

IN THE SUPREME COURT OF THE STATE OF FLORIDA

Case No: SC02-2645

FIRST INTERIM REPORT
OF THE
SEVENTEENTH STATEWIDE GRAND JURY

I. Introduction

We, the members of the Seventeenth Statewide Grand Jury have been called upon to examine, among other matters, the safety of prescription drugs in Florida. In particular, we have examined the situation concerning the sale and re-sale of prescription drugs in the wholesale market. We have received testimony from representatives or owners of large and small wholesalers as well as the pharmaceutical manufacturers. We have also heard from agency officials with the Department of Health, the Bureau of Statewide Pharmacy Services and the Agency for Health Care Administration. Testimony was also received from Florida Department of Law Enforcement Special Agents and Bureau of Statewide Pharmacy Services Investigators. As a result of what we have learned, we make certain findings and recommendations, though we hasten to add that as the title of this report indicates, we are only at the beginning of our inquiry.

Because of the potential danger to the public, we have sought to work as quickly and efficiently as possible and pledge to continue to do so through the duration of this Grand Jury.

II. Scope of Problem

There exists in Florida approximately 422 licensed wholesalers in the prescription drug industry. In addition, there are approximately 977 wholesalers outside of the state of Florida that are licensed by the State to ship prescription drugs into Florida. These wholesalers buy and sell prescription drugs to one another and eventually to end users such as hospitals, clinics, doctors, and pharmacies. An alarming percentage of the drugs flowing through the wholesale market have been illegally acquired. That is, they have been stolen from shipments, pharmacies, clinics, and hospitals; purchased on the black market from recipients and health care professionals who are defrauding insurance companies or Medicaid with bogus prescriptions; or illegally imported from overseas. This activity is commonly referred to as drug diversion.

Many of the wholesalers in Florida's market are unqualified, inexperienced, irresponsible and incompetent to properly handle, store or deal in pharmaceuticals. Some even have criminal records, though how many is impossible to know since Florida only does minimal background checks before issuing wholesale permits. Any drugs that come into the possession

of these wholesalers, whether acquired legally or illegally, are likely to become tainted due to improper handling and storage.

Some of these drugs are re-labeled by counterfeiters to hide the fact that they have expired, been previously dispensed, or illegally imported; to falsely overstate their strength (sometimes by as much as 2,000%); or to pass off some other substance as a genuine pharmaceutical. These drugs enter the market place through corrupt secondary wholesalers. Once in the system they move from wholesaler to wholesaler and ultimately to unknowing consumers. These tainted drugs can move easily into and through the system largely due to the failure of federal and state agencies to strictly enforce the law, as well as the complicity of wholesalers who turn a blind eye to the corrupt practices of other wholesalers that supply them with some of their pharmaceuticals. Though the overall amount of tainted pharmaceuticals is likely to be small, we believe the percentage is undoubtedly higher among the more expensive injectable pharmaceuticals often used to treat patients suffering from cancer, AIDS, or undergoing transplants. These are obviously some of the most vulnerable patients and the ones that can least tolerate adulterated drugs. We have seen increasing evidence that more common drugs such as antibiotics and cholesterol reducing medication are also being diverted and counterfeited. We do not find it useful to list the specific drugs being counterfeited since the list is not static and any list would likely be outdated as soon as written. Investigators regularly find new counterfeit drugs to add to the list.

Exactly how much of Florida's drug supply has been stolen, mishandled, tainted or fraudulently re-labeled is impossible to tell with any accuracy. Our inability to get a handle on the size of the problem is alarming to say the least and is a part of the overall larger problem of drug diversion. Whatever the true figure is, we recognize that any amount of adulterated pharmaceuticals is too much.

We have learned that the Florida Department of Law Enforcement (FDLE), Miami-Dade police and investigators from the Bureau of Statewide Pharmacy Services (BSPS) have been investigating numerous targets involved in counterfeiting and diversion and we anticipate returning indictments in the near future based on the evidence presented to us so far. What we have heard so far is shocking and disturbing. The potential profits available to corrupt wholesalers rival those found in narcotics trafficking. The drugs most commonly trafficked in by secondary wholesalers are some of the most expensive made today. These are drugs used to treat cancer and AIDS patients, as well as drugs used in organ transplants. As an example, a box of Epogen with a strength of 2000 units may sell for \$258. Re-labeled as 40,000 units, the same box might sell for \$4,570. One investigation revealed a shipment of 11,000 boxes of counterfeit Epogen and Procrit which resulted in a profit of \$28,000,000 to the counterfeiters. There are many other examples, but all have in common that the profits from the crime far outstrip the potential penalties. While the conduct is clearly illegal, to say nothing of reprehensible, we have learned that many violations of Chapter 499, Florida

Statutes, which governs the regulation of pharmaceuticals, carry only weak penalties. As an example of this weakness, under the current statutes forging documents that accompany prescription drugs is a felony, but buying and selling these drugs without any documentation is a misdemeanor. Even the sale of adulterated drugs is itself only a misdemeanor. As a result, many unscrupulous people have been drawn to the wholesale market in Florida and even many who began legitimately have been corrupted.

The direct threat to people's health is not the only social cost of drug diversion. Last year Florida's Medicaid program spent \$1.8 billion in reimbursements for pharmaceuticals. We cannot know with certainty how much of Medicaid's pharmacy budget went to pay for diverted drugs. We do know that Medicaid paid \$218 million just on the top ten most commonly diverted and counterfeited drugs. It is safe to say that much of this Medicaid fraud is fueled by the ready market for diverted drugs in the secondary wholesale industry. This is particularly true of scams whereby Medicaid recipients are encouraged to purchase unnecessary drugs with the help of corrupt doctors, clinics and pharmacies and then trade these expensive pharmaceuticals for cash or illegal street drugs. Often times, these drugs wind up back on the shelves of pharmacies to be re-dispensed and paid for again by Medicaid.

