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Justification Review

February 2003 Report No. 03-18

Counterfeit and Diverted Drugs Threaten Public Health and Waste State Dollars

at a glance

Counterfeit and diverted drugs are a growing problem in Florida and threaten public health and waste government resources. Regulators estimate that the problem costs Florida millions of dollars annually. Counterfeit and diverted drug cases in Florida's prescription drug wholesale industry have risen in recent years, and several Florida permitted drug wholesalers are under active investigation. Current state law does not provide adequate controls over wholesale drug market practices, and current administrative and criminal penalties fail to provide an adequate deterrent.

We recommend that the Legislature

- clarify state law requiring drug pedigree papers to track drugs back to manufacturers and direct the Department of Health to enforce provisions of Florida law;
- strengthen the drug wholesale permitting process; and
- increase administrative and criminal penalties for prescription drug violations.

Scope

Section 11.513, *Florida Statutes*, directs the Office of Program Policy Analysis and Government Accountability to complete a program evaluation and justification review for each state agency that is operating under a performance-based program budget. Justification reviews assess agency performance measures and standards, evaluate program performance, and identify policy alternatives for improving services and reducing costs.

This report examines the activities of the Community Public Health Program administered by the Department of Health relating to controlling counterfeit and diverted drugs within the prescription drug wholesale market. A companion report will address the program's delivery of public health services in Florida.

Background

Drug marketing is regulated by both federal and state law. The federal Prescription Drug Marketing Act (PDMA) of 1987 establishes minimum standards for the prescription drug wholesale industry. This includes a standard designed to prevent drug diversion and counterfeiting that requires wholesalers to provide purchasers with a written sales history tracing each drug back to its initial manufacturer. These written histories, commonly referred to as pedigree papers, provide an audit trail and should contain specific information about each sales transaction, such as the name and address of each previous purchaser of the drug. See Appendix A for an example of a pedigree paper.

A related provision of the federal act establishes the designation of *authorized distributor of record* (ADR) and defines ADRs as wholesalers who routinely purchase prescription drugs directly from manufacturers. It exempts ADR wholesalers from providing pedigree papers when they sell drugs purchased from the manufacturer to another wholesaler. This exemption assumes that ADR wholesalers purchase legitimate and safe drugs directly from the manufacturer, making a chain of custody unnecessary. To become an ADR wholesaler, the law requires a minimum number of transactions during a specified time period between a wholesaler and manufacturer. [1]

The Florida Drug and Cosmetic Act, Ch. 499, *Florida Statutes*, incorporates the standards set forth in the federal PDMA. [2] The state law directs the Department of Health to provide regulatory oversight of the manufacture and distribution of drugs, devices, and cosmetics in Florida. The Bureau of Statewide Pharmaceutical Services carries out the responsibilities and activities associated with these regulatory functions, which include the regulation of Florida's prescription drug wholesale market.

The bureau regulates the wholesale market by permitting, inspecting, and investigating drug wholesalers. Drug wholesalers must obtain a permit from the bureau to legally sell drugs in Florida. Bureau inspectors inspect in-state wholesaler facilities as part of the initial application process and annually thereafter. If inspections reveal infractions, the bureau investigates and may impose administrative fines and penalties.

The bureau also investigates wholesalers suspected of misconduct such as counterfeiting or diverting drugs. To combat illegal activities in the wholesale market, the bureau works closely with local, state, and federal law enforcement officials, the Agency for Health Care Administration, the Medicaid Fraud Control Unit, the Statewide Prosecutor's Office, and the Food and Drug Administration.

[1] FDA guidelines define a wholesaler who makes two purchases in 24 months as an ADR. Florida Administrative Code requires ADR wholesalers to conduct three transactions with a manufacturer within six months to gain ADR exemption status. Another method of becoming an ADR is through a written agreement with the manufacturer that specifies a time period for which the wholesaler will be an ADR; at least one transaction must occur during this time period.

[2] The law also states that once a pedigree paper is generated for a drug, it must be passed to all subsequent wholesalers who purchase the drug.

