BEFORE THE UNITED STATES
FOOD AND DRUG ADMINISTRATION

Re: Anti-counterfeit Drug Initiative	)	Docket No. 2003N-0361

COMMENTS OF:

The Center for Regulatory Effectiveness

The Center for Regulatory Effectiveness
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November 3, 2003

2003N-0361 C21

Center for Regulatory Effectiveness

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November 3, 2003

Division of Dockets Management (HFA-305)
US Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland, 20852

SUBJECT: Anti-counterfeit Drug Initiative, Docket No. 2003N-0361

The Center for Regulatory Effectiveness (CRE) respectfully submits the following comments to the Food and Drug Administration (FDA) on their Anti-Counterfeit Drug Initiative.

Key Recommendations

Based on CRE's working draft report on drug diversion and the intertwined crimes of counterfeiting, tampering and adulteration, as well as comments we have received on our report from stakeholders, we offer FDA the following key recommendations:

1. FDA should ensure that there are no further delays in fully implementing the pedigree provisions contained in their December 1999 Final Rule.

2. FDA should require that pharmaceutical manufacturers disclose the identities of their authorized distributors.

3. FDA should work with the Office of Pharmacy Affairs (OPA) to ensure that 340B covered entities make public, in a manner consistent with patient privacy, records documenting that discounted drugs have been administered to only eligible patients. The 340B program is an important source of diverted drugs.

About The Center for Regulatory Effectiveness

The Center for Regulatory Effectiveness (CRE) is a regulatory watchdog committed to improving the quality of the federal regulatory process. Established in 1996 by former senior career officials from the White House Office of Management and Budget, the CRE supports improving the effectiveness of the regulatory process through a number of mechanisms including, participating in specific regulatory proceedings, advocating specific regulatory improvements and structural improvements in the regulatory process.

CRE's Pharmaceutical Policy Project and White Paper

The drug diversion issue came to CRE's attention through a number of routes including information from the Department of Health and Human Services, the Department of Justice, articles in the popular press, and actions by state officials. Drug diversion is an important issue to CRE since it is a growing national problem that could be significantly ameliorated through increased federal regulatory effectiveness. CRE has established its Drug Diversion Project to develop and support implementation of regulatory recommendations for curtailing the diversion trade. As an initial step, CRE has written a working draft white paper *Dirty Deals: The Drug Diversion Trade, How It Victimizes the Vulnerable and How to Stop It.* The draft paper, along with a letter providing the paper and key recommendations to Secretary Thompson, are attached and constitute an integral part of our comments to FDA.

Inadequacies in the Current Federal Regulatory System

CRE has identified two key instances in which federal agencies have failed to implement the regulatory steps need to protect the integrity of the nation's pharmaceutical supply. Although taking the needed steps would not be a comprehensive solution to the problems of diversion and counterfeiting, they would be important first steps which should help significantly reduce the problems. Specifically:

1. FDA has repeatedly delayed allowing the pedigree paper regulatory requirements in their December 1999 Final Rule [64 FR 67720] to take effect.

2. The Office of Pharmacy Affairs has not implemented a system to effectively prevent discounted drugs from being diverted from 340B covered entities. Drug diversion from the 340B program helps sustain the distribution channels used by counterfeiters.

CRE Regulatory Recommendations FDA

1. **Implement Pedigree Paper Requirements**. Ensure that there are no further delays in fully implementing the pedigree provisions contained in the FDA's December 1999 Final Rule.

2. **Disclosure of Authorized Distributors**. Require manufacturers to publicly disclose current, accurate lists of their authorized distributors.

3. **Preventing Diversion From The 340B Discount Drug Program**. Work with OPA to ensure that 340B covered entities make public, in a manner consistent with patient privacy, records documenting that discounted drugs have been administered to only eligible patients.

4. **Certification of Proper Handling**. Add to the pedigree paper requirements a certification that the pharmaceuticals have been stored and handled under the appropriate conditions at all times.

5. **Pedigree Disclosure**. Add to FDA's pedigree requirements the disclosure of pedigree records to all parties to the transactions, including the patient. Empowering patients to protect their own health will provide a powerful additional mechanism for fighting counterfeiting, tampering, adulteration and diversion.

6. **Electronic Pedigrees**. Initiate a proceeding to require use of electronic pedigree paper systems, at least for injectables which are the most susceptible to counterfeiting, tampering, adulteration and mishandling. However, plans for a future improved pedigree system should not be used to delay implementation of paper-based pedigrees.

7. **Partner with the Drug Enforcement Administration**. Consult with DEA on ways to further strengthen the regulatory system to combat drug diversion and counterfeiting.

Sincerely

Bruce Levinson
Director, Pharmaceutical Policy Project

Enclosures

Center for Regulatory Effectiveness

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October 9, 2003

The Honorable Tommy G. Thompson
Secretary
U.S. Department of Health and Human Services
Room 615F
200 Independence Avenue, S.W.
Washington, DC 20201

Dear Secretary Thompson:

I am writing to compliment you on the leadership you have demonstrated on the drug diversion issue. You and your team have been proactive in investigating and seeking solutions to the public health problems associated with drug diversion, and the related crimes of adulteration, tampering and counterfeiting. The just-released Interim Report from the FDA's Counterfeit Drug Task Force, along with the upcoming public meeting, are the most recent tangible results of your initiative on this issue. As someone who has extensive personal experience in federal regulatory management, I particularly appreciate that you were on top of this issue prior to all of the media attention, including the recent articles in the *Wall Street Journal.*

The Center for Regulatory Effectiveness (CRE), a regulatory watchdog, has been closely following the drug diversion issue for some time. Established in 1996 by former senior career officials from the White House Office of Management and Budget, CRE supports improving the effectiveness of the regulatory process through a number of mechanisms including, participation in regulatory proceedings, advocating specific regulatory improvements and seeking structural improvements in the regulatory process. Additional information about CRE and our activities may be found on our website at www.TheCRE.com.