We conclude that while there are a number of issues and circumstances to

address, there are some basic reasons for the existence of this problem: weak permitting requirements, lax agency oversight of wholesalers, insufficient criminal penalties and the failure of wholesalers to use due diligence in their purchasing decisions.

III. Findings

A. Structure of Pharmaceutical Drug Market

In 2001 the American pharmaceutical industry produced and shipped approximately \$172,000,000,000 worth of prescription drugs for the American market. Of that amount, approximately 46% was shipped directly to dispensers such as hospitals and pharmacy chains, and 54% went to wholesalers. Of the amount that went to wholesalers, approximately 90% went to the three largest wholesalers in the country. The balance of the manufacturer's output went to the several thousand smaller wholesalers that collectively make up what is referred to as the secondary wholesale market. (Some in the industry describe the market in three tiers, with the 3 largest wholesalers in the first tier, approximately 12 to 15 regional distributors as the second tier and the rest of the smaller wholesalers making up the third tier). There are over 14,000 different prescription drugs being produced today. Most of these drugs are fairly stable and tolerant of a range of storage conditions. Many, particularly expensive injectables, are not stable and must be carefully maintained in regards to both temperature and humidity. Some, like Epogen, must be stored between 36°F and 46°F and can break down simply by being shaken excessively. Manufacturers publish the conditions under which their product must be stored and handled, but other than agreements with their wholesale purchasers, manufacturers have no ability to control how their products are handled once they move down the

distribution chain.

Wholesalers sell pharmaceuticals to both dispensers and to smaller wholesalers which, in turn, may sell to even smaller wholesalers or dispensers. This distribution system is typical of most industries and, for the most part, described the pharmaceutical industry in 1988. Since then, however, there has been a sharp increase in the number of small wholesalers in this country. In Florida alone there are 422 instate and 977 out of state wholesalers licensed to sell pharmaceutical products within this state. To put this number in context, there are approximately 3,400 walk-in and 1,000 institutional pharmacies in Florida, or approximately one wholesaler for every three pharmacies. The three largest wholesalers get more than 95% of their stock directly from the manufacturers, making them an Authorized Distributor of Record (ADR) for virtually every drug maker. On the other hand, they buy something less than 5%, and perhaps as little as 1% to 2% of their stock from other wholesalers, mostly in the secondary market. Smaller wholesalers also sell to dispensers but most of their sales are to each other or to a larger wholesaler that is an ADR. Drugs ultimately being sold to dispensers are then moving up, down and sideways through the distribution system. This creates opportunities for adulterated drugs that have been diverted from other sources to enter the distribution system.

The primary protection against acquiring drugs that have been diverted is the statutory requirement that documents tracing all sales of the drug back to the manufacturer must be provided to a prospective buyer before the transaction

takes place. Licensing and inspection of wholesalers is intended to add another layer of protection. We review these two statutory requirements in order.

B. History of Pedigree Papers

In 1988 Congress enacted the Pharmaceutical Drug Marketing Act (PDMA). A key component of the act, which was aimed at stopping the diversion of pharmaceutical drugs, was a requirement that wholesalers pass on what became known as “pedigree papers” with every sales transaction all the way to the dispenser, such as a doctor, hospital or pharmacy. These pedigree papers are nothing more than a document which shows every purchase and sale of the pharmaceuticals from the first wholesaler that purchased the drugs directly from the manufacturer. Pursuant to this statute, the Food and Drug Administration (FDA) first proposed a rule setting out the specific requirements of these pedigree papers in 1994. The rule was to take effect in 1999. Due to the efforts of some drug wholesalers, the rule has been stayed three times since 1999 while FDA considers the economic impact of the rule on wholesalers.

Florida incorporated the pedigree paper requirements into Chapter 499, Florida Statutes, in 1993 and promulgated its own rule in 1996. Florida’s rule differs from the federal rule in two important respects. First, the Florida rule requires that the pedigree paper trace the transaction all the way back to the manufacturer and not just the first wholesaler. Secondly, Florida does not

require the pedigree papers to reach all the way to the dispensers.

Florida's rule, unfortunately, had not been strictly enforced for some years. In November 2001, the Bureau of Statewide Pharmacy Services (BSPS), Department of Health (DOH), sent a letter to the wholesale industry detailing the requirements of Florida law and signaling its intention to strictly enforce the rule. This action was taken in response to information the Bureau was receiving of diversion and counterfeiting in the wholesale industry and of the almost total failure of the industry to comply with the pedigree paper rule. In February of 2002, after objections were raised by the industry, DOH temporarily set aside the November letter and instead impaneled an Ad Hoc Committee on Pedigree Papers. The committee was charged with resolving what DOH viewed as a dilemma between protecting the public from adulterated drugs and lessening the regulatory burden on the wholesale industry. Enforcement of Florida's rule, as written and interpreted by DOH, was therefore suspended as of February 2002. The Ad Hoc Committee finally issued its recommendations to DOH on October 31, 2002. Subsequently, DOH proposed a new rule to take effect on March 1, 2003, which simply and concretely spelled out that pedigree papers would have to be provided by all wholesalers. This proposed rule would have required pedigree papers to trace pharmaceuticals from manufacturer to dispenser.

This proposal drew immediate fire from the wholesale industry and was thereafter withdrawn by DOH in favor of another, two-tiered rule. This newly proposed rule would require pedigree papers to be provided from manufacturer to dispenser, but only for a list of 30 or so drugs that are often counterfeited or diverted. All other pharmaceutical drugs (over 14,000)

would be handled according to what has evolved as industry practice as explained below.