Findings

Counterfeit and diverted prescription drugs pose a substantial public health risk to patients and cost Florida millions of dollars annually

In recent years, state regulatory and law enforcement agencies have observed a significant increase in the incidence of counterfeit and diverted drugs. Bureau officials reported that between 50 and 55 of the 1,458 Florida permitted wholesalers are under suspicion for counterfeiting or diversion activities. [3] In addition, criminal prescription drug counterfeiting and diversion cases have increased from almost none in the 1990's to more than 50 since 1999. [4]

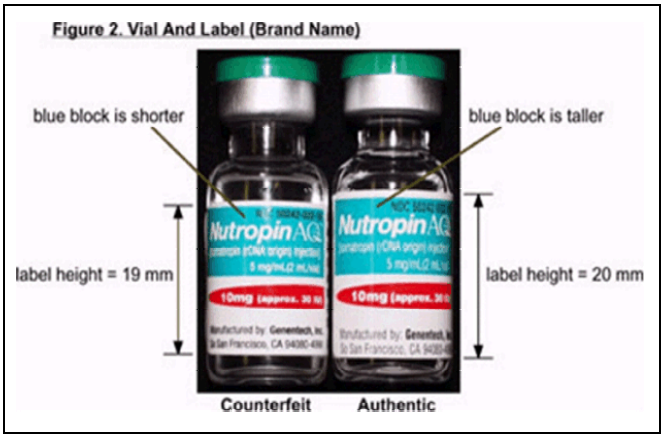
Counterfeit drugs pose major health risks. Criminals create counterfeit drugs by either producing substances that have no active ingredients but are labeled as genuine drugs or by relabeling genuine drugs as a higher strength version of the same drug or as an entirely different drug. These offenders duplicate manufacturer packaging and labels and falsify pedigree papers to sell the counterfeit drugs into the wholesale market as legitimate products. Counterfeit products are difficult to distinguish from authentic drugs, making it unlikely that health care professionals will detect them.

Counterfeiters have become experts at forging packages and labels. Exhibit 1 illustrates the small variations in size and label configuration between real and counterfeit products. Counterfeit and genuine prescription drugs are sometimes intermingled when they are sold to end-users, such as hospitals and pharmacies, decreasing the likelihood that the products will be identified.

[3] These wholesalers have suspicious pedigree papers, have bought or sold drugs without pedigree papers, or have permits but no records of conducting legitimate business.

[4] These cases involve both permitted wholesalers and individuals who are not permitted for wholesale drug distribution.

Exhibit 1
Counterfeit Drug Label Closely Resembles the Genuine Drug Label



Source: Department of Health.

Counterfeiters tend to target vulnerable populations. A current trend is to counterfeit high-priced drugs that are used to boost immune systems of cancer and HIV/AIDS patients. Because these patients are seriously ill, doctors may not immediately recognize the effects of a counterfeit drug. For example, physicians may attribute a patient's failure to respond or adverse side effects to the disease and not to a counterfeit drug.

A single case of counterfeit drugs can place thousands of individuals at risk and result in huge profits for criminals. For example, a 2001 investigation discovered that South Florida criminals had counterfeited Procrit®, a drug used to boost the immune systems of cancer and HIV/AIDS patients. The criminals relabeled approximately 110,000 bottles of low strength Epogen® to make the bottles appear to contain a high strength Procrit®, a drug 20 times the strength of the Epogen® in the bottles. The criminals resold the relabeled drugs into the wholesale market with forged pedigree papers, passing the drugs through four states and four wholesalers. Florida investigators located 800 boxes of the counterfeit Procrit® in the warehouse of a large Texas wholesaler, which had unknowingly purchased the counterfeit Procrit®. In addition, investigators found some of the product in North Carolina. Investigators recovered less than 10% of the counterfeit Procrit®.

The remaining amount consisted of dosages sufficient to treat 25,000 cancer patients for one month had it been the high strength Procrit®. Thus, instead of receiving the proper dosage, a large number of seriously ill cancer or HIV/AIDS patients may have received lower dosages than needed. Bureau officials estimated that the counterfeiters made an illicit profit of approximately $46 million. [5]

Diverters fraudulently obtain prescription drugs and sell them back into the wholesale market for substantial profits. Diversion occurs when individuals buy drugs from end-users such as patients, nursing homes, practitioners, and pharmacies and resell these drugs to wholesalers. Offenders obtain drugs for prices substantially below the market value, often from closed pharmacies, such as those in hospitals and clinics. [6] Diversion is a major problem in the Medicaid program, because criminals can obtain these drugs at low cost. Diverters persuade Medicaid clients to 'doctor shop', encouraging them to get prescriptions written and filled they do not plan to use. The diverters buy the drugs from the clients for a small fee, and then sell the drugs back into the wholesale market for a profit. Diverters also may obtain reduced-price drugs intended for export to charitable foreign missions or steal them from warehouses, clinics, or trucks.

