of their danger. Thus, counterfeit pharmaceuticals often contain the wrong or no active ingredients, or are contaminated by additional toxic chemicals or poor sterilization practices. This creates drugs that are either ineffective at treating disease or cause additional injury. As a result, counterfeiters cause more damage in the realm of pharmaceuticals than in more traditionally counterfeited products. In addition to health concerns, the effect on the pharmaceutical industry is a decrease in profits and brand credibility, which results in a disincentive to research and ultimately cure disease.

Experts have proposed a number of ideas to reduce the amount of counterfeit drugs entering the U.S. market. One of the most discussed options is the electronic pedigree system, which would provide electronic tracking of drug shipments and help address counterfeiters entering the supply chain. Unfortunately, the technology is not yet advanced enough to provide reliable, safe, and affordable implementation. Further complicating the situation, there is political pressure to open up importation of drugs to reduce consumer costs. Opening up importation may reduce prices for consumers, but at the cost of importing counterfeit drugs from other sources. Safety should be the primary concern because of the dangers counterfeiters pose. Accordingly, we should first ensure the safe delivery of genuine pharmaceuticals to consumers. Technology permitting, e-pedigree will further guarantee safety. Then, and only then, should we consider opening up importation to reduce consumer costs.

This Note will address the dangers of pharmaceutical counterfeiting and why current legislation is premature, and will propose legislation

2. See, e.g., Walt Bogdanich & Jane Hooker, From China to Panama, a Trail of Poisoned Medicine, N.Y. TIMES, May 6, 2007, at 1.
6. Id. at 591–97.
that includes benchmark clauses which limit implementation of premature projects until the achievement of certain objective standards. Part I will discuss the dangers of counterfeit drugs, how those drugs make their way into the legitimate market, and why counterfeiting is such a lucrative business. Part II will discuss why current legislation, including the e-pedigree system and bills similar to the Dorgan Bill, is premature. Finally, Part III will discuss why a plan based on objective "benchmarks" is the best way to approach the problem.

I. THE COUNTERFEIT PHARMACEUTICAL CRISIS

In recent years, the pharmaceutical industry has ballooned in size, with sales soaring to $291 billion in 2008, doubling the $145 billion sold in 2000. As a result, the industry has become an increasingly attractive target for criminal enterprises focused on counterfeit drugs. In 2005, the World Health Organization (WHO) estimated that the global market for counterfeit and substandard drugs was worth $35 billion per year. Furthermore, the Center for Medicines in the Public Interest estimated that the counterfeit market might reach $75 billion per year by 2010. WHO authorities estimate that, of the global pharmaceutical industry, more than ten percent of drugs are counterfeit.

A. DANGERS TO HUMAN HEALTH

The WHO defines "pharmaceutical counterfeiting" to include counterfeiting, tampering, and diversion. Under the general "counterfeiting" label, the WHO includes "drugs that are deliberately mislabeled as to identity and/or source; which may contain correct or incorrect ingredients, no active ingredients, insufficient active ingredients, or fake packaging." Tampering "is a criminal manipulation..."
of a pharmaceutical by an unauthorized party,” including manufacturing
drugs that are diluted and sold at higher profits. Finally, diversion is
defined as “the criminal importation and resale of pharmaceuticals
intended for another country,” typically by diverting pharmaceuticals
destined for third-world relief efforts to developed nations at marked-up
prices.

Counterfeiters typically target the most popular drugs such as
antibiotics. However, counterfeit drugs have surfaced in distribution
channels to treat illnesses “including malaria, AIDS, tuberculosis, fungal
infections, bacterial infections, cancer, high cholesterol, erectile
dysfunction, pain, and flu,” in addition to “counterfeit vitamins, steroids,
and hormones.” Counterfeiters thrive in environments with little
regulation, rampant corruption, and/or weak law enforcement. In the
developing world, “counterfeit pharmaceuticals can range up to seventy
percent of the entire drug market.” One disturbing example is the
extent to which glycerin, a syrup used in cough and cold medicine, is
replaced with ethylene glycol or diethylene glycol, which are toxic
ingredients used in antifreeze. Counterfeiters reap vast profits by
replacing glycerin with much cheaper ingredients without regard to the
end result. In Panama, 365 people died as a result of ingesting cough
syrup that contained diethylene glycol. More than 100 children died in
Nigeria and over eighty children died in Haiti after taking similar
medications that were adulterated with poisonous solvents. In 2001, the
Shenzhen Evening News reported that “an estimated 192,000 Chinese
people died in 2001 due to fake pharmaceuticals.”