C. Industry Practice

In the absence of a federal rule and the failure of Florida to enforce its own rule, the industry has developed a practice that it claims is consistent with its own interpretation of Florida law. Wholesalers state that, in their interpretation, if they meet the definition of an Authorized Distributor of Record (ADR) for a particular manufacturer, then they are exempt from the requirements of providing a pedigree paper for any of that manufacturer's drugs in any transaction, regardless of where the wholesaler acquired the drugs being sold. That is, even if a wholesaler purchases Procrit out of a car trunk, they believe that they are not obligated to provide a pedigree paper in any subsequent sale of that product as long as they are an ADR of that manufacturer for that product. Once at the wholesaler's warehouse, drugs from all sources are co-mingled and the ability to trace drugs back to their particular source is lost. Some wholesalers go so far as to say that they are not required to pass pedigree papers on for any product of a manufacturer for which they are an ADR, regardless of where the wholesaler acquired the drugs being sold in the transaction.

We have not heard from a single witness who adopts this bizarre interpretation other than the wholesalers themselves. It is directly contrary to the interpretation of Florida regulators, but without any strong enforcement

action on Florida's part it has become the "status quo" in the wholesale industry. As a result, we see transactions moving "up" the distribution chain to an ADR so that any pedigree paper previously created stops at that transaction and the sales history of the drug is effectively washed away.

There is an assumption among some dispensers that pharmaceuticals purchased from a wholesaler claiming ADR status came directly from the manufacturer. That assumption is not valid and we hope that one result of this report is to alert dispensers of this misconception. The reality is, and the operating assumption should be, that some percentage of drugs sold by wholesalers today, even those that are ADRs, come from the secondary market. Without a pedigree paper being provided and verified through the chain of transactions, it is impossible for consumers to know with absolute confidence that the drug they are getting from their doctor or pharmacy has not been diverted or adulterated.

D. Agency Oversight

The purpose of Chapter 499 as expressed in section 499.002(1), F.S., is to safeguard the public health and promote the public welfare by protecting the public from injury by product use and by merchandising deceit involving drugs, devices, and cosmetics. DOH's specific mandate, as expressed in section 499.004, is to administer and enforce sections 499.001 to 499.081 to prevent fraud, adulteration, misbranding, or false advertising in the

preparation, manufacture, repackaging, or distribution of drugs, devices, and cosmetics. Unfortunately DOH's efforts in regard to pharmaceuticals has been less than exemplary. This does not appear to be the result of a lack of hardworking and dedicated people. There seems to be plenty of people like that working for DOH and in particular BSPS. It does appear to us that the personnel most involved in the enforcement effort have not been getting the support they need, particularly in regards to resources and statutory authority. We believe it is incumbent upon the leadership of both DOH and BSPS to examine practices in their organizations and find the cause of the problems outlined in this report.

1. Permitting

BSPS is charged under Chapter 499, F.S., with the task of licensing and inspecting wholesale pharmaceutical distributors who are either based in Florida or who wish to distribute drugs into Florida. Permit applications go to Tallahassee for processing. The applications are checked to ensure all boxes on the form have been filled out, but no information is verified. Only recently has DOH even required minimal criminal background checks. Citing a lack of authority, DOH only requires applicants to submit a letter from their local law enforcement agencies stating that they have no criminal record in the county where they wish to be licensed. Some wholesalers have been issued permits despite one or more felony convictions. (This year DOH is asking the Florida Legislature for authority to take fingerprints and perform

national criminal background checks.) The applications themselves are exceedingly brief and ask very little information of the applicant. There are no questions regarding the applicant's financial viability, education, training or any specialized knowledge in the field of pharmaceuticals. There is no certification or testing of any kind. A bond is required, but only in the token amount of \$200.00. In short, virtually anyone with \$200.00 for a bond and \$700.00 for permit fees, can be licensed as an instate pharmaceutical wholesaler in Florida.

Once applications are checked in, a BSPS inspector is assigned to do a physical inspection of the establishment. If the facility passes inspection, the permit is issued as a matter of due course. Virtually any facility with a thermostat controlled air conditioner, a burglar alarm and a refrigerator (even a table top size) will pass inspection. But for the specific prohibition against residences in the rule, any condo or apartment in Florida would likely pass inspection. There appears to be little room for exercise of discretion by agency officials in Tallahassee as applications are rarely denied by BPS.

2. Enforcement

a. Pedigree Papers

Buying drugs with missing or forged pedigree papers is like buying an open bottle of medicine off the drugstore shelf. No one in their right mind would buy such drugs, but that is what many Floridians are unwittingly doing as a

result of lax enforcement of the pedigree papers requirement.

DOH had been aware of the problems with diversion and counterfeiting at least as early as the fall of 2000. Its own field investigators were conducting investigations into counterfeit drugs and additional information was being received from FDA investigators. By the Spring of 2001, DOH knew it had a serious problem on its hands and that the wholesale pharmaceutical industry in Florida was largely ignoring the pedigree paper requirements. These facts led to BSPS's attempt to strictly interpret and enforce Florida's pedigree paper rule in November of 2001.

As we explained earlier, Florida's statute on pedigree papers was enacted in 1993 and the rule was promulgated in 1996. We fail to understand why, almost 10 years after the passage of a state law, and 7 years after promulgating its own rule, a state agency would have to embark on a nearly year long debate with the industry it regulates as to when, whether and how to enforce state law; but that is precisely what occurred when DOH receded from its expressed intention in the November 2001 letter and instead impaneled the Ad Hoc Committee on Pedigree Papers. To this day Florida's pedigree paper rule is not being strictly enforced and it appears that a new rule which, at the industry's suggestion, will limit the requirement of pedigree papers to approximately 30 drugs, will not take effect until this summer at the earliest.

We sharply disagree that the protection afforded by pedigree papers should be limited to 30 pharmaceuticals out of over 14,000 that exist in the market today. Such a limitation would inhibit the state's ability to address the problem of diversion and counterfeiting. Criminals can change the drugs they divert and counterfeit much faster than the state can amend its rule to add or delete drugs from the list.

