SICK CRIME: COUNTERFEIT DRUGS IN THE UNITED STATES

HEARING

BEFORE THE

SUBCOMMITTEE ON CRIMINAL JUSTICE, DRUG POLICY, AND HUMAN RESOURCES

OF THE

COMMITTEE ON GOVERNMENT REFORM

HOUSE OF REPRESENTATIVES

ONE HUNDRED NINTH CONGRESS

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CONTENTS

	Page
Hearing held on November 1, 2005	1
Statement of:	
Eban, Katherine, author, Dangerous Doses; Kevin Fagan, father of Timothy Fagan, counterfeit drug victim (Epogen); and Max Butler, brother of Maxine Blount, counterfeit drug victim (Procrit)	62
Butler, Max	75
Eban, Katherine	62
Fagan, Kevin	71
Lutter, Randall W., Ph.D., Acting Associate Commissioner for Policy and Planning, Food and Drug Administration	16
Pitts, Peter J., director, Center for Medicines in the Public Interest; Carmen Catizone, executive director, National Association of Boards of Pharmacy; James A. Dahl, former Assistant Director of Investigations, FDA Office of Criminal Investigations; and Donald Dekieffer, Dekieffer & Horgan	96
Catizone, Carmen	100
Dahl, Jim	109
Dekieffer, Donald	115
Pitts, Peter J.	96
Letters, statements, etc., submitted for the record by:	
Butler, Max, brother of Maxine Blount, counterfeit drug victim (Procrit), prepared statement of	77
Catizone, Carmen, executive director, National Association of Boards of Pharmacy, prepared statement of	102
Cummings, Hon. Elijah E., a Representative in Congress from the State of Maryland, prepared statement of	10
Dahl, James A., former Assistant Director of Investigations, FDA Office of Criminal Investigations, prepared statement of	111
Dekieffer, Donald, Dekieffer & Horgan, prepared statement of	117
Eban, Katherine, author, Dangerous Doses, prepared statement of	64
Fagan, Kevin, father of Timothy Fagan, counterfeit drug victim (Epogen), prepared statement of	73
Gutknecht, Hon. Gil, a Representative in Congress from the State of Minnesota, Pharma ad	89
Lutter, Randall W., Ph.D., Acting Associate Commissioner for Policy and Planning, Food and Drug Administration, prepared statement of	19
Pitts, Peter J., director, Center for Medicines in the Public Interest, prepared statement of	98
Souder, Hon. Mark E., a Representative in Congress from the State of Indiana:	
Prepared statement of	5
September 17, 2005 article	92

SICK CRIME: COUNTERFEIT DRUGS IN THE UNITED STATES

TUESDAY, NOVEMBER 1, 2005

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON CRIMINAL JUSTICE, DRUG POLICY,
AND HUMAN RESOURCES,
COMMITTEE ON GOVERNMENT REFORM,
Washington, DC.

The subcommittee met, pursuant to notice, at 2:05 p.m., in room 2154, Rayburn House Office Building, Hon. Mark E. Souder (chairman of the subcommittee) presiding.

Present: Representatives Souder, Burton, Gutknecht, Schmidt, Cummings, Watson, and Norton.

Staff present: Marc Wheat, staff director and chief counsel; Michelle Gress, professional staff member and counsel; Malia Holst, clerk; Tony Haywood, minority counsel; and Jean Gosa, minority assistant clerk.

Mr. SOUDER. The subcommittee will come to order. Good afternoon and thank you all for being here. We're here because selling fake prescription drugs within the United States is a serious public threat and a growing problem.

This hearing will examine the vulnerabilities that allow counterfeit or substandard drugs to end up in legitimate pharmacies, how such vulnerabilities expose this Nation to terrorist attacks through our medicines, and the anticipated widespread counterfeiting of lifesaving avian flu treatment in the midst of a potential pandemic, compounding the deadly toll of an outbreak.

Just this morning the President asked Congress for $1.2 billion for vaccines to prepare for an avian flu pandemic. We cannot risk vaccinating Americans with counterfeited therapies. This is a very serious issue to which we are calling our attention. According to the World Health Organization, 10 percent of global pharmaceutical commerce this year will be counterfeit. That is expected to double by the year 2010 as international criminal organizations become more sophisticated.

Last year within the United States the FDA's counterfeit drug investigations rose 150 percent in only 12 months. One key to understanding this disturbing problem is the so-called "gray market" which stems from the practice of drug diversion. Drug diversion is the principal method by which counterfeits enter the legitimate drug market. The FDA confirmed with subcommittee staff that drug diversion was the entry point for every case investigated by that agency involving counterfeit drugs going into legitimate pharmacies. For example, closed-door or own-use pharmacies are pri-

mary sources for diversion. Own-use pharmacies such as nursing homes or hospitals agree to provide medications solely to their own patients. Accordingly, such pharmacies acquire medication at a price much lower than wholesale. This opens the door to fraud, exemplified by some own-use pharmacies overstating their patient populations, reserving surplus drugs, then selling them at a higher price into the gray market.

Once drugs are on the gray market they may be bought and sold dozens of times, passed among several hands, mishandled and relabeled. This happens easily because the pharmaceutical supply chain is not regulated by any entity, private or governmental. The pharmacies within a State are monitored by State boards of pharmacy which enforce the standards of care within each State. However, the State boards of pharmacy lack police power and many are limited to only a handful of inspectors.

Drug manufacturers have to comply with the FDA for safety, effectiveness and labeling of their drugs. The drug manufacturers typically exercise no control over their drugs once they're shipped out of the manufacturing facility; rather, the drugs are bought and sold by distributors and frequently pass in and out of the secondary market. Distributors, like retailers and physicians, are licensed by the States, which must only meet the minimal standards set by the prescription drug marketing act.

If you could display the first illustration.

In order to obtain a distributor's license, some States' licensing standards provide an opportunity for unscrupulous distributors to legitimately buy and sell pharmaceuticals. One of the most notorious recent counterfeit drug bust cases which we'll hear about in our second panel involved a convicted felon who obtained a State distributor license in Florida. As you can see on this map, 11 States, including Florida, have recently toughened their licensing standards for distributors. However, this leaves a patchwork of laws across the country allowing for unscrupulous distributors to obtain legitimate State licenses and trade drugs on the secondary market.

This situation of inconsistent standards throughout the country has prompted the Health Care Distribution Management Association [HDMA], to recently advocate uniform Federal licensing standards for prescription drug distributors.

Having a private business association advocate vigorous licensing standards is something we rarely see, but it's clear that the gravity of this problem and the issues at stake have prompted the HDMA to take this radical step in order to promote the safety and security of our Nation's drug supply.

Nevertheless, the current system allows drugs to pass through several middlemen before reaching the patient's hands. When they resell the drugs, they sometimes relabel them to reflect higher and more valuable doses, mishandle them to contaminate or to degrade the drug, or substitute fake products for the legitimate goods.

This is a photo of an alleged tablet of Lipitor, a popular cholesterol-lowering drug, and a suspected counterfeit. They are virtually indistinguishable. The FDA recently indicted 11 individuals, a drug repacker and 2 wholesale distributors in cases related to the sale of Lipitor.

Go to the third illustration.

This is a closeup photo of Lipitor's registered trademark. The measurement in the upper left-hand corner shows the scale of 1/20th of a millimeter, which is incredibly small. While the microscope can reveal the counterfeiting, the naked eye may not. Counterfeit or substandard drugs like this counterfeit Lipitor can end up on the shelves of the trusted pharmacy and ultimately distributed to unsuspecting victims. For the patient, there is no commercial transaction like this. The patient has virtually zero ability to inspect the drug packaging or compare it to other samples.

The patient who goes to a pharmacy to have his prescription filled is helpless in determining the quality of the drug and dependent on a system that has experienced some tragic breaches. Moreover, it is impossible to measure the scope of the problem, and we cannot say with any degree of certainty how many or which counterfeit drugs make it to the pharmacy shelves, because a health indication or ultimate death may be attributed to the patient's underlying illness rather than the drug.

One way to verify a drug's authenticity is through a pedigree which would show the drug's chain of custody. Some of the States toughened licensing standards to distributors, such as Florida, who will soon require paper pedigrees for drugs purchased within that State. However, the FDA delayed until September 2006 the effective date for national regulations requiring a pedigree in the hopes an electronic track-and-trace program such as radio frequency identification [RFID] will be viable.

The FDA has reported to the subcommittee staff that their Office of Criminal Investigations [OCI], has turned out 71 indictments on their counterfeit drug cases, many of which involve multiple counts, leading to 67 convictions so far. Several more cases not yet in the formal judicial process are in the pipeline. Moreover, OCI's robust investigations have interdicted counterfeit drugs that would have made it to pharmacy shelves.

However, significant vulnerabilities in this system still exist. In addition to providing a way for unscrupulous enterprises to obtain massive prices by distributing phony high-price drugs, the vulnerabilities in the systems provide a way for terrorists to target our citizens. One widely discussed scenario, among dozens of possibilities of how they might exploit our vulnerability, involves a deliberate anthrax scare to trigger a run on Cipro, the antibiotic used for anthrax poison. A phony and deadly version having been injected into the pharmaceutical stream by terrorists would cause thousands more deaths.

Baswa Hamad, a Taliban-linked terrorist recently extradited from Afghanistan, defends a Jihad of taking Americans' money at the same time the drugs we are paying for kill us.

Finally, the counterfeit drugs issue is well illustrated by the immediate worldwide concern over an avian flu outbreak in the FDA's announcement last week that anticipates an increase in the sale of counterfeit or fraudulent treatments for such a pandemic. Tamiflu, currently the only known treatment for this virus strain, is expected to be widely counterfeited. Counterfeit treatment in the midst of a pandemic would certainly compound the deadly toll of the flu.

I do not want to wait until there are catastrophic failures in the system to examine the problems that allow counterfeit drugs into our pharmaceutical market. The time for examining and acting on this problem is now.

Our first panel today is Mr. Randall Lutter, Acting Associate Commissioner for Policy and Planning at the Food and Drug Administration.

The second panel consists of Katherine Eban, author of Dangerous Doses; and family members of two patients who are victims of counterfeit drugs purchased at mainstream pharmacies: Kevin Fagan, the father of Timothy Fagan who received counterfeit Epogen after his liver transplant operation; and Max Butler, the brother of Maxine Blount who received counterfeit Procrit in the midst of her battle against breast cancer.

The third panel consists of Mr. Peter Pitts from the Center for Medicines in the Public Interest; Carmen Catizone, executive director of the National Association of Boards of Pharmacy; Jim Dahl, Former Assistant Director of Investigations, FDA Office of Criminal Investigations; and Donald deKieffer of deKieffer & Horgan.

Now I'd like to yield to our ranking member, Mr. Elijah Cummings.

[The prepared statement of Hon. Mark E. Souder follows:]

Subcommittee on Criminal Justice, Drug Policy and Human Resources

Opening Statement of Chairman Mark Souder

"Sick Crime: Counterfeit Drugs in the United States"

November 1, 2005

Good afternoon, and thank you all for being here.

We are here because selling fake prescription drugs within the United States is a serious public threat, and it is a growing problem. This hearing will examine

- the vulnerabilities that allow counterfeit or substandard drugs to end up in legitimate pharmacies;
- how such vulnerabilities expose this nation to devastating terrorist attacks through our medicines;
- and the anticipated, widespread counterfeiting of a life-saving avian flu treatment in the midst of a potential pandemic, compounding the deadly toll of an outbreak. (Just this morning, the President asked Congress for 1.2 billion dollars for vaccines to prepare for an avian flu pandemic. We simply cannot risk vaccinating Americans with counterfeit therapies.)

This is a very serious issue to which we are calling our attention.

According to the World Health Organization, 10 percent of global pharmaceutical commerce this year will be counterfeit. That number is expected to double by the year 2010, as international criminal organizations become more sophisticated. Last year, within the United States, the FDA's counterfeit drug investigations rose 150% in only twelve months.

One key to understanding this disturbing problem is the so-called "gray market," which stems from the practice of drug diversion. Drug diversion is the principal method by which counterfeits consistently enter the legitimate drug market. The FDA confirmed with Subcommittee staff that drug diversion was the entry point for every case investigated by that agency involving counterfeit drugs going into legitimate pharmacies.

For example, "Closed door" or "own use" pharmacies are primary sources for diversion. "Own use" pharmacies, such as at nursing homes or hospitals, agree to provide medication solely to their own patients. Accordingly, such pharmacies acquire medication at a price much lower than wholesale. This opens the door to fraud, exemplified by some "own use" pharmacies overstating their patient populations, receiving surplus drugs, then selling them at a higher price into the gray market. Once drugs are on the gray market, they may be bought and sold dozens of times, passed among several hands, repackaged, mishandled, or relabeled.

This happens easily because the pharmaceutical supply chain is not regulated by any single entity, private or governmental. The pharmacies within a state are monitored by the state Boards of

Pharmacy, which enforces the standards of care within each state. However, the state Boards of Pharmacy lack police power, and many are limited to only a handful of inspectors. Drug manufacturers have to comply with the FDA for the safety, effectiveness, and labeling of their drugs. But drug manufacturers typically exercise no control over their drugs once they are shipped out of the manufacturing facility. Rather, the drugs are bought and sold by distributors, and frequently pass in and out of the secondary market.

Distributors, like retailers and physicians, are licensed by the states, which must only meet the minimal standards set by the Prescription Drug Marketing Act. *Please display the first illustration.* In order to obtain a distributor's license, some states' licensing requirements are more lenient than others. Lenient licensing standards provide an opportunity for unscrupulous distributors to legitimately buy and sell pharmaceuticals. One of the most notorious recent counterfeit drug busts, the Carlow case – which we'll hear more about in our second panel - involved a convicted felon who obtained a state distributor license in Florida.

As you can see on this map, eleven states, including Florida, have recently toughened their licensing standards for distributors. However, this leaves a patchwork of laws across the country, allowing for unscrupulous distributors to obtain legitimate state licenses and trade drugs on the secondary market. This situation of inconsistent standards throughout the country has prompted the Healthcare Distribution Management Association, or "HDMA," to recently advocate uniform federal licensing standards for prescription drug distributors. Having a private business association advocate rigorous federal licensing standards is something we rarely see. But it is clear that the gravity of this problem, and the issues at stake, have prompted the HDMA to take this radical step in order to promote the safety and security of our nation's drug supply.

Nevertheless, the current system allows drugs to pass through several middle-men before reaching a patient's hands. When unscrupulous middle-men resell the drugs, they sometimes re-label them to reflect higher (and more valuable) doses, mishandle them to contaminate or degrade the drug, or substitute fake products for the legitimate goods. *Please display the second illustration.* This is a photo of a legitimate tablet of Lipitor, a popular cholesterol-lowering drug, and a suspected counterfeit. They are virtually indistinguishable. The FDA recently indicted eleven individuals, a drug repacker and two wholesale distributors in cases related to the sale of Lipitor.

Please display the third illustration. This is a close-up photo of Lipitor's registered trademark. The measurement in the upper left hand corner shows the scale as one-twentieth of a millimeter, which is incredibly small. While a microscopic examination can reveal the counterfeiting, the naked eye may not.

With a vulnerable supply chain, counterfeit or substandard drugs like this counterfeit Lipitor can end up on the shelves of a trusted pharmacy, and ultimately distributed to unsuspecting victims.

For the patient, there is no commercial transaction like this. The patient has virtually zero ability to inspect the drugs' packaging, or compare it to other samples. The patient who goes to a pharmacy to have his or her prescription filled is helpless in determining the quality of the drug, and completely dependant on a system that has experienced some tragic breaches. Moreover, it is impossible to measure the scope of the problem, and we cannot say with any degree of certainty how many, or which, counterfeit drugs make it to the pharmacy shelves because a health indication, or ultimate death, may be attributed to a patient's underlying illness rather than the drug.

One way to verify a drug's authenticity is through a "pedigree" which would show the drug's chain of custody. Some of the states that have toughened their licensing standards for distributors, such as Florida, will soon require paper pedigrees for every drug purchased within that state. However, the FDA has delayed until December, 2006 the effective date for national regulations requiring a pedigree, in the hopes that an electronic track-and-trace program such as Radio Frequency Identification, or "RFID," will be viable.

The FDA has reported to Subcommittee staff that their Office of Criminal Investigations, or "OCI," has turned out 71 indictments on their counterfeit drug cases, many of which involved multiple counts, leading to 67 convictions so far. Several more cases, not yet in the formal judicial process, are in the pipeline. Moreover, OCI's robust investigations have interdicted counterfeit drugs that would have otherwise made it to pharmacy shelves. However, significant vulnerabilities in the system still exist.

In addition to providing a way for unscrupulous enterprises to obtain massive profits by distributing phony, high-priced drugs, the vulnerabilities in the system provide a way for terrorists to target our citizens. One frightening and widely discussed scenario, among dozens of possibilities of how terrorists might exploit our vulnerabilities in this area, involves a deliberate anthrax "scare" in order to trigger a run on Cipro, the antibiotic used for fighting the anthrax poison. A phony, and deadly version of this medicine, having already been injected without detection into the nation's pharmaceutical stream by terrorists, would then cause thousands more deaths. Baz Mohammad, a Taliban-linked narco-terrorist who was recently extradited from Afghanistan, defends a "Jihad" of taking Americans' money at the same time the drugs we are paying for kill us.

Finally, the counterfeit drugs issue is well illustrated by the immediate, worldwide concern over an Avian Flu outbreak and the FDA's announcement last week that it anticipates an increase in the sale of counterfeit or fraudulent treatments for such a pandemic. Tamiflu, currently the only known treatment for this virus strain, is expected to be widely counterfeited. Counterfeit treatment in the midst of such a pandemic would most certainly compound the deadly toll of the flu.

I do not want to wait until there are catastrophic "failures" in the system to examine the problems that allow counterfeit drugs into our pharmaceutical market. The time for examining and acting on this problem is now.

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The third panel consists of Peter Pitts, from the Center for Medicines in the Public Interest; Carmen Catizone, Executive Director of the National Association of Boards of Pharmacy; Jim Dahl, Former Assistant Director of Investigations, FDA Office of Criminal Investigations; and Donald deKeiffer, of deKeiffer and Horgan.

Mr. CUMMINGS. Thank you Mr. Chairman. Counterfeit drugs represent a threat to the safety of the drug supply globally. The World Health Organization estimates that in poor countries as much as 25 percent of the medicine consumed may be counterfeit or substandard. In some developing countries the percentage is as high as 50 percent.

In the United States consumers can be confident that the safety and effectiveness of the drugs they obtain through the legitimate market are extremely safe and effective in relative terms. Nevertheless, there is ample evidence that counterfeit drugs are an increasing challenge for Federal and State regulatory bodies, pharmacies, and drug manufacturers and wholesalers. The health risk to consumers that obtain drugs that are fake, diluted, or mislabeled as to dosage, potency, or other characteristics is potentially quite serious, depending on the drug and the illness or condition the drug is being used to treat. Such drugs may be simply ineffective, resulting in a patient's condition going untreated, or they may very well be harmful.

Charged with ensuring the safety and effectiveness of the drugs available to consumers in the United States, the FDA is the lead Federal agency for investigating U.S. counterfeit drug cases. Over the past several years there has been a sharp increase in the number of counterfeit drug investigations undertaken by FDA's Office of Criminal Investigations. The number of these investigations ranged from 5 and 11 annually between 1997 and 2000.

In 2004 FDA's OCI conducted 58 investigations, up from 30 the year before, and 27 in 2002. This increase coincides with a similar increase in the amount of counterfeit drugs seized in the United States in recent years.

In 2000 an estimated 100,000 doses of counterfeit drugs were seized in the United States, whereas last year an estimated 3 million fake medications were seized in our country. This suggests a substantial increase in the volume of counterfeit drugs available in the United States.

Although most of the counterfeit drugs seized in the United States are destined for the black market or illegitimate Internet pharmacies, FDA investigations have also led to seizures of counterfeit drugs offered for sale in legitimate pharmacies. This raises legitimate serious concerns about the integrity of the supply chain between manufacturer and pharmacy.

As we will hear today, the course a drug takes from the shipping docks to the pharmacy shelf can be convoluted, one that offers unscrupulous distributors numerous opportunities to exploit weaknesses in regulation and security.

In 1987 Congress enacted the Prescription Drug Marketing Act to protect the American public from the emerging problem of counterfeit drugs. For a variety of reasons, 18 years later, some of the law's requirements have yet to be implemented by regulation.

In July 2003, FDA formed the Counterfeit Drug Task Force to develop recommendations for addressing all aspects of drug counterfeiting. In February 2004, the task force issued a report entitled, "Combating Counterfeit Drugs: A Report of the Food and Drug Administration." The FDA report highlights measures that can be taken to better protect Americans from counterfeit drugs, focusing

on six areas, and they are: securing the actual drug product and its packaging; securing the movement of the product as it travels through the U.S. drug distribution chain; enhancing regulatory oversight and enforcement; increasing penalties for counterfeiters; heightening vigilance and awareness of counterfeit drugs; and, finally, increasing international collaboration.

Prominent among the proposed means for securing drugs through the supply chain is new technology design to track and trace drugs as they travel in the stream of commerce from the manufacturer to the pharmacy. Adoption of drug authentication technology and stricter State licensing standards for drug distributors are other key measures recommended by the report.

State regulators and industry also have taken notice of the counterfeit drug threat. For its part, the National Association of Boards of Pharmacy has taken the important step of proposing new model rules for the licensing of wholesale distributors, and to date 11 States have adopted the tougher standards. In addition, some major wholesalers and retailers have announced their attention to avoid obtaining drugs from secondary markets.

Still, there is much to be done to ensure the efforts to protect the drug supply, to catch up to and keep pace with the actions of bad actors who think nothing of jeopardizing the health and safety of American consumers in order to turn a fraudulent profit.

Today we will hear valuable testimony from the FDA, other industry stakeholders, outside observers, and representatives of victims of counterfeit drugs about the threat that fake, mishandled, or mislabeled products pose to the integrity of the U.S. drug supply and about what progress is being made to secure the U.S. drug supply against threats like diversion and illegal importation.

And so, Mr. Chairman, I thank you for holding this important hearing and I look forward to the testimony.

[The prepared statement of Hon. Elijah E. Cummings follows:]

Representative Elijah E. Cummings, D-MD7
Ranking Minority Member
Subcommittee on Criminal Justice, Drug Policy and Human Resources
Committee on Government Reform
U.S. House of Representatives
109th Congress

Hearing on "Sick Crime: Counterfeit Drugs in the United States?"

November 1, 2005

Mr. Chairman,

Counterfeit drugs represent a threat to the safety of the drug supply globally. The World Health Organization estimates that, in poor countries, as much as 25% of the medicine consumed may be counterfeit or substandard. In some developing countries, the percentage is as high as 50%.

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Although most of the counterfeit drugs seized in the United States are destined for the black market or illegitimate internet pharmacies, FDA investigations have also led to seizures of counterfeit drugs offered for sale in legitimate pharmacies. This raises serious concerns about the integrity of the supply chain between manufacturer and pharmacy. As we will hear today, the course a drug takes from the shipping dock to the pharmacy shelf can be a convoluted one and one that offers unscrupulous distributors numerous opportunities to exploit weaknesses in regulation and security.

In 1987, Congress enacted the Prescription Drug Marketing Act to protect the American public from the emerging problem of counterfeit drugs. For a variety of reasons, 18 years later, some of the law's requirements have yet to be implemented by regulation.

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- Securing the actual drug product and its packaging
- Securing the movement of the product as it travels through the U.S. drug distribution chain
- Enhancing regulatory oversight and enforcement
- Increasing penalties for counterfeiters
- Heightening vigilance and awareness of counterfeit drugs
- Increasing international collaboration

Prominent among the proposed means for securing drugs through the supply chain is new technology designed to track and trace drugs as they travel in the stream of commerce from the manufacturer to the pharmacy. Adoption of drug authentication technology and stricter state licensing standards for drug distributors are other key measures recommended by the report.

State regulators and industry also have taken notice of the counterfeit drug threat. For its part, the National Association of Boards of Pharmacy has taken the important step of proposing new model rules for the licensing of wholesale distributors, and, to date, eleven states have adopted the tougher standards. In addition, some major wholesalers and retailers have announced their intention to avoid obtaining drugs from secondary markets.

Still, there is much to be done to ensure that efforts to protect the drug supply catch up to and keep pace with the actions of bad actors who think nothing of jeopardizing the health and safety of American consumers in order to turn a fraudulent profit.

Today we will hear valuable testimony from FDA, other industry stakeholders, outside observers, and representatives of victims of counterfeit drugs about the threat that fake, mishandled, or mislabeled products pose to the integrity of the U.S. drug supply and about what progress is being made to secure the U.S. drug supply against threats like diversion and illegal importation.

At this time, Mr. Chairman, I'd like to ask unanimous consent that the written statement of the American Free Trade Association be included in the official hearing record.

Thank you, Mr. Chairman, for holding this important hearing. I look forward to the testimony, and I yield back the balance of my time.

##

Mr. SOUDER. Mr. Burton, do you have any opening comments?

Mr. BURTON. No.

Mr. SOUDER. Ms. Holmes Norton.

Ms. NORTON. Thank you very much, Mr. Chairman, because I do think this is a very important issue to focus upon. Frankly, I was surprised that there was no Federal regulation here. No one can doubt we're in interstate commerce this time, I think, and when we have the industry saying that the hodgepodge of State regulations and difficulty of enforcing at the State level means we ought to have Federal regulation, I'm about to listen. And I hope you are, Mr. Chairman, because it looks like this problem is growing way out of proportion and anybody can understand why.