Last July, consistent with our mission of improving the effectiveness of federal regulations and with our work on drug diversion, we released the enclosed working draft white paper, *Dirty Deals: The Drug Diversion Trade, How it Victimizes the Vulnerable and How to Stop It.* The paper may be downloaded from our website at http://thecre.com/emerging/20030721_drug.html. Since that time, we circulated our paper and received comments from diverse stakeholders.

The FDA Task Force's Interim Report makes a number of invaluable observations and recommendations. However, based on our work, we have identified a number of additional important regulatory steps that need to be given serious consideration by your Department. Key among our recommendations for curtailing drug diversion are:

- The Food and Drug Administration (FDA) ensure that there are no further delays in fully implementing the pedigree provisions contained in their December 1999 Final Rule.

- The Office of Pharmacy Affairs (OPA) require that 340B covered entities make public, in a manner consistent with patient privacy, records documenting that discounted drugs have been administered to only eligible patients.

- Manufacturers shall disclose the identities of their authorized distributors.

Pursuant to your publication of the *Federal Register* notice of the Public Meeting, CRE will not only be providing our comments on the issues you have raised but also, since this is a continuing project of the Center, we will be providing you with additional information on a regular basis. To this end, we will be contacting your staff to ensure that the information in communicated through an appropriate channel.

Sincerely,

Jim Tozzi
Member, Board of Advisors

Enclosure

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Sincerely,

Jim Tozzi
Member, Board of Advisors

Enclosure

Working Draft
July 2003

DIRTY DEALS:
THE DRUG DIVERSION TRADE
HOW IT VICTIMIZES THE VULNERABLE AND HOW TO STOP IT

The Center for Regulatory Effectiveness
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DIRTY DEALS:
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EXECUTIVE SUMMARY

- Drug diversion, and the intertwined crimes of adulteration and counterfeiting, is a widely recognized threat to public health. Drug diversion occurs when prescription pharmaceuticals do not follow the proper distribution chain from manufacturer to patient.

- Drug diversion allows subpotent, tampered, adulterated, improperly handled and counterfeit medicines into the pharmaceutical distribution chain.

- Patients with cancer, kidney failure, AIDS and schizophrenia are among the most vulnerable to the consequences of drug diversion.

- Effective federal regulation is the key tool for preventing drug diversion.

- The resale of prescription drugs purchased at below-wholesale prices is the leading source of diverted drugs.

- The 340B Drug Pricing Program operated by the HHS' Office of Pharmacy Affairs (OPA) allows thousands of large and small health care entities to buy drugs at below-wholesale prices.

- OPA has not established regulations requiring 340B entities to report on their transactions or otherwise demonstrate that all of the specially-discounted medications were used only on patients allowed by the law despite concerns expressed to the agency that failure to institute such requirements could lead to drug diversion.

- Smaller, unauthorized pharmaceutical wholesalers have been recognized as the leading market makers for diverted pharmaceuticals.

- The FDA has not allowed key provisions of their 1999 Final Rule regulating unauthorized wholesalers and the resale of blood derivatives to take effect.

- FDA should not further delay implementation of all provisions of their December 1999 Final Rule regulating implementing the PDMA.

- OPA should require that 340B entities to certify that they have not engaged in drug diversion and to make public records documenting that discounted drugs have been administered to only eligible patients.

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I. Drug Diversion Endangers Public Health

A. Issue Overview: Why Drug Diversion is a Threat to Public Health

Drug diversion, and the intertwined crimes of adulteration and counterfeiting, is widely recognized by the federal government, state governments, industry and the media, as a growing threat to public health throughout the United States. Drug diversion occurs when prescription pharmaceuticals do not follow the proper distribution chain from manufacturer to patient. Instead, diverted pharmaceuticals pass through a complex series of transactions before being dispensed to patients or other persons. Diversion is a threat to public health for a number of reasons including:

1. Improper storage. Diverted drugs may not be stored under proper conditions, e.g. maintained at required temperatures, which can result in a spoiled product being dispensed to the patient.

2. Expired products. Diverted drugs may be past their expiration date, and thus of reduced or no effectiveness, when finally dispensed to patients.

3. Dilution and adulteration. Pharmaceuticals may be diluted or otherwise adulterated during the diversion process.

4. Counterfeiting. Diversion allows for counterfeit, i.e. fake, drugs, to be introduced into the distribution chain.

5. Forged labels. Diverted drugs may reappear on the market with false labels which indicate the wrong (usually higher) dosage or other incorrect information to increase the value of the product.

6. Reimportation. Drug diversion allows for illegally imported or reimported drugs to be introduced into the distribution chain. These imported/reimported substances may themselves be adulterated, spoiled, counterfeit, falsely labeled, subjected to inappropriate temperatures, or otherwise not fit for use.

7. Drug abuse. Diversion allows prescription pharmaceuticals, including narcotics, to become a source for illegal drugs sales.

B. Congressional Findings About Drug Diversion

Concern about drug diversion and the associated contamination of the nation's pharmaceutical supply was a key factor spurring Congress to pass the Prescription Drug Marketing Act (PDMA) of 1987. In the legislation, Congress reached a number of conclusions concerning the problems, including the threat to public health, associated with drug diversion. Congressional findings included:

- "The integrity of the distribution system for prescription drugs is insufficient to prevent the introduction and eventual retail sale of substandard, ineffective, or even counterfeit drugs."[1]

- "The existence and operation of a wholesale submarket, commonly known as the 'diversion market', prevents effective control over or even routine knowledge of the true sources of prescription drugs in a significant number of cases."[2]

- "Large amounts of drugs are being reimported to the United States as American goods returned. These imports are a health and safety risk to American consumers because they may have become subpotent or adulterated during foreign handling and shipping."[3]

- "The bulk resale of below wholesale priced prescription drugs by health care entities, for ultimate sale at retail, helps fuel the diversion market and is an unfair form of competition to wholesalers and retailers that must pay otherwise prevailing market prices."[4]

C. Drug Diversion Remains a Serious Problem

A growing body of evidence demonstrates that drug diversion, in its many forms, remains a serious problem and is a growing threat to public health. Concerns about drug diversion, counterfeiting and adulteration have been raised by:

- **USA Today**. An extensive front page article in the May 15th, 2003 issue of *USA Today*[5] discussed the growing problem of "fake, mislabeled and mishandled drugs..." The article discusses health threats such as:

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1 P.L. 100-293, Section 2 (2).