To facilitate diversion, dishonest wholesalers seek to own or have business interests in pharmacies and clinics. In one case, two individuals with interests in seven corporations obtained $1.3 million in drugs through fake Medicaid HIV/AIDS prescriptions then sold the drugs back into the wholesale market for $2.3 million.

Even when diverted drugs are genuine products, they pose significant public health risks. Diverted drugs circulate in environments that are not regulated or inspected which compromises their safety and effectiveness. Prescription drugs often have specific storage and shipping requirements to ensure efficacy. However, diverters may not store or ship products under proper conditions.

[5] While the low strength Epogen® costs $22.40 per bottle, the high strength Procrit® sells for approximately $445 a bottle. As the fraud case involved 110,000 bottles, the illegal profits would equate to approximately $46 million.

[6] Closed pharmacies are not open to the general public, but fill prescriptions for patients in these facilities.

For example, bureau investigators in South Florida confiscated diverted drugs requiring refrigeration from the trunk of a car, where they had been for an unknown period of time during August without any form of coolant.

Drug diversion is estimated to cost Florida's Medicaid program millions of dollars annually. While the amount of diverted Medicaid drugs is unknown, regulatory officials estimate that of Florida's nearly $2 billion Medicaid prescription drug budget, millions of dollars are lost annually due to drug diversion. According to these officials, Medicaid drugs comprise the single largest source of diverted prescription drugs.

In some diversion cases, Medicaid may well pay for the same drugs several times. For example, in 2002 investigators confiscated $297,000 worth of Panglobulin® as it was about to be diverted from the market for a third time.[7,8] The diversion was detected when a clinic billed Medicaid for the drug two months after a pharmacy had billed Medicaid for the same exact boxes of Panglobulin®.

Regulation of Florida's prescription drug wholesale market needs to be strengthened to control drug counterfeiting and diversion

Florida's current laws and procedures for regulating the prescription drug wholesale market have three major weaknesses that need to be addressed in order to reduce drug counterfeiting and diversion.

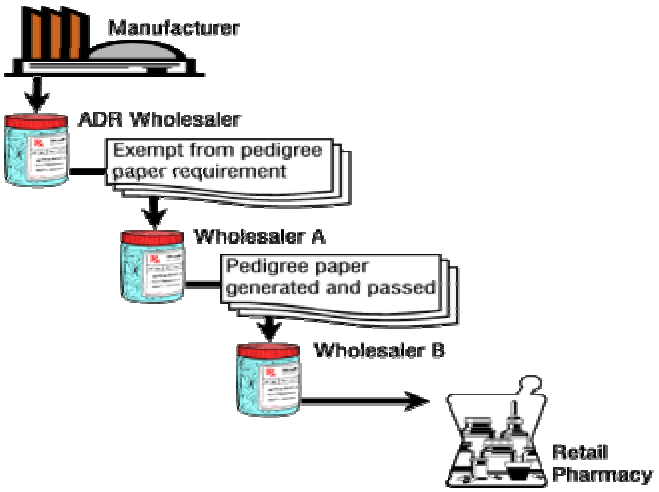
- Lack of clarity in the law allows counterfeiters and diverters to introduce illicit drugs into the prescription drug wholesale market.
- Inadequate safeguards for current drug wholesaler permit requirements make it easy for unscrupulous individuals to invade Florida's wholesale market.
- Inadequate administrative and criminal penalties for drug counterfeiting and diversion do not deter criminal behavior.

Unclear definition of Authorized Distributor of Record (ADR) designation contributes to criminals concealing counterfeit and diverted drugs

Pedigree paper requirements should prevent criminals from introducing counterfeit and diverted drugs into the wholesale market**.** However, current laws regulating Florida's prescription drug wholesale market do not clearly define when authorized distributors of record (ADRs) are exempt from providing pedigree papers. As a result, ADR wholesalers do not provide pedigree papers for drugs that they purchased from other wholesalers, resulting in concealed counterfeit and diverted drugs that can reach end-users.