It seems to me it coincides simultaneously with the huge increases in pharmaceutical drug prices. The more you get of that—and that seems to be out of control. Even seniors, when they get access in January to our bill, will find that the prices continue to go up because there is nothing that the bill does about it. At least they're going to be safe, I believe, in the safe HMOs or other organizations. But what could be more dangerous to the general population, who do not have access to such a bill, than fake pharmaceuticals? It is very, very foreboding to know about this increase when we know that people need many of these pharmaceuticals and will now have, because there is no Federal regulation between the manufacturer and the pharmacy, the temptation to in fact take advantage of what looks like a cheaper version of the drug. We Americans, if you can get it cheaper, if it's on sale, I think that's why you have Wal-Mart, then of course people are going to go for it.

So I really pity the Federal Government trying to do this in the context of no real strong Federal legislation, and I hope that we are encouraged to move swiftly.

When I think of the of medicines that my constituents tell me about, when I say, for example, you ought to use generics, particularly if you're on Medicaid or Medicare, because you're using up scarce dollars, and people then begin to tell me about differences in medicines that I am not very familiar with. For example, high blood pressure medicine and how they try one or another until they get the right one. I can just imagine somebody getting a cheaper high blood pressure medicine and thinking, "I guess this is it." This is very, very dangerous.

And of course, if I may say so, Mr. Chairman, the people who are most likely to look for cheaper drugs are going to be middle-class and poor people who just say, "This is it. If this is all I can get and costs half as much, I am going to do this."

We already have blocked reimportation. We could have reimportation legislation that controls this, at least from outside of the United States, controlled how importation took place. You would think that at least within the United States, we could find a way to make sure that people aren't getting fake medicine. I think we ought to try to see what we can do about this before we go home this session. And I thank you again for this hearing, Mr. Chairman.

Mr. SOUDER. Thank you.

I would also like to recognize Ms. Schmidt from Ohio. Do you have any opening comments you'd like to make?

Mrs. SCHMIDT. Just glad to be here and looking forward to a lot of the discussion on this very serious issue.

Mr. SOUDER. Thank you very much.

I ask unanimous consent that all Members have 5 legislative days to submit written statements and questions for the hearing record. Any answers to questions provided by the witnesses must also be included in the record. Without objection, it is so ordered.

Also ask unanimous consent that all exhibits, documents, and other materials referred to by Members, will be included in the hearing record, that all Members may be permitted to revise and extent their remarks. Without objection, it is so ordered.

Our first panel is composed of Mr. Randall W. Lutter—once again in my head I couldn't get it out, even though they corrected me—who is the Acting Associate Commissioner for Policy and Planning at the Food and Drug Administration. As an oversight committee it's our practice to ask witnesses to testify under oath.

[Witness sworn.]

Mr. SOUDER. Let the record show the witness responded in the affirmative. Thank you for joining us today. We're looking forward to your testimony.

STATEMENT OF RANDALL W. LUTTER, PH.D., ACTING ASSOCIATE COMMISSIONER FOR POLICY AND PLANNING, FOOD AND DRUG ADMINISTRATION

Mr. LUTTER. Thank you, Mr. Chairman and members of the subcommittee. I'm Randall Lutter, Acting Associate Commissioner for Policy and Planning at the U.S. Food and Drug Administration. Thank you for the opportunity to testify about FDA's efforts fighting counterfeit prescription drugs.

Let me emphasize, first, that the overall quality of drug products that consumers purchase from U.S. pharmacies remains high. The American public can be confident that these medications are safe and effective. The FDA cannot, however, offer the same assurance about the safety and quality of drugs purchased from sources outside the U.S. regulatory system. Counterfeit drugmakers operating outside the system seek profit by peddling fake medicines to sick patients who need real treatment, sometimes with tragic consequences.

My testimony today will focus first on the growing counterfeit drug problem and then on FDA's effort to secure and approve the safety of our drug supply.

U.S. law defines counterfeit drugs as those sold under a product name, without proper authorization, where the product is knowingly and intentionally mislabeled in a way that suggests it's the authentic approved product. Counterfeit drugs include products without the active ingredient, with too little of the active ingredient, with the wrong active ingredient, or with fake packaging. This definition reflects fraud. Consumers wrongly believe they're buying a genuine product. Counterfeit prescription drugs are illegal and they're inherently unsafe.

As you can see from the first slide, the number of newly initiated counterfeit drug cases has risen in the last few years. We believe

the unusually high number of cases in fiscal year 2004 stems in part from the increased awareness and vigilance throughout the drug distribution chain, as a result of FDA's 2004 Counterfeit Drug Report, increased referrals from other law enforcement agencies, as well as improved communications with manufacturers.

Fortunately, because of the expertise and extensive investigative experience of the Office of Criminal Investigations at FDA, we've been successful in stopping most of these drugs before they could reach consumers, and we've also detected and dismantled many counterfeit schemes. Counterfeiters have become so sophisticated that many counterfeit drugs are indistinguishable from genuine FDA-approved products.

As shown in the second slide, fake Viagra appears superficially identical to the genuine product.

As shown in slide three, fake Lipitor appears very much like the authentic product.

As shown in slide four, even the packaging of fake Serostim is cleverly made to look like the real thing.

Counterfeit drugs can have serious adverse health consequences for patients. For example, counterfeit Procrit, which is an injectable sterile drug used by cancer and AIDS patients, contains not the active ingredient of Procrit but nonsterile tap water which could have caused a severe infection in the patients who received it.

The second example is counterfeiters tried to pass aspirin tablets as Zyprexa, a drug for schizophrenia and bipolar disorder. This could have been dangerous for patients who were aspirin sensitive, who were aspirin allergic, or who have bleeding disorders. In addition, patients wouldn't receive their appropriate treatment for this potentially serious disorder.

In 2001, in a report to Congress regarding the Prescription Drug Marketing Act of 1987, FDA noted that in order for secondary wholesalers to have full pedigrees for their products, Congress would have to amend section 503(e) of the Food, Drug and Cosmetics Act. FDA issued final regulations implementing the Prescription Drug Marketing Act in 1999, but it stayed on several occasions certain provisions in response to public comments and to allow Congress to consider the 2001 report. The stay was most recently extended to December 2006 in the expectation that electronic track-and-trace technologies would offer a low-cost alternative to paper pedigrees.

In July 2003, FDA established an internal Counterfeit Drug Task Force to campaign against the growing threat of counterfeit drugs. The task force report released in February 2004 highlighted a multitiered approach to better protect Americans from counterfeit drugs.

See slide five, please.

The multitiered approach consisted of securing the actual drug product, securing its packaging, and securing its movement through the U.S. distribution chain; also enhancing regulatory oversight and enforcement, increasing penalties for counterfeiters, heightening vigilance and awareness of counterfeit drug; and, last, increasing international collaboration.

For brevity I focus here on new technologies that might help us secure more effectively the product, its packaging and movement through the supply chain.

New technology that could electronically track and trace the product could provide a reliable electronic drug pedigree.

Slide six shows the information that an electronic might accumulate as a product moves through the distribution system. Radio frequency identification, the most promising electronic track-and-trace technology uses a radio frequency chip, an example of which appears in slide seven.

Adoption of RFID technology will allow supply chain stakeholders to track the chain of custody or pedigree of every package of drugs through every step of the supply chain.

Our other initiatives include encouraging health professionals to use the MedWatch form to report suspect counterfeit drugs to FDA. We have created a network to provide timely notification of verified counterfeit events to members and constituents of a variety of groups. We're distributing public service announcements to consumers and collaborating with international partners.

Before I conclude, I'd like to touch on an issue of recent interest for public health regulators. As public awareness grows on the avian flu as a potential public health threat, FDA anticipates an increased risk of counterfeit or fraudulent treatments. Although the agency is not aware at this point of any counterfeit Tamiflu cases in the United States, there are initiatives in place to deter counterfeiters and parties who sell fraudulent or phony products against avian flu.

In conclusion, despite recent progress, there remains a viable and concrete threat of counterfeit drugs entering distribution in the United States. We must all work together to pursue the measures identified in the FDA's counterfeit report to protect U.S. patients against counterfeit and unsafe drugs. Thank you.

[The prepared statement of Mr. Lutter follows:]

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

Statement of

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Acting Associate Commissioner for Policy and Planning
Food and Drug Administration

Before the

Subcommittee on Criminal Justice, Drug Policy, and Human Resources
Committee on Government Reform
House of Representatives

"Hearing on Counterfeit Drugs within the United States"

November 1, 2005

Release Only Upon Delivery

INTRODUCTION

Mr. Chairman and Members of the Subcommittee, I am Randall W. Lutter, Ph.D., Acting Associate Commissioner for Policy and Planning, at the U.S. Food and Drug Administration (FDA or the Agency).

Thank you for the opportunity to testify about FDA's efforts regarding counterfeit prescription drugs. Let me emphasize that the overall quality of drug products that consumers purchase from United States pharmacies remains high. The American public can be confident that these medications are safe and effective. FDA cannot, however, offer the same assurance to the public about the safety and quality of drugs purchased from sources that are outside the U.S. regulatory system. My testimony today will focus on FDA's efforts to further secure the safety of our nation's drug supply.

THE COUNTERFEIT DRUG PROBLEM

U.S. law defines counterfeit drugs as those sold under a product name without proper authorization, where the identity of the source of the drug is knowingly and intentionally mislabeled in a way that suggests that it is the authentic approved product. This definition can apply to brand name, generic products, or the bulk ingredients used to make the product. Counterfeit drugs under this definition may include products without the active ingredient, with an insufficient quantity of the active ingredient, with the wrong active ingredient, or with

packaging that falsely suggests the drug was manufactured by the FDA-approved manufacturer. This definition depicts fraud toward the consumer believing they are receiving the genuine FDA-approved product and does not include products that are marketed as being similar to or a foreign version of an approved drug. Those types of products are illegal and referred to as "unapproved new drugs," not counterfeit.

Counterfeit prescription drugs are illegal and unsafe. Many are visually indistinguishable from authentic drugs, and they pose a potentially serious health threat.

FDA is concerned that the drug supply is under unprecedented attack from a variety of increasingly sophisticated threats. This disturbing trend is evident in the increased efforts to introduce counterfeit drugs into the U.S. market.

Although FDA believes domestic counterfeiting is not widespread, the Agency has witnessed an increase in counterfeiting activities and a more sophisticated ability to introduce finished dosage counterfeits into legitimate drug distribution channels. Illicit wholesale drug diverters provide the window through which most counterfeit drugs have historically entered legitimate distribution channels.

In fiscal year (FY) 2004, FDA's Office of Criminal Investigations (OCI) initiated 58 counterfeit drug cases, a significant increase from the 30 cases initiated in FY 2003. We believe that this is in part due to an increased awareness and vigilance at all levels of the drug distribution chain as a result of FDA's Counterfeit Task Force's, February 18, 2004, final

report entitled, "Combating Counterfeit Drugs: A Report of the Food and Drug Administration." In addition, this increase in investigations is due to increased referrals from and coordination with other state and Federal law-enforcement agencies and communication with drug manufacturers.

Fortunately, most of the counterfeit drugs at issue did not reach consumers because we focused our resources and developed proactive investigations that enabled us to identify components of counterfeit products and interdict finished counterfeit drug products before they entered domestic distribution. Counterfeit, stolen, and otherwise fraudulently obtained pharmaceutical drugs all enter legitimate channels through pre-existing illicit diversion networks. OCI enforcement efforts targeting these diverters also have resulted in detection and dismantling of counterfeit schemes. Without the intimate knowledge of diversion borne of extensive investigative experience it would be difficult, if not impossible, to effectively combat pharmaceutical counterfeiting.

Although the number of counterfeit drug cases has increased and the threat to the public health is real, most of the suspect counterfeits that we discovered in FY 2004 were found in smaller quantities, compared to those found in FY 2003.

Counterfeit drugs may be contaminated or contain inactive ingredients, incorrect ingredients, improper dosages, sub-potent or super-potent ingredients. As a result, patients may be at risk for serious adverse health consequences. For example, Procrit, an injectable, sterile drug

used by cancer and AIDS patients, was counterfeited when the drug was replaced with non-sterile tap water, which could have caused a severe infection of the bloodstream.

In another counterfeiting incident, counterfeiters labeled aspirin tablets as Zyprexa, a drug for schizophrenia and bipolar disorder. This could have been particularly dangerous for patients who are aspirin-sensitive or aspirin-allergic, or who have bleeding disorders. In addition, patients who took the counterfeit drugs no longer received appropriate treatment for their illness.

Counterfeiters also have been known to use lower-strength active ingredients in their products. As a result, patients receive lower than expected doses of drug, leading to ineffective treatment and therapeutic failure.

While the rate of counterfeiting in the U.S. is difficult to estimate, on a global scale, counterfeiting is a widespread problem and affects both developing and developed countries. The World Health Organization (WHO) has reported that up to 25 percent of medicines consumed in poor countries are counterfeit or substandard. It has been reported that up to 50 percent of drugs for sale in some countries are counterfeit. Counterfeit drugs are most prevalent in developing countries.

This problem is not confined to counterfeiting the drug itself. Today, everything from product packaging to labeling and containers can be readily purchased, created or counterfeited, and counterfeiters and diverters take advantage of this opportunity. Moreover,

the skill and ingenuity demonstrated by counterfeiters and diverters have improved significantly. As a result, more than ever before, well-organized criminals have the ability to exploit our regulatory system and profit at the expense of public health.

PRESCRIPTION DRUG MARKETING ACT

Sixty-five years ago, Congress responded to widespread concerns about domestic drugs by enacting laws to provide FDA with the authority to create a system to assure the safety of the nation's drug supply.

During the 1980s, at least two high profile cases prompted further congressional action. In one instance, over two million unapproved and potentially unsafe and ineffective Ovulen-21 birth control tablets from Panama were distributed throughout the U.S. They were falsely imported as American goods returned. In another case, a counterfeit version of Ceclor, a widely used antibiotic at the time, entered into the U.S. drug distribution system from a foreign source. These concerns prompted Congress to pass legislation to correct this threat. After investigating the cases, Congress determined that the safeguards in the prescription drug distribution system were insufficient to prevent the introduction and retail sale of substandard, ineffective, or counterfeit drugs. Further, Congress found that a wholesale drug diversion sub-market had developed that prevented effective control over, or even routine knowledge of, the true sources of drugs.

Thus, in 1987, the Prescription Drug Marketing Act (PDMA) was enacted to further ensure the safety and effectiveness of prescription drug products and to safeguard the American public from the risk of counterfeit, adulterated, misbranded, sub-potent, or expired drugs. Key provisions of the PDMA include:

- A requirement for state licensure of wholesale distributors of prescription drugs.
- A requirement that wholesale distributors of prescription drugs who are not authorized distributors provide a statement of origin, also known as a drug "pedigree," to each wholesale customer. The pedigree traces each prior sale, trade, or purchase of the prescription drug.
- Requirements regarding the distribution and accountability of drug samples.

In 1999, FDA published final regulations implementing the PDMA. Shortly thereafter, the Agency received comments objecting to provisions concerning the pedigree requirement. These comments included letters and petitions and other communications from industry, industry trade associations, and Members of Congress. In addition, FDA received a petition requesting that the Agency issue a stay to suspend the implementation of the section of the final rule requiring: 1) a written agreement with a manufacturer establishing that a drug wholesaler was an authorized distributor, and 2) that unauthorized distributors provide a pedigree showing all prior drug sales extending back to the manufacturer. FDA received a second petition from the Small Business Administration raising these concerns and asserting that the rule would have severe economic consequences on more than 4,000 small businesses.

In response to these concerns, FDA delayed the effective date of certain regulations relating to written authorization agreements and drug pedigrees until October 1, 2001. We took this action to give the Agency time to evaluate the possible consequences of implementing these regulations and to further evaluate the issues at stake. These concerns included the high cost and logistics of maintaining a pedigree and the inability, in some cases, to obtain a transaction history from prior authorized distributors traceable back to the manufacturer, thus calling into question the usefulness of the pedigree. FDA was told that taking steps to address these regulations, using traditional methods, could impose substantial cost at a time when access to affordable drugs is a major concern.

In June 2001, FDA submitted a Report to Congress required by the FDA Appropriations Act for 2001. Our report noted that in order for secondary wholesalers to comply fully with the pedigree requirements, Congress would have to amend section 503(e) of the Food, Drug, and Cosmetic (FD&C) Act to make the pedigree requirement universal, thus enabling so-called secondary wholesalers to obtain the transaction history from all prior purchasers of the drug, including those currently designated as authorized distributors. To allow Congress to consider the information contained in the Agency's report, and in light of the problems associated with written authorization agreements and drug pedigrees, in 2001, 2002 and 2003, FDA has annually delayed the effective date of these provisions of the PDMA rule.

In February 2004, concurrent with the release of FDA's Counterfeit Drug Task Force Report, FDA further extended the stay of these provisions until December 2006. As further discussed later in this testimony, FDA was encouraged by the comments and information that

it received from drug supply chain stakeholders that an electronic track and trace system would be in place in the supply chain by that date. This electronic system would create a *de facto* pedigree that followed the product from the place of manufacturer through the U.S. drug supply chain to the final dispenser. If developed properly, this electronic pedigree could be used to meet the statutory requirements of the PDMA to provide a pedigree under certain circumstances. To allow stakeholders to continue to move toward implementing widespread use of an electronic pedigree and focus their efforts, the effective date of the relevant provisions were delayed until December 2006, a date that stakeholders believe was adequate to achieve the goals.

COUNTERFEIT DRUG TASK FORCE

In order to explore all options to reduce drug counterfeiting, on July 16, 2003, the Agency established an internal FDA Counterfeit Drug Task Force as part of the heightened battle against the growing threat of counterfeit drugs. The Task Force was charged with developing recommendations for FDA, other government agencies, and the private sector to minimize the risks to the public from counterfeit drugs entering into the U.S. drug distribution system. The goal of this initiative is to enhance existing safeguards that protect the nation's drug supply from counterfeit drugs.

As part of this effort, the Task Force met with several Federal agencies, such as the Secret Service, U.S. Customs and Border Protection, the Bureau of Engraving and Printing, and the Department of Justice, as well as various private sector stakeholders. The Task Force also

reviewed reports prepared by, or on behalf of, Federal and state governments, and heard from the public, including such stakeholders as pharmaceutical manufacturers, wholesale distributors, pharmacy associations, consumer groups, academicians, independent consultants, and manufacturers of anti-counterfeiting measures.

FDA released the Task Force's final report on February 18, 2004, entitled, "Combating Counterfeit Drugs: A Report of the Food and Drug Administration." This report and a May 2005 update can be found on FDA's website at: *www.fda.gov/counterfeit.*

The comprehensive report highlights several measures that can be taken to better protect Americans from counterfeit drugs. These measures rely on public and private sector efforts to address six critical areas:

- Securing the actual drug product and its packaging;
- Securing the movement of the product as it travels through the U.S. drug distribution chain;
- Enhancing regulatory oversight and enforcement;
- Increasing penalties for counterfeiters;
- Heightening vigilance and awareness of counterfeit drugs; and
- Increasing international collaboration.

Technology: Securing the product, packaging, and movement through the supply chain

In the Report, we stated that it is critical to implement new technologies to better protect our drug supply. We concluded that a combination of rapidly improving track and trace technologies and product authentication technologies could be used to provide a greater level of security for drug products. These technologies are intended to secure the product, packaging, and movement of the product as it travels through the drug supply chain.

Track and Trace Technology

In the Report, we stated that adoption and widespread use of reliable track and trace technology may be feasible by 2007. This would help secure the integrity of the supply chain by providing an accurate drug "pedigree"; a record documenting that the drug was manufactured and distributed under secure conditions. We explained that the implementation of electronic track and trace mechanisms would provide better protection and we noted that radio-frequency identification (RFID) is the most promising technology to meet this need. RFID technology uses a tiny radio frequency chip containing essential data in the form of an electronic product code (EPC). Implementation of RFID will allow supply chain stakeholders to track the chain of custody (or pedigree) of every package of medication. By tying each discrete product unit to a unique electronic serial number, a product can be tracked electronically through every step of the supply chain.

Over the last year, stakeholders have made tremendous progress in the development and implementation of EPC/RFID. This is a huge endeavor that requires close collaboration

among all constituents of the pharmaceutical distribution system. We have observed and supported this collaboration, and we continue to support it today.

A critical piece of this undertaking is the development of standards for the type of technology to be used and the systems for storing and sharing pedigree information. This activity will ensure that the electronic track and trace technologies adopted are comprehensible and data communication systems are interoperable. We have been present at and actively participated in many industry, standard-setting, and government meetings and workshops where implementation issues were discussed.

We received a number of questions over the past year regarding RFID and regulatory issues from members of the supply chain. In response to these common questions, on November 15, 2004, we issued a Compliance Policy Guide for implementing RFID feasibility studies and pilot programs as an important and essential step in moving this technology forward. The Compliance Policy Guide presents FDA's current thinking regarding several labeling, current good manufacturing practices, and other regulatory issues that may arise by affixing an RFID tag to a drug product for a feasibility study or pilot program. Several members of the supply chain simultaneously announced their intention to move forward with pilot programs (joint programs across the supply chain or within an individual company) that will involve the tagging of products susceptible to counterfeiting. In fact, three major pharmaceutical companies said that they will incorporate an RFID tag into at least one of their products by the end of 2005. We have been in close communication with participants in these and other pilot studies and provided input when appropriate.

In November of last year, we also announced the creation of an internal, cross-agency "RFID Workgroup." This group is charged to monitor adoption of RFID in the pharmaceutical supply chain, pro-actively identify regulatory issues raised by the use of this new technology, and develop straightforward processes for handling those issues. We believe that the workgroup will improve communication with members of the supply chain on RFID related issues and will facilitate both the performance of pilot studies and the collection of data needed to formulate policy.

It is important to gain a better understanding of the effects of RFID on drug products, particularly biological products because they may be more susceptible to change in their environment. We developed a protocol for companies to follow for studies examining the impact of radio-frequency on drug and biological products. Also, a laboratory within FDA's Center for Devices and Radiological Health is conducting analyses of the heating and the radio-frequency field strengths induced in certain liquid pharmaceuticals by some RFID systems. To date, we have not received much data looking at the effects on drug and biological products and are looking at several options for how to obtain this information.

FDA continues to play an active role in supporting public and private sector efforts toward developing an "electronic safety net" for our drug supply, including the adoption and widespread use of reliable track and trace technology by 2007. We continue to facilitate and monitor standard-setting activities, including efforts by epcGlobal (an entity that has taken a lead role in developing standards) to establish standards for numbering systems, chip frequency, electronic pedigree, and data-sharing and security. In addition, we continue to

encourage and foster research on the use and potential impact of RFID on drug and biological products.

Authentication Technology

In the Report, we noted that authentication technologies for pharmaceuticals (such as color-shifting inks, holograms, taggants, or chemical markers imbedded in a drug or its label) have been sufficiently perfected that they can now serve as a critical component of a layered approach to control counterfeit drugs. FDA's Report acknowledged the importance of using one or more authentication technologies for drug products, in particular those most likely to be counterfeited. Over the past year, we have worked with individual drug manufacturers who sought to incorporate such technologies into their product, labeling, or packaging. When asked, we have provided advice and suggestions regarding application and use of authentication technologies and worked with sponsors on the regulatory issues associated with making changes to approved product labeling.

In the Report, we said that in order to facilitate the use of authentication technologies on or in approved products, we would consider publishing a draft guidance document on notification procedures for making changes to products, their packaging, or their labeling. We decided not to issue guidance in the past year because we would like to gain additional experience working with companies in their application and use of authentication technologies so the guidance can have appropriate general applicability.

We continue to work with companies and organizations to facilitate use of authentication technologies in products, labeling, and packaging.

Regulatory Oversight and Enforcement

Electronic Pedigree

In the Report, we said that adoption of electronic track and trace technology would help stakeholders meet and surpass the goals of the PDMA. We said that we intend to focus our efforts on facilitating industry adoption of this technology.

We are pleased with the progress stakeholders, standard-setting bodies, and software and hardware companies have made thus far toward implementing an electronic pedigree for drug products. We recognize that there have been, and continue to be, challenges along the way. Although we are optimistic that this progress will continue, and that widespread track and trace technology may be feasible by 2007, we are concerned that the private sector may not meet this and related goals stated in the Report.

We are closely monitoring the progress of widespread use of electronic pedigrees as we assess whether to lift, maintain, or pursue other options regarding the stay of implementation of the provisions in the PDMA final rule.

State Efforts

In the Report, we recognized the important role that the states have in regulating the drug supply chain, and we stated that adoption and enforcement of strong, proven anti-

counterfeiting laws and regulations by the states would help in our collective effort to detect and deter counterfeit drugs. FDA strongly supported the efforts taken by the National Association of Boards of Pharmacy (NABP) in revising the Model Rules for Licensure of Wholesale Distributors for states to adopt. These Model Rules make it difficult for illegitimate wholesalers to become licensed and then to transact business. Eleven states have laws in place that are similar to the Model Rules. FDA has provided advice and input on a few state legislative proposals and we recommend that more states move in this direction in the coming year.

NABP last year also announced the creation the Verified-Accredited Wholesale Distributors™ (VAWD) program as a complement to the Model Rules. Applicants for VAWD accreditation undergo a criteria compliance review, licensure verification, an inspection, background checks, and screening through NABP's clearinghouse. It is intended to provide assurance that the wholesale distribution facility operates legitimately, is validly licensed in good standing, and is employing security and best practices for safely distributing prescription drugs from manufacturers to pharmacies and other institutions. Indiana was the first state to pass a law that requires VAWD accreditation for all drug wholesale distributors who do business in Indiana.