While most cases of counterfeit pharmaceuticals are reported in
developing nations, counterfeiters have also infiltrated the U.S. market.
In 2004, CooperVision, Inc. announced that counterfeit versions of its

15. Amy M. Bunker, Deadly Dose: Counterfeit Pharmaceuticals, Intellectual Property and Human
16. Id.
17. WHO, Regional Office for the Western Pacific, Counterfeit Drugs (Nov. 2003), http://

www.wpro.who.int/media_centre/fact_sheets/fs_200311_Counterfeit+drugs.htm.
19. Id.
20. Id. at 497.
22. Id.
23. Id.
24. Global Pharma Health Fund 2004, Cruel Reality: Examples of Medicine Counterfeiting,

FOOD & DRUG L.J. 537, 540 (2004); Bogdanich & Hooker, supra note 2.
contact lenses were found in the United States. In 2003, authorities in the United States recalled 130,000 bottles of Lipitor, one of the world's best selling drugs, after discovering at least 30,000 of the bottles were counterfeit.

B. How Do Counterfeit Drugs Enter the Market?

The previous section discussed the dangers of counterfeit pharmaceuticals and the profound effect both internationally and domestically. This portion of the Note discusses the two major sources of counterfeit drugs: the "gray market" and internet pharmacies.

1. The "Gray Market"

Of the pharmaceuticals imported into America, about ninety percent "move from the manufacturer to large wholesalers and then directly to pharmacies." The market is dominated by the big three wholesalers: Amerisource Bergen, Cardinal Health, and McKesson Corporation. However, the secondary "gray market", which is highly vulnerable to counterfeits, represents the other ten percent. The "gray market" represents thousands of interactions between smaller wholesalers and provides the perfect opportunity for criminals to infiltrate the supply chain. Additionally, the "big three" are not immune to counterfeit drugs because they "sometimes buy back drugs from the smaller secondary wholesalers to cover short-term shortages." Additionally, pharmacies and smaller wholesalers often sell bulk product among themselves in cases of excess or impending expiration. Each stop is an opportunity for criminals to infiltrate the supply chain with counterfeits.

The "gray market" causes even more problems abroad, particularly in the European Union, where principals of free movement mandate that "no country within the EU may place legal, legislative, or other barriers preventing trade between members, nor may an owner of a trademark use its rights to prevent repackaging of the medicinal product if the

32. Id.
33. Id. at 288.
34. Id.
repackaging will not adversely affect the original condition of the product."

The result is an immensely complicated distribution chain where drugs can pass between tens or hundreds of parties before reaching the final consumer.

2. Internet Pharmacies

In addition to the “gray market,” U.S. consumers are exposed to counterfeit drugs through less reputable pharmacies, including many internet pharmacies. Experts estimate that internet pharmacies accounted for an estimated $15 to $20 billion in annual sales in 2004. Compounding the problem, eighty-five percent of those websites do not require a prescription. Companies that do not require a prescription to dispense pharmaceuticals will likely have few qualms dispensing dangerous counterfeit versions. While legitimate internet pharmacies pose less of a risk, illegitimate pharmacies exist outside the realm of legislative protection and import drugs to unsuspecting customers. Many of those companies advertise as if they are located in the United States or Canada. However, a study for the FDA found that, of 11,000 sites claiming to be Canadian pharmacies, only 1099 actually sold prescription drugs, and only 214 of those were registered to a Canadian entity. Furthermore, “products that are not earmarked for domestic consumption” in a country are not required to pass those countries’ health and safety laws.


40. Id.; Alonso-Zaldivar, supra note 38.

41. Liang, supra note 29, at 310.

42. See id.
C. Risk and Reward

The previous section of this Note discussed the complicated methods criminals use to ship counterfeit drugs to consumers. This portion discusses why the pharmaceutical industry is such an attractive target to counterfeiters. Drug counterfeiters go to such lengths to infiltrate the supply chain because the industry promises immense profits, little risk of being caught, and low penalties if convicted. Generally, criminals will choose to distribute drugs with the highest pricing ratio—the ratio of the drug’s sale price to the drug’s marginal cost.43 Intriguingly, some assert that this is a result of our intellectual property system itself.44

To recoup research and development costs, patented brand-name drugs are sold at very high pricing ratios.45 While it is impossible to know the average marginal cost of producing brand-name drugs, it is always “a small fraction of the commercial price.”46 For example, in the United States, an annual supply of the anti-HIV medication Trizivir is over $12,000.47 Without the research and development costs for producing brand-name pharmaceuticals, generic companies are able to sell the same drug for less than $200 per year in other countries.48 The result is a “pricing ratio” of at least 60:1 for that particular drug.49 Cocaine, by comparison, has a pricing ratio of 25:1.50 Consider, also, that these prices are for manufacturing a pharmaceutically effective drug.51 Targeting the pharmaceutical industry is even more profitable because most counterfeiters use substandard or ineffective materials that are less expensive.52

Counterfeiting a drug, without infringing a trademark, is punishable by at most three years in prison and often no jail time at all.53 Other countries have similarly weak criminal punishments. For example, in the

43. See id. at 537–38.
45. See Bunker, supra note 15, at 507.
46. Outterson & Smith, supra note 44, at 537.
49. Id. at 538.
50. Id. at 539.
51. Id.
52. Id. at 540.
European Union, Allen Valentine, who was responsible for an immense counterfeit operation throughout Europe and was convicted fourteen times on charges of medication fraud, received a sentence of only five and a half years. In Latin America, illicit substance manufacture and sale is punishable by ten to fifteen years if caught, but production of fake pharmaceuticals results in less than six months of jail time, and often perpetrators are released within days of making bail.