As illustrated in Exhibit 2, Florida's drug marketing laws assume that most prescription drugs pass in a linear manner from a manufacturer to an ADR wholesaler and then to one or two more wholesalers prior to a retailer or other end-user. Legislation presumes that drugs purchased from ADR wholesalers are safe and effective because they come directly from the manufacturer, and thus exempts ADR wholesalers from providing pedigree papers when they sell the drugs. However, current law provides that the next wholesaler that buys the drugs must provide a pedigree paper when it sells those drugs to another wholesaler. In addition, pedigree papers, once generated, should be passed to all subsequent wholesalers that purchase the drugs and should trace drugs back to the manufacturer.

Exhibit 2
Florida State Law Presumes That the Prescription Drug Industry Is Linear and Simple



Source: OPPAGA.

[7] Panglobulin® is a plasma-based drug used to treat immune system deficiencies.

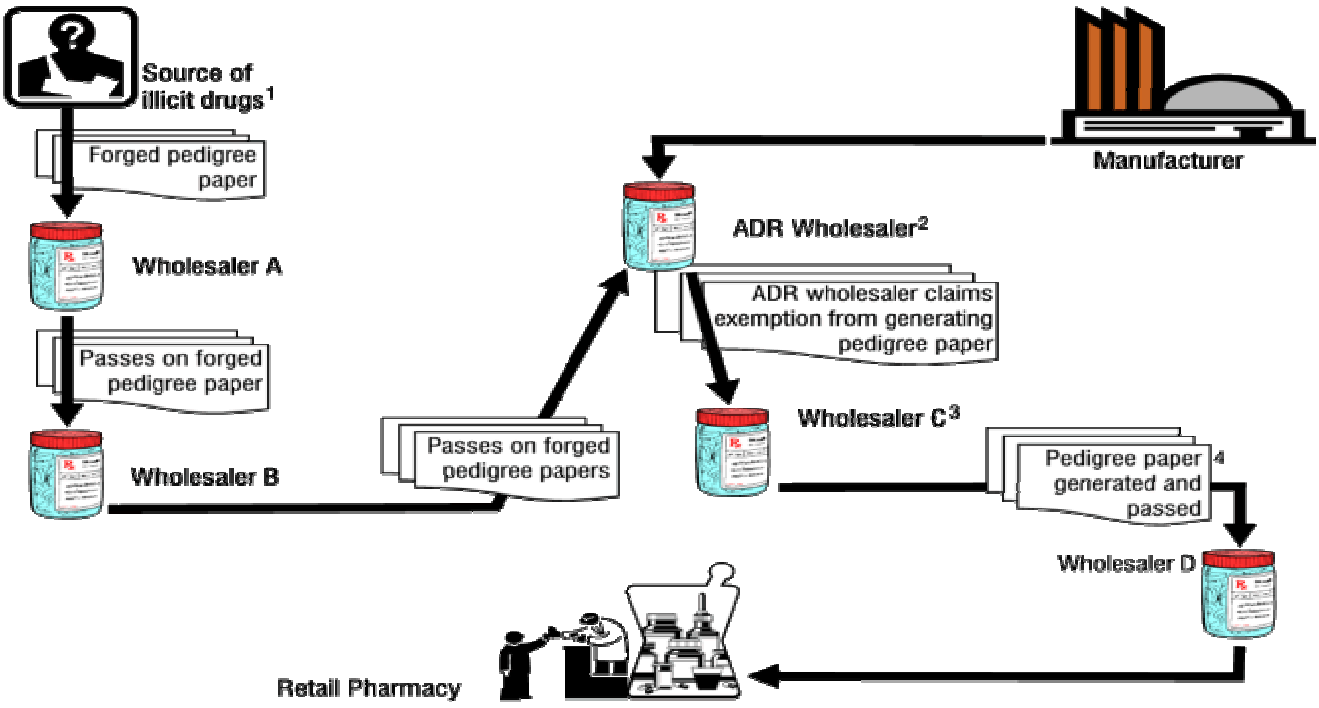
[8] The value of Panglobulin® was calculated based on 413 boxes of 12 gram vials priced at $720 per box.