2 Ibid., Section 2 (3).

3 Ibid., Section 2 (4).

4 Ibid., Section 2 (7).

5 Julie Appleby, "Fake drugs show up in U.S. pharmacies," *USA Today*, May 15, 2003, p. 1A.

- AIDS patients who "have fallen ill after injecting a fake [drug]"; and

- Vials of anemia drugs containing only a 1/20th of the level of the active ingredient that was stated by the label.

The *USA Today* article also highlighted that the scope of the drug diversion problem is large and growing. For example

- In just South Florida, inspectors, "seized $20 million worth of adulterated pharmaceuticals in the past year..."

- Since 1998, 73 investigations into counterfeit or tampered drugs have been opened by the FDA, "with an uptick in the past two years."

- A pharmacist is quoted as saying, "I've been in this business for 40 years. I have less confidence in the integrity of the supply line today than ever before. It scares me."

- **New York Daily News**. A front page article in the June 3rd, 2003 edition of the New York's *Daily News*[6] discussed the illegal diversion of Serostim, a drug usually given to AIDS patients. Diversion of Serostim, which normally costs $6,300 a month for each patient, to body builders has resulted in multi-million dollar fraud schemes against Medicaid. The article quotes New York state Attorney General Elliot Spitzer as stating, "Drug diversion schemes are a nationwide problem that not only robs the city, the state and federal government of millions of dollars each year but places the public in jeopardy."

- **National Association of Boards of Pharmacies**. The NAPB, an association representing boards of pharmacy in all 50 states as well as the District of Columbia, US territories, and several foreign countries, appointed a Task Force on Drug Diversion through Institutional Outlets in May 2000. The NABP resolution[7] establishing the Task Force noted that, "diversion of prescription pharmaceuticals has been found to be an extensive enterprise affecting the safety, quality, cost, and availability of those products to consumers, thereby endangering the public health and welfare;"

- **Government and Industry Conferences Discussing Drug Diversion**. A variety of conferences are held around the country discussing drug diversion issues. These conferences often bring federal and state government officials, industry and other stakeholders. Examples of such conferences include:

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6 Thomas Zambito, "Pumped by AIDS Drug," *Daily News*, June 3, 2003, p. 5.

7 National Association of Boards of Pharmacies, Resolution 96-5-2000.

- The Drug Enforcement Agency's 10th Pharmaceutical Industry Conference was held in Fort Worth, Texas in February 2002 and focused on initiatives and strategies for combating drug diversion.[8]

- The 7th Annual Medicaid Drug Rebate Program Conference in September 2002. The Conference featured a panel which included officials from, The US Department of Health and Human Services' Bureau of Primary Health Care, Medi-Cal, and industry to discuss HHS' 340B program. One of the topics covered was, "Compliance issues: How can manufacturers protect against diversion..."

- The 2nd Annual West Coast Conference of the National Association of Drug Diversion Investigators in May 2003. The goal of the conference was to: "bring together local, state, and federal law enforcement personnel, health regulators and industry professionals in the specifics of pharmaceutical drug diversion to share their knowledge and experiences."

- **The Kansas City Star**. An August 1999 article in *The Kansas City Star*[9] discussed the extensive role of organized crime in drug diversion. The article stated that, "Two men who helped send the reputed head of the Kansas City mob to prison in a pharmaceutical fraud scheme now face charges in a similar but far larger case." The article goes on to explain that the defendants, "were charged with operating a similar pharmaceutical diversion scheme that brought them at least $8 million between 1995 and early 1999."

- **The Washington Post**. A May 2003 article in The Washington Post[10] discusses the recall by a pharmaceutical wholesaler of 100,000 bottles of Lipitor, a widely prescribed cholesterol lowering medication, because they contained counterfeit pills. The FDA described the pills as "a potentially serious danger to consumers."

- **The President's FY '04 Budget**. One of the strategic objectives discussed in the President's Budget for the Drug Enforcement Administration (DEA) is to, "Identify and target the national/regional organizations most responsible for the...diversion of licit drugs..."[11]

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8 US Department of Justice, Drug Enforcement Administration, 10th Pharmaceutical Industry Conference Report.

9 Mark Morris, "Witnesses in Civella case prepare for their own trial," *Kansas City Star*, August 21, 1999.

10 Rick Weiss, "Bottles of Cholesterol Drug Recalled," The Washington Post, May 24, 2003, p. A-02.

11 Budget of the United States Government, Fiscal Year 2004, Appendix, p. 631.

D. Patients with Chronic Illnesses are Most at Risk from Drug Diversion

Patients who have need pharmaceutical products to treat serious chronic physical and mental illnesses are those most at risk from the health threats resulting from drug diversion. The adulterated and counterfeit drugs discussed in the *USA Today* article included; Serostim, Epogen, Procrit, Zyprexa, Combivir and Retrovir. These medicines are mostly used to treat conditions such as anemia resulting from cancer and kidney failure, AIDS and schizophrenia. Patients who depend on these drugs have little alternative to trusting that the medicines have been stored properly and are not adulterated, mislabeled or counterfeit. Furthermore, the pharmacists who dispense the drugs also need sound assurances that the medications they provide have not been corrupted.

II. CRE's Interest in Drug Diversion

A. About the Center for Regulatory Effectiveness

The Center for Regulatory Effectiveness (CRE) is a regulatory watchdog committed to improving the quality of the federal regulatory process. Established in 1996 by former senior career officials from the White House Office of Management and Budget, the CRE supports improving the effectiveness of the regulatory process through a number of mechanisms including, participating in specific regulatory proceedings, advocating specific regulatory improvements and structural improvements in the regulatory process. The CRE was the key advocate supporting passage of the Data Quality Act, legislation requiring standards for the quality of virtually all data disseminated by federal agencies. CRE also actively participated in the public process of developing agency-specific implementation guidelines.