In the Report, we said that there would be great value in the creation of a national list of drugs most likely to be counterfeited based on factors that are likely to contribute to counterfeiting risk. The Model Rules called for such a national list as a starting point for application of pedigree requirements in the short term so that there would not be 50 different state lists. In

December 2004, NABP convened a National Drug Advisory Coalition, which included industry and state and national government representation. FDA has served in an *ex-officio* role on this Coalition. The Coalition developed criteria for inclusion or removal from such a list and created a national list that includes 31 drugs. FDA applauds NABP on this accomplishment.

We recognize that states have implemented and are considering provisions requiring a pedigree (in some cases electronic) for drug products. We are pleased that these efforts complement Federal requirements and believe that rapid and uniform implementation of a pedigree that starts at the point of manufacture and accompanies the drug product until it is dispensed would be beneficial. As stated in the Report, adoption and enforcement of the Model Rules by all states would have the greatest impact on protecting the nation's drug supply.

In the Report, we also said that increased penalties would help deter counterfeiting and more adequately punish those convicted. As we continue the efforts on the Federal level, it is equally important that states adopt stronger penalties (like those outlined in the Model Rules) so the penalties associated with counterfeiting drugs are commensurate to the significant threat they pose to the public health.

Secure Business Practices

In the Report, we described the important role that all participants in the drug supply chain have in adopting secure business practices. Around the time the Report was issued several

trade associations for wholesale distributors issued guidelines for their members regarding best practices for drug distribution system integrity. In fact, in the past year, the Healthcare Distribution Management Association released new membership rules that require active members to adopt best practices that include extensive regulatory, financial, security, and due diligence processes and procedures.

It also is important to note that many of the secure business practices outlined in these trade associations' best practices guidelines are included in the Model Rules for Licensure of Wholesale Distributors for adoption by the states.

Increasing Penalties for Counterfeitors

FDA has contemplated this issue and contacted the Sentencing Commission to ask for higher penalties for counterfeiters. Although this is a complicated legal issue, we believe that more stringent sentencing guidelines would offer more appropriate penalties for offenses related to counterfeiting.

Heightened Vigilance and Awareness

Health Professional Reporting Via MedWatch

In the Report, we indicated that we would encourage and educate health professionals to use the MedWatch form as a mechanism to report suspect counterfeit drugs to FDA. To make the reporting of suspect counterfeits easier, we changed the instructions for the MedWatch reporting form, both paper and electronic versions, so reporters will know how and when to report suspect counterfeits. We also have amended the MedWatch website description of

product problems and added "suspect counterfeit" to the list of product problems to report to FDA using the MedWatch form. FDA staff has promoted the use of MedWatch for reporting suspect counterfeits in numerous speeches to health professional organizations over the past year. A small number of such reports are starting to come in using the MedWatch form.

Counterfeit Alert Network

In the Report, we stated that we would create a Counterfeit Alert Network (CAN) and partner with health professional and consumer groups to provide timely and effective notification to their members or constituents of a verified counterfeit event. By signing the CAN co-sponsorship agreement, organizations become CAN partners and agree to deliver time-sensitive messages and information on specific counterfeit incidents and educational messages about counterfeits in general, as well as information about how and when to report suspect counterfeit drug products. In the past year, we formed the CAN and currently 13 organizations have signed the CAN co-sponsorship agreement.

Also, in the Report, we stated we would develop internal guidelines for the informational contents of outgoing FDA messages that would be useful to communicate a counterfeiting incident to CAN partners. In the past year, we have developed these guidelines, in the form of a template, in collaboration with CAN partners. This template will allow for the efficient preparation and delivery of uniform counterfeit alert messages for partners to further disseminate.

Streamline FDA's Internal Rapid Response to Reports

In the Report, we said that we would streamline our internal processes to respond quickly to reports of suspect counterfeits by improving coordination and communication among all initial responders in the Agency. In the past year we amended our internal standard operating procedures and developed a protocol for more efficient internal communication and coordination when a suspect counterfeit drug is reported to the Agency, regardless of where the report is received (e.g., MedWatch, an FDA field office, call to the FDA hotline).

Educating Consumers and Health Professionals

In the Report, we noted that educating consumers about the risks of counterfeits is a critical piece of the effort to stop counterfeits from entering the stream of commerce. In the past year we have taken many steps towards educating consumers. First, we developed two public service announcements (PSAs) geared to consumers. These PSAs ran in 4.5 million magazines. In addition, 4.6 million medication leaflets distributed by retail pharmacies with patient's prescriptions also carried these PSAs along with additional consumer information about counterfeit drugs. Also, FDA drafted an article about counterfeit drugs that was printed in several local papers nationwide, with an estimated readership of about 9.5 million consumers.

We also set up a webpage on FDA's website for consumers to obtain information about counterfeit drugs, FDA initiatives, and educational information. This website can be found at *www.fda.gov/counterfeit*. In addition, the National Consumers League developed a highly informative website containing useful consumer information about counterfeit drugs.

In the past year, FDA partnered with the National Health Council (NHC) to jointly create and disseminate educational messages on counterfeit drugs. NHC is a private, non-profit organization of over 100 national health-related organizations. Under this partnership, messages to raise awareness of the dangers of counterfeit drugs and how to avoid them will be developed and tested to measure their effectiveness. In addition, products will be created to deliver these messages to the target audience.

In addition, FDA is developing educational messages to inform pharmacists about how to recognize counterfeits, counsel patients on how to minimize the risk of exposure to counterfeits, and on how to notify FDA if a counterfeit drug is suspected. These efforts are in the early stages.

In the Report, we said that we would re-launch our safe online buying practice campaign. In March 2005, we launched a new campaign with tips for consumers on how to buy drugs safely on the Internet and minimize their risks of getting a counterfeit or otherwise substandard drug.

In the coming months, we plan to take steps to increase dissemination of the PSAs and counterfeit drug messages. We also will continue to update and post relevant information on our counterfeit drug webpage. We also plan to continue to work with the NHC to finalize educational messages and develop a dissemination strategy for those messages. We are currently working with pharmacy organizations to finalize educational messages for pharmacists and develop a strategy to disseminate these messages.

International Collaboration

In the Report, we recognized that counterfeit drugs are a worldwide concern, and we stated that we would collaborate with foreign stakeholders to develop strategies to deter and detect counterfeits globally. In February 2004, the WHO hosted a meeting to discuss an approach for developing global strategies for combating counterfeit drugs. FDA participated in this meeting and supports WHO's efforts in this area. It was decided at the WHO meeting that a concept paper would be drafted with a proposed strategy to address this problem. In March 2005, we attended the Fourth Pan American Conference on Drug Regulatory Harmonization held by the Pan-American Health Organization (PAHO) where a report was presented and recommendations were discussed regarding combating counterfeit drugs in the Americas. FDA's counterfeit drug initiative is consistent with the recommendations of the PAHO report.

OCI, within FDA, continues to work with foreign law-enforcement agencies directly and through Interpol on individual international counterfeit cases.

OCI also has provided training on counterfeit drugs to foreign law-enforcement, customs and judicial officers from various parts of the world through the U.S. Patent and Trademark Office, Intellectual Property Enforcement Academy. In addition, in the past year, several individual countries have sought FDA's insights, advice, and/or training on combating counterfeit drugs. Although the approaches that we outlined in the Report were specific to the U.S. drug distribution system, many of the principles outlined in the Report are applicable generally.

RECENT SIGNIFICANT COUNTERFEIT CASES

Below are a number of significant counterfeit drug cases that were closed in the past year:

Counterfeit Lipitor

Although we continue to see individuals dealing in counterfeit drugs via the Internet, there are others that use the under-regulated system of secondary wholesalers to distribute their counterfeit drugs, which then end up at the pharmacy level. The Albers Medical investigation is the most prolific example. On August 21, 2005, the U.S. Attorney's Office for the Western District of Missouri issued a press release announcing that three businesses and eleven individuals were indicted for their involvement in a $42 million dollar conspiracy to sell counterfeit, smuggled and misbranded Lipitor and other drugs and for participating in a conspiracy to sell stolen drugs. As part of this investigation, FDA initiated a recall of more than 18 million Lipitor tablets, which ranks as one of the largest recalls in the history of criminal investigations of counterfeit medications.

Participants in this scheme conspired to purchase and sell counterfeit, misbranded and illegally imported drugs. Foreign versions of Lipitor and Celebrex were smuggled into the U.S. from South America and re-sold after being re-packaged to conceal the true origin of the drugs. Counterfeit Lipitor also was manufactured in South America and then smuggled into the U.S. where it was co-mingled with the genuine foreign Lipitor and sold in the U.S. In addition, participants conspired to buy, sell and traffic almost eight million dollars worth of stolen Glaxo Smith Kline and Roche drugs, using fake pedigrees to launder the drugs and

thereby concealing that they were stolen. There also were charges related to the sale of counterfeit Procrit, as well as counterfeit and misbranded Serostim and Neupogen. Procrit is an injectable drug used in the treatment of anemia and Neupogen is an injectable drug used by cancer patients to stimulate the production of white blood cells in order to decrease the incidence of infections.

Counterfeit Lipitor and Viagra

In another counterfeit Lipitor case, an OCI undercover operation resulted in the arrest and conviction of a Belize citizen for violating Title 21, United States Code (U.S.C.) §331 (a) – Introduction into Interstate Commerce of a Misbranded Drug. In September 2004, the defendant was sentenced to 10 months incarceration and 1 year probation.

Counterfeit Viagra, Cialis, and Lipitor

On September 12, 2005, the U.S. Attorney's Office for the Southern District of Texas announced the indictment and arrest of an individual from the state of Washington for his alleged involvement in the importation from China and subsequent distribution of counterfeit drugs, including Viagra and Cialis. This joint OCI and U.S. Immigration and Customs Enforcement (ICE) investigation was significant in that it also involved the direct assistance of OCI and ICE in China to determine the source of the counterfeits. As a result of this collaborative effort, Chinese authorities arrested 11 individuals who will be prosecuted by the Chinese government for their involvement in manufacturing and distributing counterfeit Viagra, Cialis, and Lipitor. In addition to the arrests, Chinese officials recovered 600,000

counterfeit Viagra labels and packaging, 440,000 counterfeit Viagra and Cialis tablets, and 260 kilograms of raw materials used to manufacture counterfeit drugs.

Counterfeit Risperdal and Zyprexa

In October of this year, the U.S. Attorney's Office for the Southern District of Florida issued press releases following the sentencing of two individuals involved in drug diversion and counterfeiting. One individual was sentenced to 30 months in jail for counterfeiting Zyprexa and Risperdal prescription labels and selling them to various individuals. In a related investigation, a second individual was sentenced to 24 months in jail for the illegal wholesale distribution of prescription drugs and possession with the intent to distribute controlled substances.

Counterfeit Drugs from Mexican Border Pharmacies

In the summer of 2004 and again in the spring of 2005, OCI received Voluntary Suspect Counterfeit Drug notifications from the drug manufacturers of Zocor, Carisoprodol, Lipitor, Viagra, and Evista. Counterfeit versions of these drugs were being sold to U.S. consumers from Mexican pharmacies along the U.S. border. The analysis of all these drugs showed they either contained little or no active ingredients.

OCI coordinated with FDA regulatory authorities who issued two *Talk Papers* (July 30, 2004, and May 10, 2005) alerting consumers to the counterfeit drugs. OCI and FDA regulatory authorities also established contact with the Mexican Federal Commission for Protection from

Sanitary Risks to provide them with details and samples of the counterfeit drugs so they could take appropriate action in Mexico.

Genapharm.com (Counterfeit Human Growth Hormone)

On March 9, 2004, an Austin, Texas man pled guilty to four counts of conspiracy to introduce misbranded and unapproved new drugs into interstate commerce, counterfeiting human growth hormone, and possessing controlled drugs with intent to distribute. Two other persons involved in these offenses were previously convicted and sentenced.

Counterfeit Viagra

On June 23, 2004, an individual pled guilty to charges of conspiracy, trafficking in counterfeit goods, and a felony violation of the FD&C Act. In pleading guilty, the defendant admitted that he conspired with a manufacturer in Beijing to import thousands of counterfeit Viagra tablets into the U.S., which he would then resell. The defendant was sentenced, on March 25, 2005, to 18 months in prison, followed by 3 years probation and was fined $6000.

Counterfeit Serostim

On June 16, 2004, an indictment was unsealed in San Diego that charged an individual with conspiring to unlawfully distribute human growth hormone and trafficking in counterfeit goods. According to the indictment, this individual obtained counterfeit Serostim and sold it to bodybuilders who did not possess lawful prescriptions for the drug. Another individual involved in this investigation pled guilty to similar charges on February 19, 2003. Serostim

is a prescription drug containing the active ingredient "somatropin," a form of human growth hormone. Serostim is approved by FDA for use in the U.S. to treat AIDS wasting disease.

Counterfeit Labeled Pharmaceuticals

An Alabama drug wholesaler was convicted for violating Title 21, U.S.C. §331 (i) (3) – Selling and Holding for Sale a Counterfeit Drug. In October 2004, the company was sentenced to 5-years probation and fined $24,000.

Counterfeit Viagra

In January of this year, a southern California man pled guilty to importing counterfeit Viagra from China and manufacturing 700,000 counterfeit Viagra tablets at a lab in the U.S. An accomplice was convicted of similar charges in September 2004. The total value of the counterfeit Viagra in this case is more than $5.65 million.

World Express Rx

In January of this year, a San Diego man was sentenced to serve a 51-month prison term and forfeit substantial cash proceeds for his role in operating a large Internet pharmacy scheme. The drugs distributed included a variety of products counterfeited in Mexico, smuggled into the U.S. and sent throughout the country. Some of the ingredients for the drugs were shipped from India and China. In other instances, unapproved and counterfeit drugs made in India and Pakistan entered the U.S. via the Bahamas. At least 14 other individuals also are being prosecuted in California or Florida as part of this international conspiracy.

MONITORING THE TAMIFLU SUPPLY

As the threat of pandemic flu emerges as a public health threat, FDA anticipates an increase in the sale of counterfeit or fraudulent treatments. Presently, the Agency is not aware of any counterfeit Tamiflu cases in the U.S. However, through the implementation of the measures outlined in FDA's Counterfeit Drug Task Force Report and the vigilance of our experienced enforcement and investigative staff, efforts are in place to deter and detect counterfeiters and parties who sell fraudulent or phony products to treat or prevent Avian flu.

CONCLUSION

Significant progress has been made towards implementing the measures outlined in FDA's Combating Counterfeit Drugs Report, issued in February 2004. Although the use of electronic track and trace technology is still in the implementation stage, adoption and widespread use is closer to becoming a reality as stakeholders work diligently to find solutions to the challenges faced along the way. The use of authentication technologies is gaining acceptance as manufacturers realize that steps should be taken to protect their products from sophisticated counterfeiters. States are starting to adopt stricter laws and harsher penalties to ensure that only legitimate wholesalers do business in their state and they are taking measures to do their part in protecting supply chain integrity. OCI will continue to target illicit diversion to further protect the integrity of the drug supply. Trading partners in the drug supply chain also are taking steps to ensure secure business practices are adopted and utilized as drug products are bought and sold. Educational efforts have been undertaken to help health professionals and consumers develop a greater awareness and knowledge about

counterfeit drugs and how to minimize the risks of exposure. In addition, efforts are underway to tackle counterfeit drugs on a global level.

Despite the progress made, there remains a viable and concrete threat of counterfeit drugs entering the U.S. drug distribution system. We must all continue to work together to expeditiously pursue the measures outlined in the Report to further protect the safety and security of the U.S. drug supply.

I would like to thank the Subcommittee for this opportunity to testify today on this important issue. I would be pleased to respond to any questions.

Mr. SOUDER. You said in your testimony that you asked Congress in 2001 in the report to amend section 503(e) to make the requirement universal. Are you maintaining that that is a major reason you haven't gone ahead with the pedigree? I don't understand what the point of that is.

Mr. LUTTER. Since the time that recommendation was offered, there has been no legislative action. Our current proposal is to do the best we can given current law and the authorities we have.

Mr. SOUDER. You're saying without a universal pedigree, there's no point in——

Mr. LUTTER. Our expectation is that the track-and-trace technology exemplified by RFID would offer a way to implement an electronic pedigree given the existing authorities.

Mr. SOUDER. So you wouldn't need to do the amendment.

Mr. LUTTER. It would still be helpful and the recommendation still stands. It's unclear. While we have substantial optimism about the availability of RFID, by 2007, after the end of 2006, there's of course uncertainty about the schedule, that it would be adopted.

Mr. SOUDER. So the criticism that the State—are you maintaining that the reason you haven't implemented any kind of pedigree is because of the failure to amend 503?

Mr. LUTTER. The decision behind the stay was in response to a variety of public comments, including from Members of Congress and the Small Business Administration as well as from industry, that it would be very difficult to comply with the regulation as drafted. It related in part to the cost of implementing the paper pedigree, which was the best available technology at the time, and also with respect to the difficulties of 503.

Mr. SOUDER. This bill was passed 18 years ago. Have private companies done anything to improve that, to establish a pedigree? What have they done to move ahead?

Mr. LUTTER. There are some initiatives in some States where States have already adopted stringent regulations, Florida being one. A variety of major pharmaceutical companies have taken active steps recently to adopt voluntarily the RFID track-and-trace technology. We think that the actions by those companies, and also by Wal-Mart, which, as you know, is a leader in retailing and in distribution, provide a way for the industry to move forward toward a lower-cost electronic track-and-trace technology.

Mr. SOUDER. Did Florida move to an electronic track and trace or to the paper trail?

Mr. LUTTER. They have not adopted the electronic RFID.

Mr. SOUDER. So they did in Florida what you said would be difficult for us to do at the Federal level?

Mr. LUTTER. Yes.

Mr. SOUDER. Are other States copying the Florida——

Mr. LUTTER. There have been examples of other States. They're in a variety of stages of implementation. FDA's policy in general has been to facilitate and support more stringent licensing requirements on wholesalers at a State-by-State level where there has been evidence that the existing programs are lax.

Mr. SOUDER. Why would you favor it on a State-by-State level but not nationally?

Mr. LUTTER. We at this point have no particular policy. We're still studying the proposal by the HDMA, which you alluded to in your earlier remarks.

Mr. SOUDER. For 18 years?

Mr. LUTTER. Excuse me?

Mr. SOUDER. For 18 years you have been studying it; 1987, 1999 made more specific questions. Part of the question is how long do you have to study something?

Mr. LUTTER. We issued the regulation on the pedigrees in 1999 and we've stayed it repeatedly since then. It did take a while following the enactment of the law.

Mr. SOUDER. Are you going to continue to stay this until you figure out whether the electronic will work?

Mr. LUTTER. At the time that we issued the last stay, we received ample public comment from the industry, from manufacturers, and from retailers that they believe that based on available information that they had, that electronic track and trace would be feasible and widespread by the year 2007. Because electronic track and trace offered a lower-cost way of satisfying pedigree requirements, we believed at that time the track and trace would be a way of satisfying the pedigree requirements after December 2006, and that's why we issued—extended the stay of the rule through December 2006.

At this time, we continue to be optimistic that RFID would be economically feasible to the industry and available at that time, but of course there's uncertainty about how the technology will develop.

Mr. SOUDER. I have been more immersed in this last stretch trying to figure out how we regulate pseudoephedrine with meth, and the arguments you're making are so similar as we try to deal with this at a Federal level. The administration's position has been why not a State-by-State level? And so we have chaos, that people in one State go over to the next State to get it. We've been meeting about the difficulty of the paper trail and whether it can be done electronically, which people hold out may be a possibility to do this electronically. Now we're hearing that in a sense everything is somewhat in danger, and we'll hold out hope that electronic will do it.

That's why my question is: Has anything been done in 18 years, or is it in fact the threat of a Federal regulation? I have a family business. I grew up in a family business. And part of the question is at what point do you start to react proactively to avoid the Federal intervention, or how long do we wait and stay and stay and stay? That's kind of where my questions were driving, if you could tell us directly that the electronics will be implemented by date certain and will work in small business.

What we found in pseudoephedrine is Target and Wal-Mart can agree, but small business can't really function, because the bigger distributors will have electronic ability; the smaller ones may not. So then you get into a situation of having electronics, but it automatically biases toward the big retailers unless you have a paper combined with it, which is what we're finding in the other areas.

I just don't see—do you really think there will be electronic availability in every little pharmacy and grocery story in the United States in, what did you say, 2006?

Mr. LUTTER. The information that was given to us from the industry a couple of years ago as we were preparing the Counterfeit Task Force report, and at the time we developed the decision on the stay, was that there was substantial optimism. A lot of that was because the RFID is not primarily for counterfeit control in the sense of providing a pedigree, but also it provides substantial business advantages to the wholesalers and to the industry, the manufacturing companies, in terms of giving them information about management of their inventories to lower inventory control costs and to provide an opportunity for them to better manage the distribution of their entire product. The information that we had from them is that this would be economically feasible by the year 2007. Clearly these expectations depend on their judgment about the development of the new technology. We will have to reassess the development of that new technology as we approach the expiration of the stay late next year.

Mr. SOUDER. Why wouldn't you do what States are doing in meth and other things; that is, put a paper trail in and when the electronics come, you replace it with electronics.

Mr. LUTTER. In 2001 when we originally issued the stay, there was substantial opposition from the industry, including the Small Business Administration, that this would put out of business many small secondary wholesalers. And since this is also in response to these concerns expressed by the industry and by the Small Business Administration and by Members of Congress, we decided to implement the stays.

Mr. SOUDER. Thank you. Mr. Cummings.

Mr. CUMMINGS. Who are these counterfeiters, do you know? Do you have any idea who they are? Are the people in this country or outside of the country?

Mr. LUTTER. The counterfeiters are identified primarily through the ongoing criminal investigations. In terms of who they are, when the products are sold in this country where FDA has jurisdiction, they're sold by American, typically American, pharmaceutical product wholesalers, and the products are typically intercepted at that level, but people who are masquerading in any event as such wholesalers.

Mr. CUMMINGS. You say in your testimony, I think you said that we catch them usually before they get to the retail.

Mr. LUTTER. We have been successful to date in catching most of the products before they reach retail distribution.

Mr. CUMMINGS. Why is that? How has that come about?

Mr. LUTTER. I think it's largely because of the quality of the tips and the information that we gather from the manufacturers and from the wholesale distribution system. Most counterfeit investigations that we initiate are not the result of a consumer saying I got a product which isn't genuine—because it's clearly extremely difficult for consumers to make the distinction. Instead, they're sometimes from manufacturers who give tips that a product has been brought to their attention which is not one of theirs, but in fact resembles theirs; or is from a wholesaler who also has information

that the products are being sold as if they were FDA-approved, when in fact they're products which are not. And it's that sort of information that is usually the impetus for the investigations that we undertake.

Mr. CUMMINGS. Just recently we had on the national news this thing about the folks trying to sell some fake flu vaccines. How did that come about? How did that information come about?

Mr. LUTTER. That was a case in Texas where the flu vaccine was injected at a workplace. It's actually not a counterfeit product, because apparently it was not sold as if it was a brand-name vaccine. It was surely fake, it was fraudulent, it was unsafe, it was potentially dangerous.

Mr. CUMMINGS. Unapproved.

Mr. LUTTER. Unapproved, surely. My understanding, the syringes were filled with sterile water. Surely the people received no benefit in terms of protection against the flu, which is the primary interest that they were seeking the vaccinations.

Mr. CUMMINGS. So you're saying, then, that we are able to catch most—the people that we have been able to at least catch, they have gotten to them before they got the product to the retailer. Who are these retailers? Is there any particular part of the country where you see this more prevalent?

Mr. LUTTER. I don't think it's easy to generalize about what types of retailers are more inclined to be buying this. I think many retailers are business people and are potentially vulnerable to sales of counterfeit products when they're made available. So I think in that sense it's a potentially widespread problem.

Mr. CUMMINGS. How often do we find these drugs actually get to the retailers, from what you can see? Is that a major problem? I know what you just said, that we see a number of cases where they actually get to the retailer.

Mr. LUTTER. Based on conversations with the senior staff in the Office of Criminal Investigations at FDA, I don't think I'm able to generalize about that. We just don't know.

Mr. CUMMINGS. There seems to be an increase in FDA counterfeiting investigations recently. How much is this attributed to heightened vigilance or to the extent the problem may be getting worse? Do you have any idea?

Mr. LUTTER. We've had extensive discussions internally about that question. The best professional judgment is that the problem is indeed getting worse. There are probably more counterfeit drugs out now than there used to be.

Notwithstanding that, we believe the overwhelming majority of all products available in the United States are safe. As to why there's an increase, that's a very difficult question. We believe that the increase in initiated new investigations, the first chart that I presented today, reflects largely two things: One is a growing threat in terms of the number of counterfeits that may exist; and the second one is improved information that we get from manufacturers and from wholesalers from the law enforcement community both at a Federal level and at a State and local level, and those better tips are ones that help us initiate more investigations than was the case in the past.

Mr. CUMMINGS. Do you feel that you have enough money to do the things that you need to do? Here we have an increase in the investigations, and based upon what you just said, it seems as if people have decided that this is a business that they want to be a part of; this counterfeiting business, that is.

Do you feel we have enough money? We're trying to concentrate on a number of issues, as you well know, in our country. And I'm wondering if you believe your folks have enough money to do what you need to do, because if this continues to increase, I can see a situation where a lot of people can be harmed, and I was just wondering.

Mr. LUTTER. Let me say, first, that most recent available data on the number of investigations is somewhat reassuring. A very high number in fiscal year 2004, 58, fell the following year to 32. And that suggests that the very high number in that 1 year was somewhat unusual. The decline may be due in part to successful deterrents, may be due in part to the fact that when we initiated new investigations in the most recent year, we discovered that some of those were in fact linked to investigations initiated in the earlier year and therefore were not independent. And when accounting for these investigations, taking in a manner that attempted to count merely the number of independent ones, the independent investigations initiated in the last year was lower.

