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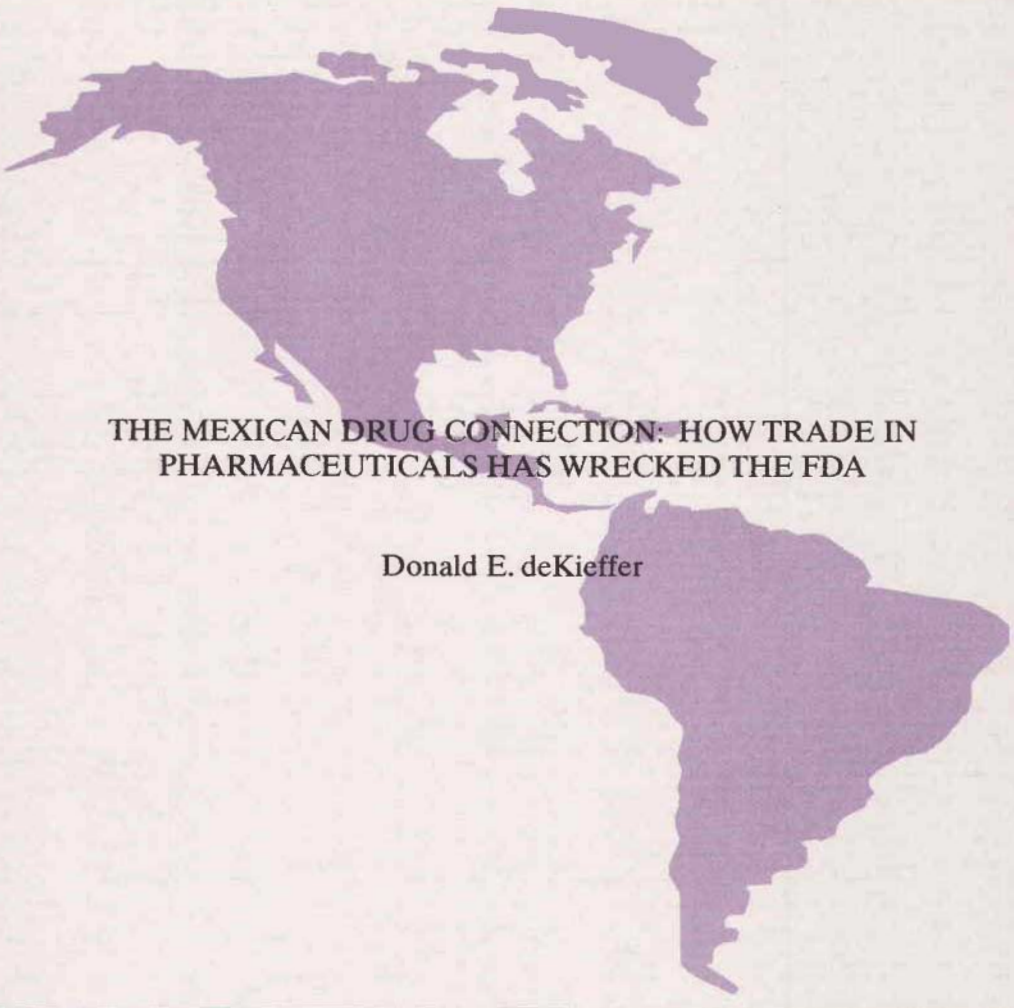

THE MEXICAN DRUG CONNECTION: HOW TRADE IN PHARMACEUTICALS HAS WRECKED THE FDA

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I. INTRODUCTION

When most people think about drugs crossing the United States border from Mexico, they presume that the drugs consist of contraband marijuana, cocaine, or other illicit drugs.[1] While this is a significant problem, an equally vexatious issue is rarely discussed: illegal imports of prescription drugs. The true extent of Mexican drug exports into the United States is not known since many of the transfers are not declared, and thus not recorded in either U.S. or Mexican trade statistics.[2] American tourists regularly visit Mexican border towns to purchase pharmaceuticals at much lower prices than in the U.S., and are not required to declare such personal use

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1. *See* U.S. Drug Enforcement Admin., *Drug Trafficking in the U.S., at* http://www.dea.gov/concern/drug_trafficking.html (last visited Mar. 18, 2003).