Why would a criminal risk ten to fifteen years in prison for a 25:1 pricing ratio, when they can risk less than six months in prison for a more than 60:1 pricing ratio? They don’t. Because of the great penalties for making illegal drugs, some criminals have shifted production to the much more lucrative, less risky, counterfeit pharmaceutical market. For example, two former convicted cocaine traffickers, Domingo Gonzalez and Julio Cruz, were caught leading a multi-million dollar counterfeit ring responsible for the sale of at least four million cholesterol medicine tablets with sales exceeding $10 million.

II. CURRENT LEGISLATIVE DEBATE

Part I discussed the dangers of counterfeit pharmaceuticals, how they enter the legitimate supply line, and why criminals find the counterfeit drug market so appealing. In addition to counterfeit drug problems, Congress is constantly looking for ways to reduce pharmaceutical prices for consumers. Unfortunately, these two goals often conflict. Part II described two such conflicting proposals being discussed in Congress: the electronic pedigree system and reimportation bills such as the Dorgan Bill. Electronic pedigree systems provide sophisticated tracking devices on drugs or shipments of drugs that theoretically reduce the opportunity for counterfeiters to infiltrate the system. The Dorgan Bill was one of many plans to allow reimportation of drugs from other countries to reduce consumer costs. While the Dorgan Bill was recently defeated, similar bills will surely follow.

55. Liang, supra note 29, at 286 (citing Kerry Capell et al., What’s in That Pill? In Latin America, Fake Drugs Are as Lucrative as Cocaine, BUSINESSWEEK, June 18, 2000, http://www.businessweek.com/magazine/content/01_25/b3737153.htm).
56. Id. at 286–87.
57. Id. at 287.
59. See infra Part II.B.
Unfortunately, these proposals fail to address the dangers of counterfeit pharmaceuticals. Electronic pedigree systems are expensive and unreliable, and the free importation of pharmaceuticals would expose us to additional risks from countries with their own counterfeit problems. With a continually worsening economy and growing prescription drug costs, many look to the free importation of pharmaceuticals as a quick fix. However, until we implement adequate safety measures, we should not even consider importation. Cheaper pharmaceuticals will only help patients if they are safe and effective.

A. OPENING UP IMPORTATION—THE DORGAN BILL

For years, several Senators have attempted to pass a bill that would open up drug importation from other countries with government-controlled prices. The Dorgan Bill was designed with the noble purpose of reducing prescription drug costs, which are often prohibitively high for some consumers. The Bill would have allowed importation from a number of countries, including Japan, Australia, New Zealand, Switzerland, and the European Union. President Obama originally supported drug importation, later agreed not to pursue importing drugs from Canada or Europe, and has finally pledged his support for drug importation, despite the Dorgan Bill’s defeat.

While the Bill provided many local safeguards, it failed to address the fact that many of the importing countries have their own counterfeit drug problems. Studies have suggested that many of the proposed countries in the Bill have significant counterfeit problems. For example, Japan was one of the “top 10 countries where counterfeit drugs were most frequently seized or discovered in 2008.” Furthermore, the WHO estimated that more than twenty percent of the pharmaceuticals in the former Soviet Republic are counterfeit. Many of those counterfeit drug problems are a result of free importation and exportation of pharmaceuticals within those countries. Supporters may argue that the

62. See infra Part II.B.
63. Press Release, Byron Dorgan, supra note 60.
64. See id.
65. Id.
66. Liang, supra note 29, at 299.
68. Id.
69. Taylor, supra note 61.
70. Those countries include Austria, Germany, Belgium, Bulgaria, Denmark, the Czech Republic, Estonia, Latvia, Lithuania, Japan, and the United Kingdom. See Thomas T. Kubic, Dangerous Assumptions Drawn From List of Permitted Countries (July 9, 2009), http://www.safemedicines.org/2009/07/dangerous-assumptions-drawn-from-list-of-permitted-countries.html.
71. Id.
72. Id.
73. See Liang, supra note 29, at 299.
Bill required the imported drug to have a detailed pedigree. However, as discussed below, neither written nor electronic pedigrees are sufficient to protect American consumers because they can be tampered with and they fail to close all the gaps in the supply chain.74

Bills similar to the Dorgan Bill may someday contribute to greatly reducing pharmaceutical costs, but we currently have too many problems with counterfeit drugs to endorse a bill that could add to security concerns without providing any meaningful protection. For now, the legislature should focus on actions that will secure current and future drug distribution channels before rushing into legislation that could put us in the same situation as other countries plagued by drug counterfeiting.