With respect to your question of whether or not we need more money, we have a variety of priorities at the FDA in the Office of Regulatory Affairs and with respect to criminal investigations in particular. The Office of Criminal Investigations is responsible for medical devices, also foods as well as drugs. It also investigates cases of fraud regarding new drug applications. Given those competing priorities, we do the best we can with the resources that we have.

Mr. CUMMINGS. Well, what does that mean, though?

Mr. Chairman, I have to finish this. Give me 1 second. We are here talking about the drug counterfeiting, and I need to know where that falls in all the things that you just stated; that's the one question.

The other question is, help me understand, isn't it possible that we still may have a very significant problem in the mere case, the mere fact that there have been, maybe, as you just testified, less investigations may not necessarily mean that there are less problems? I mean, can you answer those two? And then I'm finished.

Mr. LUTTER. Well, there's a very tenuous relationship between the number of investigations and the extent of the problems. We believe that there's more problems associated with counterfeit drugs in recent years, call it the last 2 or 3, than there were 5 or 6 years ago. In that sense the trend is disturbing.

I'm sorry; your other question?

Mr. CUMMINGS. I was trying to figure out exactly where in the line of priorities—I asked the question, first of all, do you have enough money? Then you gave me a whole list, a laundry list, and rightfully so, of the things that are priorities for you. And I'm just trying to figure out where this falls in the list. Is this something that's at the top of the list, is this at the bottom? Where is it?

Mr. LUTTER. The way the OCI is managed is that the investigators are generalists. They are assigned to different topics according to where the opportunities are and where the information lies so that they can be most effective. And in that sense, I think it's very difficult to come up with a single ranking of where the priorities are, because it depends on the particular circumstances available in any particular investigations.

Mr. CUMMINGS. Thank you.

Mr. SOUDER. I understand your testimony to say that the FDA, that you systematically random test drugs at pharmacies and grocery stories, that you systematically random test things on the Internet or at, say, flea markets or other selling points to see if there's fraud.

Mr. LUTTER. No.

Mr. SOUDER. Then how in the world can you say under oath that you know what the level of the problem is? In other words, all you can testify to us is how many——

Ms. NORTON. Mr. Chairman, can you speak up?

Mr. SOUDER. I'm questioning how he can testify under oath that he knows the extent of the problem if you're not doing any testing other than from a tip.

Mr. LUTTER. Mr. Chairman, I mentioned earlier that it was based on the best professional judgment of——

Mr. SOUDER. In other words, tips.

Mr. LUTTER. The staff of the Criminal Investigations that the trend is increasing.

Mr. SOUDER. You said earlier that you believe it's generally been an increasing trend, but I was responding really to Mr. Cummings' first question. You downplayed, you said the overwhelming numbers and all this kind of stuff. The fact is you don't know. Based on the tip, which is one indicator, but if you're not doing random testing, particularly in high-risk areas, you don't know. We do that all the time in all other kinds of narcotics, and you can't make that statement, because you don't have a border check that systematically—or do you? Are you basing this solely on how many criminal investigations are initiated from tips?

Mr. LUTTER. We lack the resources to conduct the sort of randomized testing of products sold in the market that I think you're describing. We have not contemplated that. We've never done it.

Mr. SOUDER. That is a very fair statement and we may all have to decide that the risk isn't there, but then we can't make sweeping statements about safety if we haven't random tested.

Mr. LUTTER. The statement about safety is based on many years of experience of the FDA professional staff who are responsible for ensuring the safety of and effectiveness of drugs sold in America, and their collective judgment is that the vast majority of these products are safe.

Mr. SOUDER. Thank you. Mr. Burton.

Mr. BURTON. We're all against counterfeit drugs. You probably don't know this, but we had Mr. Hubbard before my committee when I was chairman of the full committee, about five times, and we were talking about the reimportation of pharmaceutical products. He said that they couldn't guarantee the safety of them, and I asked him how many people died from aspirin or Tylenol last

year, and he didn't know. I said, do you have any records about that? And he says, well, no. I said, how many people were injured last year from pharmaceutical products imported from Canada, where they have a pretty rigid pharmaceutical policing system? And he says he didn't know.

And I have all the testimony here from two or three hearings if you would like. I'd be glad to give you all of it. The fact is you don't know. You just don't know. And policing it is very, very difficult. The reason that people import pharmaceutical products is because the cost disparity is so great. The pharmaceutical pharmacy charges 8, 9, 10, 20 times more in the United States for the very same product sold in Germany, France, England, Canada and elsewhere. And you've got people on fixed incomes who have to split their pills. You talk about being safe: They split their pills, split their medication, because they can't afford to buy the pills because they cost so much here, when they can go across the border in Canada and get the same thing, 10 times as many pills for the same price. That's the problem.

And we never heard about this kind of a problem before we started talking about reimportation, the counterfeits. We had hearings for 4 years, we never talked about counterfeit drugs until we started talking about reimportation. And all of a sudden, the pharmaceutical industry and HHS said we've got a problem with counterfeit drugs and it's going to create a terrible problem for the American people. Never heard about it until then because of the profit margins that we were talking about.

I'm a free enterprise advocate. I believe in the companies making a big profit, I want them to, but I don't want Americans to pay 10 times for Taxol. My wife died of cancer a few years ago. I don't want them paying 10 times for Taxol what they do in Canada, France or Germany, or someplace else. And hiding behind the counterfeit things bothers me; we want the purity to be there. But to keep saying, my gosh, we can't have reimportation, we can't import drugs from Canada and France and Germany, because of—that is just an argument that's being fostered by those who want to make a lot more money here in the United States and saddle the profits on the back of the Americans while the rest of the world gets off scot free. You can give me all the stuff you want to about the FDA being concerned. That really bothers me.

I want to talk to you just a little bit about the wholesalers, and I'm disappointed we don't have any wholesalers here today on the panel, and I don't blame the staff or the chairman for that. I just wish they were here so they could defend themselves when you talk about the problems that they face. Can you detail for us any significant counterfeit drug cases since late 2003?

Mr. LUTTER. I'm not prepared to do that.

Mr. BURTON. Give me one. OK, you can't. When the Health Distributor Management Association published their recommended guidelines for pharmaceutical wholesaler operations that track counterfeit stolen products, specifically back through licensed secondary market wholesalers, that was in 2003. I don't think FDA can give us any counterfeit evidence since then. I'm not so sure you can go back any further than that. What's been done by the industry, the wholesale industry, particularly wholesalers in reaction to

the counterfeit problems that we heard about? Can you give us any idea what they've done to protect the buying public?

Mr. LUTTER. I'm sorry. What's been done by the wholesalers?

Mr. BURTON. What has been done by the wholesale industry, particularly wholesalers, in reaction to the counterfeit problems that you have been talking about?

Mr. LUTTER. I think one might, sir, ask that question of the wholesale industry.

Mr. BURTON. Well, you guys are at the FDA, and you've been talking to the wholesale industry about a problem that has been created by these counterfeit drugs going through the process. Have you talked to anybody in the wholesale industry about what they've done?

Mr. LUTTER. We have talked to them about the——

Mr. BURTON. What have they done?

Mr. LUTTER. They came to present to us recently their proposal with respect to uniform national licensing standards.

Mr. BURTON. Have you heard of the Health Distributors Management Association [HDMA]?

Mr. LUTTER. Yes, sir.

Mr. BURTON. OK. What have they done to help protect the buying public from the products that are going to the wholesale operation? You don't know?

Mr. LUTTER. I'm not prepared to answer that, sir.

Mr. BURTON. Well, why is it fair to cast a blanket across the entire secondary market when in fact many legitimate businesses are providing a valuable service? And you don't have any answer for me today.

You know, I can see I'm out of time, but I just want to say, obviously we want to protect the buying public from counterfeit drugs because they're not safe in many cases, but at the same time there is a responsibility on the part of the pharmaceutical industry in this country to make sure that Americans buy a product at a fair price, that we don't saddle the American people with a product like Paxil where they may have to pay 8 or 10 times as much as they do right across the border or in Canada. That's the reason why people import. And with the Internet being the way it is today, you have a herculean problem because if you stop the importation of products from Canada, they'll get on the Internet and buy it from Germany and if you stop it from Germany they'll get on the Internet and buy it from France, or they will buy it from Spain. And it's very difficult for you to regulate everything that's going through the U.S. mail. And you're talking about little old ladies and little old men who can't afford to buy this product because it's so much more expensive here than abroad, and so you've got really a herculean problem in controlling this. And I want you to control it because we don't want counterfeit products in the marketplace, but we want to make sure that Americans don't pay an exorbitant price for the same life-saving drugs that right across the Canadian border are costing a Canadian woman with breast cancer one-tenth of what it costs here in the United States.

Mr. SOUDER. Ms. Norton.

Ms. NORTON. Thank you very much. And I think the gentleman has a point.

Dr. Lutter, this subcommittee has had a lot of hearings, and one of the things—one of our major frustrations is with the problem law enforcement has in getting control of any valuable drugs, and many of our hearings are, of course, about drugs which are very valuable to addicts and to people who sell to them. So I was taken aback by your statement on page 2, that most of the counterfeit drugs at issue did not reach consumers. How do you know that most counterfeit drugs do not reach consumers?

Mr. LUTTER. The statement is intended to apply to the counterfeit drugs found during the course of the investigations. So with respect to other counterfeit drugs, we just don't know, and that's——

Ms. NORTON. That is like saying that the drugs we confiscate, the heroin we confiscate does not reach the streets of New York and D.C. So, I mean, you really have to watch out for these blanket statements. Sure, anything that you are investigating, if it turns out to be legitimate it may not reach it for that matter, but that is an unqualified statement, that most of the counterfeit drugs at issue do not reach consumers.

Mr. LUTTER. The counterfeit drugs that we find in the course of our investigations as a generalization don't reach consumers. I'm trying to clarify that here.

Ms. NORTON. I very much appreciate the clarification, because later on in your testimony you talk about how cleverly—in fact, in your oral testimony right after you indicated that you were catching everything, you then went on to show us a set of slides about just how cleverly these drugs are packaged so that you would have to have a trained eye to even know they were counterfeit. So I take it that there may be many consumers out here without an FDA's trained sense of what is counterfeit and what is not, since even your people have to look closely at it, who may be passing these counterfeit drugs off.

Would that be a true statement?

Mr. LUTTER. It is absolutely true that there may be some. First of all, it's very difficult for people to distinguish these counterfeit drugs from the genuine. That was the key point of the slides that I tried to show earlier.

With respect to the comment about whether or not consumers may be exposed to counterfeit drugs, absolutely, our system is not foolproof. We do the best we can with——

Ms. NORTON. But those are only law enforcement folks, and no. I mean, no prosecutor will tell you that he catches all the criminals. You know, he catches a tiny number and he hopes that has an effect on the rest who might be inclined toward criminality.

I understand that about 50 percent of the drugs on sale in some countries are counterfeit. What percentage of the drugs on sale in this country would you believe are counterfeit? Because surely you can interpolate, once you know how much you have, you're a Ph.D., you know then how to calculate how many go on sale that may be counterfeit or at least are offered for sale that may be counterfeit. What would be your estimate?

Mr. LUTTER. Let me begin by saying we don't have a scientific basis for coming up with an accurate estimate of that——

Ms. NORTON. Do you have any statisticians in your department?

Mr. LUTTER. We do have statisticians.

Ms. NORTON. Do you agree, you have a Ph.D, that you could extrapolate, once you know how many you catch, and then try to at least estimate, even if you truthfully said of course, as you must, this is only an estimation of how many counterfeit drugs are out there?

Mr. LUTTER. Our best estimate is it is significantly less than 1 percent.

Ms. NORTON. And you have just now told me you couldn't, and now you're telling me that less than 1 percent in the United States are counterfeit.

Mr. LUTTER. Significantly less than 1 percent.

Ms. NORTON. How do you know that, sir?

Mr. LUTTER. That's based only on the professional judgment of the staff at FDA.

Ms. NORTON. But not based on the kind of extrapolation that I have asked for, the statistical——

Mr. LUTTER. It is not based on a statistical calculation.

Ms. NORTON. Let me tell you something, Dr. Lutter, to the extent that you are truthful to people by saying these things are out here, we have only our own professional judgment, but they're out here in larger and larger numbers, to the extent that you say that you make people more and more leery about purchasing drugs that may be counterfeits. I don't find it very helpful that you are operating without, that the FDA is operating without doing the necessary statistical work so as to warn consumers of the statistical probability of in fact having counterfeit drugs to reach them. Wouldn't that help people, including pharmacists and others, to help you in the law enforcement challenge you reach?

Mr. LUTTER. Undertaking that sort of statistical analysis is something that we haven't previously contemplated. It would take significantly more resources than are available to date.

Ms. NORTON. Oh, my God, I'm sure I could—come on. I'll put you in touch with some Ph.D math students in statistics who could help you out, Dr. Lutter. I do not think that this is a complicated statistical problem.

And Mr. Chairman, I ask that the agency be requested, using its existing resources, to try to find out what the statistical probability is. I really don't believe that is a complicated problem. And I do believe at the very least the public, if it knew that, might be more inclined to be careful.

Dr. Lutter, one more question. You say on page 7, in order for secondary wholesalers to fully comply with pedigree requirements by which we mean understanding throughout the chain whether drugs are legitimate, Congress would have to amend Section 503(e), and you say later in questions that you're just doing the best you can and you indicated what some of the problems were when questioned. Does the agency recommend that we in fact amend 503(e)?

Mr. LUTTER. That was the recommendation we issued in 2001, and we still stand by it, yes, ma'am.

Ms. NORTON. Thank you very much, Mr. Chairman.

Mr. SOUDER. Ms. Schmidt, do you have any questions?

Mrs. SCHMIDT. Not at this time.

Mr. SOUDER. Ms. Watson.

Ms. WATSON. Thank you, Mr. Chairman. I was listening very closely to the questions that my colleague was asking and the response, and it occurs to me that maybe this hearing is premature, and my good friend, Dan Burton, has the same concern I have. And you know, a lot of it goes to the price of manufacturing, and of course there should be concern about these fake drugs, but I'd like to know the magnitude of the problem. I tell you what I'm more concerned about, and you can respond if you heard these rumors, that there seems to be a consistent rumor that terrorist organizations are planning to spike up drugs and things, and that's one way of killing off Americans.

And Mr. Chairman, I'd like to hold a hearing maybe on that kind of threat to us because they're getting very clever in the way they plan to attack us. But I think to make the kind of assertion that we've got these counterfeit drugs running rampant and we need to be cautious, we need to base it on a little more statistical data than I'm hearing. Of course I came in late. I don't know how much transpired before I came in, but hearing on counterfeit drugs within the United States takes, for me, more statistical evidence that there is a real serious problem with the counterfeit drugs. That's the excuse you use for being opposed to reimportation. And what I would like to do is, and this goes to the Chair and our committee, is to really look into the rumors that I'm hearing because the addiction level in the United States of America, because of the marketing of drugs the way we do, could be the beginning of something that could have an impact on our society, which I'm on Homeland Security. Well, we better start looking at these rumors.

So I just want to say that I'd like to kind of back up what Eleanor Holmes Norton was saying, that we really need more evidence that this is a problem that should take priority right now. I think the threat to us, as rumored, is more of a priority.

So thank you for the time. I yield back, Mr. Chairman.

Mr. SOUDER. Thank you.

Mr. Gutknecht.

Mr. GUTKNECHT. Thank you, Mr. Chairman.

And Dr. Lutter, I don't know if we've met before, but I have been involved and interested in this issue for a long time. And since you couldn't answer the question that Ms. Norton had, let me answer at least according to the FDA's open counterfeit drug cases report, the report done by the Task Force on Importation, in 1997 there were 6 cases, in 1998 there were 4 cases, in 1999 there were 6 cases, Representative Norton, in 2001 there were 20 cases, in 2002 there were 22 cases, and the last year we have numbers for is 22.

Just out of curiosity, do you know how many people died in hospitals last year due to getting the wrong drug?

Mr. LUTTER. There are estimates by the Institute of Medicine a few years back where up to high tens of thousands of deaths per year are attributed to medication errors.

Mr. GUTKNECHT. It generally is over 5,000 a year, and here we're talking about 22 cases.

Now, the other thing I just want to call your attention to, we have been trying to get the FDA to get involved in anti-counterfeiting packaging for at least 4 years. And I remember the first time we had a meeting on this with one of the directors, who is no

longer with FDA, and we talked about this. He said, well, this can't be done. And then I reached in my pocket and I showed him a $20 bill and I said well, you know, the U.S. Treasury now has come up with a pretty good anti-counterfeiting technology for our $20 bills, and he said that can't be done in drugs. I thought that's kind of an interesting attitude, but that technology exists today; it is being used in Europe. At least five of the major pharmaceutical companies are using it. This is a problem; I mean, counterfeiting is a problem. But it just strikes me that the FDA is not really serious about that, because if they were they would be focusing on really helping us solve the problem.

There is also a technology, and I don't know if it's been talked about here in this hearing yet today, using these little computer chips. Frankly, I don't know if my staff stuck them in here, but we can show them to you. We brought the cost down now to about 10 cents per chip, and they are incredibly amazing little chips; you can literally tell where the drug was made and the day it came off the line, simply through a relatively simple reader.

Now the drug companies themselves are interested in this because they have a keen interest. I would have a question, though, in the studies that you've done in counterfeit drug cases, is most of the counterfeiting being done in the United States or is it coming in from other countries?

Mr. LUTTER. The products themselves are often manufactured overseas and smuggled into the United States.

Mr. GUTKNECHT. I didn't say often. No, no, no. Where is most of the counterfeiting actually being done for the drugs being sold in the United States?

Mr. LUTTER. You mean the manufacturing of the products or their distribution for sale?

Mr. GUTKNECHT. Where are they actually making these counterfeit drugs? Because the studies I've seen, most of them are actually made here in the United States.

Mr. LUTTER. The information that we have from the Office of Criminal Investigation suggests that the manufacturing itself is often overseas.

Mr. GUTKNECHT. I'm sorry, that doesn't square with what we've been told.

And the real issue, and this is where the FDA continues to miss the point, people don't counterfeit $1 bills do they? They counterfeit $20 bills, but mostly they counterfeit $100 bills. The reason that there is an industry developing, both illegal importation and counterfeiting, is because we have done nothing to help level the prices that Americans pay for prescription drugs, and that's the real issue here that nobody wants to talk about. That's why more and more people say, you know, "I can make more money in getting into the business of selling Celebrex or Tamoxifen," which it used to sell for about $500 in the United States, this is one of the examples, Mr. Chairman, it used to sell for about $500 a month in the United States. You can buy it in Canada for less than $100 a month. You can buy it in almost every European country for less than $100 a month.

The reason that people are starting to look at doing these kinds of things is because we have done nothing to help level the prices

that Americans have to pay for these drugs. So it seems to me that if the FDA ever wants to get serious about addressing these kinds of issues, you ought to go to where the big problems are. The big problem is that Americans are being held hostage; they pay way too much for their prescription drugs. They know it and everybody else knows it, and yet the FDA says, well, we have to go after these 22 cases, right; 22 cases. When thousands of people are dying every year from prescriptions given in hospitals, and the FDA is doing nothing about it; there is no plan to deal with that. And yet we can use bar coding technology, we can use all kinds of things that are available today to change those numbers.

So I'm sorry, I'm a little, I get a little emotional about it because we've been in this battle now for 4 years and for 4 years the FDA has said "you know what, we want to work with you," and for 4 years there has been absolutely no help whatsoever. I'm sorry that you're the one on the hot seat today and I happen to be in this seat today, but we're not going to give up on this. And trying to scare people because you have 22 cases of counterfeit drug cases when we have literally millions of other problems dealing with prescription drugs—and let me add one last point, Mr. Chairman. I know my time has expired, but the FDA is the Food and Drug Administration. Do you know what percentage of the food coming, the fruits and vegetables coming into the United States, are contaminated with foodborne pathogens, including things that can kill you? Do you know what percentage it is?

Mr. LUTTER. I'm not——

Mr. GUTKNECHT. The answer is the FDA has actually got a report on that. It's roughly 2 percent. Now that is a much higher percentage than the numbers, and with all due respect, your guess I think is way high in terms of the counterfeit drug problem, but I think we have a lot bigger problems. And they're largely—the problems with drugs today are all centered around one fact, and that is Americans pay way too much for what they get. We're doing almost nothing to stop importing fruits and vegetables, even though we know by our own studies that 2 percent of the fruits and vegetables coming into the United States are contaminated with foodborne pathogens that can kill you.

I yield back my time.

Mr. SOUDER. Before we move to our second panel, I just want to clarify that you've informed the committee, the OCI did, that there are 58 cases in 2004 and not 22, and that is a jump; is that correct?

Mr. LUTTER. Fifty-eight cases in 2004?

Mr. SOUDER. Yes.

Mr. GUTKNECHT. Mr. Chairman, there were 22 cases in 2003.

Mr. SOUDER. And it jumped to 58 in 2004?

Mr. GUTKNECHT. But it wasn't 10,000.

Mr. SOUDER. Yes. And when you have a case, is that 58 people got one pill, or are these cases that could in fact affect thousands of people in each case?

Mr. LUTTER. Sir, these are independent criminal investigations, so in that sense, yes, they vary in terms of their scope. Some may be very small, others may be quite large and potentially infecting large numbers of people, including thousands.

Mr. SOUDER. Thank you. I thank you for your testimony today. If Members have additional questions we will send those to you in writing. Thank you for participating.

If the second panel could come forward. Before I swear the second panel in, we've been joined today by Congressman Israel from New York, and he would like to introduce one of the witnesses.

Mr. ISRAEL. Thank you very much, Mr. Chairman. I want to express my appreciation for the courtesy that you and the ranking member have extended in allowing me to sit in on this subcommittee, although I'm not a member, and allowing me to introduce one of my constituents, Kevin Fagan, who will be sharing his family story with you today.

Kevin Fagan is a long time resident of Deer Park, NY. He works as a second line supervisor at Con Edison, a company that he has proudly served for 22 years. He is married to Jean and is the father of three children, Timothy Lauren, and Caitlyn.

I first met Mr. Fagan in 2003 when he informed me that his older child, Tim, had been injecting himself with counterfeit Epogen, a drug he picked up from a national pharmacy to help him recover from a liver transplant, a drug that somehow found its way to the Playpen South Strip Club in Miami, where it had been tampered with.

This ordeal changed Mr. Fagan into a public advocate determined to do what he could to ensure that more families don't suffer from loved ones receiving counterfeit medicines. He has dedicated himself to teaching elected officials and the public about the dangers of our prescription drug supply chain. Since prescription drugs can change hands up to a dozen times between the manufacturer and the pharmacy, these drugs, as we've learned today, can be tainted, diluted, relabeled and counterfeited.

As a result of my association with the Fagans I have introduced Tim Fagan's Law, H.R. 2345, which gives the FDA the authority to recall drugs, implements harsher penalties for criminals of counterfeit drugs, and requires pedigrees of a drug's origin.

Kevin Fagan has been a remarkable champion of this legislation named in his son's honor, an outspoken advocate for the need to clean up our Nation's drug supply, and I am pleased to introduce him as he shares his story, and to again thank the chairman and the ranking member for holding this vitally important hearing.

Mr. SOUDER. Thank you very much for being here. This panel consists of Katherine Eban, author of Dangerous Doses, Mr. Fagan, who you've just heard described by his Congressman, and Max Butler, brother of Maxine Blount, counterfeit drug victim. So if you would each stand. It is the guidelines of this oversight committee to swear the witnesses in.

[Witnesses sworn.]

Mr. SOUDER. Let the record show that each of the witnesses responded in the affirmative.

We thank you for being here today and we're going to start with Katherine.

STATEMENTS OF KATHERINE EBAN, AUTHOR, DANGEROUS DOSES; KEVIN FAGAN, FATHER OF TIMOTHY FAGAN, COUNTERFEIT DRUG VICTIM (EPOGEN); AND MAX BUTLER, BROTHER OF MAXINE BLOUNT, COUNTERFEIT DRUG VICTIM (PROCRIT)

STATEMENT OF KATHERINE EBAN

Ms. EBAN. Mr. Chairman and members of the committee, thank you for having me here.

Mr. SOUDER. You need to tap your mic. There should be a button.

Ms. EBAN. Mr. Chairman and members of the committee, my name is Katherine Eban. Thank you for having me here.

As an investigative journalist and book author, I've spent the last 3 years documenting a rising tide of counterfeit medicine in our pharmacies and hospitals. My book, Dangerous Doses: How Counterfeiters Are Contaminating America's Drug Supply, was published this May. It is based on more than 160 interviews, over 13,000 pages of documents and several years of firsthand reporting.

Adulterated medicine routinely lands on our pharmacy shelves in part because major wholesalers seek out discounted medicine from smaller ones. This extremely dangerous trading has degraded our medicine and endangered patients.

A few numbers: 97,000 vials of counterfeit Epogen and Procrit, enough to treat 30,000 cancer patients for a month, are believed to have entered the supply chain and reached patients in 2002. In 2003, 600,000 patients may have received counterfeit Lipitor, according to Pfizer's own estimate. One percent of the Nation's drug supply is 35 million prescriptions, the FDA estimates less than 1 percent of the Nation's drug supply is counterfeit.

Some States and other players have made significant efforts to restrict the flow of counterfeit medicine, yet recently 1,000 Exxon Mobil employees in Texas were injected with counterfeit flu vaccine.

In our poorest supply chain, medicine may move through a dozen hands on its way to the pharmacy. The wholesalers who buy and sell it may be narcotics traffickers, mafia members or high level diverters, some with legitimate State licenses. Though wholesaler in name, many never buy directly from manufacturers or sell directly to pharmacies. They are traders who buy and sell to one another in an all-hours auction. Every single counterfeit to reach American patients has moved through their hands with scant proof of its origin.