2. Kristin E. McKeithan & Marvin D. Shepherd, *Pharmaceutical Products Declared by U.S. Residents On Returning to the U.S. from Mex.*, 18 Clinical Therapeutics No. 6, at 1242-51 (1996).

purchases under U.S. law.[3]

More ominously, drug "brokers" on both sides of the border buy large quantities of drugs from Mexican *Farmacias*, and bring them into the United States with impunity.[4] Most of these drugs are then sold in the "black" and "gray" markets in the U.S.[5] The volume of undocumented prescription drug imports from Mexico, combined with the increasing ability of to purchase prescription medications via the Internet[6] have severely damaged the regulatory regime of the Food and Drug Administration ("FDA").

There are approximately ten times as many pharmacies in Tijuana, Mexico than there are in San Diego, California,[7] two metropolitan cities of roughly equal population.[8] Notably, a disproportionate number of pharmacies between these two cities do

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3. Office of Regulatory Affairs, U.S. Food and Drug Administration, *Regulatory Procedures Manual, Ch. 9: Subchapter Coverage of Personal Importations, at* http://www.fda.gov/ora/compliance_ref/rpm_new2/ch9pers.html (last visited Mar. 18, 2003) [hereinafter Regulatory Procedures Manual].

4. Jen McCaffery, *7 Plead Guilty in OxyContin Ring,* ROANOKE TIMES & WORLD NEWS, Sept. 2, 2001, at B4.

5. *See* David Rosenzwieg, *17 Indicted in Sale of Bootlegged Medications; Courts: U.S. Authorities Launch Crackdown on Back-Door Clinics, Stores Selling Illegal Prescriptions in Immigrant Neighborhoods. Two Children Have Died in Related Cases,* L.A. TIMES, Dec. 6, 2000, at B1 ("Illicit mediations are typically smuggled across the border from Mexico, where drugs that require a doctor's prescription in the United States are often sold on the open market."); *see also* David Peirson, *2 Arrested in Probe of Illegal Pharmacies; Inquiry: Willimington Man and Santa Ana Woman Are Accused of Selling Illegal Medicine,* L.A. TIMES, Mar. 10, 2001, at B10; Penni Crabtree, *Bad Medicine: Legal Loopholes, Poor Oversight and Pricing Practices Give Rise to "Gray Market" that Encourages Counterfeit Prescription Drugs,* THE SAN DIEGO UNION & TRIB., Aug. 5, 2001, at H1.

6. John Henkel, *Buying Drugs Online: It's Convenient and Private, But Beware of Rogue Sites,* FDA CONSUMER, Jan-Feb. 2000, at 24, 25-27, *available at* http://www.fda.gov/fdac/features/2000/100_online.html (last visited Mar. 18, 2003); *see also* Sana Siwolop, *Buying Your Pills Online May Save You Money, But Who's Selling Them,* N.Y. TIMES, Sept. 29, 2002, § 3, at 10. A search conducted on the National Associations of Board of Pharmacy's (NABP) website, located at http://www.nabp.net, indicated that there are 13 online pharmacies certified by the NABP's Verified Internet Pharmacy Practice Sites program (last visited Mar. 18, 2003). The FDA estimates that there are some 1000 Internet pharmacies. *See* http://www.fda.gov/oc/buyonline/fags.html (last visited Mar. 18, 2003).

7. John A. MacDonald, *Fake Drugs Color Debate on Imports: Congress Ponders Risks of Bringing Medicines Across the Border,* THE HARTFORD COURANT, Aug. 21, 2002, at A1 ("More than 1,400 'farmacias' operate in the Mexican border town of Tijuana. . . . By contrast, there are about 100 pharmacies in nearby San Diego, Calif.").

8. Paul Ganster, *Tijuana, Basic Information, at* http://www-rohan.sdsu.edu/~irsc/tjreport/tj1.html (last visited Mar. 18, 2003). Paul Ganster is the Director of the Institute for Regional Studies of the Californias at San Diego State University.

not exist because Mexican nationals are more prone to illness than U.S. nationals; rather, this discrepancy exists because many U.S. citizens are looking for prescription drugs that cost much less than those in the United States.

Significantly, the great imbalance of pharmacies is repeated in almost every Mexican border city.[9] Mexican *Farmacias* offer a vast array of products, including almost all U.S.-approved drugs, and many other drugs which are not U.S.-approved.[10] Prices can range from ten to fifty percent cheaper than those sold only a few miles away in the United States.[11] Busloads of seniors regularly travel to Mexico to purchase drugs without prescriptions from Mexican outlets.[12] Hundreds of others visit Mexico to purchase commercial quantities of drugs.[13] Whether for personal use or illicit re-sale, this cross-border trade undermines the FDA regulatory regime.