B. "E-PEDIGREE" IS NOT A PANACEA AND WILL ONLY CREATE A FALSE SENSE OF SECURITY

In 1987, Congress implemented the Prescription Drug Marketing Act,75 which required many drugs to have a "pedigree," which is a statement recording all the transactions of a drug throughout the supply line.76 However, such traditional pedigrees are of limited use because they are easily forged.77 As a result, many suggest that an electronic pedigree ("e-pedigree") system is the solution.78 E-pedigree systems track drugs using either a radio frequency identification (RFID) system or barcodes.79

RFID systems typically consist of a reader, a database, and a tag containing a silicon chip and antenna.80 RFID systems can typically read multiple tags at the same time, which allows manufacturers to individually tag smaller quantities, even individual pill bottles, within a larger pallet.81 This is advantageous when compared to traditional pedigree systems, which are limited to tracking large shipments, because it decreases the incentive to substitute counterfeits into the pallet or subdivide the pallet.82 Users can also read the information more quickly than they could with a paper pedigree or even with barcodes that must be scanned individually.83 In addition, some RFID chips are capable of

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74. See discussion infra Part II.B.
76. Ghosh, supra note 5, at 578 & n.1. This section is largely based on Suchira Ghosh’s thorough treatment of e-pedigree proposals.
77. Id. at 578.
78. E.g., id.
79. Id.
80. Id. at 591 (citing Fed. Trade Comm’n, Radio Frequency Identification: Applications and Implications for Consumers 3 (2005)).
81. Id. at 592.
82. Id.
83. Id.
being "written" on, which would allow the information to be updated throughout the distribution process.\textsuperscript{84}

Despite these benefits, an RFID e-pedigree system is not ready to be implemented because the cost is not justified in light of privacy and accuracy concerns. Implementing an RFID system is extremely expensive, even for major companies, as individual tags can cost anywhere from $0.20 to $20, and total costs per manufacturer can range from $9 million to $25 million.\textsuperscript{85} For example, a pilot program for Viagra "cost several million dollars to tag retail packages and cases of the drug."\textsuperscript{86} While the costs may be justifiable to the pharmaceutical companies because they prevent lost sales for high-profit drugs, less frequently used drugs and generic drugs may not be counterfeit often enough to justify the economic cost of the system from a lost-profits perspective.\textsuperscript{87}

Despite the enormous costs, legislation can compel drug companies to use RFID tags. However, Congress should avoid doing so. Increased costs will force drug manufacturers to produce fewer drugs and sell them at a greater price, which will prevent many consumers from receiving the drugs they need. This could drive these consumers straight into the hands of the counterfeiters by forcing them to buy cheaper drugs from more risky sources.\textsuperscript{88} Additionally, the cost to bring drugs to the market is so extreme that there are already few incentives to research treatment for very rare diseases.\textsuperscript{89} Increasing the costs even more by requiring an RFID system for these drugs may prevent life-saving research.

Alternatively, legislation could require RFID tags only for drugs that are very popular or frequently counterfeited. But, how much risk to human life is required before forcing a drug manufacturer to implement a system that could chill research and distribution of the drug? Furthermore, pharmaceutical counterfeiters are sophisticated criminals. They can easily shift production to drugs that do not require RFID tags. In the end, lines would have to constantly be redrawn to alter which drugs require RFID tags. The result is increased costs that will be passed on to consumers, a disincentive to research, and little to no assurance of safety.

Various consumer privacy groups\textsuperscript{90} and government agencies\textsuperscript{91} have stepped forward to question the privacy implications of RFID use. By

\begin{enumerate}
\item \textsuperscript{84} \textit{Id.}
\item \textsuperscript{85} \textit{Id.} at 593–94.
\item \textsuperscript{86} \textit{Id.} at 594.
\item \textsuperscript{87} \textit{Id.}
\item \textsuperscript{88} \textit{See, e.g., discussion supra Part I.B.}
\item \textsuperscript{90} Ghosh, \textit{supra} note 5, at 596 (citing Spychips.com: How RFID Will Compromise Privacy, Security, Freedom, \textit{http://www.spychips.com/} (last visited Jan. 12, 2010); Electronic Privacy
tagging individual pills or bottles, “consumers’ whereabouts, tastes, purchases, and medical information” may be tracked. While these concerns should not be ignored, one simple solution to this particular problem is deactivating the RFID chip after a consumer purchases the drug via a “kill” command.