Who in their right mind would buy this medicine? Everyone unfortunately. Even the Nation's major wholesalers set up trading divisions to scout for bargains from these middlemen, purchases that allow substandard and even counterfeit medicine to reach patients.

Among recent reforms, major wholesalers, Cardinal Health and AmerisourceBergen, announced they would limit or cease their pharmaceutical purchases from secondary wholesalers, but gaping holes remain. Because our distribution system is national and medicine that is in California 1 day winds up in New York the next, our drug supply is only as clean as its dirtiest link.

Tim Fagan, a 16-year-old liver transplant patient, learned this the hard way when life-saving Epogen from his CVS pharmacy

proved counterfeit. His medicine required constant refrigeration and stable handling, yet it was uplabeled by a counterfeiter, transported in used paint cans, and allegedly stored in the beer cooler of a Miami strip club. Its journey took me several years to reconstruct.

If we could please show the slide. Thank you.

His medicine began as low dose, or 2000 U/mL Epogen. Cardinal Health and AmerisourceBergen, near at the top, sold 110,000 vials of it to a small Miami pharmacy, which never dispensed it to a single patient, but instead sold it all to an accomplice of an alleged counterfeiter, Jose Grillo. Grillo packed the low dose medicine into paint cans and carried them to a south Miami trailer where a friend soaked the vials overnight, and rubbed off the low dose labels and glued on fake high dose ones for 40,000 U/mL. Grillo, awaiting trial, allegedly transformed each $25 vial into a $470 vial, a scheme worth $46 million. Investigators were only able to recover 13,000 of his vials, which means that 97,000 remained in the supply chain and is presumed to have reached patients.

Once he had uplabled the vials, Grillo allegedly brought them to his customers, including the Miami strip club, where investigators believe he sold the medicine for one-sixth the average wholesale cost. The medicine then moved through a network of shell companies, as represented by the dark gray in the middle of the chart, each one raising the price. An Arizona wholesaler, which ultimately bought the medicine, then offered AmerisourceBergen a deal, high dose Epogen for a price lower than the manufacturer's. Amerisource bought back the very low dose Epogen it had originally sold, counterfeited in the interim.

Despite recent reforms, numerous diverters with wholesale licenses still peddle substandard medicine for all those seeking a discount and willing to take the risk. Consumers need to know where their medicine has been. The most important reform would be comprehensive pedigree records for every drug. Those who say "impossible" are likely committed to a Byzantine and opaque drug supply. Only Federal regulations that mandate pedigree records will shed light on and eliminate the hidden paths that our medicine may take.

I urge the committee to look at Tim Fagan's Law, introduced by Representative Steve Israel of Long Island, which requires paper pedigree records, strict regulation of wholesalers, severe criminal penalties for counterfeiting, and stronger enforcement powers for the FDA's Office of Criminal Investigation.

Thank you for your commitment to protecting America's drug supply.

[The prepared statement of Ms. Eban follows:]

Written Testimony of Katherine Eban

Investigative Journalist, Author of Dangerous Doses:

How Counterfeiters are Contaminating America's Drug Supply,

May 2005, Harcourt Inc.

For the Subcommittee on Criminal Justice, Drug Policy and Human Resources

Government Reform Committee

"Sick Crime: Counterfeit Drugs in the United States,"

November 1, 2005

Mr. Chairman and members of the committee, thank you for your commitment to safeguard the nation's medicine. As an investigative journalist and book author, I spent the last three years documenting a rising tide of counterfeit medicine in the nation's pharmacies and hospitals. My book on this topic, *Dangerous Doses: How Counterfeiters are Contaminating America's Drug Supply*, was published in May by Harcourt. It chronicles the work of a Florida task force, Operation Stone Cold, whose findings led to the overhaul of Florida's drug-supply laws, making them the toughest in the country.

My findings in *Dangerous Doses* are based on more than 160 significant interviews. I also obtained more than 13,000 pages of documents. Many of the incidents I describe in the book I witnessed first hand.

My investigation revealed that a stream of adulterated medicine, traded by felons and accompanied by false paperwork, routinely lands on our pharmacy shelves. This happens in part because major wholesalers seek out discounted medicine from small secondary wholesalers. This extremely dangerous "trading" between wholesalers has degraded our medicine and endangered consumers.

In 2003, this trading allowed counterfeit Lipitor to reach some 600,000 patients. In 2002, 110,000 vials of counterfeit Epogen and Procrit, lifesaving injectable medicine, entered the supply chain and reached patients including Tim Fagan in New York and Maxine Blount in Missouri. Last year, patients undergoing hernia surgery were implanted with counterfeit and non-sterile Prolene mesh. At least one suffered horrible complications from a recurring infection.

Despite recent positive efforts by some manufacturers, wholesalers, pharmacy chains and states to tighten the supply chain, the problem is no less urgent today. As we meet here, 1,000 Exxon Mobil employees are absorbing the news that they were recently injected with counterfeit flu vaccine at a company health fair.

How does this happen?

Because our supply chain is porous and minimally-regulated, our medicine may move through a dozen hands on its way from the manufacturer to the pharmacy. The "wholesalers" who buy and sell it along the way may be narcotics traffickers, mafia members or common criminals. Though these individuals call themselves wholesalers or distributors, many never buy directly from manufacturers and never sell directly to pharmacies. They are middlemen, who buy and sell medicine to one another in a process that resembles an all-hours auction. Every single counterfeit to reach American patients has first moved through their hands, and comes with scant proof of its origin or purity. Who in their right mind would buy this medicine? Everyone, unfortunately. Finding their discounts irresistible, even the nation's major wholesalers set up "trading divisions" to scout for bargains from these secondary wholesalers. Those purchases have allowed medicine that is recycled, stolen, expired, subpotent, mishandled and even counterfeit to reach patients.

Our drug supply remains vulnerable despite some recent reforms. Since my book's publication, two of the nation's largest wholesalers, Cardinal Health and AmerisourceBergen, made important announcements: Cardinal that it would close its trading division and limit purchases from secondary wholesalers; Amerisource that it would no longer buy secondary-source drugs for American consumers. The CVS pharmacy chain has also said that it will no longer buy from distributors who purchase pharmaceuticals from the secondary market.

But loopholes remain. Because our distribution system is national and medicine that is in California one day could wind up in New York or Missouri the next, our drug supply is only as clean as its dirtiest link. Even when Florida overhauled its laws in 2003, several rogue wholesalers left the state and set up shop in North Carolina and elsewhere.

The American pharmaceutical market has become a profit center for counterfeiters and the criminals who traffic in their products. With soaring prices, weak laws and numerous opportunities for arbitrage, narcotics traffickers have taken note: they can make as much, if not more, dealing in cancer and AIDS medicine. Their deterrents? Minimal jail sentences and nominal fines.

In many states, minimal regulations make it easy for almost anyone to become a pharmaceutical wholesaler. Before Florida changed its laws, its Bureau of Statewide Pharmaceutical Services required that applicants fill out a three-page form with a question: have you ever been convicted of a felony? Felons checked the "No" box, and the Bureau did not check their criminal backgrounds. Consequently, the state of Florida issued pharmaceutical wholesaling licenses to convicted narcotics traffickers, and their medicine reached patients across the country.

While reporting *Dangerous Doses*, I determined to learn how the counterfeit Epogen that Tim Fagan received made its way to a CVS Pharmacy in Long Island. In the attached chart, I document the likely path Tim Fagan's medicine took, a route that took me over two-and-a-half years to reconstruct. His medicine, which requires constant refrigeration and stable handling, was uplabeled by a counterfeiter, transported in used paint cans and blazing car trunks and was allegedly stored in a beer cooler in a Miami strip club.

His medicine, made by Amgen, began as 2,000 U/ml Epogen. The distributors Cardinal Health and AmerisourceBergen sold 110,000 vials of it to a small Miami pharmacy, J&M Pharmacare. Though this no-name pharmacy bought an amount that could have stocked a chain of oncology hospitals – a strong signal that the pharmacy was intending to divert it -- the major wholesalers did not take note. The pharmacy never dispensed it to a single patient. Instead, it sold all the medicine to a man who had ordered it on behalf of the alleged counterfeiter, a former body builder named Jose Grillo.

Grillo packed the low-dose Epogen vials into paint cans and carried them to a South-Miami trailer, where a friend of his soaked the vials overnight in his back yard, rubbed off the low-dose labels and glued on fake high-dose ones for 40,000 U/ml. The setting

was as far from sterile and controlled as one could possibly imagine. But the math was compelling: Grillo had allegedly transformed each $25 vial into a $470 vial, a scheme that was worth $46 million.

Once he had uplabeled the vials, Grillo is alleged to have brought them to his customers, which included a strip club in Miami, and sold the medicine for one-sixth the average wholesale cost. Investigators believe that the club's owners bought the medicine and stored it in a beer cooler in a back room. They in turn are alleged to have sold it to their customers.

The medicine then moved through a network of shell companies, some with legitimate licenses, some without. Some $20 million of the medicine is believed to have moved through a licensed wholesaler run by an eighth-grade dropout and heroin addict with a rap sheet that included kidnapping and aggravated battery. As a Florida grand jury noted, these are people you wouldn't trust to mow your lawn, let alone handle your medicine. Tim's medicine moved through seven sets of hands before even reaching a company legitimately licensed to distribute it.

The local wholesaler AmeRx sold it to a regional wholesaler, Dialysist West, which then contacted AmerisourceBergen with a seemingly lucky offer: high-dose Epogen for a price lower than the manufacturer's. Amerisource bit, buying back the very low-dose Epogen it had originally sold, but which had been counterfeited in the interim.

Despite the important changes announced by Amerisource, Cardinal and CVS, I contend that the same thing could happen today. Numerous secondary wholesalers are still in operation, peddling substandard medicine to their customers, namely anyone seeking a discount and willing to take the risk.

What can we do about this? I propose that we need strong federal regulations to close these loopholes and protect consumers and urge the committee to look at Tim Fagan's Law, H.R. 2345, introduced by the Fagan's congressman Rep. Steve Israel of Long Island. It proposes strict regulation of wholesalers, severe criminal penalties for those who counterfeit medicine, or knowingly traffic in it. It requires old-fashioned paper pedigree records to document each step our medicine takes. It allows for stronger enforcement and increased funding for the FDA's office of criminal investigations, and gives the FDA the recall authority that it now lacks.

It was an honor to appear before this committee. I appreciate your commitment to protecting America's drug supply.

For more information on Dangerous Doses, counterfeit drugs and other links, please visit www.dangerousdoses.com, or e-mail Katherine Eban at keban@dangerousdoses.com.

THE EPOGEN TRAIL TO TIMOTHY FAGAN

The chart on the following page illustrates the likely pathways that counterfeit Epogen from lots P002970 and P001091 took to reach Timothy Fagan on Long Island, based on indictments, affidavits, witness statements, invoices, and shipping and pedigree records. Solid black lines represent confirmed sales. Broken black lines represent probable Epogen sales based on documented sales of counterfeit Procrit that traveled the same path. Dotted lines indicate unknown sources for those portions of the Epogen's path. The ovals represent those who aided José Grillo in his counterfeiting scheme but were not directly involved in the sale of the Epogen.

The high-dose Epogen originated with the manufacturer Amgen Inc. Sales records show that J&M Pharmacare purchased 3,363 boxes of low-dose Epogen from Amerisource and 8,931 boxes from Cardinal between January 2001 and May 2002. Armando Rodriguez told investigators that he bought up to 200 boxes at a time of low-dose Epogen for Grillo from J&M Pharmacare. The owner of Ocean Press described for investigators how he counterfeited labels at Grillo's direction. In a statement to investigators, Silvino Morales described how Grillo came to his trailer with five hundred vials at a time for him to relabel. Witnesses told investigators they saw Grillo sell his medicine, particularly high-dose Procrit, to Nicholas Just and Paul Perito of Playpen South. Grillo himself said that he sold his medicine to Nicholas Just.

A schedule of sales maintained by Dialysist West shows that the company sold $4.4 million of the Epogen from lots P002970 and P001091 to AmerisourceBergen from September 1, 2001, to May 10, 2002. Invoices show that the medicine was shipped to Pharmabuy, a division of Amerisource in Kentucky. Pedigree papers also show that Dialysist West bought 460 boxes of lot P001091 and 812 boxes of lot P002970 from CSG Distributors; CSG had bought it from Premier Medical Group. According to a statement the owner of Premier Medical gave to investigators, all of the medicine his company sold came from Double J Consultants. The sales were brokered and delivered to him by the owner of YW Consultants.

Pedigree papers AmeRx gave to Dialysist West for 181 boxes of lot P002970 show that two boxes originated at Metro Medical and were sold to AD Pharmaceuticals and that 180 boxes originated at Medix International and were sold to Express Rx. Express Rx sold 129 boxes to Armin Medical, which in turn sold them to AmeRx. Express Rx also sold fifty-one boxes directly to AmeRx.

Mark Novosel told investigators that he bought all his medicine from Ivan Villarchao.

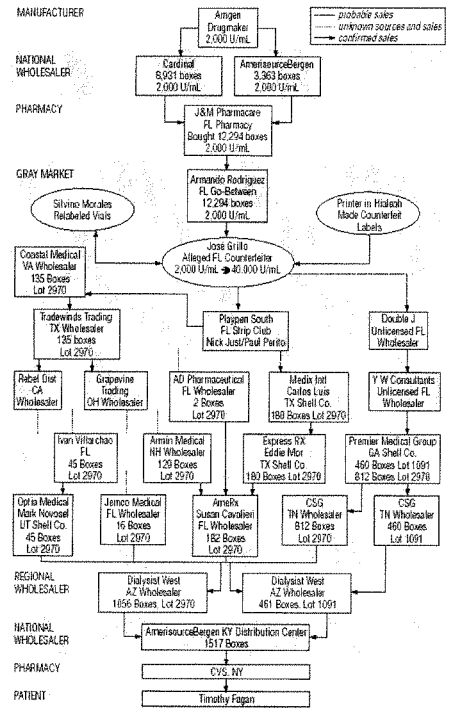
The owner of Coastal Medical told investigators that he bought his medicine from Paul Perito and sold it to Tradewinds Trading. Tradewinds notified Coastal by letter that the Epogen lot P002970 it had sold them could be counterfeit. Tradewinds also sent letters notifying Grapevine Trading and Rebel Distributors that the Epogen they bought from Tradewinds could be counterfeit.

Inclusion in this chart does not suggest that a company or individual participated in any wrongdoing. The text and endnotes discuss the roles of most of those listed.

DangerousDOSES

How Counterfeiters Are Contaminating America's Drug Supply

Katherine Eban • May 2005 • Harcourt, Inc.



5/16/05
By Bernadine Healy, M.D.
Mean-Street Medicine

One of the nasty little secrets surrounding prescription drugs is that they don't always find their way from drug company to needy patients without some dangerous detours. Because of a numbingly complex network of middlemen, it's easy for crooks to sneak in and adulterate, spoil, and intentionally mislabel enough good medicine to make millions on the side. It's estimated that counterfeits represent less than 1 percent of our drug supply, but they are on the rise, particularly among the newer, more expensive brands.

How can this happen in America? Aren't we the ones who righteously outlaw a prescription filled in a Canadian drugstore for fear of fakery? Investigative reporter Katherine Eban in her new book, Dangerous Doses, out this week, will tell you that Canada is not the problem. It's our own poorly regulated distribution system. Eban provides a riveting account of a 2 1/2-year investigation in south Florida in which corrupt middlemen, many with criminal records, worked a typical scam: Drugs, sometimes stolen, were hidden in old paint cans or unmarked boxes and moved around in their hot SUV s. Shady "repackagers" diluted or "up-labeled" vials and containers as higher-dose, higher-priced products. The adulterated drugs were then released back into the legitimate drug-supply chain.

Bartering in the shadows like peddlers of fake designer watches, these drug thugs have it easy. Since drugs are consumed, evidence is gone without the victims or their doctors having a clue as to why their medicine failed them. Drug counterfeiting draws soft penalties, and it's hard to prosecute since the wholesalers leave no audit trails. Like expensive pets, drugs are supposed to carry papers of their "pedigree," listing all transactions. But phony papers and loopholes make compliance a joke. There are also lawful opportunities to wipe pedigrees clean when drugs are resold, in effect making them virgin products, despite having passed through numerous hands.

About 90 percent of drugs in this country are handled by the Big Three companies: AmerisourceBergen, Cardinal Health, and McKesson, the primary distributors who offer efficient one-stop shopping for pharmacies, medical institutions, and mass merchandisers. But more than 6,000 small wholesalers work the secondary market by buying up odd lots or excess products from whomever they can, including the Big Three, drugstores, and nursing homes or clinics overstocked with deeply discounted drugs. They resell to other wholesalers, pharmacies, or back to the big distributors at prices often lower than manufacturers charge. With all this back and forth, it's no wonder spoiled or counterfeit drugs can seep in. Even a small amount of mean medicine mixed with the good contaminates the whole system. Though manufacturers and big distributors have voluntarily tightened up dealings with small wholesalers, the problem still festers.

Racketeers. As Eban recounts, the Florida scam was blown wide open by a "ragtag" group of seasoned investigators who seem as if they were cast right out of an episode of The Wire. Calling themselves "Horsemen of the Apocalypse," they teamed with determined

state prosecutors, including one who herself is on insulin for diabetes. They pursued the perpetrators with the passion usually directed at mob racketeers or murderers, and their storied success led to tough counterfeit laws in Florida. But this is about more than Florida.

Though manufacturers have a system to gather and share among themselves information on counterfeit drugs in all states, their findings are kept out of public view for fear that they might lead people to stop taking needed medicines. But the 2005 Global Pharmaceutical Report, called Progressions and released last week by Ernst & Young, states that nearly three quarters of manufacturers see the secondary wholesale market as a threat to both their good names and unwitting victims. Meanwhile, the Food and Drug Administration has been restrained in its ability to audit wholesale or retail transactions and in demanding new electronic "track and trace" technology.

As we smoke out offshore Internet pharmacy crooks and endlessly debate buying drugs from Canada, let's put our own house in order. Drug thugs enriching themselves with crimes that harm the sick will surely find their own dark place in hell. Until then, some heavy-duty perp walks in broad daylight are in order.

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Mr. SOUDER. Thank you for your testimony. Mr. Fagan.

STATEMENT OF KEVIN FAGAN

Mr. FAGAN. Good afternoon. My name is Tim Fagan, and in 2002 my son Timothy received counterfeit Epogen after a life-saving liver transplant. While I am thankful for your time today, I wish I had never heard of this topic.

Tim was very sick for a long time, and our trek to find a cause and a cure for his disease took us as far as the Mayo Clinic in Rochester, MN. No answers could be found. Upon returning back from the Mayo Clinic, Tim's health took a severe turn for the worse, and he required a liver transplant.

After surviving a 9-hour operation and a hospital stay, Tim returned home to further recuperate. Our family thought our prayers had been answered when my son came home. Shortly after returning home, Tim became severely anemic and his transplant team prescribed Epogen, which is an anti-anemia injectable drug to combat his anemic condition and bolster his already weakened health. We received the Epogen from a nationally known pharmacy, Brightwaters Pharmacy. There was nothing over the Internet. Upon receiving the Epogen injections once a week, several hours after each injection my son woke up screaming in pain. Through everything my son has been through, I have never heard him scream like this before.

Several hours after the first injection the pain caused him to wake out of a sound sleep. My wife and I ran into his bedroom. I fully anticipated finding a robber or burglar from his blood curdling screams; I had never heard him scream like this before in my life. We found his whole body wrapped in pain. Tim was doubled over crying, screaming, "help me," and I didn't know what to do to help my son.

We immediately called his doctors. They were dumbfounded by the reaction, having never seen anything like this to this drug that they've prescribed to numerous patients. And this same episode proceeded for 8 more weeks.

Finally, my wife receives a call from our local pharmacy informing her that the FDA notified them that counterfeit Epogen was on the market and to check the vials in our possession. My wife checked the vials and found that they were indeed counterfeit based upon the information supplied to her; they were missing a degree symbol and they had a certain lot number.

We were understandably frantic with worry as to what this might have done to my son in the short term and the long term. I asked the pharmacy how this happened. They said, "We get all our drugs, all our Epogen, exclusively from AmerisourceBergen." I had never heard of AmerisourceBergen before. I looked up their number. I called them in Pennsylvania and asked them how it happened. They rushed me off the phone, to say the least, and ended the call saying it's not their problem. As it turns out, it is their problem. AmerisourceBergen is the number 22 company on the Fortune 500 list. AmerisourceBergen is one of the three largest drug distributors in the United States, and AmerisourceBergen has revenues approaching $50 billion a year. Yet instead of purchasing drugs directly from the manufacturer, they chose to purchase these

drugs from the second or gray market where elected officials and law enforcement agencies have identified as the source of counterfeit drugs into the supply chain.

This was a domestic issue; it was no international trading of drugs. It started in Florida, went through several hands throughout the country and wound up in my son on Long Island.

Fortunately for us, we have a Congressman who is very much, like you, interested in protecting their constituents, the regular people, and I contacted Representative Israel for help. And his law, H.R. 2345, Tim Fagan's Law, calls for tougher criminal penalties for those engaging or distributing counterfeit drugs. It calls for increased funding for the FDA to perform the very inspections that the committee called on earlier today at random. It calls for increased funding for law enforcement investigations. It calls for public education and track and trace technology. And I ask each and every one of you if you would please co-sponsor this legislation which would protect all the Tim Fagans and potentially every American citizen from counterfeit drugs.

I thank you for your time. And again, I ask you to co-sponsor, I plead with you to please co-sponsor this legislation and make it a reality. Thank you very much.

[The prepared statement of Mr. Fagan follows:]

Kevin Fagan
22 Jersey Street
Deer Park, NY 11729

To: House Subcommittee on Criminal Justice, Drug Policy and Human Resources
Date: November 1, 2005
Subject: Counterfeit Drugs

My name is Kevin Fagan, and while I am pleased to be invited to speak here today, I do so only because my son Tim was injured by counterfeit drugs. I would have preferred to have never heard of this subject.

Tim was 16 when he had an emergency liver transplant in 2002 in New York. He had a diseased liver, the cause of which was never determined. He was exceedingly fortunate to survive the disease and the surgery.

After being discharged home, he was given a medication called Epogen. This was designed to fight his anemia, a by-product of his medical condition. This is a very expensive drug, which he was injected with once a week.

Unfortunately, the drug that we thought he was receiving, and that my wife was personally injecting into him, was not the drug that was marked on the label. Hours after each injection, he would wake up in the night screaming in pain – as if someone had broken into the house and was attacking him. His entire body was racked in a cramp, which was not only excruciatingly painful, but terrified both Tim and the rest of the family as we did not know what, if anything was happening to his new liver.

Tim went through this each week for two months.

We finally learned from our local pharmacy -- one of the largest pharmacy chains in the country -- that there was counterfeit Epogen in the marketplace. Someone had apparently bought massive quantities of low dose Epogen at 2,000 u/ml and then re-labeled it as high dose Epogen at 40,000 u/ml. The low dose Epogen cost about $22. The high dose Epogen cost about $450. After the labels had been criminally changed, the vials were then re-sold into the secondary market. This delicate medication, which must be constantly refrigerated and never shaken, was then bought and sold by companies that simply turned a blind eye, not only to its origins, but also to the ways in which it had been handled and stored. They did this for one reason only. Greater profits. There was little concern about the criminal justice system, since the penalties are so light.

For two months my son was injected with a product that had been bought and sold about a dozen times. Our pharmacy bought the product from drug wholesaler AmerisourceBergen, which I have since learned is one of the largest companies in America, standing now at #22 on the Fortune 500 list with almost $50B in revenues. Rather than buy the drugs from the manufacturer, AmerisourceBergen turned to the secondary market to fatten their profit margins.

When they bought the drugs, they did not know who all the prior owners were, or the conditions under which it had been stored. To this date, AmerisourceBergen has never paid a price before any governmental entity of any kind for its careless and reckless conduct in buying mystery medicine and peddling it as bona fide.

It is clear that our pharmaceutical supply system has holes in it, and that the holes are exploited by those who care more for profit than for safety.

One way to put a stop to this is with lawsuits and punitive damages, which we are currently pursuing. But such suits are difficult since the evidence is destroyed at the time it is injected or ingested, and proving an injury is difficult since the patients are already sick. Further, the fact that the industry does not track drugs by lot number -- as is done in many other industries -- makes it even more difficult to determine the prior owners of a particular lot of medication. The vast, vast majority of victims have no idea they were even victimized, with their doctors no doubt chalking up the ineffectiveness of the drug to the underlying disease.

I am therefore hopeful that you will assist us by supporting Tim Fagan's Law that is currently pending in Congress. This law will give far tougher penalties for counterfeiters and give the FDA far more investigative and enforcement capabilities.

On behalf of my son I thank you for the opportunity to come here and be heard.

For more information on counterfeit drugs:

Food and Drug Administration:
http://www.fda.gov/counterfeit/

Rep. Steve Israel:
http://www.house.gov/israel/issues/counterfeitdrugs.htm

Turkewitz Law Firm Counterfeit Drug Resource Page:
http://www.ericturkewitz.com/counterfeit-drugs.htm

Dangerous Doses: How Counterfeiters Are Contaminating America's Drug Supply:
http://www.dangerousdoses.com/

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Eric@EricTurkewitz.com

Mr. SOUDER. Thank you for coming today.
Mr. Butler.

STATEMENT OF MAX BUTLER

Mr. BUTLER. Good afternoon, Mr. Chairman, and members of the committee. My name is Max Butler, brother of the late Maxine Blount of Holister, MO, a victim of counterfeit drugs. I'm honored that the committee has provided me with the opportunity to testify. I hope to illustrate the impact that this crime has had on our family and friends.