We are of the belief that the debate was settled when our legislature passed the legislation and our governor signed it into law. As an executive agency DOH should be carrying out the mandate of our elected officials. The intent of the pedigree paper law is to protect the public by safeguarding our drug supply; that is nothing less than the will of the people as expressed through its elected legislature and governor. We have not heard any testimony that would justify a state agency undermining a legislative mandate, particularly in the area of public health and safety. Unfortunately, enforcement of the pedigree papers requirement is not the only area where enforcement must be improved.

b. Facilities Inspections

Rule 64F-12.013, Florida Administrative Code, sets out strict requirements for the storage and handling of pharmaceuticals. This rule is based on section 499.05, F.S., and is one of the mechanisms for protecting the public from tainted or adulterated drugs. Many drugs, if not stored properly, are

rendered worthless due to the breakdown of the active pharmaceutical ingredient. Violation of rules rarely result in license revocations. Last year, only two emergency license suspensions were signed by the Secretary of Health and only seven licenses revoked, while seven other licensees surrendered their licenses while under investigation. (Again, approximately 1,400 in-state and out of state wholesalers hold Florida wholesale licenses.)

Last year alone, Florida issued another 46 in-state licenses and 103 out of state licenses. Today there are 9 field inspectors in the entire state to inspect 422 wholesalers. That is one more inspector than in 1992. These same inspectors also have to inspect 1,500 retail oxygen distributors, 91 over the counter drug manufacturers, 78 pharmaceutical manufacturers, 122 cosmetic manufacturers, and 155 medical device manufacturers. In addition to their inspection duties, these same inspectors are tasked with the responsibility of investigating cases of adulterated or counterfeited drugs they discover during their inspections.

We frankly don't understand how DOH could possibly expect to adequately perform its inspection function with only 4 (we heard testimony that it may soon be 5) inspectors between St. Lucie and Monroe counties where almost 70% of the licensed wholesalers are located. Given that BSPS is self-funded, that is, their operations are funded by fees collected from the industry rather than tax dollars, we believe it is DOH's responsibility to collect the fees necessary to carry out its duties. We note that DOH's proposed

amendments to Chapter 499, F.S., include a fee increase, which we believe to be appropriate and necessary. We also support DOH's proposal to reduce the licensing period from two years to one and to perform inspections annually rather than bi-annually.

Regardless of how many inspectors BSPS has at its disposal, we believe that DOH should take a much more demanding approach to their inspections. It appears to us that BSPS takes a very accommodating view of the rules regarding the adequacy of wholesaling facilities. While individuals within BSPS might acknowledge that a 10 foot by 10 foot room with two desks, a table top refrigerator and a couple of thermometers hanging from a ceiling fails to meet a common sense definition of a wholesale facility, DOH has made the determination that such a facility does meet the requirements of their statutes and rules. As such , we recommend they promulgate new rules to redefine what is adequate and to seek whatever authority they feel is necessary to do so from the legislature.

BSPS's efforts to enforce their statutes and rules are hampered by significant limitations on their power to conduct on-site inspections of wholesale facilities and their ability to immediately respond to violations. For example, although pharmaceuticals stored in violation of the rules are considered adulterated, BSPS can not remove and destroy the drugs immediately. Instead, they must issue a stop sale order which prevents the wholesaler from disposing of the drugs until BSPS takes some further action.

If BSPS determines it is necessary to seize or destroy the adulterated drugs, it must apply for a court order. Furthermore, when BSPS determines that a facility falls below minimum requirements, although it can stop sale the drugs on the premises at that time, it has no authority to close the establishment and to keep it closed until the deficiencies are corrected. Consequently, there is nothing to stop the wholesaler from continuing to receive and store more drugs the moment the inspector leaves. This lack of authority in such an important field contrasts sharply with DOH's authority under a different statute to close restaurants that fail inspection.

DOH has the authority and obligation under section 381.0072, F.S., to inspect all food service establishments in the state. In addition to imposing fines and suspending or revoking licenses, the department may, at any time it finds a restaurant to be an imminent danger to the public health, order the immediate closure of the establishment. The establishment must remain closed until the deficiencies are corrected. We think that if the DOH has the authority to close restaurants that are a danger to the public, it only makes sense to give them the same authority to immediately close establishments warehousing drugs in an unsafe manner.

Section 381.0072, F.S., also gives DOH authority to immediately seize and destroy food that is determined to be a threat to the public health. In contrast, section 499.06 only gives DOH authority to *detain* or *stop sale drugs* that are dangerous, unwholesome or fraudulent. Again, it only makes

sense to give DOH the same authority over tainted drugs that it has over tainted food.

We reiterate that as Chapter 499, F.S., clearly spells out, the primary responsibility of the Department of Health is to protect the health of Floridians. There are some legitimate, honest, law-abiding wholesalers providing an important service in Florida. But it is just as clear that there are many more that are not by any definition legitimate. Uneducated, inexperienced, ill-informed rank amateurs with no pharmaceutical experience, many with criminal records, make up a sizeable portion of Florida's drug wholesalers. There are people who can not be trusted to perform the most trivial tasks, yet through their hands pass some of the most expensive and delicate life saving drugs that exist today. No one has to go to their warehouses to buy their tainted product, for eventually they show up in our hospitals, clinics and pharmacy shelves. The fact that Florida has licensed so many wholesalers with such minimal requirements should be of concern to all citizens. We understand and acknowledge that to some degree DOH's hands are tied due to a lack of statutory authority. We also believe, however, that whenever a state agency finds itself unable to carry out its mandate due to statutory limitations, especially a mandate to protect public safety, that it has an obligation to bring those issues to the attention of the legislature. At the same time, we expect agencies to do everything possible with the means at its disposal to carry out its mandate even in the face of such limitations.