However, more alarmingly, recent tests indicate that data from RFID chips may not be accurate because the system has a high failure rate and is susceptible to tampering. While the technology has made significant improvements, a study by Cardinal Health found that twenty-seven percent of the RFID tags were unreadable. Supporters of RFID pharmaceutical tracking point to the successful implementation of similar RFID applications ranging from toll payment and passports, to U.S. Postal Service and military shipments. Unfortunately, hackers have demonstrated that many of these systems are susceptible to tampering. For example, the San Francisco Bay Area's “FasTrak” system uses an RFID chip that a security researcher easily read and reprogrammed. Even more disturbing, using a $250 RFID reader and an antenna connected to a laptop, a researcher drove around San Francisco and cloned two U.S. citizens' passports in just twenty minutes. Both of these examples involve misappropriation of and tampering with data stored on RFID tags that are not in possession of a criminal. The process becomes much easier when the criminal is a pharmaceutical counterfeiter who is in the possession of the RFID chips and has the time, resources, and incentive to alter data. This is even more problematic when using RFID chips that can store data because a counterfeiter could adjust the quantity or relabel the concentration on the RFID chip itself.

The other medium for e-pedigree is either one-dimensional or two-dimensional bar codes. The main advantage of using barcodes instead

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92. Id.
93. Id.
95. Ghosh, supra note 5, at 592.
96. Posting of Eliot Phillips to Hack a Day, Black Hat 2008: FasTrack Toll System Completely Broken (Aug. 6 2008, 3:50 pm), http://hackaday.com/2008/08/06/black-hat-2008-fastrak-toll-system-completely-broken/. Nate Lawson is a security researcher who presented a variety of security and technical problems in the FasTrak system at the annual Black Hat Conference. Id. Black Hat is a leading conference focusing on information security. Id.
98. Ghosh, supra note 5, at 597.
of RFID tags is cost. Some assert that one disadvantage is that barcodes are read-only and cannot track the supply chain like a writable RFID tag can. However, barcodes may be advantageous because at least the quantity, quality, and type of drug could be permanently recorded in a database and linked to a bar code.

Overall, the e-pedigree system is a step in the right direction. However, given the problems associated with the technology, it will take more work before the cost of RFID chips is justified. Additionally, e-pedigree systems should not be touted as a panacea. Even if it worked perfectly and cost nothing to implement, it would still not close every gap in the supply chain. For this reason, we should continue to develop e-pedigree systems, but they should not be implemented at this time because they would only give a false sense of security.

III. BENCHMARK LEGISLATION ADDRESSES BOTH IMMEDIATE AND FUTURE NEEDS

The previous Part discussed current legislative debate regarding counterfeit pharmaceuticals and concluded that neither an e-pedigree system nor a bill similar to the Dorgan Bill should be implemented at this time. Part III suggests actions pharmaceutical companies can take to provide immediate relief and proposes a comprehensive bill that would be implemented in phases based on objective criteria to provide long-term relief.

One common theme in current proposals and legislative debate is that everyone is looking for a quick fix. Various bills purport to be the universal panacea. Many tout RFID technology as the holy grail of pharmaceutical safety. The Dorgan Bill was equally intriguing because it sought to reduce pharmaceutical prices, but also claimed to contain the cure to safety concerns. Those concerned primarily with the rising cost of pharmaceuticals cite reimportation as a method of decreasing those costs. However, such plans will expose the market to even more safety risks. E-pedigree enhances safety, but increases costs for manufacturers and wholesalers. The result is a debate about which we should choose: price over safety, or safety over price. If done correctly, however, we will not need to choose at all.

99. Id. at 597–98.
100. Id.
101. See, e.g., Press Release, Byron Dorgan, supra note 60; see also, Ghosh, supra note 5, at 590.
102. See, e.g., Ghosh, supra note 5, at 591–93.
103. See Press Release, Byron Dorgan, supra note 60.
104. See discussion supra Part II.A.
105. See Ghosh, supra note 5, at 593.
The industry needs significant changes that must occur in stages over time. I propose a series of steps that address immediate concerns and provide for additional actions as technology evolves and previous phases take effect. First, pharmaceutical companies should communicate the danger of counterfeits to consumers. They should also place more emphasis on trademark protection, which is a stronger deterrent against counterfeits than patent or copyright. Next, the legislature should pass a comprehensive bill that is implemented in phases based on objective benchmarks. The bill should immediately increase criminal penalties and limit the number of authorized wholesalers. Then, e-pedigree should be implemented when it has passed tests for reliability and efficiency. Finally, the bill will reconsider opening up importation after the earlier stages have taken effect and a corresponding safety benefit is realized.

A. PHARMACEUTICAL COMPANIES PROVIDE THE FIRST LINE OF DEFENSE

Legislation takes a significant amount of time to be implemented. Conversely, pharmaceutical companies have relative free-reign to control marketing and distribution of their products. As a result, the quickest way to reduce pharmaceutical counterfeiting comes from the pharmaceutical industry itself. Pharmaceutical companies should communicate the risk of counterfeits to consumers, stigmatize the counterfeiters, and adequately protect their intellectual property rights. The costs of such programs are justified both by protecting the consumer from dangerous goods and protecting the company's profits and reputation.