CRE's anchor website, TheCRE.com, provides information and analyses on a broad spectrum of regulatory issues. CRE staff use such analyses as the basis for discussions with federal agency officials. CRE also operates the CyberActivist.US website which is designed to provide a new, substantive and transparent mechanism for expanding the opportunities – and quality – of stakeholder participation in the public policy process.

CRE has no members, but it receives, from time to time, financial support, services in kind, and work product from trade associations and private firms. Consequently, at any one time, CRE benefits from the input or advice of literally hundreds of small and large firms. Additional information about CRE may be found on TheCRE.com.

B. CRE and Drug Diversion

The drug diversion issue came to CRE's attention through a number of routes including information from the Department of Health and Human Services, the Department of Justice, articles in the popular press, and actions by state officials. Drug diversion is important to CRE

since it is a growing national problem that could be significantly ameliorated through increased federal regulatory effectiveness. CRE has written this white paper and will advocate associated regulatory changes to reduce the prevalence and human toll associated with drug diversion.

III. Elements of Drug Diversion Deals

There are three components to the drug diversion trade:

- Sources of pharmaceuticals;
- Buyers of pharmaceuticals; and
- Market makers, i.e. intermediaries between the supply and demand.

A. Pharmaceutical Sources

Pharmaceuticals, real and counterfeit, can enter the diversion market through a number of sources ranging from theft to forged prescription to resale by patients to imports/reimports from foreign countries. However, the primary source of diverted pharmaceuticals are institutions that are able to purchase pharmaceuticals at sharply discounted prices and then illicitly resell the medications. The role of discounted pharmaceuticals in drug diversion enterprises has been noted by diverse organizations including:

- **The Department of Justice**. The United States Attorneys' Manual states that "...the sale of deeply discounted drugs to hospitals and health care entities -- have helped fuel a multi-million dollar drug diversion market that provides a portal through which mislabeled, subpotent, adulterated, expired, and counterfeit drugs are able to enter the nation's drug distribution system."[12]

- **The US Food and Drug Administration**. The FDA's Office of Regulatory Affairs website provides information about the September 2001 conviction of various individuals "in a multi-state pharmaceutical diversion scheme that was responsible for defrauding drug manufacturers of over $8,000,000.00."

- **The National Association of Boards of Pharmacies**. The NABP's Task Force on Drug Diversion through Institutional Outlets discussed the problem of closed pharmacies reselling discounted drugs to "secondary source wholesalers" in a report made available on NABP's website. The report states, "Experts have estimated that

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[12] US Department of Justice, "United State Attorneys' Manual," Title 4, 113 Prescription Drug Marketing Act.

between 50% and 80% of 'closed door pharmacies' are participating in these diversion schemes."[13]

- ***USA Today***. The May 15, 2003 article on drug diversion discussed "closed pharmacies" that sell only to certain institutions which qualify for price discounts, not the public. The article explains that these closed door pharmacies then illegally sell the discounted medicines to wholesalers. A senior FDA official is quoted in the article as saying, "It is easy to see how this system ... facilitates the entry of counterfeit and otherwise unsafe drugs into the marketplace."

- ***The Kansas City Star***. The Star's article discussing the role of organized crime in drug diversion explained that the defendants in the pharmaceutical fraud case opened a pharmacy that distributed only to nursing homes, purchased drugs at the special discounted rate for nursing homes and then resold them to wholesalers.

- **The State of Florida**. In April 2002, the State of Florida's Medicaid office issued new requirements for the dispensing of drugs in selected counties, "[i]n an effort to control drug diversion..."[14]

B. Buyers

In order for the diverted pharmaceuticals to be dispensed to consumers, someone has to buy the products. The ultimate buyers, according to the *USA Today* are "pharmacies, clinics, physicians and each other." The extent to which buyers may or may not be aware that they are purchasing diverted pharmaceuticals is not clear from available information. However, an April 2003 article in Florida's *Sun-Sentinel*[15] discussed a recommendation by a statewide grand jury that pharmaceutical buyers "be required to verify every step..." on the substance's pedigree papers. The pedigree is a document that is supposed to provide a complete paper trail documenting ownership of the product from manufacture to final disposition.

C. Market Makers

Market makers facilitate the drug diversion trade. Market makers are usually small pharmaceutical wholesalers who buy and sell drugs in the often shadowy secondary

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13 http://www.nabp.net/ftpfiles/task_force_reports/Task_Force_on_Drug_Diversion_through_Institutional_Outlets.doc

14 http://www.fdhc.state.fl.us/Medicaid/Prescribed_Drug/banners.shtml.

15 Bob LaMendola, "Deal reached on regulation of wholesale drug industry," *Sun-Sentinel*, April 18, 2003.

wholesale market. The secondary wholesale market, composed primarily of unauthorized distributors, is a sub-segment of the overall prescription wholesale market.

The Prescription Drug Marketing Act divides pharmaceutical wholesalers into two categories for regulatory purposes:

- Authorized Distributors of Record; and
- Unauthorized distributors.

Authorized Distributors. Section 503(e)(4)(A) of the PDMA defines the term "authorized distributors of record" as distributors that have an "ongoing relationship" to distribute the manufacturer's products. The FDA defined the term "ongoing relationship" in 21 CFR §203.3(u) as meaning that the manufacturer and a distributor have entered "into a written agreement under which the distributor is authorized to distribute the manufacturer's products for a period of time or for a number of shipments. If the distributor is not authorized to distribute a manufacturer's entire product line, the agreement must identify the specific drug products that the distributor is authorized to distribute." Under the PDMA regulations, authorized distributors have privileges that unauthorized distributors do not have, such as the ability to distribute samples.