This crime undermines the trust that society has in its doctors and pharmacies. It targets victims that are already fighting for their lives and one that often results in suffering and sometimes an early death.

In 1998 Maxine Blount was diagnosed with breast cancer. Her doctor explained that her cancer was very serious and promised to provide Maxine with every opportunity to beat the cancer. Treatments began; she received chemo and radiation treatments to reduce the size of the tumors in her breast so that the doctors could safely do a mastectomy. After the mastectomy Maxine continued to receive regular treatments until she began to take the counterfeit Procrit. The counterfeit Procrit made it impossible for her to rebuild her strength between chemo treatments.

At the time that Maxine was diagnosed she owned and operated a Mailboxes Etc, a business that she loved and worked long hours at. The business did well and resulted in many clients that depended on Maxine to help them succeed. She was an active member and officer of the Chamber of Commerce, taking great pride in her civic responsibilities and caring about the community and businesses. After 2 years of fighting cancer, Maxine sold her business so that she could concentrate her efforts on surviving.

Maxine had 5 children and 11 grandchildren. She loved her family, and as her condition worsened, she noted that she would be unable to enjoy the future with her family. At age 61, Maxine should have had many years left to enjoy life.

As her cancer advanced, the doctor would change her medication. Most changes were successful in slowing or arresting the cancer for some period of time, forever giving Maxine and the family hope. Several months before Maxine's death she noted that the Procrit was no longer working. Procrit is a drug that helps cancer patients to rebuild blood cells and strength between chemo treatments. As a result of the counterfeit drugs, Maxine had to lengthen the time between treatments. This allowed the cancer to advance much more rapidly.

After Maxine informed the nurse at the doctor's office that Procrit was not working, it was determined that her medication was counterfeit. She was receiving 5 percent of the dosage needed.

As earlier noted, the counterfeit Procrit prevented Maxine from taking chemo treatments as needed. In addition, she had no strength, more pain, problems concentrating, and felt much worse than she ever had. The mistreatments, combined with her loss of confidence in the pharmacy system, resulted in the quality of Maxine's life taking a nose dive. It took her hours just to shower and dress. As she dressed, she would have to take a break between

each garment. Sometimes she would have to take a nap between garments.

Maxine had dedicated all effort to trying to get well or survive until a drug could be developed that would be a cure for her. She had total confidence in her doctor and pharmacy until this happened. She had purchased her drugs at one of the largest and most reliable pharmacies in St. Louis. At first she blamed the pharmacy, then she learned that the controls in prescription drugs were not effective and that counterfeit drugs were not all that uncommon. She was spending thousands of dollars each month on counterfeit drugs, and the pharmacy even refused to return her money when they found they were counterfeit. Maxine's confidence was gone, and at this point she pretty much resigned herself that the end was near.

I don't pretend to know that Maxine would be alive today if she had not received counterfeit drugs. What I do know is that she would have lived longer, would have experienced much less pain and suffering, and she would have been able to spend more time with her family. Maxine died on October 24, 2002.

The criminals that deal in counterfeit drugs are murderers. They steal people's dignity, cause unbelievable pain and often early death for their victims. When they distribute counterfeit drugs, they have no way to know who the victims will be. Anyone in our families or the counterfeiter's families could be a victim of this crime. I don't understand how these criminals can look at themselves in the mirror.

In closing, I would like to reiterate that stronger controls would have delayed Maxine's death, reduced her suffering, and allowed her to die with more dignity. Thank you.

[The prepared statement of Mr. Butler follows:]

"Sick Crime: Counterfeit Drugs in the United States
Tuesday, November 1, 2005
James M. Butler

My name is Max Butler, brother of the late Maxine Blount, a victim of counterfeit drugs.

In my testimony at this hearing, I hope to illustrate the impact that this crime has had on our family, friends and community. Counterfeiting medicine is a crime that undermines the trust that society has in its doctors and pharmacies. A crime that targets victims that are already fighting for their lives and one that often results in tremendous suffering, and sometimes in early death. It also places additional emotional and financial burdens on already stressed families.

In 1998 Maxine Blount of Harvester Missouri, was diagnosed with a serious type of breast cancer. Her doctor explained that her cancer was serious, however, the doctor promised to provide Maxine with every opportunity to beat the cancer. Treatments began. Maxine received chemo treatments and radiation treatments over a period of 7 or 8 months to reduce the size of the tumors so that doctors could more safely do a radical mastectomy. After the mastectomy, Maxine continued to receive regular treatments, taking Procrit between each treatment, to build her blood, strength and stamina, in preparation for the next round of Chemo. She did this until she began to receive the counterfeit Procrit, The counterfeit Procrit made it impossible for her body to rebound enough for regular treatments.

At the time that Maxine was diagnosed with cancer, she owned and operated a Mail Boxes Etc. store. She loved this business and worked long hours to make it thrive. The business did well and resulted in many professional clients that depended on Maxine's ingenuity and work ethic to help them succeed in their respective businesses. She was available to assist anyone in shipping, creating documents or other services almost any time, day or night. She was an active member and officer of the Chamber of Commerce, taking great pride in her civic responsibilities, caring about the community and businesses. When someone needed help, Maxine was always first on the list to offer help. Local business and the Chamber of Commerce worried about Maxine throughout her illness, missing her greatly when she became too ill to run her business. About two years after being diagnosed with breast cancer, Maxine sold her business. She felt she needed to concentrate all of her strength on fighting the biggest battle of her life, cancer.

Maxine had five children, eleven grandchildren and 2 great grand children. She loved the children dearly and as her condition worsened, she noted that she was especially sad because she would be unable to see her future grand children. At age 61, Maxine should have had many years to enjoy her life; family, and work. Maxine was especially bitter when she realized that the counterfeiters had robbed her of precious time with her loved ones so that they could buy expensive cars, mansions and live the "high life". She sometimes wondered how they would feel if they lost loved ones because of counterfeit drugs.

As Maxine's cancer advanced, the doctor would change her medication. Most changes were successful in slowing or arresting the cancer for some period of time. However, this progress stopped as soon as Maxine began taking the counterfeit drugs.

Several months before Maxine's death, she noted that the Procrit did not appear to be working any longer. Maxine had to lengthen the time between treatments, allowing the cancer to advance more rapidly. Maxine informed the nurse at her doctor's office that the Procrit was no longer working. The nurse indicated that it should still work and took Maxine's prescription to a lab. They determined that the Procrit was counterfeit.

As noted earlier, the result of the counterfeit drug was that she could no longer take the chemo treatments as needed. In addition, she had no strength, more pain, problems concentrating and felt really bad. These missed treatments, combined with her loss of confidence in the pharmacy system, resulted in the quality of Maxine's life taking a nose dive. It would take her hours just to shower and dress. As she dressed, she had to take a break between each garment. Although Maxine's family helped her every way possible, it bothered her that she might become a burden on them.

Maxine dedicated all of her effort to trying to get well or survive until a miracle drug could be developed that would cure her. She had total confidence in her doctor and pharmacy until this happened. She had purchased her drugs at one of the largest and most reliable pharmacy's in St. Louis. At first she blamed the pharmacy, then she became even more depressed when she learned that controls on prescription drugs were really poor and that counterfeit drugs were not that un-common. It appeared to Maxine that because of the tremendous amount of money associated wth cancer drugs, the "system" allowed counterfeiting to continue with little control. She had spent thousands of dollars each month on counterfeit cancer drugs and the pharmacy refused to repay the fees they had collected for the counterfeit medicine. Maxine's confidence was gone. At this point she pretty much resigned herself that the end was near.

I don't pretend to know if Maxine would be alive today if she had not received counterfeit drugs. What I do know is that she would have lived longer, experienced much less pain and suffering, spent more time with loved ones, and would have died with more dignity. Maxine died on October 24, 2002. Maxine has had one grandchild born since her death.

The criminals dealing in counterfeit drugs are murderers. They steal people's dignity, cause unbelievable pain and often the premature death of their victims. All because of greed and a lack of moral and ethical values. My father taught us that at the end of each day, you should be proud of the person that you see in the mirror. I don't understand how these criminals can face themselves when they look in the mirror.

In closing, I believe that our society deserves and expects to receive reliable, high quality medication without being concerned that the medicine is counterfeit.

Mr. SOUDER. I want to thank each one of you for your testimony, and our sympathy goes out to your families. I appreciate your willingness to speak out and share your personal sorrows so we can try to figure out how best to deal legislatively with this and put as much oversight on this as possible.

Mr. Butler, in your testimony you said that they determined that the Procrit was counterfeit. How did that process work?

Mr. BUTLER. The nurse took the Procrit that my sister had with her and she sent it to the laboratory. The laboratory analyzed it, and it came back that it was counterfeit. Counterfeit meaning a reduced amounts, it was 5 percent of the volume she should have been getting.

Mr. SOUDER. So the nurse initiated the process and the hospital paid for the process, is that how——

Mr. BUTLER. Yes, that is correct. My sister didn't realize that the reason the drugs had stopped working was because it was counterfeit; she thought it was because the cancer had advanced to a point where it just wasn't doing any good.

Mr. SOUDER. Do you know in that case, did the hospital then go to the pharmacy, or what happened from there?

Mr. BUTLER. The hospital notified the pharmacy and my sister notified the pharmacy. They did an investigation from there in terms of where they got the counterfeits from or where they got the medication from. I don't know the whole story of what the pedigree said at the time. The Procrit had been acquired from the cheapest vendor, and they had purchased the drugs from a number—that same type of drug from a number of different vendors. There are specific lot numbers involved, and I'm not that familiar with exactly what happened on that side.

Mr. SOUDER. Mr. Fagan, have you met other people who have been through your problem in the course of exploring this?

Mr. FAGAN. No, I haven't, outside of today. But the unique thing is that I believe I haven't because we were in a very unique situation in that we were in possession of vials. We would receive a month's worth of vials at a time from our pharmacy for Tim's weekly injections. Think of how many senior citizens go to the doctor for a shot, the injection is administered, the vial goes in a garbage, or the same thing in a hospital. So the proof is destroyed, the patient doesn't get better and the underlying disease is blamed for what happened.

And what the scent of it is is that companies like AmerisourceBergen, large Fortune 500 companies, choose to put profit before patient safety, and it is absolutely criminal. What happened to my son is unconscionable. I sit here before you and it's just surreal that this thing is even happening, but it is, and that's the disturbing truth of it is that this problem potentially affects every American citizen. If it could happen to me, if it could happen to my son, it could happen to anyone.

Mr. SOUDER. Mrs. Eban, could you describe a little bit about what you have learned about the gray market? You talked about that in Mr. Fagan's case. How exactly is this working? Is that the main source of the problem? Clearly we've heard about the pedigrees; that's a big problem with it. In your feeling about, you heard of someone on the first panel going back and forth about how kind

of random and rare this is. Is it only when we get a very dramatic case that we actually learn of any kind of problem?

Ms. EBAN. If I can answer the second part of your question first. We don't know how big a problem this is. The FDA put out a report and said that less than 1 percent of the Nation's drug supply is counterfeit. In my reporting, I went down to Washington and met with the authors of the report and asked them, how did you come to that number, and they said to me basically, well, we don't know, we guessed but we don't imagine it's any worse. So there haven't been any studies done on this problem.

I tend to say, all right, less than 1 percent, they're making what I think is a conservative estimate. If we say 1 percent of the Nation's drug supply is counterfeit, and even that sounds conservative and relatively reassuringly small, 1 percent is 35 million prescriptions a year. And it's likely that number is concentrated among the high cost brand name pharmaceuticals for the sickest patients who need it the most, the reason being, as committee members have noted, that counterfeiters favor the most expensive drugs as an excellent return on investment. So I think you are looking at a fairly big problem.

I'd like to add that when the FDA mentioned cases, 32 a year, 58 a year, those cases often represent thousands or hundreds of thousands of counterfeit doses that have potentially reached patients. One of those cases in 2003 was counterfeit Lipitor, and by Pfizer's own estimate 600,000 tablets of counterfeit Lipitor reached patients. Again, in 2002 Jose Grillo's counterfeiting of 110,000 vials of Epogen and Procrit, taking very weak doses and making them look like strong doses, only 13,000 of those vials are recovered, which means that 97,000 vials are estimated to have reached patients.

I think from these examples we can gather that the problem is fairly big, and the numbers demonstrate that it's growing, but because no definitive studies have been done we don't know for sure the size of it.

In my reporting I identified over a dozen patients, but we know that the FDA's Med Watch system has received reports from dozens and dozens and dozens of patients who believe they have received counterfeit medicine.

Mr. SOUDER. In those dozen patients, when they went into the pharmacy, did you find a consistent pattern that here Mr. Fagan said that actually he was notified indirectly through the pharmacy to check whether it was counterfeit, Mr. Butler is saying that the nurse sent it out for testing? Is that a pretty typical pattern of what you have been seeing, or do some of them get nonresponsiveness?

Ms. EBAN. The way that it is detected is entirely random. And sadly I have to say that Tim Fagan and Maxine Blount are the lucky ones only in the sense that they learned that they had taken counterfeit medicine, whereas many patients never know, they simply don't get better, and because they have serious diseases of course they don't know why they're not improving.

So in my reporting I began to realize that we all know someone whose medicine suddenly stopped working, and once you immerse yourself in this problem you really do begin to ask yourself why,

and you begin to think of a whole new set of reasons why that might have happened.

Mr. SOUDER. Thank you.

Mr. Cummings.

Mr. CUMMINGS. First of all, I want to thank all of you for your testimony. To Mr. Fagan and to Mr. Butler, I want to thank you for taking your pain and what you have gone through and using it as a passport to hopefully help other people in the future.

I'm going to start with you, Ms. Eban, and I'm just curious. Today I note that—well, yesterday the USA Today said effective immediately that the CVS chain said it would purchase pharmaceuticals only directly from manufacturers or from wholesalers who certify they are not buying from what has been dubbed the secondary market. How significant is that?

Ms. EBAN. It is very important, and it's the right step; if every pharmacy chain in the United States insisted upon that, I think you would find that the gray market, the wholesalers who simply trade sideways among themselves, would shrink considerably. The problem is that the reforms that have been taken, the steps that have been announced by players in the supply chain, are random, individual, and have many loopholes. Many doors still remain open.

Mr. CUMMINGS. You know, I remember a while back when we had the Tylenol contamination and how it just sent a rippling effect, and now we have these containers that have seals and whatever. And when I think about say, manufacturers, are they—it seems as if they had—if there was any idea, if the word got out that maybe their drug had been contaminated in any way. When I say contaminated, I don't mean—I know these are counterfeits, I understand that, but it has their label, it has something that is supposed to be their label. It seems like that would cause them to really be major players in this. Do you find that to be the case, in other words, trying to help to make sure the problem is solved? Because if it gets out there, say, for example, that Lipitor, if there is lot of counterfeit Lipitor out there, then I think that sends a terrible message from an economic standpoint, and sadly sometimes economics, as what Mr. Fagan said, is what drives things.

Ms. EBAN. I think that manufacturers have changed their stance about the problem. Earlier on, as I found, they were not really willing or likely to raise their hands to say our medicine is being counterfeited for fear that patients would then go to possibly a rival's medicine in order to try to get safe medicine. But I think that the problem has grown enough that they have become quite concerned about it. They have ramped up significantly tamper-proof packaging, holograms, chemical taggants and markers that are embedded in the packaging or even in the product themselves. But many security directors of drug companies I've spoken to have said, given 12 to 18 months, counterfeiters can pretty much copy anything. So the approach has to be on many levels to solve the problem.

Mr. CUMMINGS. You know, one of the things that you said that kind of stuck in the DNA of every cell in my brain is you said that 1 percent may be as many as 35 million prescriptions?

Ms. EBAN. Yes, that is right.

Mr. CUMMINGS. Now, did you hear the testimony of the gentleman, Mr. Lutter, from FDA?

Ms. EBAN. Yes, I did.

Mr. CUMMINGS. Do you think he is underestimating the problem, or overestimating, or you don't have a clue?

Ms. EBAN. I think that the FDA has always wanted to reassure the public that they should take their medicine and that their medicine is safe, but I don't think they really know the size of the problem because they have not done any studies. They are guessing as to the size of the problem, and I do think that historically they probably have played down problems because they don't want to panic consumers.

Mr. CUMMINGS. And let me say this to you, Mr. Fagan and Mr. Butler, if this Congress wanted to do this it could be done overnight, period. It has to be the will of the Congress to do it, but it can be done. I've seen things much harder than this done. And it was suggested to keep fighting. I, for one, will make sure my name is on that bill.

Mr. FAGAN. Thank you.

Mr. CUMMINGS. And last, but not least, I think one of the things that should not be lost in all of this is something that you emphasized, Mr. Fagan, and you, Ms. Eban, I think you, too, Mr. Butler, to a degree. As you were sitting here talking I was thinking about all the people in my district, and I represent a lot of poor people and lower middle class people, and I'm sure that in some of those instances—and I have a lot of seniors—so they get the medication, and like you all said, they may die or may be harmed because they're not getting the right dosage or they may be getting just completely fake medication with none of the ingredients it's supposed to have in it, but yet still when the autopsy is performed or when the final report is done they died because of cancer or whatever it might have been. So we really don't know, we don't know how many of these people are being affected by all of this. I just, I'll tell you, one of the things I think we must do, and I think all of us, and the reason why this is so significant, this hearing is so significant, and I do compliment you, Mr. Chairman, for putting together a balance here of witnesses, is because this affects, it can affect every single one of us, all of us. We do have to have trust in the medicine we take and the food we eat, so I really thank you, and I'm hoping that we will be able to move this along, but thank you all so very, very much.

Mr. SOUDER. Thank you.

Mr. Burton.

Mr. BURTON. First of all, let me just say you have my sympathy. My wife died of liver cancer, and she had breast cancer prior to that, and she took Tamoxifen, and when we were going through her chemotherapy and her other treatments, we had ladies that were sitting next to her taking chemotherapy that were talking about Tamoxifen and talking about how they couldn't afford it. I presume the same thing was true with Procrit. That's when I started checking with my colleagues about the costs in other countries. In Canada the things that she was taking was one-fifth, one-sixth what it cost here. One of the reasons that we have this counterfeit problem, I believe, is because of the price disparity. Somebody is going to testify that Willie Sutton said the reason he robbed banks was because that's where the money was. I mean, if it costs six

times as much for a product in Canada as it does here, and you can get it or counterfeit it, you're going to make a lot of money just by doing it here in the United States.

But we really do have to do something about the counterfeit problem. I'm not downplaying that.

As I understand it, in the case of your sister, the druggist took the pill and cut the amount by one-fifth or one-sixth or one-tenth or whatever it was. I don't know how you deal with that kind of a guy. I mean, he needs to be in the slammer, no question about that. I think the same thing is true when somebody's taking a product that deals with people who suffer from a liver transplant and they start watering it down or anything. And the price disparities, I think, have a lot to do with that as well.

I've got a list here that my colleague, Mr. Gutknecht, has compiled on the differences in prices. One of the Gordian knots that we have to deal with in dealing with this problem, in my opinion, is that we're in a global marketplace right now. Let's say that we're able to come up with a mechanism to make absolutely sure that every product, that every pharmaceutical product, is pure and packaged properly in the United States. If it costs so much more, like Tamoxifen does, here than it does in France or Germany, the people who have to rely on that are going to try to get it through the Internet, and then you have to police everything coming through the mail from a foreign country because people are going to buy it where they can afford it, if they can't, whether it's drugs or almost anything. So what we've got to do is we've got to, and I've sat down with the leaders of the various pharmaceutical companies Lilly and Merck and others, and I said what we need to do is sit down and talk about some way of coming up with a pricing structure that is fair for the people of this country, as it is elsewhere. If you do that, you're going to minimize this kind of a problem.

There's always going to be people that are going to cut somebody to make more money, and as long as the money is there to be made they're going to do it. So I just say that you have my sympathy for what you've gone through, but this is a problem that is not going to be easily solved, as one of my colleagues just said, because you can get these products from other parts of the world and you can get them at much lower prices.

So the root cause of it, in my opinion, is trying to come up with some kind of, not a government imposed price index, but some way that we can make sure that the American people are paying a price that's not completely out of line with what they're paying in other parts of the world. I think that's the reason this whole issue has arisen, not because we don't have counterfeit products, we've had those for a long, long time, but because the importation of products has become such a big issue that I think the pharmaceutical companies and our health agencies have said hey, we've got to do something to stop this, and one of the main ways to stop it is to start raising cane about counterfeit drugs and put the fear of God into everybody that's taking it.

That's not to say that there aren't counterfeit drugs, that's not to say that there is unscrupulous pharmacists that are going to cut something to one-fifth of its strength in order to make a buck.

You're always going to have people like that, but the main issue, in my opinion, is to try to make sure that Americans pay a fair price, just like the rest of the world does, for pharmaceutical products, and that is one of the things that Mr. Gutknecht and I have and others have been working on for a long time.

The unfortunate thing is the pharmaceutical industry has over 600 lobbyists in Washington, DC, over 600. There are only 535 Members of Congress, so they have a tremendous amount of impact on what we do around here. Plus, they give out millions and millions and millions of dollars in contributions for campaigns, so they have a tremendous amount of influence.

So this problem is very important, Mr. Chairman, in dealing with counterfeit pharmaceutical products, but I think of equal import or as much import is dealing with the disparity in prices, which I think is one of the most—is the genesis of this problem.

And I yield back the balance of my time.

Mr. SOUDER. Ms. Watson.

Ms. WATSON. These questions go to the author. In listening to the testimony, it seems that the drug—let me address this to Mr. Butler first, and then to the author. The drug that your sister was using was a counterfeit prescribed or obtained through what process?

Mr. BUTLER. My sister obtained it by going to the local pharmacy, a very large pharmacy chain, a reputable chain in St. Louis, one of the largest. That's where she got it from. They had purchased it from a wholesaler. Where the wholesaler got it, I'm not sure. I think Ms. Eban's book indicated it may have come through a strip club in Miami, I'm not sure.

Ms. WATSON. Was it prescribed by her doctor?

Ms. BUTLER. Yes, it was.

Mr. BURTON. Will the gentlelady yield?

Ms. WATSON. I certainly will.

Mr. BURTON. I think it's very important. When the pharmacist got the drug, it was at normal strength, was it not?

Mr. BUTLER. It was not at normal strength.

Mr. BURTON. Who did the cutting of it; who cut the volume of it down?

Mr. BUTLER. That was prior to—I'm not sure who did the cutting. Katherine did the investigation and she may know, I think she probably does.

Mr. BURTON. All right. Thank you.

Ms. WATSON. I have been reading the bill and what I'm trying to ferret out is how and what is the procedure that would be used to stop this, because apparently your sister initiated it on her own or the doctor said you need this kind of drug. I'm trying to figure out how we can get to that point where we could prohibit or stop or cease the sale of this counterfeit drug. I don't know where in the system we could go, and I'm looking at the bill to see that it addresses this. There is an investigation; they do ask for additional money in the bill to investigate. But how does the process get started. And I see that the sponsor of the bill is not here, and I know there's an order to recall drugs. And certainly if drugs are not—here's the author.

In listening to Mr. Butler, his sister went to a pharmacist and got a particular drug. Where in your bill, what provision in the bill would address that, initiated by—and I didn't know whether it was a doctor's prescription or what, but I think she initiated it herself.

Mr. BUTLER. The doctor prescribed the Procrit. It's necessary to help build the blood and strength back up between chemo treatments.

Ms. WATSON. When she went to purchase it, she learned afterwards that it was a fake or they were cutting—whatever. I just wanted to know from the author, is there a provision that would address that process?

Mr. ISRAEL. Mr. Chairman, you're very kind to allow me. Do I have permission to answer?

Mr. SOUDER. Of course.

Mr. ISRAEL. One of the most important things that the bill does is provide a very significant disincentive to criminals who are counterfeiting drugs by increasing penalties from current Federal law of 3 years in prison to life in prison. That would be a very significant penalty.

With respect to what immediate action can be taken to prevent, to deal with the purchase or the acquisition of counterfeit medication, the most important thing we can do is make sure we have pedigrees, that we know every single step that medication has gone through so that you know the integrity of that medication has been maintained. And the final point I would make is that, right now, the FDA has no ability, no true ability to recall counterfeit medicines from the pharmacy shelves. It's easier to recall a defective toaster oven than counterfeit medications. This would give the FDA the ability to recall counterfeit drugs immediately when there is a report of such drugs.

Ms. WATSON. Mr. Butler, did your sister have a prescription?

Mr. BUTLER. Yes, she did.

Ms. WATSON. From the doctor? And when she purchased it, she found that it wasn't having the desired effect, and then she found out later it was counterfeit?

Mr. BUTLER. Yes. She had taken the Procrit for some time and it had worked very well. She had gotten that from the same pharmacist. When it stopped working, she made an assumption that it was because her cancer had worsened, and that was the reason it wasn't working. So she didn't immediately tell her doctor, but she started delaying. It got so she had to delay the process before she could go back for chemo. Then when she told the doctor or told the nurse, the nurse sent it in and had it analyzed. The pharmacist did not know the medication was counterfeit. They had purchased it from a wholesaler.

Ms. WATSON. I see. I want to be sure that, in the bill, which I'm very sympathetic to, that there is a provision that would require the pharmacists some way to check out those drugs when they get them from a probably unauthorized manufacturer. I don't know, but I'm hoping that this bill would address how we attempt to try to save your sister's life through this bill, and I think that something has to be in here to indicate—the pharmacy didn't know, but they purchased it somewhere, and probably whoever was marketing this sold them a bill of goods.

Mr. BUTLER. Actually, they purchased it from a legitimate wholesaler.

Ms. WATSON. I'd like to yield back to the author because it's your bill, and you might want to kind of elaborate on that.