However, actual industry practice departs sharply from assumptions of the law, and a prescription drug can change hands or 'churn' through many wholesalers. Prescription drug wholesalers gain profits by purchasing drugs at lower than market value from manufacturers or other wholesalers that they then resell at a markup to other wholesalers. If obtained well below market value, a drug can pass through several wholesalers before it is sold at retail cost. In addition to purchasing from manufacturers, ADR wholesalers also buy from other wholesalers. It is this multi-layered and circuitous, or 'churning', environment that provides multiple access points to introduce illegitimate products into the wholesale market, making pedigree papers important for detecting these products.

However, because Florida law currently defines authorized distributors of record as wholesalers having an "ongoing relationship" with the manufacturer, large wholesalers typically claim the ADR exemption from pedigree papers for *any* purchase they make, even those purchased from another wholesaler and not from a manufacturer.

When an ADR wholesaler does not provide pedigree papers for *all* purchases not from a manufacturer, it can inadvertently conceal counterfeit and diverted drugs. As illustrated in Exhibit 3, the ADR claims an exemption for a drug shipment purchased from the manufacturer as well as a shipment of the same drug purchased from another wholesaler. The ADR stores the drugs purchased from both sources together and randomly selects packages of the drug for shipment to its customers. Wholesalers that purchase from the ADR could receive both counterfeit and genuine drugs in their shipments. Because the pedigree paper generated by such wholesalers traces the drug back to the ADR and not to its origin, the entire sales history is concealed and drug safety is not guaranteed.

Exhibit 3
Illegal Drugs Cannot Be Traced if Passed Through the Authorized Distributor of Record Wholesaler



[1] Drug counterfeiters and diverters introduce drugs to the wholesale market by using forged pedigree papers.
[2] The ADR purchases drug shipments from another wholesaler as well as from the manufacturer; the ADR stores these shipments together and randomly selects packages of the drug for shipment.
[3] Shipments to wholesaler C from the ADR may include both counterfeit and genuine drugs.
[4] This pedigree paper only traces the drug back to the ADR wholesaler, not to the manufacturer.

Source: OPPAGA.

Enforcing Florida law to trace pedigree papers back to the manufacturer would likely reduce churning and make it harder for criminals to introduce counterfeit and diverted drugs into Florida's wholesale market. We believe that the ADR designation should be limited to wholesalers who buy drugs solely from the manufacturer; wholesalers who buy drugs from other wholesalers should be required to maintain and pass drug pedigree papers. This would make it harder for counterfeit and diverted drugs to pass through the system undetected because the sales histories would not be erased. If, as a result of stricter adherence to pedigree paper requirements, ADR wholesalers limit purchases from other wholesalers, the churning that currently allows multiple access points for criminals could decrease. Pedigree papers that trace all sales of a drug also can assist bureau investigators and law enforcement officials in tracking the origins of drugs they suspect have been counterfeited or diverted.

Weak permitting process makes it easy for wholesalers to enter Florida's prescription drug wholesale market

According to bureau officials, the state process for permitting prescription drug wholesalers needs to be strengthened to help ensure that only legitimate wholesalers do business in Florida. Bureau officials asserted that under current procedures some individuals who they might otherwise deny a permit are able to gain access to the wholesale market by using another person, usually a relative, as a front. In order to deter criminals from gaining access to the wholesale market, the bureau needs to collect background information on all individuals who are or intend to be affiliated with wholesalers seeking a permit and be able to deny or revoke permits based on this information.

Bureau officials also said that they have concerns about some wholesalers that maintain warehouses but do not appear to be actively doing business. Routine inspections of wholesalers' premises have found that some wholesalers maintain warehouses but have no drug inventory. Bureau officials suspect these premises may be used for illegal transactions. However, the bureau has no authority to deny or revoke permits for such businesses. Bureau officials need to ensure that only wholesalers actively doing business can obtain permits.

Moreover, the bureau extends reciprocity to wholesalers that are permitted in other states, even though Florida law provides that reciprocity should be granted only to wholesalers from states with comparable permitting procedures. Bureau officials interpret comparable permitting procedures to mean that the other states follow federal requirements. The federal requirements are less stringent than Florida's; for example, federal requirements do not require inspection of wholesalers' premises prior to issuing a permit. To strengthen the permitting process, the department should define the conditions under which other states' permitting procedures will qualify for reciprocity. By extending reciprocity only to out-of-state wholesalers in states that meet these conditions, the bureau would ensure that they are held to the same standards as in-state wholesalers. Wholesalers from states with less stringent requirements would then have to meet state requirements before receiving a permit.[9] Strengthening the permitting process should help the bureau ensure the legitimacy of wholesalers seeking permits in Florida.