E. Criminal Investigations

BSPS investigators have been working closely with FDLE and the Miami-Dade Police Department over the last year. Their cooperative efforts have led to significant seizures of adulterated pharmaceuticals and laid the basis for criminal prosecutions in the near future. Just four BSPS inspectors, along with a handful of investigators from FDLE and Miami-Dade Police, have in the last year seized \$20 million in adulterated pharmaceuticals in South Florida alone. Leads from cases developed by these investigators have led to additional multi-million dollar seizures of adulterated pharmaceuticals in other states.

These investigations have uncovered shocking conditions at many South Florida wholesalers, including counterfeit relabeled drugs, sensitive pharmaceuticals kept in hot, non air-conditioned warehouses, missing paperwork and phony pedigree papers. Some of these so-called businesses had invoices and receipts written on scraps of paper, or had no paperwork at all. Some inspections turned up employees who did not, or pretended not to, know anything about the business they were standing in.

Some of the investigations have turned up horror stories. One case concerned a father in Michigan who repeatedly injected his son with what he thought was a growth hormone. Alerted by his young child's complaints that the injection was burning him, he discovered that the vials actually contained

insulin. He did not buy that medication out of a car trunk or a back alley. Those drugs were traced to a legitimate pharmacy in Orlando, Florida, but it is obvious that this mislabeled, adulterated product was brought into the stream of commerce by some counterfeiter. Had the wholesaler bothered to check the pedigree by verifying the transactions, it would have discovered that the drugs could not be traced to the manufacturer. In fact, FDA, assisted by BSPS inspectors, traced the drug from the pharmacy to one of the major wholesalers then back to three prior secondary wholesalers. The last wholesaler in the chain did not have a valid license, but because it claimed to be an ADR the pedigree paper trail stopped there. This entire process took the investigators only minutes to accomplish.

Last year, a joint investigation by Florida and Texas investigators led to the seizure of over 1,000 boxes of 40,000 unit Procrit, a drug used to boost the immune system of cancer and HIV patients. If the drugs had been legitimate they would have been worth \$1,600 per box. In fact, the bottles were really 2,000 unit Procrit that had been re-labeled. Though the Texas wholesaler was in possession of a pedigree paper, it had not bothered to verify it. It took less than an hour for investigators to follow the pedigree trail from Texas to Miami, to Utah, to a closed wholesaler in California. From there, a phone call to the manufacturer revealed that they had never sold 40,000 unit Procrit to the wholesaler listed in the pedigree. That entire process took investigators less than one hour.

The most reprehensible individuals involved in the pharmaceutical wholesale market are the criminals who engage in counterfeiting or re-labeling drugs.

Investigators have uncovered millions of dollars worth of prescription drugs that have been counterfeited in different ways. Sometimes prescription drugs which have passed their expiration date are re-labeled with new (false) expiration dates. Prescription drugs are also re-labeled or repackaged in order to convert a lower strength and less expensive drug to a higher strength, more expensive drug. In other instances, containers of completely different substances are labeled as pharmaceuticals. Due to the lack of pedigree papers in many instances, or of insufficient information on the papers that do exist, investigators find it nearly impossible to track down those responsible for counterfeiting or re-labeling. Wholesalers who don't have a pedigree paper and can't remember the source of their drugs face only misdemeanor charges.

These people, through greed and malice, expose our most vulnerable citizens to death or grave injury every day. At the same time, they taint our pharmaceutical drug supply by introducing weakened or even dangerous substitutes into the stream of commerce and undermine public confidence in the safety of our pharmaceuticals. If this activity is not stopped, we can predict that, sooner or later, serious bodily harm or death will result, if it has not happened already.

The fact that these criminals act with such callous disregard for human suffering is immoral and despicable, but we find that others involved in the industry bear responsibility by turning a blind eye to this activity for the sake of profit. By doing so, they enable these counterfeiters and re-labelers to thrive. Counterfeiters and re-labelers simply wouldn't be in business if they did not have a steady supply of willing buyers in the marketplace.

Investigators have turned up countless examples of pedigrees showing multiple sales of the same parcels of drugs, sometimes going through the same wholesaler more than once, before winding up for sale to the end user. We have seen drugs pass through as many as five wholesalers before coming to rest. How these transactions make economic sense has not been satisfactorily explained to us. We make the basic assumption here that all wholesalers are in business to make money. How multiple sales between wholesalers, with its associated transactional and overhead costs, can legitimately make money for everyone in the chain is difficult to make sense of. It does, however, make sense if the pharmaceuticals in question were purchased for a small fraction of their true cost, as would be the case if the drugs had been illegally diverted in the first place.

F. Wholesale Industry Opposition

As we stated earlier, large pharmaceutical wholesalers buy some of their stock from secondary wholesalers. Their stated purpose for doing so is that,

from time to time, they claim there are shortages in the marketplace that they can only address by purchasing from secondary wholesalers. They also state that manufacturers on occasion offer pharmaceuticals to the secondary market at a significant discount from the wholesale price. These deals are not offered to the larger wholesalers which creates an opportunity for the major wholesalers to buy from the secondary market and lower their overall acquisition cost.

The essence of the wholesale industry's opposition to pedigree papers, as expressed in numerous forums, is that it would be prohibitively expensive to segregate within their warehouse stocks of drugs purchased from other wholesalers and stocks of drugs bought directly from the manufacturers. Furthermore, regardless of the cost, they claim they do not have the technical ability to successfully segregate and track these drugs bought on the secondary market. The industry is also opposed to pedigree papers because they would be required to pass on these documents in intra-company transfers, that is, shipments of drugs from one warehouse to another within the same company. Finally, even if these hurdles could be overcome, they claim that pedigree papers have no real value in deterring or discovering diverted or adulterated drugs. They also state that if they were required to verify the contents of the pedigree papers they received, their entire purchasing system would grind to a halt and they would no longer be able to buy in the secondary market.