1. Communicating the Risk of Ordering Drugs from Internet Pharmacies Will Limit the Number of People Who Order Drugs Online

Counterfeit products are designed to appear, on the surface, to be the same as a legitimate product. When brand recognition is the goal of the consumer, as is often the case for purchasers of expensive purses and sunglasses, the consumer believes he or she is getting a deal by buying a counterfeit. The naïve consumer will assume that all counterfeits work the same way and provide the same benefit. Unfortunately, the naïve consumer may not realize that counterfeit pharmaceuticals are unique and specifically not designed to provide the same effect as the real product.

Few studies have been conducted regarding the attitudes of counterfeit purchasers. One of the few studies to compare counterfeit pharmaceuticals to other types of counterfeits found that consumers decided whether to buy a likely counterfeit product based on factors

107. See Konski, supra note 1, at 3.
108. See id.
inherent to the type of product. For Ray Ban sunglasses, product attributes and shopping environment influenced the purchaser's decision. By contrast, for pharmaceuticals, the potential ill effects of taking the counterfeit drug influenced the decision whether or not to purchase the drug. While this study indicates that consumers are aware of safety when buying pharmaceuticals, the study was conducted on graduate students who were told to assume they knew the product was counterfeit. The situation may be much different for budget-conscious shoppers and people who believe the product might not be counterfeit. Such consumers may be more willing to take a risk if they believe that risk is small and they can save a significant amount of money.

The study further found that stigmatizing counterfeiting also reduced the likelihood that a consumer would purchase a counterfeit. For this reason, highlighting the illegal nature and danger of counterfeit pharmaceuticals may decrease consumers' willingness to buy from risky sources. One such example was when the Heinz Corporation confronted significant counterfeiting of their products in China. Heinz encouraged law enforcement to conduct raids and brought reporters to publicize the event. The campaign was highly successful and eliminated all of Heinz's serious counterfeiting problems.

In these challenging economic times, consumers will do whatever they can to cut costs, and for many that includes turning to internet pharmacies for their prescription drugs. While some propose shutting down nearly all internet pharmacies, doing so would be impractical. However, communicating risks to consumers is entirely within the

110. Id. (citing Birgit Leisen & Alexander Nill, Combating Product Counterfeiting: An Investigation into the Likely Effectiveness of a Demand-Oriented Approach, 12 Marketing Theory & Applications 271, 275 (2001)). Subjects were to imagine they were shopping in a store in Mexico and had been told by a reliable source that the store only sold counterfeit products. Id. at 391 n.29. The subjects were asked about their willingness to purchase Ray Ban sunglasses, Rolex watches, and a small white bottle with a red cap and a TYLENOL label that cost one dollar. Id.
111. Id. at 391.
112. Id. at 391 & n.29.
113. "Education level correlates positively with the purchase of counterfeit literature and software, but negatively with the purchase of fashion-related items such as leather products and watches." Id. at 394 (citing Chow-Hou Wee et al., Non-Price Determinants of Intention to Purchase Counterfeit Goods, 12 Int'l Marketing Rev. 19, 39-40 (1995)).
114. Id. (citing Wee et al., supra note 113, at 40).
115. Id. at 396-98.
116. Id. at 403-04.
117. Id. (citing John Donaldson & Rebecca Weiner, Swashbuckling the Pirates: A Communications-Based Approach to IPR Protection in China, in Chinese Intellectual Property Law and Practice 403, 426 (1999)).
118. Id. at 404.
119. See, e.g., Liang, supra note 106, at 370.
pharmaceutical industry's control. By educating consumers about the dangers of counterfeit pharmaceuticals, pharmaceutical companies may be able to convince consumers to purchase drugs from a more reliable source.

Professor Bryan Liang advocates for a broad federal statute that will provide a no-cost or low-cost drug program, registered wholesalers, a prohibition on internet pharmacies, public education, and enhanced criminal penalties. One of his central arguments is that the most vulnerable consumers are those with low income looking to cut prices, and that by providing a no-cost or low-cost drug program, those consumers will be less likely to buy drugs from high-risk sources. While Professor Liang's proposal sounds good on paper, it would require too much time and expense to implement. Additionally, it assumes that the myriad internet pharmacies can be shut down. In essence, Professor Liang's premise is the same as mine—low income consumers looking to cut costs are the most vulnerable and likely to order drugs from high-risk sources—but his proposal is more bloated than necessary. While arguably not as effective as Professor Liang's proposal, pharmaceutical companies have the potential to immediately decrease the number of consumers willing to order from high-risk sources such as internet pharmacies.

2. **Properly Protecting Traditional Intellectual Property Rights Will Provide Stiffer Penalties and Greater Deterrence**

Traditionally, the first line of defense for pharmaceutical companies is a portfolio of strong intellectual property rights. Much of the legislation and criminal sanctions discussed below depend on pharmaceutical companies adequately protecting their intellectual property. This provides the company with private redress as well as the ability to fully utilize government aid and criminal prosecution. Some forms of intellectual property are uniquely suited for preventing counterfeit drugs from entering the market.