Current administrative and criminal penalties may not deter criminal behavior

Criminals who counterfeit and divert drugs put the public at risk, make huge illicit profits, and waste government resources. Yet, current administrative and criminal penalties for counterfeiting and diverting prescription drugs may not be severe enough to deter criminals.

Administrative penalties may not deter criminal wrongdoing or discourage wholesalers from making questionable purchases. According to state law, when routine inspections or investigations reveal that wholesalers have violated prohibited acts, the bureau can impose administrative penalties (see Appendix B).[10] The bureau applies penalties based on the severity of a violation in terms of the threat to public health.

[9] While it may not be practical for the bureau to conduct routine on-site inspections of out-of-state wholesaler facilities, the bureau could conduct them as needed and could also require out-of-state applicants to submit photographs or videotapes of facilities.

[10] Inspectors conduct investigations generated from complaints by consumers and the industry, referrals from other government agencies, and as a result of routine inspections.

The least severe penalty the bureau can impose on wholesalers is a fine ranging from $250 to $1,000. For violations it considers most severe, the bureau can impose fines ranging from $1,000 to a maximum $5,000 and suspend or revoke a wholesaler's permit. For investigations closed in calendar year 2001, the bureau assessed permitted wholesalers fines totaling $116,600 of which it collected $65,352 and revoked 13 wholesaler permits.

This administrative fine structure likely has little deterrent power given the very large potential profits from diverted or counterfeit drugs (up to $50 million in some cases). Rather than viewing administrative fines as deterrents, unscrupulous individuals may simply regard them as a small price to pay for such a lucrative business.[11] A greater deterrent would be increasing the maximum fine to a level that would more closely match the potential illicit financial gain from diverted or counterfeit drugs, such as maximum of $50,000.

In addition, the fines are difficult to collect because, according to bureau officials, permitted wholesalers that intentionally counterfeit and divert drugs usually close their businesses and flee once they learn they have been detected. Even though these individuals have personally profited, they leave no business assets upon which the bureau can impose and collect fines. The Legislature could consider establishing additional administrative requirements, such as requiring wholesalers to be bonded as assurance against administrative fines, to strengthen the bureau's ability to collect fines.

Current criminal penalties may not discourage criminal behavior. Even though a single case involving counterfeit or diverted drugs can negatively affect the health of thousands of innocent people, criminals who commit such egregious crimes are subject to spending little time in prison. Under current criminal code, some prohibited acts involving counterfeit or diverted drugs are classified as third degree felonies, while others are first or second-degree misdemeanors. For example, first-time offenders diverting drugs from a hospital or a charity could be prosecuted only as a second-degree misdemeanor with a maximum sentence of 60 days incarceration and a $500 fine. The maximum sentence for first-degree misdemeanors is one-year incarceration and a $1,000 fine, while third-degree felonies carry a maximum sentence of five years incarceration and a $5,000 fine. In some instances, state attorneys may decline to prosecute offenses classified as misdemeanors given their other criminal caseloads. Without harsher criminal penalties to deter individuals from counterfeiting or diverting prescription drugs, corrupt individuals may continue to manipulate Florida's prescription drug market without fear of serious consequences.

[11] Investigators and statewide prosecutors have investigated individuals that live in multimillion-dollar homes and drive expensive cars and boats.

Conclusions and Recommendations

The Bureau of Statewide Pharmaceutical Services is charged with protecting the public from misbranded and adulterated drugs and regulating Florida's prescription drug wholesale market. However, counterfeit and diverted drugs are a major problem in the state. Counterfeit and diverted drugs cases in Florida's prescription drug market have risen in recent years. Counterfeit and diverted drugs pose a substantial public health risk, and regulatory officials estimate that Florida's Medicaid program loses millions of dollars annually to these fraudulent activities.

Florida's current system to regulate prescription drug wholesalers needs to be strengthened to help eliminate counterfeit and diverted drugs. We therefore recommend that the Legislature consider four actions described below.