Unauthorized Distributors. Any prescription wholesaler who does not meet the definition of an authorized distributor of record is considered to be an unauthorized distributer. Unauthorized distributors, as is the case for all wholesalers, need to be state licensed.

To better characterize the pharmaceutical wholesale market from an economic standpoint, FDA, in a report to Congress, classified the market into four tiers.[16]

1. The Big Five Wholesalers

According to the FDA Report to Congress, pharmaceutical wholesaling is a highly concentrated market with the "Big Five" controlling about 90% of the market. Due to competitive conditions, the FDA states that there are "narrow profit margins" and "the wholesale markup is modest." These Big Five companies buy a "large majority of their drugs directly" from the manufacturer although they buy some drugs from other distributors. All of the Big Five are multi-billion dollar businesses. The largest of the Big Five was estimated to have over $20 billion in revenue in 1998. The major wholesalers sell to large retail chains and hospitals.

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16 US FDA, "The Prescription Drug Marketing Act: Report to Congress, Attachment G, June 2001.

2. Regional Wholesalers

In addition to the Big Five, there are about 70 regional prescription drug wholesalers. Most of these companies do not have formal written distribution agreements with manufacturers, i.e. they are unauthorized distributors, although they may purchase from them on a regular basis. These regional firms sell to the same industry segments as the Big Five as well as to independent drugstores and other entities, such as dialysis centers and physicians' offices. The larger regional wholesalers have annual sales worth hundreds of millions of dollars.

3. Smaller Wholesalers

Smaller wholesalers are a varied group. Some may carry a full line of pharmaceutical products while other may specialize in only certain types of products, such as injectables that require special storage and handling. The FDA does not estimate the number of these smaller wholesalers other than to say that they are "numerous." The FDA notes that some of these firms have an annual revenue of $10 million and a staff of fewer than 10. These firms generally do not purchase directly from manufacturers and they sell to independent pharmacies, physicians' offices and other small entities.

4. Secondary Wholesalers

Secondary wholesalers sell primarily to other wholesalers. They buy selected discounted pharmaceuticals, sometimes from manufacturers offering special deals, and then sell them to other wholesalers, including some large companies. The FDA describes these firms as being "distinguished by their willingness to risk substantial capital in buying and trading discounted drugs." The FDA notes that, although there are three relatively large secondary wholesalers, there is no actual definition or count of these secondary wholesalers. Furthermore, a wide range of wholesalers, including Big Five companies, engage in some pharmaceutical trading activities. The FDA Report to Congress stated that there are "believed to be numerous, smaller, secondary wholesalers...." FDA also noted that there is no "quantitative data or distinct industry statistics...to characterize further the population of small secondary wholesalers."

In that there is not the data to even quantify the number of secondary wholesalers, serious concerns are raised as to how an agency, federal or state, can effectively regulate this segment of the wholesale market.

Secondary wholesalers, as is the case with many types of market makers, can play an important role in enhancing market efficiency. Furthermore, there is no reason to doubt that many of these secondary firm engage in fully legitimate transactions and provide all necessary product storage and handling safeguards. However, it is also

clear that law enforcement authorities have raised significant concerns about the secondary market in general as well as about specific secondary wholesalers. These concerns relate not only to wholesalers' business practices but, more importantly, to the impact those practices could have on public health.

- A February 2003 Florida grand jury report stated that there were nearly 1,400 wholesalers licensed to distribute prescription medication in the state. The report, according to *USA Today*, stated, "Uneducated, inexperienced... rank amateurs, many with criminal records, make up a sizable portion of Florida's drug wholesalers. No one has to go to (wholesalers') warehouses to buy their tainted product, for eventually they show up in our hospitals, clinics and pharmacy shelves."

- An Assistant Statewide Prosecutor in the Florida Attorney General's Office, Health Care Fraud Liaison, in discussing the need for strengthened pedigree paper requirements, told the state's Pedigree Paper Ad Hoc Committee that, "There is no way to know what the dirty secondary wholesalers are doing. They will no longer have to be creative and invent a company name or some explanation how drugs can travel 3000 miles in two days. Dirty secondary wholesalers need to be identified and prosecuted so they can be taken out of the food chain."[17]

- *USA Today* also noted that drugs may change hands four, five six times or more before being sold to the consumer. The General Counsel for the Nevada State Board of Pharmacy is quoted as saying, "No good can come to a drug that travels through seven or eight wholesalers and literally crosses the entire country."

IV. Potential Mechanisms for Preventing Drug Diversion

There are four potential mechanisms for reducing or virtually eliminating the drug diversion trade:

- Federal regulation;
- State regulation;
- Law enforcement; and
- Legislation

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[17] Minutes, Pedigree Papers Ad Hoc Committee, April 30, 2002.

With regard to legislative changes, they have the potential for both reducing as well as potentially assisting drug diversion. On the side of the potential for legislation to reduce the drug diversion trade, The United States Attorneys' manual notes the PDMA's "complexity and potential loopholes" and explains that, as a result, "prosecution of institutional diversion cases under the PDMA has been rare." However, some legislation changes which have been proposed, such as easing pedigree paper requirements for secondary wholesalers, could further fuel the drug diversion market. In any case, consideration of such changes in the basic framework governing prescription drugs is beyond the scope of this paper.

Vigorous law enforcement at all levels of government is a vital element of any comprehensive strategy to reduce drug diversion. As has been discussed, federal, state and local law enforcement authorities have been active in investigating and prosecuting the drug diversion trade. However, law enforcement activities generally take place after law has been violated. Thus, the best way of preventing drug diversion is through regulatory actions that reduce the opportunity for crime and also assist authorities in investigating and prosecuting any violations that eventually occur.