Quite frankly we find these arguments to be weak and unpersuasive. The major wholesalers themselves have said that they buy over 95% of their product directly from the manufacturers, perhaps as little as 1% to 2% from other wholesalers. If that is true, then the industry, at most, would only have to provide pedigree papers for a small fraction of their volume. The number shrinks even further when we remember that only product going to another wholesaler requires pedigree papers. Pharmaceutical drugs going to dispensers do not require pedigree papers to precede or accompany it, at least not under current Florida law. We cannot understand how an industry with over \$93 billion in sales volume does not have the financial capability and technical expertise, or at least the ability to acquire the technical expertise, to more definitively track that 1-2% of their volume that they purchase from the secondary market. In fact , we understand from at least one smaller wholesaler that his company could segregate and track product by pedigree paper if only the major wholesalers would pass on those papers to his company.

Corporations that buy and sell billions of dollars in pharmaceuticals yearly undoubtedly have in place systems to track inventory for their own business reasons. Inventory must be carefully tracked in order to make optimal purchasing decisions. Lot numbers must be tracked in order to handle recalls. Expiration dates must also be tracked to make sure that older stock is sold first, just as in any other business. We know of no reason why the same methods and practices used to track inventory for these purposes

cannot also be applied to authenticate the source of their drugs.

The argument advanced by the wholesale industry that pedigree papers are worthless in deterring or discovering counterfeit and diverted drugs is based on their belief that pedigree papers can be easily forged. It is true that a pedigree paper alone is not much help if the buyer does not verify its authenticity. That is why we believe due diligence by the wholesale industry in authenticating pedigree papers is essential to guaranteeing a safe supply of pharmaceuticals. The purpose of pedigree papers is to give buyers a tool with which to protect themselves from buying diverted or counterfeited pharmaceuticals. That is why pedigree papers have to be provided before the transaction. If pedigree papers don't work it is because wholesalers have stubbornly refused to take advantage of this tool by not verifying their contents. This refusal has allowed phony pedigree papers to proliferate and has given counterfeiters easy access to introduce their products into the legitimate stream of commerce. It appears that no one in the industry cares enough to call and verify for fear of losing a purchasing opportunity. Under Florida law, a drug shipment accompanied by a forged paper is adulterated by definition and cannot be bought or sold. No legitimate company should touch such a product. It's not surprising to us then that no one checks the pedigree papers because they simply don't want to know the true background of what they're buying. This is nothing less than a blatant example of willful blindness.

We understand and acknowledge that pedigree papers can be forged, but that is not a reason to ignore them as the industry asserts; to the contrary, it

is why they must be verified. The industry puts forth the assertion that verifying and passing on pedigree papers would be so costly and time consuming that their operations would cease or they would go bankrupt. We believe this claim to be absurd. We have taken testimony of investigators who have verified or attempted to verify pedigree papers themselves and we see how quickly, cheaply and effectively it can be done. Furthermore, we note that not one industry witness has testified to any cost estimate or time estimate as to what it would take to verify pedigree papers in the normal course of business. It appears that no one in the industry has undertaken any controlled study to bolster their claims of prohibitive costs. In the absence of any good faith effort by the industry to substantiate their claims, we have no choice but to disbelieve it.

Finally, the industry's concerns that some critical drugs may be unavailable under some emergency circumstances can be easily addressed. For example, the Secretary of Health can be given authority to waive the pedigree paper requirements in cases such as bio-terrorist attack or other public emergencies.

It would appear that the wholesale industry wants the right to sell pharmaceutical products without explaining or even knowing where all of their products came from. In order to get a sense of the fairness of imposing a pedigree paper requirement verified through due diligence, we decided to see what, if any, other similar requirements were imposed on other

industries.

G. Rules for Other Industries

A very brief review of the Florida Statutes reveals a host of regulations imposed on many industries in Florida. The specific requirements of statutes and regulations vary with the potential harm being addressed and the history of problems in the industry. By any reasonable measure, the regulations imposed or sought to be imposed on the wholesale pharmaceutical industry are extraordinarily light given the enormous danger not only to the public health, but secondarily to Florida's economy.

As an example, in order to protect Floridians from tainted oysters, section 370.1603, F.S., directs the Department of Agriculture and Consumer Services to promulgate rules so that all oysters produced and sold in Florida can be traced back to their source. In this way, retailers can avoid oysters harvested from beds closed for health reasons. If people are sickened by a batch of oysters, the oysters can be immediately traced back to the point of origin so that health authorities can determine whether or not to close these beds to harvesting.

The rules promulgated pursuant to this statute are contained in Rule 5L-1.007, F.A.C., and require that oyster containers have attached a plastic

waterproof tag that contains the harvester's license number, the date, time and precise location where the oysters were harvested, time of refrigeration, the common name and quantity of the shellfish. The tag must remain on the container until empty and thereafter kept for 90 days.

Metals recyclers are covered by section 538.19, F.S. That section requires recyclers to keep legible records of all sales transactions including: the name of the person filling out the paperwork, the date and time of the transactions, the weight or quantity and a description of the materials purchased, the amount paid, a signed statement from the seller that he is the rightful owner of the goods, a distinctive number from the identification card of the seller and a clear photograph of the seller. All of this information must be retained for five years.

There are many more examples, but these two demonstrate to us how shallow and weak the wholesale pharmaceutical industry's argument is. If oyster harvesters and metals recyclers can do what is required of them, then we believe that drug wholesalers who handle approximately \$93 billion of pharmaceuticals products nationally can come up with a methodology to authenticate the products they are buying and selling.