- **Clarify state law related to pedigree papers and direct the department to enforce the state law.** Currently, prescription drug wholesaler industry practices allow drugs to pass through numerous wholesalers before retail purchase. Requiring pedigree papers to accurately trace drug sales histories back to the manufacturer is vital to ensuring the integrity of Florida's prescription drug market. Redefining Florida's definition of *authorized distributor of record* to include only drugs purchased from the manufacturer will eliminate wholesalers from claiming pedigree paper exemptions for prescription drugs not

purchased from the manufacturer. Churning also likely would decrease making it more difficult for offenders to introduce counterfeit or diverted drugs into the market. Further, pedigree papers are necessary for investigators to trace counterfeit and diverted drugs back to their source.

- **Authorize the department to strengthen the permitting process.** Improving the permitting process will strengthen the bureau's ability to exclude individuals with criminal intent from legal access to Florida's prescription drug wholesale market. In order to verify true ownership and business legitimacy, the bureau needs to access and review additional information such as financial records.

  The department also should take action to ensure that it only gives reciprocity to out-of-state wholesalers from states that have a comparable permitting process to Florida's. To accomplish this, the department should define the conditions under which other states' permitting procedures will qualify for reciprocity. If a state meets these conditions, the department can presume that applicants from that state meet permitting qualifications; however, the department needs the ability to deny permits for any out-of-state applicant not meeting Florida standards regardless of reciprocity.

- **Authorize the department to levy increased administrative penalties and fines.** The current administrative penalty structure does not deter criminals from counterfeiting or diverting drugs nor does it promote conscientious behavior of legitimate wholesalers. Fines and penalties are minimal compared to the public health threat created by counterfeit and diverted drugs. Refining the penalty structure by raising the severity of violations with corresponding increases in severity of penalties and fines may effectively deter fraudulent conduct and encourage more thoughtful behavior of wholesalers regarding questionable purchases. The Legislature should consider increasing the maximum fine that may be levied by the department from $5,000 to $50,000. The Legislature should also consider additional methods of reaching assets, such as requiring wholesalers to be bonded, as assurance against administrative fines, which would strengthen the bureau's ability to collect fines.

- **Consider increasing criminal penalties for prohibited acts involving prescription drugs.** To more effectively deter criminals from counterfeiting and diverting drugs, the Legislature should consider raising criminal penalties for prohibited acts involving counterfeit prescription drugs and drug diversion to second-degree felonies. Stiffer criminal penalties for counterfeiting and diversion will also more likely result in criminal prosecution and consequences that are commensurate with the violation of threatening public health and individuals' well-being.

OPPAGA provides objective, independent, professional analyses of state policies and services to assist the Florida Legislature in decision making, to ensure government accountability, and to recommend the best use of public resources. This project was conducted in accordance with applicable evaluation standards. Copies of this report in print or alternate accessible format may be obtained by telephone (850/488-0021 or 800/531-2477), by FAX (850/487-3804), in person, or by mail (OPPAGA Report Production, Claude Pepper Building, Room 312, 111 W. Madison St., Tallahassee, FL 32399-1475).

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Frank Alvarez, Staff Director (850/487-9274)
John W. Turcotte, OPPAGA Director

Appendix A

Pedigree Paper Traces Sales History of a Drug

Table A-1 is an example of a pedigree paper that Wholesaler XYZ would pass on to the next purchaser. XYZ, the most recent purchaser, received the drugs from ABC Group, Inc., who purchased the drugs from PQR Medical. As shown in Table A-1, Cardinal Distribution is an ADR wholesaler and was not required to disclose the previous owner, which could have been the manufacturer or another wholesaler.

Table A-1

XYZ PHARMACEUTICAL, INC.
41 SOUTH SMITH CIRCLE
SUITE 3
BOCA RATON, FL 33487
License #22:00XXX

STATEMENT IDENTIFYING PHARMACEUTICAL SALE

XYZ Pharmaceutical, Inc. ("Supplier"), a licensed wholesale pharmaceutical distributor, is providing the following statement pursuant to the requirements of section 503(e)(1) of the Federal Food, Drug and Cosmetic Act, and Prescription Drug Marketing Act ("PDMA"), as amended:

INVOICE # 2000315

PRODUCTS

NDC #55513-0209-10	Neupogen 480 MCG .8 ML Vial (10/BX) Lot #: P002660 Expiration: 08/03 - 3

For the products listed above, Supplier is:

Authorized Distributor _____ *(check one)*
Licensed Wholesaler ___X___

If Supplier is not an Authorized Distributor for the products listed above, the pedigree is listed below:

NAME: ABC GROUP, INC.
ADDRESS: 114 OAKDALE CIRCLE
SUITE 1003
BOCA RATON, FL 33487
LIC. #22-00000
DATE OF SALE: 3/15/02
Authorized Distributor _____
Licensed Wholesaler ___X___

NAME: PQR MEDICAL
ADDRESS: ROAD WEST
SALT LAKE CITY, UT 84054
DATE OF SALE: 3/15/02
Authorized Distributor _____
Licensed Wholesaler ___X___

NAME: CARDINAL DISTRIBUTION
ADDRESS: 4422 S. 38TH PLACE
PHOENIX, AZ
Authorized Distributor ___X___
Licensed Wholesaler _____

Supplier hereby warrants that each product listed above fully complies with the PDMA and the Federal Food, Drug and Cosmetic Act ("the act"), 21 U.S.C. & et seq. as amended.

Angela Weldon
Authorized Signature

3-15-02
Date

Source: Department of Health.

Appendix B

Administrative Enforcement

Table B-1 lists some of the prohibited acts related to counterfeiting and drug diversion that constitute a violation of Ch. 499, *Florida Statutes*.

Table B-1

Lowest level of severity—warning notice, letter of violation with no fine, or notice of violation or administrative complaint with fine of $250 to $1,000 per violation per day.

Facility/Storage

- Inadequate facility, storage, security; unrestricted access to prescription drugs; ventilation, physical access

Operations

- Failure to notify department of address change

Recordkeeping

- Not maintaining a complete audit trail
- Failing to maintain records, inventories [1]
- Failing to make records available [1]

Adulterated/misbranded

- Receiving adulterated / misbranded product
- Activity with adulterated or misbranded product [1]

Unauthorized source or recipient

- Purchase or receipt of prescription drug from unauthorized source

Middle level of severity—notice of violation or administrative complaint with fine of $500 to $2,500 violation per day.

Facility/Storage

- Improper temperature conditions

Operations

- Refusing entry, inspection, taking evidence [1]

Recordkeeping

- Absence of/ not providing pedigree papers

False/misleading

- Forging, counterfeiting, falsely representing a product [1]
- Making false or fraudulent statements [1]

Highest level of severity—notice of violation or administrative complaint with a fine of $1,000 to $5,000 per violation per day, suspension of the permit with a fine, or revocation of the permit with a fine.

Counterfeit

- Making/dealing in a counterfeit product

Samples

- Sample drug distribution or related activity

[1:] Depending on the seriousness of the violation, the level of severity can be increased.

Source: Rule 64F-12.024, *Florida Administrative Code*.

Appendix C

Jeb Bush
Governor

John O. Agwunobi, M.D., M.B.A.
Secretary

February 24, 2003

John W. Turcotte, Director
Office of Program Policy Analysis
& Government Accountability
111 West Madison Street
Room 312
Tallahassee, FL 32399-1475

Dear Mr. Turcotte:

Thank you for the opportunity to respond to the Office of Program Policy Analysis and Government Accountability's [OPPAGA] justification review, *Counterfeit and Diverted Drugs Threaten Public Health and Waste State Dollars.* Please find enclosed our response to the report recommendations made to the Legislature.

We appreciate the opportunity to comment. If you have questions, please contact us.

Sincerely,

/s/
John O. Agwunobi, M.D., M.B.A.
Secretary, Department of Health

JOA/mhb
Enclosure

Preliminary and Tentative Findings Response

Counterfeit and Diverted Drugs Threaten Public Health and Waste State Dollars

Finding	*Recommendation*	*Management's Response*	*Corrective Action Plan*
Regulation of Florida's prescription drug wholesale market needs to be strengthened to control drug and counterfeiting and diversion.	We recommend that the Legislature consider four actions: 1) Clarify state law related to pedigree papers and direct DOH to enforce the state law; 2) Authorize DOH to strengthen the permitting process; 3) Authorize DOH to levy increased administrative penalties and fines; and 4) Consider increasing criminal penalties for prohibited acts involving prescription drugs.	The department concurs with the recommendation and has submitted a proposed bill for consideration in the 2003 Legislative session. The recommendation is directed toward the Legislature, not the department, so no additional action is required on the part of the department.	Not applicable.