Mr. ISRAEL. Thank you. The simple answer is that the pedigree requirement would have notified the pharmacy immediately that this particular medication did not go through the appropriate transactions; that it may have gone elsewhere, may have been tampered with. That's what's really at the heart of this bill, requiring the FDA to require the paper pedigree that was supposed to be implemented 17 years ago.

Ms. WATSON. Another question, Mr. Chairman, if I still have time, who would have the authority in that process to carry this out? You see, apparently the pharmacy purchased a bad batch of this prescription drug. Somewhere we've got to stop that kind of thing from happening, if it is a bad batch.

Mr. ISRAEL. The enforcement would be by the FDA. It provides an additional $325 million for the FDA for spot checking, additional enforcement and training pharmacies to be able to recognize potentially counterfeit drugs.

Ms. WATSON. Thank you.

I yield back my time.

Mr. SOUDER. Thank you.

Ms. Schmidt, do you have any questions?

Mrs. SCHMIDT. Yes, I do. Thank you very much. First off, my heart goes out to you, Mr. Fagan, and to you, Mr. Butler, on the situations that you had to deal with.

Drugs are very important to all of us. They allow us to live a lot longer, a lot more comfortably, and so we want to make sure that the drugs we are receiving are the drugs we expect to receive. I think there are two issues that are going on here. The first is the affordability of drugs in the United States versus the affordability of drugs in Germany and Canada and other places. But I think, the second is the kind of drugs that we're receiving, and are they pure? Have they been tampered with? What I'm hearing from Ms. Eban is that the drugs she discovered were not tampered with in Germany or in Ireland or in Canada; they were tampered with in the United States. So we have two issues: One is price and an unfairness of the price here in the United States, and the second is the purity of the drugs.

I think the second part is easily remedied by putting some sort of a tracking system on those drugs, something like what is in Germany, putting them in the little individual tablets, putting blister packs or putting something like this on them to make sure the drug is pure because when we worry about something coming through from the mail, the insurance policy that my husband and I have, our health insurance policy requires that if we're taking drugs for a long period of time, that we get them through the mail. So worrying about whether you get it through the mail and if it's been tampered with, that's something that's already here.

The second thing is trying to make the drug prices more fair to our U.S. customers. I worry that any legislation that we pass that tries to correct the first part of it by making sure that our drugs are pure but doesn't address the price of the drug will not correct

the purity or the lack of purity of the drug. So that is my concern, and I know that Mr. Butler and Mr. Fagan probably don't have a solid answer for that, but, Ms. Eban, do you?

Ms. EBAN. Thank you very much. First of all, I think many American consumers assume that when they go to a pharmacy and pay top dollar for their drugs, that their drugs are guaranteed to be safe, but in fact, the soaring prices of our drugs actually puts their safety at risk because America has become a go-to market for counterfeiters. We offer the best return on investment for counterfeiters who want to move their products into our market. My book deals exclusively with counterfeit medicine that has reached consumers through pharmacies and through hospitals and through legitimate mail order, so that is our legitimate drug supply, and counterfeits have infiltrated that. I just want to say that in the case of Maxine Blount and Tim Fagan, this was not a case in either situation of a rogue pharmacist diluting drugs or tampering with drugs. This was about systemic corruption of our drug supply in which major wholesalers, who are responsible, legitimate wholesalers, look for bargains or discounts in the secondary market. They buy even from licensed wholesalers, but that medicine still proves to be counterfeit because it doesn't have a proven origin, which is what a pedigree paper would correct.

They are looking for discounts in the secondary market because they want to be able to buy low and then sell high. As we all know, they can sell very high. So these are players whose sole profit is coming from arbitrating the price of the drug. That whole gray bandwidth in the middle of that chart, every single box is a different wholesaler and the drugs moved through. Every wholesaler bought low and sold high, and it finally got to a regional wholesaler and then a national wholesaler once it approached the market rate. Once the price came up, then it could be sold to a pharmacy and ultimately to a consumer, but it is the buying from unknown sources from that gray market that is driving this problem. That's what needs to be corrected.

In order to have a record that follows each drug, whoever buys or sells it would need to commit to its origin, and that's extremely important. I hope that answers, in part, your question.

Mrs. SCHMIDT. Thank you, it does.

Mr. SOUDER. Mr. Gutknecht.

Mr. GUTKNECHT. Thank you, Mr. Chairman, and I want to thank all the panelists, and I would extend my condolences as well. Finally, I think I understand. Mr. Butler, are you familiar with a case in the Kansas City area of the pharmacist who was intentionally doctoring? They were principally cancer drugs as well.

Mr. BUTLER. Yes.

Mr. GUTKNECHT. This is not that case. Second, I want to come back, Ms. Eban; there was a story, and I will submit for the record, Mr. Chairman, an article that appeared within the last 2 weeks I believe in the Wall Street Journal about the pharmaceutical marketing association hiring writers to write a novel.

Are you familiar with that story?

Ms. EBAN. I am familiar with that story, and in fact, I even heard that the editor at the publishing house who was going to be

editing it was none other than Jayson Blair, who was a former colleague of mine from the New York Times.

Mr. GUTKNECHT. That's correct. Just for the record, you are not now or never have been under contract from any of the pharmaceutical companies or marketing associations?

Ms. EBAN. Absolutely not.

Mr. GUTKNECHT. Let me point out, I didn't know I had this with me, but I would share this with any of the people here and certainly other members of the committee. I talked earlier about the new computer chips. In this little vial, there are 50 computer chips. They sell now, I believe, for like 10 cents apiece. They have the ability to do exactly what we're talking about. The FDA has known about these for at least 2 years because I told them about them, and they have consistently refused to do exactly what we're talking about. The reason I say that, and I'm certainly empathetic to what we're talking about, and I would certainly like to work with the author and you to come up with a safer way to protect our drug supply. That has never been my intention. What I want to make certain is that Americans have access to world class drugs at world market prices.

But I'm also going to submit for the record, I believe this may be from today's, one of today's Hill newspapers, and this is a scare ad, and it's done by Pharma. Let me just read what it says: "Real or counterfeit, the answer could be a click away."

[The information referred to follows:]

REAL OR COUNTERFEIT?

THE ANSWER COULD BE JUST A CLICK AWAY

NEARLY 2 MILLION AMERICANS HAVE TURNED TO WWW.BUYSAFEDRUGS.INFO FOR FACTS ABOUT THEIR MEDICINES

When your local pharmacist fills a prescription, you trust you're getting the medicine your doctor prescribes. But can you trust a mail-order pharmacy that's supposedly in Canada? Or somewhere in cyberspace?

Where can you turn for reliable information?

Since July, nearly 2 million Americans have visited www.buysafedrugs.info for information on safe, legal ways to save on prescription drugs.

You'll find vital information and timely news about counterfeit prescription drugs, drug importation and online pharmacies.

When your health and peace of mind are at stake, there's no such thing as too much good information.

Visit www.buysafedrugs.info and get the facts you need.

Brought to you by PhRMA Learn more at **www.phrma.org**

Mr. GUTKNECHT. Well, this is all part of an orchestrated effort to make people believe that, gee whiz, if I buy my drugs from that pharmacy in Winnipeg, it may be a counterfeit. The truth of the matter is with the technology we use in the United States today, you are more likely to get a counterfeit drug if you buy your drug from the local drug store. Unfortunately, that is a fact.

In terms of the bill, I certainly want to work with the author, but giving the FDA an army of new inspectors to go out and chase little old ladies trying to save $200 on the Tamoxifin by buying it from Manitoba is not my idea of really making America safer. So I will work with you and provide you with information on this technology, and incidentally, we have the next generation of technology already being developed. They are little digital taggants, and they can be put in every single drug so that we can know exactly what that drug is made of, where it came from, when it came off the production line, right down to the components of that drug. So there are a lot of things we can use today, technology right off of the shelf. We don't have to give the FDA an army of new people, and we don't have to make it even harder for folks in my district to try and save a few hundred bucks a month on their prescription drugs by buying them from a pharmacy in Canada.

We want to be careful, and I think our new colleague from the State of Ohio, I think, has really stated it right. There are really several issues at play here, and we want to make certain that people who break the law are held fully accountable. I will say this, though, in all fairness to the life sentence concept, if we're going to start making mandatory life sentences, I would go first after sex offenders, because every day there are stories in the papers both here and throughout the United States of sex offenders who are turned back on the streets after a couple of years, and they have the highest rate of recidivism of anybody.

Finally, Ms. Eban, I want to come back to another point that you made. There is, going back to the scare tactics of Pharma, the truth of the matter is, I know that there is a certain amount of counterfeiting going on. But some of it is so good that it is virtually impossible to tell the real from the imposter. And the bottom line is, if you are getting a counterfeit that is an exact copy of the name brand drug, ultimately, what is the harm to the consumer? I have a very good example that I have been told, and the example is of one of the male enhancement drugs, you can buy them in India for 10 cents a tablet. Here they're $10. You may call them counterfeiters; I would call them entrepreneurs that are selling them for $5. The net result to the consumer is exactly the same.

Ms. EBAN. Unfortunately, though, counterfeiters don't provide a guarantee that the effect on the consumer will be the same, and so it's a crap shoot. Of course, if it is exactly the same and it's less money, the consumer benefits, but there is no guarantee of that. I also want to say that there has been testimony, I believe it was before Congress, in the last year which said that the terrorist organization of Hezbollah was counterfeiting Viagra and selling it within the United States. So we certainly do know that terrorists do look at counterfeiting as an activity that can build profits for whatever work that they are doing, and they also do not provide any guarantees, of course.

Mr. GUTKNECHT. If you're in the crime business, clearly, you look at this, and the potential is hundreds of millions if not billions of dollars. So I would not be surprised that there are all kinds of organizations out there who have looked at this business and said, you know, if you can buy something for a dime and sell it for $5, you can make a lot of money at that 50 percent markup. I yield back my time.

Mr. SOUDER. Mr. Burton.

Mr. BURTON. I have one real quick question. First of all, you can see the computer chips in this vial, and so there is technology, as Mr. Gutknecht said, that can be utilized to track these things. The one thing I'd like to reemphasize is what you just said a minute ago, and I hope it's not lost on the rest of the audience tonight and everybody else who's paying attention to this, and that is the huge price disparity is an encouragement for counterfeiters. I'd like for you just to elaborate on that one more time. Because of this huge price disparity between a U.S. product sold here and somewhere else in the world, that is an encouragement for counterfeiters, right?

Ms. EBAN. I would agree with that statement. I will say that, traditionally, counterfeiting in the legitimate drug supply, even in Canada for example, has been lower because their prices are regulated and counterfeiters breed when there is a differential in the prices because that leads to a growing gray market where drugs are diverted and then obtained by counterfeiters. So low prices and regulated prices do decrease the instances of counterfeiting, but the more that we have a global market with differentials in different markets, different prices in differing markets, and you have more parallel trade, then you will see an increase in counterfeiting. We've seen this recently in the European Union where now England has had counterfeiting incidents and other countries because the drugs are cheaper in Portugal and Spain. That increases the number of middlemen, increases the number of counterfeiters. So the more that we can reduce prices and regulate the discrepancies or decrease the discrepancies in prices, you will see, I believe, a reduction in counterfeits.

Mr. BURTON. Thank you.

Thank you, Mr. Chairman.

Mr. SOUDER. Before going to the third panel, I have listened to two panels of two of my good friends and colleagues in effect trying to take this subject, in my opinion, off hearing. So I'm going to ask to insert in the record, "Fake Drugs Nightmare Comes to Haunt Canada," into the record.

[The information referred to follows:]

THE HAMILTON SPECTATOR

September 17, 2005

Fake drugs nightmare comes to haunt Canada

The police raid on a Hamilton pharmacy is a wake-up call for a country that's vulnerable to criminals poised to exploit cracks in the system

BY MARISSA NELSON

A health nightmare that's stalked the world for more than five years arrived on Canada's doorstep this summer – at a Hamilton pharmacy where police uncovered a quantity of fake pills.

At $36 billion, the counterfeit drug market is exploding and, in the estimation of one expert, could be turning over $70 billion a year by 2010.

"These are unscrupulous people who won't think twice about putting counterfeit drugs in the medicine chests of Canada, the U.S. or Europe," said Peter Pitts, a senior fellow at the Pacific Research Institute, a California-based think tank.

A massive batch of fake Lipitor, a Pfizer cholesterol drug, was found in the United States in 2003. It prompted the recall of more than 150,000 bottles.

This summer, the same drug was recalled in the U.K. after 70 counterfeit boxes were traced to two wholesalers, prompting the recall of 120,000 bottles.

Fakes have killed many people in Third World countries, including 2,500 in Niger after they got a phoney meningitis vaccine and 89 people in Haiti after they consumed a syrup cut with a toxic chemical widely used as anti-freeze.

Just last week, 11 Chinese and one American were arrested for a scheme that spanned 11 countries and involved millions of dollars worth of fake drugs, including 440,000 found in China. Police found knock-offs of Viagra, Cialis, Levitra, and Lipitor.

The World Health Organization estimates 10 per cent of all drugs sold in southeast Asia are fake, with one-third of a key anti-malaria drug believed to be counterfeit.

Fake drugs used in Africa for AIDS/HIV have also surfaced.

In Canada, a few fake Viagra pills have been found in Canadian clubs and on the streets – drugs made by a biker gang at a crystal methamphetamine laboratory in Quebec.

But this country hadn't – until recently – seen a single case of counterfeit medications in a legitimate pharmacy sold by a registered pharmacist.

While the United States battled a burgeoning problem with the sale of counterfeit pharmaceuticals, Canada's tight controls on the drug system appeared to keep things safe.

All that was turned on its head on June 15 when the Mounties descended on King West Pharmacy around noon with a search warrant.

With representatives from the Ontario College of Pharmacists, the Ontario Provincial Police and Pfizer Canada by their side, the RCMP spent 12 hours looking for evidence that fake heart medication had been sold to many of the store's unsuspecting elderly customers.

The Mounties were looking for fake Norvasc – a Pfizer-made, life-saving heart medication for high blood pressure and angina – which authorities say may have led to the deaths of five city residents.

A coroner's investigation was launched in an attempt to figure out whether the five deaths were linked to fake Norvasc.

Abadir Nasr, the Egyptian-trained pharmacist who owned the drugstore, is now charged with "passing off" the pills as real Norvasc when they weren't. He has since been stripped of his privileges to buy drugs and banned from managing his own pharmacy – which has been sold to new owners after being briefly in receivership.

And five Hamilton families continue to grieve their loved ones, left wondering if the death could have been prevented.

"A few of the family members feel guilty, because it was their decision to use that pharmacy," said Hamilton police Detective Joe Stewart, who is spearheading the probe into the deaths.

The deaths have shaken faith in this country's drug system. Gail Richards, an elderly woman who shopped at the pharmacy since 1994, was on Norvasc. She has handed her pills over to police.

"I don't trust any pharmacy anymore," she said.

The discovery and subsequent events have thrown into doubt whether you can be sure that what you get at your local pharmacy is the real stuff, not a cheap knock-off made in China.

Ken Hansen, head of the RCMP's federal enforcement unit and the co-chair of an Interpol committee on counterfeiting, said there's no way to know. "I can't say with confidence that there is not another pharmacy out there with counterfeit drugs," he said in an interview from Ottawa.

The RCMP have admitted there are "three or four" counterfeit pharmaceutical investigations in the Greater Toronto Area, but they won't say anything else – including what drugs are involved.

RCMP spokesperson Judy Laurence says she can't get into the specifics of any ongoing investigation.

"They're trying to figure out where this stuff came from, but how they're doing that is not something we're going to talk about."

Officials south of the border aren't as tight-lipped.

For the third year in a row, Canada is on the U.S. Trade Representative's watch list alongside countries such as Belize, Bolivia, Colombia, Costa Rica and Thailand.

American authorities fear that Canada is home to "extensive trade in counterfeited and pirated products," including fake pharmaceuticals.

Pitts, the California-based think tank's boss, said the fake drugs found in Hamilton are proof the trade in counterfeit pills is alive and well in Canada.

"It is completely implausible that it is a unique incident. There is nothing unique about Hamilton, Ontario," said Pitts, a McGill University graduate, former senior bureaucrat for Health Canada and former associate commissioner for the U.S. Federal Drug Administration.

"Canada does not exist in a pharmaceutical bubble. It does an excellent job, but it is not immune to a problem the rest of the world faces."

The World Health Organization estimates fake pharmaceuticals worth $36 billion a year.

Pitts estimates that will jump to $75 billion annually by 2010.

"It is growing at a rate almost double legitimate pharmaceutical sales," said Pitts, who next week is a speaker at a conference on drug counterfeiting in Washington DC.

Pitts said Health Canada is understaffed but said the stance of "problem, what problem?" doesn't cut it.

If the five deaths the coroner is probing turn out to be linked to fake Norvasc, it's not just a smoking gun, he said, it's "a photograph of a wound," Pitts said.

The fact the RCMP is putting resources into the King West case proves to Pitts there's more to the story then they are letting the public know. "Clearly they feel they're on to something that's more important; that needs to be addressed, which is why they're investing the dollars," he said. But he finds fault with how little disclosure there is on counterfeits in Canada.

"The first step is to let the people of Canada know these problems exist and to be extra vigilant," he said. "When it comes to public health, you can't be quiet."

The U.S. Federal Drug Administration makes as much information public as possible, he said.

"A more educated, more aware consumer is a smarter consumer, is a safer consumer."

But the only way for changes to get made is for the public to make it a political issue, as was seen in the United States when affordable drugs became part of the debate during the presidential race.

"If I was a prime minister holding on by my fingertips, I'd be worried to lose my seat in Hamilton, Ontario, especially if the Conservative Party decided to run a platform of 'There are five dead people, where is the prime minister?'"

Health Canada officials say fake drugs aren't their agency's responsibility, that they are a criminal matter and therefore up to the RCMP. Health Canada is only in charge of governing the Food and Drug Act, testing and regulating real drugs.

Jirina Vik, spokesperson for Health Canada, said they weren't involved in searching King West Pharmacy, but advised the Mounties about the Food and Drug Act.

When fake Lipitor was found in the U.K. and the U.S., Health Canada issued a warning to citizens.

Not so in the King West case.

"It was deemed to be a local issue," Vik said. However, in a three-page follow-up e-mail, Vik stated that Health Canada is responsible for helping Canadians "maintain and improve their health" and therefore is "very concerned about the risks that counterfeit drugs pose to Canadians."

Continued on the next page

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While Health Canada is responsible for the quality of the products inside pharmaceutical jars — they regulate the drugs, who makes them and who distributes them — they are still not responsible for unapproved products, Vlk insisted.

As for notifying people about the fake Norvasc, Vlk said the Ontario College of Pharmacists, which is a provincial body, and the RCMP sent out notices.

The Ontario College of Pharmacists says it's investigating the King West case but that their hands are tied; privacy legislation won't let them talk about it.

The college took drugs from King West to test, but they declined to say what those tests showed. Officials from the college say privacy legislation prevents them from even saying when King West Pharmacy was last inspected — a key part of their regulatory obligations.

Police documents show it was early in 2004, before the pharmacist who is charged owned it.

The college says it inspects all pharmacies at least once every three years. Pharmacies are warned when they will be inspected.

In an e-mailed response, a spokesperson said the college sent its press release about the Norvasc and photos of the suspected counterfeit pills to pharmacists' organizations in the U.S. and Canada, wholesale and drugstore associations, health regulatory bodies and pharmacies in Ontario, and the Ontario government.

The RCMP apparently told customs officials, but representatives of the Canadian Border Services Agency won't say what, if anything, they were told about the Norvasc case.

"Any intelligence we get, we don't disclose publicly," said Michael Proulx, a spokesperson for the Canadian Border Services Agency.

The RCMP's Hansen said his agency was the lead in "part of" the King West probe. Hansen said Health Canada and the Canadian Border Services Agency were told about the case and got more information than the public.

He said the RCMP's role is to investigate, not inform the public. That's Health Canada's role, he said.

Hansen admits the system, with each agency looking after very specific, limited things, can be fragmented. One option that is being considered is to have one, centralized office look after counterfeit goods, as the United States does — an intellectual property crime hub with officials from different agencies under one roof.

The government has known about the threat of fake pharmaceuticals for some time — it was flagged in a 2000 RCMP report — but the rate at which it is growing is why it's suddenly on the radar screens across the world, Hansen said.

"You've got to evolve to meet the crime. Status quo isn't an option. The problem will just get worse," he said.

Hansen said "virtually every organized crime group in Canada" is involved in counterfeit goods because it turns a high profit and comes with limited punishment and little enforcement.

Liberal MP for Etobicoke North Roy Cullen, who is the parliamentary secretary to the minister of public safety and emergency preparedness, said the government has to take action because organized crime is increasing the volume.

"People, when they take pills, they're assuming what's on the package is what they're taking," he said.

Cullen said a package will be brought to cabinet this fall with a list of options to try and improve this country's reaction to counterfeit goods, including pharmaceuticals.

Counterfeiting used to only be seen as an economic crime. But now it's clearly a matter of public safety and the government will have to do more, he said.

Part of the package cabinet will debate this fall is whether legislation should change to give customs officers more tools to deal with knock-offs.

Right now, they don't have the mandate to deal with counterfeit goods so when they find them, they have to call the RCMP. They also cannot tell the companies which hold the trademarks that are being contravened about the counterfeiting.

Roy Cullen

Michael Tremblay

The changes may require additional officers for customs and even potentially the RCMP — though the Mounties' budget has increased by $1 billion in the last five years, Cullen said.

"What we want to do is the best job we can, and give the authorities all the tools they need."

But with rumours of an election wafting through the halls in Ottawa, and a full fall program already lined up, it will be spring at the earliest before any changes get made.

In the meantime, companies like Pfizer are left to defend their own patents.

And it isn't easy.

John Theriault, head of Pfizer's global security, said he can't be certain all Pfizer products in Canadian pharmacies are real.

"I couldn't say with any degree of assurance or credibility how much counterfeit product is in the Canadian market or the U.S. market. We just don't know," Theriault said from New York City. "I don't have the capacity to inspect those pharmacies and authenticate the product they have there," he added.

"When we find counterfeit product, it's not because the regulators are doing inspections, it's because some consumer had an adverse reaction or is suspicious about the product."

Theriault said that when you have counterfeit product being sold to a pharmacy in Hamilton, that salesperson is likely making his or her sales pitch to more than one pharmacist.

But he also thinks the Hamilton case is a sign of how things should work — that the problem is caught quickly.

"It's a relatively secure system but it can be abused. I don't think there's any need for undue concern at this time."

Out in Vancouver, the gateway to the Orient — where many knock-offs are made — officials are just trying to keep up.

Corporal Murray Genik works with the Border Integrity Unit in Vancouver and says they could triple their officers and still not get all the work done.

"We'd like more people to deal with this problem," he said. "What gets me, is these people are not only endangering people's lives, they're getting rich doing it and aren't paying taxes."

Police and customs officers have found fake pharmaceuticals in containers coming off ships, in air cargo and mailed packages.

Counterfeit goods are seized every day. Drugs are a little more rare.

Faith St. John, spokesperson for customs in Vancouver, said they've seen fake Viagra, Levitra and Cialis, but nothing recently.

In the last few years, Genik said he has seen dozens of major pill presses — machines that make tablets — come through Vancouver. The machines can make "hundreds of thousands of pills a day" and fit into the trunk of a car.

That makes them tough to track.

"In a lot of cases, there's nothing we can do," he said.

It's not illegal to bring the machines in and they can sit in a warehouse for months.

"You can't sit there and watch it. We have limited resources at the best of times, let alone watching something that's not illegal," he said.

Michael Tremblay, a consultant in health policy in Europe for the last 15 years and former director of education at Hamilton Health Sciences, said the system used to get drugs into the hands of ill people is a complicated one that's only as strong as its weakest link.

One organization regulates the pharmacy, another the drugs in the pharmacy, but there are so many agencies and systems that don't speak the same language, the country remains vulnerable to criminals who will find and exploit the cracks in the system.

"They're looking at the holes in the system and are finding them because we haven't been looking at the holes in the systems ourselves," Tremblay said.

There needs to be a seamless flow of information, so if a knock-off is found in one place, it translates into action in other areas, like the border.

"We track cattle better than medicines," he said. "People know more about the spark plugs in their cars then the drugs they take."

Tremblay said the American stance of "sunlight is the best disinfectant" is a good one to use in Canada on this issue.

"Police would find it easier if they had millions of Canadians alert to the problem," he said. "It may be that they think the risk is they'll create unnecessary anxiety in the public. I think we're grown up enough to have an adult discussion. ... They are, after all, our medicines."

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Mr. SOUDER. I want to point out, Mexico is shipping incredible amounts of drugs into the United States where we do not have the assurances that we have from Canada. I have been back and forth on that legislation myself. We don't even know the Canadian pharmacies in the Internet are in Canada; all they have to have is an address shipping through Canada. This hearing was not to talk about what I would say is "let the buyer beware" type situations. In other words, if you want to buy on the Internet, you know you're taking a certain amount of risk; you cannot verify anything other than the shipping address. If you buy it in the flea markets, you have less protection. If you buy it from somebody selling out of the back end of a station wagon, you have different risks. You may save money, but you know you're taking somewhat "the buyer beware" if you want to do that.

What we're talking about in this hearing is going through legitimate structures where, in fact, the question is, if you believe in an FDA, if you believe in a Food and Drug Administration, do you then, if you're going to pay the price at the drug store, if you're going to pay the market price, are you then guaranteed? What reasonable guarantee do you have that it's safe?