II. THE FDA FEDERAL REGULATORY STRUCTURE

FDA regulations regarding the manufacturing and dispensing of drugs cost billions in compliance and enforcement.[14] The FDA

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9. Valdez Avelardo and Sifaneck Stephen, *Drug Tourists and Drug Policy On the U.S.-Mexican Border: An Ethnographic Investigation of the Acquisition of Prescription Drugs*, 27 J. DRUG ISS. 876, 879-97 (1997). This article is probably the best in documenting the number of farmacis in Nuevo Lareda and the their increased use by U.S. residents. It mentions that there are about 20 farmacias within walking distance from the U.S. 90% of their business is the U.S. drug tourist; *see also* Gibbs Lisa, *Drug Trips*, 30 MONEY 117, 118-28 (2001). In this article it documents that there are 39 farmacias in a ten block area in Tijuana which market to "drug tourists." It also documents the increase in volume of drug buyers and growth of clinics across the border; *see also* Stoneham Laurie, *The Southern Exodus: Is Seeking Health Care South of the Border a Health Practice?*, 96 TEX. MED. 46, 48-52 (2000). This articles mentions "the dozens of other drugstores that now dot the Mexico-Texas border and cater to American Tourists. Specifically the article addresses the problem in Matamoros, Mexico, across the border from Brownsville Tx. This article also documents the number of "drug tourists".

10. *Continuing Concerns Over Imported Pharmaceuticals, 2001: Hearing Before the Subcomm. on Oversight and Investigations of the Comm. on Energy and Commerce*, 107th Cong. 58 (2001) (statement of Marven Sheperd, Professor, University of Texas), *available at* http://energycommerce.house.gov/107/hearings/06072001/hearing267s.htm [hereinafter Continuing Concerns Over Imported Pharmaceuticals]; *see also* Natalie Singer, *Run for the Border: Seniors Hunt Prescription Price Breaks in Mex.*, THE DESERT SUN (Palm Springs, CA), Sept. 15, 2002, at A1 [hereinafter Singer].

11. Tim Weiner, *In Tijuana, A New Kind of Drug Peril*, N.Y. TIMES, Aug. 14, 2001, at A7.

12. Singer, *supra* note 10.

13. Continuing Concerns over Imported Pharmaceuticals, *supra* note 10, at 58 (testimony of Landon S. Gibbs, First Sergeant, Virginia State Police).

14. The FDA's proposed budget for fiscal year 2004 is $1.7 billion, *see* Office of Public

regulates every step of the manufacturing and marketing of prescription drugs. If a pharmaceutical company develops a compound to treat a medical symptom, it must comply with an elaborate and expensive approval process, which can take years to complete.[15]

After a drug has been approved, the manufacturer must undergo rigorous qualification testing and inspections before and during the course of its production.[16] There are elaborate standards for purchases of raw materials, manufacturing practices, labeling, and security.[17] After the drugs leave the manufacturer, they continue to be regulated by complex, often duplicative rules of the FDA and the states.[18] Doctors prescribing and pharmacists filling prescriptions are also subject to extreme scrutiny.[19] To be sure, this system was

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Affairs, U.S. Food and Drug Administration, *FDA Talk Paper: FDA's Budget Proposal for FY 2004, at* http://www.fda/gov/bbs/topics/ANSWERS/2002/ANS01195.html (Feb. 3, 2002). The agency's budget for the fiscal year 2003 is $1.39 billion, representing an increase of $16 million over fiscal year 2002. *House Panel Approves FDA Budget,* Wash. Drug Letter, July 15, 2002, *available at* http://www.fdanews.com/pub/wdl/34_28/fda/6062-1.html (last visited Mar. 18, 2003).

15. U.S. Food and Drug Administration, *Just the Facts: FDA and the Drug Development Process: How the Agency Ensures that Drugs are Safe and Effective (2002), available at* http://www.fda.gov/opacom/factsheets/justthefacts/17drgdev.pdf (Feb. 2002). ("Today, the process of brining a drug to a patient's bedside takes an average of 8.5 years, costs about $500 million, and includes a rigorous review by the Food and Drug Administration.").

16. *See generally* U.S. Food and Drug Administration, *The CIDER Handbook,* at 3-28, 41-67 (1998), *available at* http://www.fda.gov/cder/handbook/.