Antoinette Konski, an expert in global intellectual property protection, asserts that, while patents are considered the first line of defense, they are actually less practical at enforcing rights against counterfeiters than other types of intellectual property protection. Patent protection rewards innovation and generally grants the patent holder a right to exclude others from manufacturing, using, importing, selling, or offering for sale an exact or close copy of a patented technology. However, patent protection is relatively ineffective for

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120. *Id.*
121. *Id.* at 374.
patented drugs because counterfeiters do not copy the active ingredient and usually replace it with a cheaper ingredient. Additionally, generic drug manufacturers, who often manufacture drugs after the patent term expires, have no recourse through the patent system.

By contrast, trademarks seek to protect exactly what counterfeiters target: brand recognition. For this reason, Konski argues that trademark protection is the most valuable type of intellectual property that can be used to combat counterfeiting. A pharmaceutical company may obtain a trademark on the color or shape of pills as well as brand names, designs, and symbols. This allows pharmaceutical manufacturers, including generic drug companies, to register and protect all unique aspects of their products. In contrast to most patent lawsuits, in many countries the trademark owner can have counterfeit goods, documents, and equipment immediately seized after bringing suit. Furthermore, if a person knowingly infringes a trademark in the process of trafficking counterfeit drugs, criminal sanctions are increased from a maximum of three years in prison to a maximum of ten years in prison. In addition, obtaining and enforcing trademark rights is typically much less costly and time-consuming than patent prosecution and infringement actions. This unique combination makes trademarks particularly well suited as a first line of defense for drug manufacturers.

Copyrights only protect works of authorship such as literary, musical, dramatic, pictorial, graphic, sculptural, cinematic, and architectural works. As a result, only package inserts may be protected and are of little use in preventing the drug from reaching the public. In the world of counterfeit drugs, that amounts to virtually no protection. Thus, in addition to educating customers, pharmaceutical companies can best protect their intellectual property and ensure maximum punishments for criminals by maintaining strong trademarks.

B. Using Objective Criteria to Create a Multi-Step Legislative Solution

The previous section discussed why pharmaceutical companies are more capable than Congress of providing immediate relief from the threat of counterfeit drugs. However, the benefits provided by the
pharmaceutical industry are limited, and the bulk of relief must occur at the legislative level. This section proposes a comprehensive bill designed to attack counterfeiters systematically, in stages, as technology advances and the pharmaceutical supply line is secured.

Legislators are inclined to act, but proper care must be taken to ensure that those actions do not cause more harm than good. Ideas without action do nothing to solve a problem and only confuse the issue. However, implementing programs that are not ready have the potential to waste time and money, as well as actually cause harm. As discussed above, implementing an e-pedigree system will essentially waste money and implementing legislation similar to the Dorgan Bill has the potential to cause greater harm.

As discussed above, legislation should not consider reimportation until adequate safety measures have been implemented. Unfortunately, e-pedigree is not currently ready to be implemented and at this point may overcomplicate the system. For these reasons, legislation should be implemented which sets goals that must be reached before taking the next step in the fight against counterfeiters. This approach ensures that legislation is not implemented prematurely.

The goal of such legislation has both judicial and regulatory prongs. The judicial prong involves effective deterrence through criminal penalties. However, because of the difficulties in apprehending pharmaceutical counterfeiters, it is questionable whether increased criminal sanctions will have any effect. From the regulatory perspective, the goal is to package and ship pharmaceuticals in a way that prevents criminals from importing counterfeits into the country. In this respect, limiting the number of wholesalers authorized to import pharmaceuticals into the United States will result in an immediate benefit, and, when the technology is ready, the e-pedigree system will provide additional help. Such a comprehensive bill would provide immediate relief, assure future benefits as technology advances, and prevent harm from premature implementation of programs that are not ready. The individual portions of the bill are discussed below in turn.

I. Legislation Should Occur Primarily at the Federal Level

Whether fake pharmaceuticals should be addressed at the state or federal level is open to serious debate. In many situations, federal control may be preferred because it provides a universal standard that can be relied upon by manufacturers and distributors. Because counterfeiting is a national problem originating out of counterfeits that are imported from
sanctions should include life imprisonment, forfeiture of all assets, and treble damages or, at a minimum, should match those of illicit drugs. Others argue that criminal punishment should only apply to those who endanger the lives of others in order to profit by counterfeiting. In this way, resources would not be wasted prosecuting less dangerous counterfeiters.