IV. Conclusion

We have no doubt that the major wholesalers buy from the smaller

wholesalers because they can buy it cheaper than they can from the manufacturer. We believe, however, based on all the evidence we have heard, that the true reason for much of the lower prices found in the secondary market is that a significant amount of the drugs being traded among the smaller wholesalers are diverted drugs. These are drugs from Medicaid recipients, some of whom sell their pharmaceuticals through pre-arranged deals or trade them for illegal street drugs. They come from doctors' offices and clinics which get special discounts from the manufacturers and then sell them out the backdoor. These are drugs being imported illegally from foreign countries where manufacturers sell pharmaceuticals more cheaply or produce pharmaceuticals under less stringent standards. Further down the scale are items that are the fruits of Medicaid or insurance scams, or stolen outright from hospitals, clinics, doctors offices, even cargo heists from trucks.

These diverted drugs usually wind up being counterfeited or re-labeled before being sold to corrupt secondary wholesalers. Once in the hands of these wholesalers, the drugs are often further adulterated by being mishandled and improperly stored. From there, with the use of forged pedigree papers, they enter the mainstream market and wind up on the shelves of legitimate pharmacies, hospitals and clinics.

Pedigree papers, when verified through due diligence, are the cheapest, easiest and most effective way to prevent diverted or counterfeited drugs

from entering the marketplace.

We are surprised to learn that many dispensers are unaware that purchases made from wholesalers did not come directly from the manufacturer. They don't know because wholesalers are not currently required to pass on pedigree papers to non-wholesalers. The federal rule, should it ever take effect, would require wholesalers to pass on pedigree papers to dispensers. We do not believe that major purchasers, such as hospitals, pharmacy chains or government agencies, are likely to buy pharmaceutical products that have passed through multiple wholesalers, especially if there is no documentation tracing the drugs back to the manufacturer. It is not surprising then, that some pharmaceutical wholesalers have fought so hard and long to keep the federal rule in abeyance. In essence, the wholesale industry is fighting for the right to keep secret from their own customers the history of the drugs that they're being sold. We do not believe there is ever any good excuse to fail to disclose material information to buyers. The free market works best when consumers have the freedom to make informed choices. In our opinion, we cannot wait for federal authorities to enact and/or enforce a rule that has been delayed for 15 years. We believe that Florida should require pedigree papers to be delivered all the way from manufacturers to dispensers and that all buyers be required to verify pedigree papers through the exercise of due diligence. We acknowledge that if this were to happen, the market for diverted drugs would likely dry up and that some wholesalers, specifically dishonest ones, may be forced out of business. If the price we must pay to

keep these wholesalers in business is the corruption of our drug supply and the exposure of our citizens to risk of death or injury, we say that price is too high.

Our report illustrates the potential danger to the citizens of Florida. We have found that the wholesale pharmaceutical industry in Florida has been corrupted by the infiltration of a criminal element which is making a fortune while tainting our drug supply. The problem has been exacerbated by weak laws, lax enforcement, an uncooperative industry and a lack of awareness of the issues by retailers and consumers. We believe the specific conduct with which we are most concerned, i.e. the trafficking in adulterated drugs along with the fraudulent documentation and counterfeiting it goes hand in hand with, should be more concretely and specifically spelled out in Florida law and that the penalties for criminal conduct should be much harsher in keeping with the grave danger this conduct poses to the public.

Finally, we conclude that both FDA and DOH have failed to aggressively enforce their respective pedigree paper laws. We believe that strict enforcement of our pedigree paper law is essential to protecting the public from drug counterfeiters. While we understand the difficulties in making a balanced decision between competing interests, we encourage our agency officials to not lose sight of their mandate to safeguard the health of all Floridians, especially those that are sick and vulnerable and most in need of our protection.

V. Recommendations

Recommendations to the Legislature

Mandate that DOH create a standardized form for pedigree papers to be used in all transactions.

Require that pedigree papers, at a minimum, contain amounts, dosage form, strength, and lot numbers of all drugs; name and address of each owner of the drug; shipping information; a signature and license number of person certifying delivery or receipt of drugs; date of each transaction; phone number or e-mail contact of each wholesaler; signature certifying that the pedigree paper was verified.

Require that pedigree papers be provided in sales transactions all the way from the manufacturer to the dispenser.

Classify repackagers as wholesalers and require original manufacturer's lot number to be retained on new packaging.

Require that wholesalers, repackagers and dispensers perform due diligence by verifying contents of pedigree papers, making it a third degree felony for failing to do so or for falsely swearing that they have done so.

Grant DOH the authority to immediately shut down a permitted establishment operating in violation of 64F- 12.013 and to keep an establishment closed until DOH is satisfied that the deficiencies have been corrected.

Grant DOH the authority to immediately seize and destroy drugs which pose a danger to public health due to improper storage or adulteration wherever found.

Increase the penalty for failure to provide pedigree papers to a third degree felony.

Increase the penalty for forging pedigree papers to a second degree felony.

Increase the penalty for knowingly purchasing from or selling to an unlicensed person or entity, to a second degree felony.

Increase the penalty for forging a prescription label to a first degree felony.

Create the offense of trafficking in adulterated prescription drugs, making it a first degree felony.

Penalize the sale of adulterated drugs worth less than \$1,000, making it a third degree felony.

Penalize the manufacture, sale, delivery or distribution of an adulterated drug which results in great bodily harm as a result of ingesting that drug, as a first degree felony punishable by life in prison.

Penalize the manufacture, sale, delivery, or distribution of an adulterated drug which results in the death of a person as a result of ingesting that drug, as a capital offense.

Add these crimes to the list of racketeering predicates in section 895.02 ,F.S.