17. *See* Food and Drugs, 21 C.F.R. §§ 820.20, 820.50, 820.120 (2002).

18. *Drugstores on the Net: The Benefits and Risks of On-Line Pharmacies: Hearing Before the Subcomm. on Oversight and Investigations of the House Comm. on Commerce,* 106th Cong. 93-102 (1999) (testimony of Janet Woodcock, M.D., Director, Center For Drug Evaluation and Research), *available at* http://www.fda.gov/ola/drugsonline.htm, (last visited Mar. 23, 2003); *see also* Country-of-Origin-Labeling, *available at* http://www.gmabrands.com/publicpolicy/docs/whitepaper.cfm?DocID=389 (last visited Mar. 23, 2003) ("Country-of-origin labels are burdensome [and] duplicative. . . ."); *see also* Letter from Deborah R. White, Regulatory Counsel, Food Marketing Institute to Food and Drug Administration (Nov. 20, 2000), *available at* http:www.fmi.org/gr/comments/report.cfm?issueID=281 (last visited Mar. 23, 2003) (Enclosure of testimony of Ty Kelley regarding PDMA Implementation Regulations, 21 CFR Parts 203, 205; Docket No. 92N-0297. ("To the extent that drug wholesalers are already required by FDA to maintain extensive records of all transactions, which are subject to inspection by FDA and by State Boards of Pharmacy, we see a pedigree requirement as unnecessary and duplicative.")).

19. *See* Lisa Richardson & Charles Ornstein, *Out-of-State Doctors Fined by California: Board Levies $48 Million in Penalties for On-Line Prescribing,* L.A. TIMES, Feb. 12, 2003, at B6; Tom Corwin & Sandy Hodson, *Judge Jails Doctor in Fraud Case Man Who Illegally Prescribed Oxycontin, Gets 41 Months,* THE AUGUSTA CHRON., Feb. 5,

designed to protect the safety and health of consumers. By definition, prescription drugs can be dangerous if misused. For all its complexity and expense, the regulatory system has largely accomplished its goal for a half-century. The United States has enjoyed one of the safest records in the world, while at the same time providing abundant, effective, and accessible medicine to those in need. That admirable record is now under attack.

Despite the fact that the FDA employs thousands of bureaucrats,[20] the FDA itself even acknowledges that it cannot enforce its own rules.[21] The FDA and state Pharmacy Boards regularly penalize doctors and pharmacies for violating their injunctions,[22] but routinely ignore the thriving and growing "black" and "gray" markets, which may soon rival the "legitimate" prescription market.[23]

III. THE DIVERSION/COUNTERFEIT PROBLEM

The most glaring weakness in the traditional U.S. prescription drug distribution process is cost. Drug manufacturers and consumers must bear the extraordinary burden of the regulatory regime. Prescription drugs cost more in the United States than in most other countries in the world.[24] Of course, part of this cost is for the development of innovative technology.[25] However, the distribution

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2003, at B1.

20. Marc Kaufman, *FDA Nominee Sails Through Senate Hearing,* THE WASH. POST, Oct. 8, 2002, at A23 ("FDA employs about 10,000 people.").

21. *See* Susan J. Landers, *Return to Sender: FDA Takes on Issue of Imported Drugs,* AM. MED. NEWS, June 27, 2001, at 1, 4, *available at* http://www.ama-assn.org/sci-pubs/amnews/pick_01/hlsa0625.htm (last visited Mar. 18, 2003) [hereinafter FDA Takes on Issue of Imported Drugs]; *see also* Robert Pear, *Panel Calls Federal Drug Agency Unable to Cope with Rising Tasks,* N.Y. TIMES, Apr. 11, 1991, at A1.

22. *See* Robert Pear, *Investigators Find Repeated Deception in Ads for Drugs,* N.Y. TIMES, Dec. 4, 2002, at A22.

23. *See* Naomi Aoki, *Biotechnology, Real Fears Over Phony Drugs: U.S. Health Officials View Spate of Recent Cases as Evidence of Rising Trend,* THE BOSTON GLOBE, May 29, 2002, at C1 [hereinafter Aoki].

24. Larry D. Sasich, *Report on the International Comparison of Prices of Antidepressant and Antipsychotic Drugs,* Health Research Group Publication (July 15, 1998), *at* http://www.citizen.org/publications/release.cfm?ID=6642. Larry D. Sasich, Pharm. D., M.P.H., FASHP, is a pharmacist and a consumer advocate with the Public Citizen Health and Research Group.