Taking away a tool of law enforcement with the hope that enforcement will be directed to more dangerous counterfeiting may not be the best solution. A better solution is to leave current counterfeit statutes in place, add additional statutory penalties for dangerous counterfeiting, and work with law enforcement to ensure that dangerous counterfeiting is given a higher priority. Given that criminal counterfeiters are killing innocent people, often children, I would advocate for extremely severe penalties. However, the degree of criminal punishment relevant to the crime is a debate that is outside the scope of this Note and better addressed by experts in the field of criminal justice. To send an adequate deterrent message, however, penalties should at least mirror the penalties for distributing illicit drugs, such as cocaine, in order to prevent illicit drug dealers from moving to the less risky business of pharmaceutical counterfeiting.

While increasing criminal penalties will hopefully have some deterrent effect, it may be ineffective because the possibility of being caught is still relatively low. Accordingly, it may be prudent to include a provision that calls for the re-evaluation of increased criminal penalties at a later date to determine if such increases have actually been effective. If Congress determines that increased prosecutorial efforts are proving futile, those resources can be redirected to an area where more benefit will be realized.

3. Immediate Regulatory Relief: Limiting the Number of Wholesalers

The “gray market” creates extensive holes in the supply chain that allow criminals to infiltrate the chain. It is easy to infiltrate the supply chain because, while three large companies control ninety percent of the wholesaling market, the other ten percent is controlled by a large
number of small wholesalers. Professor Liang suggests that one way to exercise control is to prohibit unregistered wholesalers. Unfortunately, current state policies are not discriminating enough and a number of convicted felons were able to obtain state licenses to distribute medicine, which they used to sell counterfeit drugs. The requirements should go one step further and limit the number of licenses to an amount that can be adequately controlled and policed, even if that limits wholesalers to "the big three" for the time being. While this raises concerns of a quasi-monopoly between three companies, our first priority should be safeguarding a drug supply line that is currently peppered with security risks that seriously injure or kill people daily.

Implementing stricter requirements for wholesalers may have the immediate impact of severely limiting the number of wholesalers in order to adequately control the supply line. Such a restriction is justified presently because of the immediate health threat. However, when extra safety measures are implemented to control the supply chain, limiting the number of competitors will be unnecessary and it will drive prices up. For this reason, this portion of the legislation should have a sunset clause to limit or eventually eliminate the restrictions over time as other safety measures are implemented.

4. The Next Step: E-Pedigree

As previously discussed, the e-pedigree system is not currently ready to be implemented. Concerns over cost, safety, and security prevent the system from being beneficial in the near future. However, the idea is sound and should be implemented when technology has increased to a point where it can be reliably implemented at an affordable cost. The above actions by pharmaceutical companies and proposed legislation would reduce the immediate threat and, when e-pedigree is truly ready, counterfeiting may be eliminated at least in the U.S. market.

Previous bills have set arbitrary timelines for when the system should be implemented. While these concrete deadlines may be comforting to some, they may force action when the system is not ready, unnecessarily driving up costs without providing any tangible benefit. For that reason, the proposed bill should include limitations that the e-

151. See discussion supra Part I.B.1.
152. Liang, supra note 106, at 370.
153. See Bob LaMendola & Sally Kestin, Former Convicts Try a Safer Venture: Pharmaceuticals, SUN SENTINEL (Florida), May 26, 2003, at 1A (noting numerous cases of convicted felons who obtained state licenses to distribute medications and subsequently sold counterfeit drugs).
154. See discussion supra Part II.B.
155. Ghosh, supra note 5, at 591.
156. See discussion supra Part II.B.
pedigree system will be implemented only after the system achieves reliability and affordability standards set by the FDA.

5. **Finally, Savings Without Sacrificing Safety**

Legislation similar to the Dorgan Bill has the potential to provide real cost savings to consumers. The bill could allow consumers to import drugs from other countries that have cheaper prices as a result of foreign government price controls and free trade. Unfortunately, because of the current security holes in the pharmaceutical chain, implementing such a bill now would force us to choose consumer savings at the expense of further counterfeiting problems and the health risks associated with counterfeiting. Accordingly, the legislation should include provisions to reconsider re-importation plans after the above portions of the Bill have gone into effect and have provided a corresponding safety benefit.

**Conclusion**

This Note has outlined the dangers of counterfeit pharmaceuticals and why current legislative proposals will fail. Instead, I propose a new plan of attack against counterfeiters to reduce the real, tangible risk to anyone who consumes pharmaceuticals. The proposal includes immediate efforts by the pharmaceutical industry and comprehensive legislation that is implemented in several stages based on objective benchmarks. The goal is to provide immediate relief and, eventually, the panacea everyone is searching for.

By creating such "benchmark" legislation, the immediate concerns can be addressed quickly while allowing time for more all-encompassing solutions to develop. Critics may claim this proposal is only putting a bandage on the problem, in hope of curing it at a later date when technology advances. That is true. But when it comes to medicine, it is better to take some positive steps than to continue to gamble with this country's medical supplies while scholars debate the finer points of panaceas.

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157. *See supra* note 106 and accompanying text.
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