States have undertaken some steps to reduce drug diversion. For example, as was previously discussed, a Florida grand jury made recommendations for reducing drug diversion. A key recommendation regarded the need for pharmaceutical buyers to verify each step on a drug's pedigree papers. In response to the grand jury report, the state legislature enacted some changes in state law regarding pharmaceutical wholesalers. More recently, Florida has cracked down small unlicensed pharmacies that engage in the *de facto* sale of reimported prescription drugs.[18] However, as the notices from the FDA's Office of Regulatory Affairs made clear, drug diversion is often an interstate trade. Thus, although state legislative and regulatory reform are welcome, federal regulation will remain the cornerstone of drug diversion prevention activities.

V. Federal Regulation

There are two key agencies, both within the Department of Health and Human Services, with regulatory responsibilities directly relevant to the drug diversion problem:

- The Food and Drug Administration; and
- The Health Resources and Services Administration.

In addition to FDA and HRSA, the Drug Enforcement Administration is also active in combating drug diversion. DEA, under the Controlled Substances Act of 1970, is responsible for registering entities which are authorized to handle controlled substances. DEA also engages in substantial enforcement activities as well as in educational and other outreach activities designed to reduce drug diversion.

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[18] Barrie McKenna, "Florida hopes to shutter shops that resell drugs from Canada," *The Globe and Mail*, June 12, 2003, p. B1.

A. The Food and Drug Administration

The US FDA is responsible for regulating the companies that sell and resell prescription drugs. They are also responsible for regulating the import and reimport of drugs into the United States. Specifically, the FDA is responsible for developing and enforcing regulations under the Prescription Drug Marketing Act (PDMA).

1. Overview of the Prescription Drug Marketing Act

The PDMA, as modified by the Prescription Drug Amendments of 1992 (PDA) and the FDA Modernization Act of 1997, set a number of requirements designed to prevent drug diversion and related threats to the safety and effectiveness of pharmaceuticals purchased by consumers. The statute also created criminal penalties for violations of the law. The PDMA and PDA focused on three major sources of drugs for potential diversion:

- Reimportation;
- Samples; and
- Resale of below-wholesale-priced pharmaceuticals by health care entities.[19]

With regard to reimportation, the law banned such trade except by the manufacturer itself or, with FDA approval, other parties under certain restricted circumstances. The legislation also set a series of restrictions with regard to the drug samples including provisions that relate to distribution and recordkeeping requirements as well as a prohibition on the sale or trade of samples.

With regard to preventing the resale of below-wholesale-priced drugs, the law set three major requirements[20]:

a. Purchase/Sale/Trade Restrictions. The law calls for prohibiting most sales, purchases, or trades of pharmaceuticals which were: 1) purchased by hospitals or other health care entities; or 2) provided either free or at a reduced price to a charitable organizations.

b. State Licensing of Wholesalers. The law requires that wholesale prescription drug distributors be licensed by States under Federal guidelines.

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19 59 FR 11842.

20 Ibid.

c. Pedigree Papers. The law require wholesalers who are not manufacturer-authorized distributors, to provide to each wholesale distributor documentation identifying each sale of the drug before the sale to the wholesale distributor.

The PDA of 1992 modified a number of the PDMA requirements. The PDA authorized establishment of a temporary federal procedure for wholesaler registration for wholesalers in states not having licensing programs meeting federal guidelines. The PDA also contained additional restrictions pertaining to samples. Of particular note, the PDA "significantly tightened the drug pedigree requirement..." for unauthorized wholesalers by:

- Specifying the information to be included to be included in the pedigree;
- Mandating that the detailed pedigree records be provided, before a sale takes place, to every wholesale distributer or retail pharmacy customer; and
- Allowing FDA require additional information for the drug pedigree.[21]

2. FDA Implementation of the PDMA

Most of the PDMA provision became effective in 1988 with the exception of the state licensing requirements which became effective in 1992. In 1994, the FDA undertook a rulemaking to implement some provisions of the PDMA that had not yet been implemented and to address certain policy issues that had been brought to the agency's attention. Key issues addressed in the proposed rule included:

- Establishing procedures and requirements pertaining to the reimportation and wholesale distribution of pharmaceuticals, the transactions (sale, purchase, or trade) of pharmaceuticals by hospitals, other health care entities and charitable institutions, and the distribution of drug samples;
- Ensuring that bulk drugs were covered by the PDMA regulations;
- Ensuring that biological products that are prescription pharmaceuticals, except for blood and blood components intended for transfusion, were covered by the PDMA regulations;
- Setting pedigree documentation for unauthorized wholesalers of prescription pharmaceuticals; and

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21 Ibid.

- Setting stringent care standards for all prescription medications. Specifically the proposed rule would require that pharmaceuticals "be stored at appropriate temperatures and under appropriate conditions in accordance with the requirements, if any, in the labeling of such drugs, or with the requirements in the U.S. Pharmacopeia XXII."[22]

With regard to the resale of drugs by hospitals, other health care entities and non-profits, FDA noted that, "some hospitals and health care entities, including physicians, have obtained licenses as wholesale distributors in an effort to circumvent the statutory restrictions against the sale of prescription drugs by hospitals, health care entities, and charitable institutions."[23] The FDA rejected this creative approach by certain entities and proposed to prohibit most resales of pharmaceuticals by hospitals and other health care entities and non-profits. FDA stated that this "provision is intended to cover resales by both for profit and nonprofit health care entities. These institutions typically receive discount prices, substantially below the average wholesale price (AWP) for pharmaceuticals, based on their status as a health care entity or charity."

With regard to pedigree requirements for unauthorized distributors, the FDA proposed requiring that the documents contain:

- The proprietary and established name of the pharmaceutical;
- The dosage;
- The container size;
- The number of containers;
- The drug's lot or control number(s);
- The business name and address of all parties to each prior transaction involving the drug, beginning with the manufacturer; and
- The date of each previous transaction involving the drug.

FDA discussed the substantial controversy regarding these pedigree requirements in the proposed and that they received expressions of support for more lenient requirements from stakeholders ranging from the American Association of Pharmaceutical Distributors

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22 Ibid.