25. Continuing Concerns Over Imported Pharmaceuticals, *supra* note 10, at 157-59 (statement of James Christian, Vice President and Head of Corporate Security Novartis International); *see also* THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA, WHY DO PRESCRIPTION DRUGS COST SO MUCH... ?...AND OTHER

and manufacturing controls on prescription medications in the U.S. account for a significant percentage of the final cost of the drugs.[26]

The actual manufacturing cost of most prescription drugs is a small fraction of its ultimate price. A single dose of Viagra, for example, costs Pfizer less than ten cents to manufacture, but sells for more than $5.00 wholesale. Many drugs that are exported vary in prices tremendously, often dependant on foreign government controls.[27] In some countries, patent protections are not available, or more accurately stated ignored, in favor of receiving cheap generic substitutes at the earliest possible date.[28] Faced with this threat, American drug companies routinely discount pharmaceuticals to selected markets to compete with counterfeit drugs.[29] This multi-tiered pricing scheme is a magnet for arbitrage. Buyers routinely purchase cheap drugs in a low-priced market and attempt to sell them in the U.S. at much higher prices (albeit below the manufacturers U.S. wholesale price).[30]

This practice has been illegal in the U.S. for many years. The Prescription Drug Marketing Act ("PDMA") prohibits any party, other than the manufacturer or its designee, from re-importing drugs.[31] This law, however, has effectively collapsed due to the huge

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QUESTIONS ABOUT YOUR MEDICINES 2 (2000), *available at* http://www.phrma.org/publications/publications/brochure/questions\questions.pdf [hereinafter Pharmaceutical Research and Manufacturers of America].

26. *See* Pharmaceutical Research and Manufacturers of America, *supra* note 25, at 2.

27. Phil Galewitz, *Drugmakers Aim to Get Word Out About Discount Programs*, THE PALM BEACH POST, Nov. 13, 2002, at B7 ("Because Canada has price controls, drugs there often cost 60 percent less than they do in the United States."); *see also* Wes Allison, *Prescription for Drug Prices: Canada?*, ST. PETERSBURG TIMES, Jan. 7, 2002, at A1.

28. *See* Sabin Russell, *New Crusade to Lower AIDS Drugs Costs: Africa's Needs at Odds with Firms' Profit Motive*, S.F. CHRON., May 24, 1999, at A1 ("South Africa[s]... recently enacted law would override pharmaceutical company patents and allow 'gray market' imports of cheap drugs... [the] law would let the country pursue the lowest cost drugs on the world market.") [hereinafter Russell]; Peter S. Goodman, *In China, AIDS Crisis Is at the Mercy of Global Commerce*, THE WASH. POST, Dec. 5, 2002, at A1. ("India produces generic copies of Western AIDS drugs on a massive scale, but it has no patent law. Thailand, South Africa and Brazil... have all wielded the threat of violating patents to force sharp reductions in price from drug companies.").

29. Russell, *supra* note 28, at A1 ("Prescription drug prices vary dramatically from country to country, based on deals cut by the manufacturer.").

30. *See* Continuing Concerns Over Imported Pharmaceuticals, *supra* note 10, at 58-61 (statement of Landon S. Gibbs, First Sergeant, Virginia State Police).

31. The Prescription Drug Marketing Act of 1987, 21 U.S.C.A. §§ 331, 333, 353, 381 (West 1999 & Supp. 2003) (amending the Federal Food, Drug, and Cosmetic Act, ch. 675, 52 stat. 1040 (1938) (codified as amended at 21 U.S.C.A. §§ 301 – 397 (West 1999 & Supp. 2003))).

profits to be made in the "gray market" and the failure of effective enforcement. The evasion of the PDMA has opened a "diversion pipeline" of low-cost, legitimate drugs back into the United States. Indeed, the less obvious effect is that it has created a channel for counterfeit, ineffective drugs to enter North America.[32]

Since the re-importation of prescription drugs is generally illegal, persons in this illicit business are prone to substituting counterfeits for the "legitimate" drugs. Why pay the low export prices offered by the drug companies when a counterfeit substitute is available for one-tenth the cost?[33]