We have reviewed the recommendations of the AD HOC Committee on Pedigree Papers and are in agreement with some of what they have to say. Specifically, we endorse the following recommendations:

1. Require a \$100,000 performance bond to be posted by wholesalers with DOH.
2. Require a person in the wholesaler's business to be the designated representative responsible for all pharmaceutical receiving, shipping and warehousing activity, require that person to pass an examination of PDMA and Florida pharmaceutical wholesaling laws and rules, require that person to be employed full time and to be present during business hours.
3. Require wholesalers to carry \$2,000,000 in liability insurance.

Recommendations to the Department of Health

Deny licenses to applicants convicted of felonies or crimes involving moral turpitude.

Prohibit licenses to be issued to out of state wholesalers that do not meet requirements of Rule 64F-012.013, F.A.C.

Inspect out of state facilities and increase out of state license fees to cover the cost of inspections.

Change the permit application to require disclosures of all convictions, including those that have been sealed.

Require fingerprints and a national criminal background check on all applicants and designated representatives.

Reduce the wholesale licensing period to one year.

Increase the number of field inspectors statewide, increasing the amount of fees, if necessary, to pay for the inspectors.

Promulgate rule defining what DOH considers to be adequate facilities for pharmaceutical wholesalers.

Strictly enforce the requirements of Rules 64F-12.012 and 64F-12.013, F.A.C.

Impose fines daily for rules violations until the deficiency is corrected.

Require licensees to secure and retain receipts for all cash transactions of pharmaceuticals.

Strictly enforce section 499.0121(6)(d) ,F.S. as written including promulgating all rules necessary.

Clarify the definition and responsibility of an authorized distributor of record. Track the proposed federal rule by requiring pedigree papers to be provided all the way to dispensers.

Require all licensed wholesalers to have on-line access for verification of pedigree papers.

Post names and business addresses of all current pharmaceutical wholesale licensees on the Department of Health website.

Promulgate rules to allow for the waivers of pedigree papers during public emergencies.

Promulgate rule to require wholesale licensees to report all instances of fraud, patterned after section 626.989(6) F.S., of the Florida Insurance Code.

Recommendations to the Wholesale Industry

Require pedigree papers from all vendors tracing the pharmaceuticals to the manufacturer whether or not required by law.

Perform due diligence by authenticating all pedigree papers whether or not required by law.

Refuse to do business with any wholesaler that does not provide a pedigree paper.

Report all suspected fraud to DOH or law enforcement.

**Recommendations to the
Pharmaceutical Manufacturers**

Improve anti-counterfeiting measures for labels and packaging.

Provide complete access to all wholesalers and dispensers attempting to authenticate pedigree papers or products.

THIS REPORT IS RESPECTFULLY SUBMITTED to the Honorable Dale Ross , Presiding Judge of the Seventeenth Statewide Grand Jury, this _____ day of February, 2003.

James C. Ross
Foreperson
Seventeenth Statewide Grand Jury of Florida

I, OSCAR GELPI, Special Counsel and Assistant Legal Advisor, Seventeenth Statewide Grand Jury of Florida, hereby certify that I, as authorized and required by law, have advised the Grand Jury which returned this report on this _____ day of February 2003.

Oscar Gelpi
Special Counsel
Assistant Legal Advisor
Seventeenth Statewide Grand Jury of Florida

I, ROBERT PENEZIC, Assistant Statewide Prosecutor and Assistant Legal Advisor, Seventeenth Statewide Grand Jury of Florida, hereby certify that I, as authorized and required by law, have advised the Grand Jury which returned this report on this _____ day of February 2003.

ROBERT PENEZIC
Assistant Statewide Prosecutor
Assistant Legal Advisor
Seventeenth Statewide Grand Jury of Florida

The foregoing Report was returned before me this _____ day of February 2003.

Upon the Legal Advisor's oral motion for the disclosure for the purposes of furthering justice of the Report, the Legal Advisor is authorized to disclose the testimony and proceedings recounted in the foregoing document in furtherance of the criminal, investigative and civil administrative responsibilities of the Seventeenth Statewide Grand Jury.

Honorable Dale Ross
Presiding Judge
Seventeenth Statewide Grand Jury of Florida

Appendix "A"

GLOSSARY OF SELECTED TERMS

1. **ADR** - An authorized distributor of record, i.e. a pharmaceutical wholesaler that has established an ongoing relationship with a pharmaceutical manufacturer to distribute that manufacturer's products. Under Florida law, an ongoing relationship can be established by written agreement between the manufacturer and wholesaler; or by documenting at least three purchases by the wholesaler from the manufacturer in a six month period.
2. **Adulterated** - a drug that is expired; has been mislabeled, tainted or counterfeited; improperly stored or handled; or does not have the proper documentation to establish its authenticity.
3. **BSPS**- Bureau of Statewide Pharmacy Services, a bureau under DOH responsible for regulating and enforcing The Florida Drug and Cosmetic Act, Chapter 499 Florida Statutes.
4. **DOH** - Department of Health, an executive agency charged with promoting and protecting the health of all residents and visitors in Florida through organized state and community efforts, including cooperative agreements with counties.
5. **Dispensers** – Doctors, hospitals, clinics, pharmacies or other licensed entity that dispenses prescription drugs directly to patients or prescription holders.

6. **Drug Diversion** - The movement of pharmaceuticals from the legitimate distribution system by a variety of illegal means including organized fraud, theft, illegal importation, and repurchasing from patients. Diverted drugs are commonly relabeled and reintroduced into the legitimate distribution system, often with phony documentation.
7. **End User** - another term for dispensers.
8. **Epogen** -A recombinant DNA prescription drug used to boost the red blood cell counts of patients, commonly used in the treatment of patients suffering from renal failure as well as patients undergoing treatment for AIDS and cancer.
9. **Procrit**- another trade name for Epogen.
10. **Secondary market** - The wholesale pharmaceutical market encompassing all drug wholesalers in the U.S. other than the three largest drug wholesalers. Several thousand pharmaceutical wholesale companies make up the secondary market, of which approximately 422 are based in Florida.