23 Ibid.

(AAPD) to some Senators and member of Congress.[24] The FDA also explained that "the stricter language in the PDA revision ``makes it clear" that any wholesale distribution of a prescription drug by an unauthorized distributor, including any sale to another unauthorized distributor, an authorized distributor of record, or a retail pharmacy, must be preceded by a full and complete identifying statement."

Publication of the proposed rule in 1994 was a major step in a protracted regulatory process. The final rule was not published until December 1999.[25] In March 2000, the FDA received a Petition for Reconsideration from the Small Business Administration as well as a petition from AAPD to stay implementation of the final rule until October 2001. In May 2000, the FDA agreed to delay the effective date for certain requirements of the proposed rule and to reopen the administrative record. Hearings on the final rule were held by FDA in October 2000. Key issues at the hearing were the pedigree documentation requirements and the distribution of blood derivatives by health care entities.[26]

In May 2000, a House Appropriations Committee Report accompanying the 2001 Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Bill, 2001 that it supported the "recent FDA action to delay the effective date for implementing certain requirements of the Prescription Drug Marketing Act until October 1, 2001, and reopen the administrative record in order to receive additional comments."[27]

In March 2001, FDA further delayed the effective date of key provision of the 1999 final rule until April 2002.[28] In June 2001, the FDA submitted its Report to Congress on the PDMA. In the Report, the FDA concluded that it "could address some, but not all, of the concerns raised by the secondary wholesale industry and the blood industry through regulatory changes. However, to make other changes requested by the secondary wholesale industry, Congress would have to amend ...the act."[29]

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24 Ibid.

25 64 FR 67720.

26 65 FR 56480.

27 H. Rept. 106-619.

28 66 FR 12850.

29 68 FR 4912.

In February 2002, the FDA yet again delayed implementation of key PDMA regulatory provisions, this time until April 2003.[30] In January 2003, the FDA published another one year delay in the implementation date for the PDMA regulatory provisions. In explaining the cause for the delay, FDA noted that "although FDA can address some of industry's concerns with the PDMA regulation through regulatory changes, other concerns would have to be addressed by Congress through legislative action. The further delay is necessary to give Congress additional time to consider the information and conclusions contained in the agency's report, and to determine if legislative action is appropriate. The further delay will also give the agency additional time to consider whether regulatory changes are appropriate and, if so, to initiate such changes."[31]

Thus, in summary, key provisions implementing the PDMA of 1987 and PDA of 1992 relating to secondary wholesalers and distribution of blood derivative products have not yet been implemented even though:

- Congress found, in 1987, that the integrity of the prescription drug distribution system was insufficient, that there existed a whole "diversion market" that prevented "effective control over or even routine knowledge of the true sources of prescription drugs..."

- The PDA of 1992 was unambiguous in setting strict pedigree requirements for unauthorized pharmaceutical wholesalers.

- FDA published a final rule in 1999 that, in part, required unauthorized distributors to maintain and present detailed pedigree papers for prescription pharmaceuticals and apply the PDMA regulations to blood derivative products;

- FDA provided a Report to Congress discussing the concerns raised by some businesses and providing Congress the opportunity to amend the Act; and

- Congress has not amended the PDMA in response to the FDA Report to Congress and delays in regulatory implementation.

B. The Health Resources and Services Administration

The Office of Pharmacy Affairs (OPA) within the Health Resources and Services Administration's Bureau of Primary Health Care is responsible for administering a program to provide significantly discounted drugs to certain hospitals, clinics and other health care entities.

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30 67 FR 6645.

31 68 FR 4912.

This program allows numerous health care entities around the country to buy drugs at highly discounted prices, drugs which could potentially serve as a supply source for the diversion market.

1. Overview of the 340B Program

OPA's discounted drug program is known as the "340B Drug Pricing Program." The legislative mandate for the 340B program is found in section 340B of the Public Health Service Act. The program was established when the Act was amended by Section 602 of the 1992 Veterans Health Care Act. The legislation requires that pharmaceutical manufacturers who participate in the Medicaid program to also sell drugs to "covered entities" at the best price discounts provided to Medicaid under Medicaid Drug Rebate Program of 1990. The discount is about 15% for innovator, i.e. name brand, drugs and about 11% for non-innovator, i.e. generic, drugs.

The legislation establishing the 340B program defines a dozen different types of types of health care entities that are eligible to participate in the 340B programs. These "covered entities" range from large hospitals to small clinics. Specific types of covered entities include:

- Disproportionate share hospitals (DSH) which serve relatively large populations of low income patients (for use with outpatient care only);
- Federally-qualified health centers (as defined in section 1905(l)(2)(B) of the Social Security Act);
- State-operated AIDS drug purchasing assistance program receiving financial assistance under Title XXVI of the Public Health Services Act;
- Comprehensive hemophilia diagnostic treatment centers receiving grants under section 501(a)(2) of the Social Security Act; and
- Native Hawaiian Health Centers receiving funds under the Native Hawaiian Health Care Act of 1988.

There are currently over 8,000 covered entities.[32]

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[32] Department of Health and Human Services, "Commissioned Corps Bulletin," Vol. XVI, No. 8, August 2002, p. 11.

Covered entities that do not have an in-house pharmacy capable of purchasing and dispensing drugs, are allowed under OPA guidelines[33] to establish a "contract pharmacy" arrangement under which the drugs are billed by the manufacturer to the covered entity but shipped to the contract pharmacy. The contract pharmacy is required to provide the covered entity with quarterly financial statements, a summary of receiving and dispensing records and other documentation. The contract pharmacy is also required to develop and maintain a system to prevent the dispensing of discounted drugs to anyone who is not a patient of the covered entity.

A drug sold under the 340B discount program is not also eligible for a Medicaid rebate. Therefore, a manufacturer is not liable for a double discount, once when the drug is purchased at the 340B discount and then through a Medicaid rebate.

Section 340B explicitly prohibits covered entities from reselling or transferring discounted drugs to anyone other than a direct patient of the entity whose medical records are maintained by the entity. The law allows HHS, at their expense, to audit the records of covered entities that directly pertain to the resale prohibition and other program compliance requirements.