IV. THE DESTRUCTION OF THE FDA REGULATORY SYSTEM

The flood of "gray market" imports into the United States operates outside of the usual regulatory channels. Even more troublesome, some "gray market" drugs have found their way back into the legitimate distribution chain. This occurs when drug wholesaler/distributors purchase "odd lots" from brokers rather than manufacturers. As previously mentioned, "gray market" drugs are often "salted" with counterfeits, which is the primary reason there has been rash of counterfeit drugs emerging in legitimate pharmacies across the United States.[34]

"Gray market" pharmaceuticals, especially from Mexico, are also a large cause of drug abuse in the United States.[35] Oxycontin, for example, is imported in bulk from *Farmacias* and sold in the hills of Appalachia has resulted in hundreds of deaths.[36]

The FDA regulatory structure assumes that almost every person

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32. *See* Melody Peterson, *3 Fake Drugs Are Found in Pharmacies*, N.Y. TIMES, June 5, 2001, at C1; *see also* William H. Rastetter, *Pharmaceuticals from Abroad: A Looming Threat to U.S. Consumers*, THE SAN DIEGO UNION & TRIB., Jan. 2, 2002, at B7.

33. *See* Aoki, *supra* note 23, at C1.

> Counterfeiting is a white-collar crime with lesser penalties than those carried by trafficking of illegal drugs.... Despite the seriousness of the problem and the potential for harm... counterfeit pharmaceuticals... doesn't rise to the top of the agenda for most law enforcement agencies.... Criminals know this... and they're choosing to shift to diverting and counterfeiting prescription drugs.

Aoki, *supra* note 23, at C1.

34. *See* Susan J. Landers, *Pharmaceutical Fakes, Knockoffs A Growing Problem*, AM. MED. NEWS, Nov. 26, 2001, at 22, 23, *available at* http://www.ama-assn.org/sci-pubs/amnews/pick_01/hlsb1126.htm (Nov. 26, 2001).

35. *See* Continuing Concerns Over Imported Pharmaceuticals, *supra* note 10, at 166-71 (statement of Gene R. Haislip).

36. Domestic Strategic Intelligence Unit, Office of Domestic Intelligence, *Drug Intelligence Brief, Oxycontin: Pharmaceutical Diversion* (March 2002), *at* http://www.usdoj.gov:80/dea/pubs/intel/02017/02017.html.

involved in the hierarchical structure will comply with its regulations. After all, most drug manufacturers, distributors, doctors, and pharmacists have plenty to lose if they violate the law.[37] The regulations did not anticipate, however, that rogue traders would simply thumb their noses at the law since they have little at stake.[38] Moreover, the press has responded favorably to "gray market" dealers. These dealers have been suddenly transformed into Robin Hoods that provide cheap medicine, only fleecing rapacious drug companies, not consumers.[39] Also, many members of Congress have even been deceived by this scam.[40]

However, to the extent that the FDA regulations are designed to protect the safety of consumers, this protection is becoming illusory. The FDA's Office of Criminal Investigations ("FDA/OCI") is a small organization.[41] FDA/OCI is responsible for enforcing the PDMA and approximately a dozen other laws.[42] The FDA/OCI is dwarfed inside

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37. For example, the Generic Drug Enforcement Act of 1992 imposes a $1 million fine per company and $250,000 fine per individual and may be subject to debarment of 1 to 10 years if found guilty of fraud, bribery or misconduct. Generic Drug Enforcement Act of 1992 §§ 3, 21, U.S.C. § 335b (2000) (amending the Federal Food, Drug, and Cosmetic Act, Pub. L. 102-282, 106 Stat. 149 (1992)).

38. *See* Aoki, *supra* note 23, at C1.

39. *See* George Sjostrom, *International Drug Smuggling with a Good Purpose*, VENTURA COUNTY STAR, Nov. 9, 2002, at B13; *see also* Catherine Saillant, *Retiree Has Remedy for High Drug Costs: Ventura County Woman Uses the Internet to Help Seniors Find Cheaper Medicine in Canada*, L.A. TIMES, Jan. 19, 2003, at B1, B8.

40. Steven A. Holmes & Robert Pear, *Bill Would Lift Ban on Import of U.S. Drugs*, N.Y. TIMES, July 20, 2000, at A23 [hereinafter Holmes & Pear].

> The Senate action [in voting to overturn a ban on imports of American-made medicine is a respond] to pleas by the elderly, the country's most politically active demographic group, which has in recent years expressed concern about the high cost of prescription medicine. . . . [Senator Dorgan commented that,] [t]he pharmaceutical industry wants to scare people into believing the legislation [lifting import bans] is bad for consumers.

Id.

41. *See* James A. Dahl & Stephen H. Haynes, *FDA's Office of Criminal Investigations*, Update, Issue 4, (July-Aug. 2001), *at* http://www.fdli.org/pubs/Update/2001/Issue4/Dahl_Haynes/print.html. James A. Dahl and Stephen H. Haynes are retired Special Agents for the Office of Criminal Investigations; *see also* Dori Stehlin, *On FDA's Front Lines, Investigators Protect Public*, FDA CONSUMER, June 1992, at 14-19, *available at* http://www.gmp1st.com/protect.htm.

42. The FDA/OCI investigates criminal violations of federal laws that the FDA enforces. Examples of such laws include the Nutritional Labeling and Educational Act of 1990, the Prescription Drug User Free Act of 1992, the Federal Anti-Tampering Act, the Federal Caustic Poison Act and the Anabolic Steroids Control Act of 1990. The scope of the FDA statutory authority is printed in the FDA's Investigation Operation Manual. Office of Regulatory Affairs, U.S. Food and Drug Administration, FDA's Investigation Operation Manual (July 11, 2002), *at* http://www.fda.gov/ora/inspect_ref/iom/ChapterText/700.html#SUB700.

the FDA by the Bureau of Enforcement, which despite its name, really only enforces regulations of *known legitimate* dealers of medications. It does not target individuals operating outside legitimate markets.[43]

The FDA regulatory scheme is quickly becoming irrelevant. If "gray market" brokers and consumers can find cheaper drugs by evading this regulatory umbrella, they will. The risks of apprehension are small, the penalties are minor, and the savings are certain.

Although the FDA makes light of the threat of "gray" market drugs to their *raison d'etre,* they are truly "in denial" and deeply worried. The FDA genuinely wants to believe that they are doing something useful; however, their failure to effectively respond to this situation makes their jobs increasingly meaningless.

V. CONCLUSION

The politics of this problem are complicated. Dedicated North American Free Trade Agreement supporters are chagrined. Protectionists gloat but often support unrestricted trade in pharmaceuticals as a means of reducing drug costs.[44] The government is paralyzed. Stopping cross-border drug purchases will lead to political suicide.[45] Doing nothing is both dangerous and expensive. Abolishing the FDA is unacceptable, even though it is becoming increasingly useless.

The middle ground is hard to find. But current politics have been overtaken by the reality of open borders. Some suggestions decrease cross-border prescription drug purchases include: (1) "Return to sender" all drugs sent by mail to the United States;[46] (2) confiscate all drugs discovered at the border unless the entrant has a personal prescription for a 90-day supply;[47] (3) strictly enforce PDMA

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43. *See* Emily Richmond, *Medicine Meant for Nursing Homes Diverted, Discount Drugs Reportedly Traded on 'Gray Market'*, LAS VEGAS SUN, Oct. 16, 2001, *available at* http://www.lasvegassun.com/sunbin/stories/text/2001/oct/16/512493949.html.

> Hospitals and most medical facilities are prevented by the Food and Drug Administration's Prescription Drug Marketing Act of 1987... from reselling supplies. But the so-called "closed-door pharmacies," which serve nursing homes and aren't allowed to sell to the public, are neither hospitals nor health care entities under that law and can resell supplies to wholesalers.

Id.

44. *See* Holmes & Pear, *supra* note 40, at A23.

45. *See* Holmes & Pear, *supra* note 40, at A23.

46. *See* FDA Takes on Issue of Imported Drugs, *supra* note 21, at 1, 4.

47. *See* Regulatory Procedures Manual, *supra* note 3, at subchapter Coverage of Personal Importations; *see also* Continuing Concerns Over Imported Pharmaceuticals,

proscriptions against re-importation of prescription pharmaceuticals;[48] (4) require drug manufacturers to incorporate authentication and "track/trace" technology in their packaging and in the products themselves;[49] (5) vigorously prosecute "gray market" purveyors of prescription medications; (6) expand the size and scope of the FDA/OCI to stop the erosion of FDA's mission.

supra note 10, at 146 (statement of Marven Shepherd, Professor at the University of Texas).

48. The Prescription Drug Marketing Act of 1987 §§ 7, 21, U.S.C.A. § 331.

49. *See* FDA Takes on Issue of Imported Drugs, *supra* note 21, at 1,4.