Drug manufacturers providing medicines under the 340B program are also allowed, under certain circumstances as defined by HHS guidelines, to audit the records of covered entities. Should a covered entity be found, after notice and a hearing, to have violated the non-resale requirements, they are liable for the amount of the discount of the drugs that have been diverted. The covered entity could potentially also be excluded from the drug discount program.[34]

2. Regulation of the 340B Drug Discount Program

Under 1994 guidelines, covered entities "must develop and institute adequate safeguards to prevent the transfer of discounted outpatient drugs to individuals who are not eligible for the discount..."[35] if "individuals other than patients of the covered entity obtain covered outpatient drugs from its pharmaceutical dispensing facility..."

Larger entities which include a covered entity within its structure must establish separate purchasing and dispensing records for the covered entity. Covered entities that offer services excluded from the 340B program must develop a separate method for managing drugs for these services.

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33 61 FR 43549.

34 61 FR 65406.

35 59 FR

Covered entities are allowed, with OPA permission, to use alternative methods of demonstrating compliance with program requirements. However, OPA has made clear that in no circumstances are covered entities required to maintain separate inventories for drugs purchased under the 340B discount program.[36]

The types of potential diversion discussed in the OPA guidelines are diversion to patients who are not eligible for the discounted drugs, such as inpatients or patients of a non-covered affiliate of the covered entity. The guidelines do not appear to even contemplate the possibility of discounted drugs being sold in the secondary wholesale market.

OPA has not instituted any reporting requirements by covered entities to prevent drug diversion. Thus, over 8,000 entities are able to buy often expensive drugs at a significant discount without being required to report on their transactions or otherwise demonstrate that all of discounted medications are only being used on patients allowed by the legislation.

Concerns about diversion have been expressed to OPA in a number of forums. In the 1994 Final Notice providing the 340B guidelines, the agency notes a number of comments encouraging stronger steps to prevent drug diversion. Comments to the agency included requests that the agency:

- Develop and publish a mechanism whereby manufacturers can report to the Office of Drug Pricing when they suspect an entity of diversion;
- Require preclearance of all safeguard systems developed by entities to deter diversion and require this information to be supplied to the manufacturers upon request; and
- Issue criteria for measuring the adequacy of the safeguards.[37]

The agency's response to these comments was "no change."

Concerns about drug diversion stemming from the 340B program has also been discussed in a report from HHS' Office of Inspector General (OIG). A September 2000 HHS OIG

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36 HHS, Bureau of Primary Health Care, Office of Pharmacy Affairs, "340B Program Overview and Frequently Asked Questions," http://bphc.hrsa.gov/opa/faqs.htm.

37 59 FR

report[38] discussed drug diversion within the context of an OIG recommendation for HRSA to consider allowing multiple contract pharmacies. In analyzing the issue, the OIG discussed the need for improved safeguards against drug diversion. The report stated that:

- HRSA "should also provide guidance regarding the level of drug diversion and the client eligibility safeguards needed to reasonably consider allowing a multiple contract pharmacy model."

- "To respond to drug diversion concerns, HRSA could offer specific technical assistance to States concentrating on effective ways to safeguard against drug diversion."

C. Inadequacies in Current Federal Regulations

The concerns raised by federal and state officials, the press and other stakeholders clearly demonstrate that drug diversion continues to pose a serious threat to public health, particularly the medically vulnerable. CRE's examination of the relevant FDA and HRSA regulatory programs demonstrate serious shortcomings that provide opportunities for the drug diversion trade to exploit. The two most glaring instances in which agencies have failed to implement needed regulations are:

1. FDA has initiated repeated delays in the effective date for key requirements of their 1999 final rule pertaining to the regulation of:

    - The wholesale distribution of prescription drugs by non-authorized pharmaceutical wholesalers; and

    - Distribution of blood derivatives by healthcare entities.

2. OPA has not required that covered entities regularly provide the agency and other stakeholders with documentation demonstrating that they have provided discounted pharmaceuticals to only those patients entitled to receive the drugs.

When viewed in tandem, the shortcomings in the OPA and FDA regulatory programs inadvertently help provide both a supply and a market for the drug diversion trade. OPA's lack of reporting requirements could allow a potentially significant source of discounted drugs to be diverted into the secondary market without the agency being aware of the problem. FDA's

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[38] US Department of Health and Human Service, Office of Inspector General, "AIDS Drug Assistance Program Cost Containment Strategies," OEI-05-99-00610, September 2000.

delays in fully implementing its 1994 final rule also delay potentially effective mechanisms to help block secondary wholesalers from making a market in discounted diverted drugs.

VI. Conclusions

- Drug diversion is widely recognized as a serious threat to public health, particularly for the medically vulnerable.
- Drug diversion allows adulterated, improperly stored and counterfeit medications to enter the distribution chain.
- Organized crime is involved in the drug diversion trade.
- OPA regulation of the 340B drug discount program does not provide adequate controls to prevent drugs acquired at below-wholesale prices from being diverted.
- Implementation of FDA regulations which could help prevent secondary pharmaceutical wholesalers from making a market in diverted and counterfeit pharmaceuticals has been repeatedly delayed.

VII. Recommendations

- FDA should take immediate action to ensure that there are not further delays in fully implementing all provisions of their December 1999 Final Rule implementing the PDMA.
- FDA should require that the pedigree papers for injectables, which are most susceptible to tampering, adulteration and mishandling, be made publicly available by clinics and other dispensing entities.
- FDA should add to the pedigree requirements a certification that the pharmaceuticals have been stored and handled under the appropriate conditions at all times.
- OPA should require that 340B covered entities make public, in a manner consistent with patient privacy, records documenting that discounted drugs have been administered to only eligible patients.
- OPA should require covered entities to formally certify on an annual basis that none of the discounted pharmaceuticals purchased under the 340B program have been resold, traded or otherwise diverted.
- FDA and OPA should consult with DEA on ways to further strengthen the regulatory system to combat drug diversion.