Now everybody agrees that the bigger the price gap, the more people are going to cheat. But in this subcommittee, we have heard in all different types of testimony, for example, people in confiscated products will do this at a $4 gap if they can get enough quantity or even in a small time operator. Furthermore, copyright law does in fact matter in the United States, and the record should show that my good friend from Minnesota is incorrect in mildly encouraging industries, saying, look, as long as it's the same CD, as long as it's the same, quite frankly, Spam, it does in fact matter whether somebody stole the Spam label and sells the same quality spam, which is made in my colleague's district, sells that for the same thing. Yes, it's not a safety question then. Yes, it's not a question of whether or not somebody is going to die from it. But it is a question of copyright law.

Mr. GUTKNECHT. Mr. Chairman, I agree with that, and I believe in intellectual property rights, but this is a special class of products. Intel, for example, does not get the same protection for its intellectual property that the drug companies get. The drug companies are the only companies in the United States of America that get to control the product after the first customer. And if Intel decides to sell its chips in Japan for one-fifth of what they're selling them in the United States, distributors in the United States could buy them from the Japanese.

Mr. SOUDER. Reclaiming my time. That does not give nor should we encourage anybody to violate the national intellectual property rights or claim that those things aren't—in other words, the criteria isn't, look, as long as it's a good counterfeit, it's OK, and that we don't like this particular law, so it's OK. I mean, if you want to change the law, fine.

Mr. GUTKNECHT. Mr. Chairman, that was not my point. I do not encourage people to break the law or take illegal drugs, OK. All I'm saying is that when we talk about counterfeit drugs, we're not always talking about people being actually harmed, but the price dif-

ferential is encouraging more and more arbitrage and more and more illegal activity.

Mr. SOUDER. People aren't harmed on counterfeit dollar bills.

Mr. GUTKNECHT. We have an FDA that has turned the other way on the technology that exists today. Instead of doing what their job is of coming up with technologies, they have gone out chasing little old ladies who are trying to save money on Tamoxifin.

Mr. SOUDER. I'm sorry, that is not the evidence that we heard today. That is a claim that is not the evidence we heard of the 56 cases of the people we're hearing in this that they're chasing, trying to figure out how to make the American supply safe. Also, as I raised in my opening testimony, which we'll get into more in the third panel, the fact is that as we look at the flu shots that are about to come up, we have a huge problem if that starts to go into counterfeiting and trying to vaccinate on Asian flu virus or Anthrax, where we have terrorism questions and other types of questions in the United States. Do we believe in the Food and Drug Administration or not? That is the legitimate question. The international question, buying on the Internet, the internationalization of this is a separate question and a difficult part of this. The pricing question and the pharmaceutical companies is also a difficult part of this. The fact is, our focus is on counterfeiting in the United States and how this relates not only to the terrible tragedies that have happened to your families but what in fact could really become a huge question as we deal with terrorism, borders and other types of questions. As I have pointed out earlier, as we're trying to do the regulations that we're trying to do here, they are very similar to the types of controls that we're having on how we address pseudoephedrine and methamphetamine. I have been immersed up to my head, but it's a question whether it comes across the border, India and China producing it, paper tracking or computer tracking, is it going to be in pill form? We deal with this type of thing all the time in this subcommittee and other places. What we haven't dealt with is this particular type, and I appreciate your willingness to come forward today and to speak out, and hopefully, we can if not move some legislation at least get FDA to get the initial steps in that they should have, in my opinion, done some time ago.

Thank you very much for coming, and we'll now move to the third panel. The third panel consists of Mr. Peter Pitts, Center for Medicines in the Public Interest; Mr. Carmen Catizone, executive director of the National Association of Boards of Pharmacy; Jim Dahl, former Assistant Director of Investigations, FDA Office of Criminal Investigations; and Mr. Donald DeKieffer, DeKieffer & Horgan. I thank you all for coming and if you will stand, I can swear you in.

[Witnesses sworn.]

Mr. SOUDER. Let the record show that each of the witnesses responded in the affirmative.

Thank you for your patience during this hearing, and we'll start with Mr. Pitts.

STATEMENTS OF PETER J. PITTS, DIRECTOR, CENTER FOR MEDICINES IN THE PUBLIC INTEREST; CARMEN CATIZONE, EXECUTIVE DIRECTOR, NATIONAL ASSOCIATION OF BOARDS OF PHARMACY; JIM DAHL, FORMER ASSISTANT DIRECTOR OF INVESTIGATIONS, FDA OFFICE OF CRIMINAL INVESTIGATIONS; AND DONALD DEKIEFFER, DEKIEFFER & HORGAN

STATEMENT OF PETER J. PITTS

Mr. PITTS. Good afternoon. My name is Peter Pitts, and I'm the senior fellow for healthcare at Pacific Research Institute and director of the Center for Medicines in the Public Interest. I'm also former Associate Commissioner of the Food and Drug Administration, also a 10-year resident of Indianapolis. Nice being on a Hoosier-based committee.

I'd like to thank the committee and Mr. Chairman for giving me an opportunity to testify on the urgent and national problem of prescription drug counterfeiting. The business of creating, distributing and selling counterfeit pharmaceutical products is a criminal and growing part of the global economy. When asked why he robbed banks, Willie Sutton replied, because that's where the money is. If Sutton were alive today, he'd be selling counterfeit prescription drugs.

The bad news is that international prescription drug counterfeit is on the rise. I estimate, by 2010, counterfeit pharmaceutical commerce will become 16 percent of the total size of the legitimate global pharmaceutical industry, a 6 percentage-point increase from 2004. This illegal business will generate $75 billion in revenue for its owners in 2010, a 92 percent increase from today.

Consider this, the growth in counterfeit drugs is out pacing the sale of legitimate pharmaceuticals, and the Internet has become the 21st century's virtual drug cartel. The World Health Organization estimates between 8 and 10 percent of the global medicine supply chain is counterfeit, rising to 25 percent or higher in some countries, as already mentioned. The largest counterfeit market with close proximity to the EU, the European Union Free Trade Zone, is Russia, with a generally accepted estimate at 12 percent of drugs are counterfeit.

Now that the Baltic nations of Latvia, Lithuania and Estonia have joined the European Union, WHO has warned an increase in the risk of counterfeits entering the supply chain is "obvious." Two news items recently crossed the wires that illustrate this problem and its truly global nature. The first story from China tells of 11 Chinese nationals and 1 American invested in a counterfeit medicine scheme that spanned 11 countries, 440,000 bogus pills and $4.3 million U.S. dollars. The drugs were Lipitor, Viagra, Cealis and Levitra. The nations involved were the United States, Great Britain, Switzerland and Israel. The second frightening news item comes from Hamilton, Ontario, where a registered pharmacist was charged by Canadian Federal authorities with selling counterfeit Norvasc heart medication after five customers who bought it died of heart attacks and strokes. The Royal Canadian Mounted Police announced multiple investigations remain open in other parts of the country.

Attention must be paid to this very serious global problem because it is nothing short of international healthcare terrorism. I just returned from Europe, and they've got a lot of problems over there. One of them is that profiteers masquerading as pharmacists are selling unsafe, unregulated, mislabeled, repacked and commingled drugs to unsuspecting consumers. In Europe, the cause of this is known as parallel trade, and it's bad medicine. According to the Treaty of Rome, parallel trade is completely legal, and articles 30 and 36 prohibit manufacturers from managing their European supply chains in their own patients' interests. Counterfeiters are taking advantage of this opportunity. For example, in 2002, the wholesaler in the Basel region of Switzerland was caught selling repackaged drugs to Germany worth about 23 million Swiss francs, about $18 million U.S. dollars, and 2 years later, Swiss customs seized HIV medications stolen from a batch sent to Africa by the World Health Organization.

Swiss Medic, which is Switzerland's FDA, is also concerned about the quantity of fake drugs available on the Internet. According to the Swiss authorities, there are 15 big cases in Europe right now, and, "there is big money involved." Last year, 140 million individual drug packages were parallel imported throughout the European Union, and a wholesaler repackaged each and every one of those 140 million packages. This means that literally parallel traders open 140 million packets of drugs, remove the contents and repackage them.

But these parallel profiteers are not in the—they are strictly in the money-making business, not in the safety business, and mistakes happen. For example, new labels incorrectly state the dosage strength. The new label says the box contains tablets, but inside are capsules. The expiration dates and batch numbers on the medicine box don't match the medicines inside, and patient information is often in the wrong language or out of date. Drugs purchased from a British pharmacy and sent to an unknowing American consumer could come from the European Union from nations such as Greece, Latvia, Poland, Estonia. In fact, parallel traded medicines account for about 20 percent, one in five, of all prescriptions filled by British pharmacies. In the EU, there is no requirement to record the batch numbers of parallel imported medicine, so if a batch of medicine originally intended for sale in Greece is recalled, tracing where the entire batch has gone for example from Athens to London through Canada and Indianapolis is impossible.

"Buyer beware" is bad health care practice and even worse health care policy. Safety cannot be compromised, even if the truth is inconvenient. Facts are stubborn things, and false profits result in deadly consequences. Thank you.

[The prepared statement of Mr. Pitts follows:]

21ST Century International Drug Terrorism
Testimony by CMPI Director, Peter J. Pitts, to the Government Reform Committee Subcommittee on Criminal Justice, Drug Policy and Human Resources, November 1, 2005

The business of creating, distributing and selling counterfeit pharmaceutical products is an unregulated, criminal and growing part of the global economy.

When asked why he robbed banks, Willy Sutton, the depression-era desperado replied, "because that's where the money is." And if Sutton were alive today he'd be selling counterfeit prescription drugs. The bad news is that international prescription drug counterfeiting is on the rise. I estimate that globally, counterfeit pharmaceutical commerce will grow to become 16% of the aggregate size of the legitimate industry, a six percentage-point increase from 2004. This illegal business will generate $75 billion in revenues for its owners in 2010, a 92% increase from 2005. Consider this – the growth in counterfeit drugs is outpacing the sale of legitimate pharmaceuticals and the Internet is becoming the 21st Century's virtual drug cartel.

The World Health Organization (WHO) estimates that 8-10% of the global medicine supply chain is counterfeit – rising to 25% or higher in some countries. The largest counterfeit market with close proximity to the EU free trade zone is Russia, where the generally accepted estimate is that 12% of drugs are counterfeit. Now that the Baltic nations of Latvia, Lithuania, and Estonia have joined the European Union, WHO has warned that an increase in the risks of counterfeits entering the EU supply chain is "obvious."
Two news items recently crossed the wires that illustrate this growing problem — and its truly global nature. The first story, from China, tells of eleven Chinese nationals and one American arrested in a counterfeit medicine scheme that spanned eleven countries, 440,000 bogus pills and $4.3 million US dollars. The drugs being peddled were Lipitor, Viagra, Cialis and Levitra. The nations involved were the US, Great Britain, Switzerland and Israel. The second, more frightening news item comes from Hamilton, Ontario where a registered pharmacist, Abadir Nasr, was charged by Canadian federal authorities with selling counterfeit Norvasc heart medication after five customers who bought it died of heart attacks and strokes. Meanwhile. the Royal Canadian Mounted Police announced multiple investigations remain open in other parts of the country. Attention must be paid to this very serious global problem because it is nothing short of international health care terrorism.

I've just returned from Europe and they've got a lot of problems over there. One of them is that profiteers masquerading as pharmacists are selling unsafe, unregulated, mislabeled, repacked, and co-mingled drugs to unsuspecting consumers. In Europe the cause of this malaise is known as parallel trade -- and it's bad medicine.

According to the Treaty of Rome, parallel trade is completely legal and Articles 30 and 36 prohibit manufacturers from managing their European supply chains in their own or patients' interests. And counterfeiters are taking advantage of the opportunuity.

For example, in 2002 a wholesaler in the Basel region was caught selling repackaged drugs to Germany worth SFr23 million ($18 million). And two years later Swiss customs seized HIV medicines that had been stolen from a batch sent to Africa by the World Health Organization. Swissmedic, Switzerland's FDA, is also concerned about the quantity of fake drugs available on the Internet. According to the Swiss authorities there are 15 big cases in Europe right now, and "There is big money involved."

Last year 140 million individual drug packages were parallel imported throughout the European Union -- and a wholesaler repackaged each and every one. This means that, literally, parallel traders open 140 million packets of drugs, remove their contents and repackage them. But these parallel profiteers are in the moneymaking business, not the safety business. And mistakes happen. For example, new labels incorrectly state the dosage strength; the new label says the box contains tablets, but inside are capsules; the expiration date and batch numbers on the medicine boxes don't match the actual batch and dates of expiration of the medicines inside; and patient information materials are often in the wrong language or are out of date.

Drugs purchased from a British pharmacy and sent to an unknowing American consumer could come from European Union nations such as Greece, Latvia, Poland, Malta, Cyprus, or Estonia. In fact, parallel traded medicines account for about 20% (one in five) of all prescriptions filled by British pharmacies. In the EU there is no requirement to record the batch numbers of parallel imported medicines, so if a batch of medicines originally intended for sale in Greece is recalled, tracing where the entire batch has gone (for example, from Athens to London through Canada to Indianapolis) is impossible. Caveat Emptor is bad health care practice and even worse health care policy. Safety cannot be compromised, even if the truth is inconvenient. Facts are stubborn things and false profits result in deadly consequences.

Thank you

Mr. SOUDER. Our second witness is Carmen Catizone.

Thank you for coming today.

STATEMENT OF CARMEN CATIZONE

Mr. CATIZONE. Thank you, Mr. Chairman.

Thank you, Mr. Chairman, and members of the subcommittee. We've submitted written comments, and I'd like to vary from that testimony to address some of the issues that have been raised earlier by Representatives. First of all, as the association represents State agencies, we are not opposed to Federal legislation. We're willing to work with the industry in developing effective Federal legislation. Even though Federal preemption concerns the State agencies, we believe there's probably a compromise that can be worked.

I want to point out the State of Indiana recently enacted legislation and regulation that addresses many of the concerns that the Representatives raise today. It provides for accountability of the wholesalers. It provides for accreditation of those wholesalers to verify they are legitimate, engaging in legitimate business operations. Contrary to the criticism of the State regulations that are being enacted and passed, I would say there is more similarity than dissimilarity among the State regulations.

What I would ask the subcommittee to consider, though, is in enacting any Federal legislation to not be lulled by the promise that Federal legislation will cure everything. We've been waiting 17 years not for the FDA to implement the pedigree standards but for the industry to agree to those standards which they fought and stayed for the past 17 years. If the industry does not want to put forth an earnest effort to enact effective legislation that's been enacted in Florida, California and most notably Indiana, we ask you not to support that legislation but support what the States are doing one by one to try to create uniform legislation across the country.

In regard to pedigrees, the issue of counterfeit drugs can be resolved quickly by tracing that product from the manufacturer, through the wholesaler, through the pharmacy. Again, the industry has fought the pedigree requirements tooth and nail. In the States, where we've enacted requirements to say, "Let us use pedigree requirements," the industry has said, "It's too costly." When the States have said, "We'll rely on RFID policy and trace and track technology and implement that as technologies develop," industry has said, "Technology will be available until 2011 and we can't wait that long." When we've said, "Let's implement this process through a paper and electronic transition," the industry fought that also. We've tried to work with the industry in implementing what is normal distribution, what restricts the product from secondary markets, what tracks that product from the wholesalers, manufacturers to the pharmacy, and we have not received the cooperation that we think is needed from the industry. So the chip which Representative Gutknecht says is available, we know it's available, all you have to do is talk to people in Florida and California about the resistance the industry is giving them to implementing these programs, and you'll see that unless the industry is forthright in Federal legislation, all we're going to do is stop the momentum that

the States have created and put another staying process in place that could last another 17 years.

At MEP, the association that represents State agencies has revised final rules for the licensure of wholesale distributors to assist States in State licensure and regulation of wholesale distributors. We've created and maintained a national specified list of susceptible drug products to identify products that have been counterfeited or are likely to be counterfeited. We've made operational the Verified Accredited Wholesale Distributor Program, which is now required by Indiana and by default has set a national standard for the licensure and accreditation of wholesale distributors because very few wholesalers operate only in Indiana. Wholesalers that are licensed in Indiana, which number 600, are doing business interstate, and those wholesalers that have applied for our accreditation to date have been very happy with the process and very complimentary of the State of Indiana and the process put in place.

In fact, we will probably conclude some investigations and inspections this week of wholesalers who applied for accreditation, and that accreditation includes criminal background checks, authentication, due process, pedigree requirements, everything that people this afternoon discussed that's being necessary to protect the Nation's drug supply. We consider the problem of counterfeit drugs a significant concern that must be addressed.

The present regulatory safeguards which have been changed in response to FDA's report on counterfeit drugs require additional resources and support from State and Federal legislatures to ensure that the U.S. medication distribution system is not compromised. The cooperation among the States and the FDA is critical for the success of any effort to maintain the integrity and security of the U.S. medication distribution system. The collaboration between the FDA and ABP and the State boards of pharmacy to combat the threat of counterfeit drugs has been growing and increasing and needs to continue to grow and increase as new challenges are faced and new strategies are developed. If we do not have that support and that cooperation and the U.S. medication distribution system is compromised by counterfeit drugs, then Federal and State agencies will be powerless to create a situation where citizens will be protected. If that situation occurs, no one will be protected and no one will be safe. Thank you.

[The prepared statement of Mr. Catizone follows:]

Testimony Before the
Committee on Government Reform
Subcommittee on Criminal Justice, Drug Policy and Human Resources
Sick Crime: Counterfeit Drugs in the United States
November 1, 2005

Presented by:
Carmen Catizone, M.S., R.Ph. D.Ph.
Executive Director
National Association of Boards of Pharmacy

Mr. Chairman and Members of the Subcommittee:

I am honored to be here today and discuss with you the growing concern with counterfeit drugs and the threat these products pose to the integrity and validity of the Nation's medication distribution system.

The National Association of Boards of Pharmacy (NABP), which I represent, was founded in 1904. Our members are the pharmacy regulatory and licensing jurisdictions in the United States, District of Columbia, Guam, Puerto Rico, and the Virgin Islands, eight provinces of Canada, three Australian States, New Zealand, and South Africa. Our purpose is to serve as the independent, international, and impartial Association that assists states and provinces in developing, implementing, and enforcing uniform standards for the purpose of protecting the public health.
Testimony

THE PROBLEM OF COUNTERFEIT DRUGS

Reports from the Food and Drug Administration (FDA) and World Health Organization (WHO) estimate that the incidence of counterfeit drugs is a growing concern. Although the US medication distribution system remains safe and secure, the challenges federal and state regulators face to maintain its safety and security are significant. Further complicating this public health crisis are the illegal importation of drugs, continued erosion of state and national borders, and a complete disregard for US federal and state laws by those entities engaged in the production and distribution of counterfeit drugs.
For state boards of pharmacy, constitutionally charged with regulating an ever changing and more complex practice of pharmacy with diminishing resources, the situation is at times critical. It is a situation exacerbated by the reckless actions of local and state public officials and governments who ignore public health and safety in order to promote the illegal importation of drugs. Maintaining the security and integrity of the US medication distribution system will not be an easy task. More importantly, if the US medication distribution system is compromised by the influx of illegally imported products then state and federal regulators will be powerless to protect US consumers from the dire situation of a medication distribution system that cannot provide legitimate medications to its patients. If this situation occurs, no one will be protected, no one will be safe.

The estimates of the prevalence of counterfeit drugs released from the WHO and FDA vary from country to country but sound a similar concern. The concern is quite alarming particularly when the estimates of counterfeit drugs range as high as 40 – 60% for some African, Latin, and South East Asian countries. "The FDA believes that counterfeiting is not widespread within the system of manufacturing and distributing pharmaceuticals legally in the United States, as a result of an extensive system of federal and state regulatory oversight and steps to prevent counterfeiting undertaken by drug manufacturers, distributors, and pharmacies. However, the agency has recently seen an increase in counterfeiting activities as well as increased sophistication in the methods used to introduce finished dosage form counterfeits into the otherwise legitimate U.S. drug distribution system. FDA counterfeit drug investigations have increased to over 20 per year

since 2000, after averaging only 5 per year through the late 1990's. Increasingly, these investigations have involved well-organized criminal operations that seek to introduce finished drug products that may closely resemble legitimate drugs yet may contain only inactive ingredients, incorrect ingredients, improper dosages, sub-potent or super-potent ingredients, or be contaminated. Thus, drug counterfeiting poses real public health and safety concerns today, and may pose an even greater threat in the future if we fail to take preventative measures now. As counterfeiters continue to seek out new technologies to make deceptive products and introduce them into legitimate commerce, our systems for protecting patients must respond effectively."[1]

In a presentation to the Drug Information Association in Ottawa Canada in November of 2003, then Commissioner McClellan noted that, "we're facing more serious international threats from criminals and profiteers who are trying to make a fast buck by going where the money is – which increasingly means prescription drugs and other medical products. We're seeing international counterfeit drug operations that are increasingly sophisticated and criminal networks that are better organized than ever before."[2] Information contained on the FDA web site illustrates the complexity of this issue and the ability of counterfeiters to duplicate products and product packaging. For the unknowing and unsuspecting patient, detecting counterfeit drugs is for all practical purposes impossible.

NABP MONITORING AND FINDINGS

Internet Drug Buys

NABP and the state and federal regulatory communities continue to focus on the public health hazards of counterfeit and adulterated drugs entering the US distribution system. These medications often reach US consumers when a patient orders the drug from a Web site, sometimes one alleging to be a US or Canadian site or allegedly connected with the US or Canada, in order to increase consumer confidence. Since 2004, NABP has participated in several high profile Internet drug buy projects in order to illustrate the ready access consumers have to medications that should only be prescribed and monitored by a physician and the perils they face when ordering such products online.

Controlled Substances and Isotretinoin

In December 2003 and January 2004, NABP in conjunction with a team from Dateline NBC purchased eight (8) different drugs from five (5) suspicious Internet pharmacy sites to demonstrate the ease with which dangerous drugs can be purchased without a prescription. Disturbingly, none of the drugs NABP received appeared to be shipped from the country in which the pharmacy Web site was registered and all of the drugs were labeled in a foreign language. The site offering Roaccutane® shipped the drug without proof of pregnancy testing or

[1] Food and Drug Administration, COMBATING COUNTERFEIT DRUGS: A Report of the Food and Drug Administration, February 2004.

[2] McClellan, Mark B. Speech before the Drug Information Association. November 18, 2003, Ottawa, Canada.

other evidence to determine if the therapy was appropriate, as is required by the US Food and Drug Administration (FDA) and legitimate medical practice.

After receiving the drugs, NABP sent the following items to the United States Pharmacopeia (USP) for identification testing:

- "Valium® 10 Roche, Tabletten Wirkstoff: Diazepam" (10 mg, #90 tablets)
- "Alprazolam Normon 1 mg Comprimidos EFG" (#30)
- "Codeisan" (30 mg, #40 tablets)
- "Roaccutane® isotretinoin 10 mg" (#30 capsules)
- "Testabol Depot® Testosterone Cypionate 10 ml For Intramuscular Injection" (4 x 10 ml vials, 200 mg/ml)

USP assays found that four out of the five drugs NABP submitted for testing contained the correct and appropriate amount of the active ingredient; however, two vials of the testosterone failed the USP's specification for potency (they only contained half of the dosage) and viscosity. These results indicated that one in five patients could receive drugs that are not full strength. It is important to note that USP performed limited testing; several other tests that could uncover potential dangers to patient health were not performed, including tests for contaminants resulting from preparation or poor packaging.

Anabolic Steroids

Over a four-week period beginning October 18, 2004, NABP covertly monitored several eBay auctions and purchased four products that were purported to be anabolic steroids. All four products were shipped from different sellers located within the US without the requirement of a prescription. One product was unique because it was advertised on eBay as a "Book of Test Propionate Sustanon" with the explanation that it was a "10 chapter unopened book" of useful information on testosterone propionate 100 mg.

NABP worked with MSNBC to have all of the products sent to an independent laboratory for analysis. None of the four products contained exactly what was expected. Error attributable to analytical factors, such as extraction efficiency or yield, is most likely to blame for the inconsistency in three of the samples. It is likely that these three products are the actual pharmaceutical products they claim to be. However, the fourth sample, which claims to be Sustanon 250 by Organon, is potentially a counterfeit product because the differences between the expected and actual contents fall outside the normal error ranges.

As a result of NABP's investigation, eBay tightened its rules and its monitoring process to eliminate the illegal sales of steroids on its Web site.

Similare Drugs

In late 2004, NABP accepted a request from the pharmaceutical manufacturer, Eli Lilly, and FDA to evaluate Web sites that were allegedly selling prescription drugs that purported to be brand name medications or "similare" medications that claimed to be similar to or identical to their brand name counterparts, but, in fact, may have been subject to little or no testing or regulatory oversight. *Similares* are available in countries all over the world, particularly in Latin

America, and are considered in many countries outside the US as legal and inexpensive alternatives to patented drugs. Further, these *similares* are threatening to enter or may already have entered the US drug distribution system through the Internet and other sources.

NABP ordered several different medications including Cialis®, Evista®, and Zyprexa® from a total of 13 Web sites. No prescriptions were required by the sites. FDA performed an analysis of the submitted medications; two, in particular, were highly suspicious. Some of the sampled drugs far exceeded the level of allowed in the US medication. The amount of active ingredient present varied widely, and in at least one case, Fenilox (the "generic Evista"), no active ingredient was present. In addition, Lilly, the manufacturer of these drugs, performed a regulatory analysis on the products obtained by NABP and found that several were in fact *similares* and did not meet the company's US standards.

In May 2005, FDA issued a consumer advisory referencing the Evista that NABP purchased in addition to FDA's results from comparable tests on counterfeit versions of Lipitor® and Viagra® that were purchased in border towns of Mexico. Like the Evista *similare* in the NABP project, neither the counterfeit Lipitor nor the counterfeit Viagra contained any active ingredient.

NABP's findings of the availability of, and increasing occurrences of counterfeit drugs are troubling and concur with the findings of the FDA Task Force on Counterfeit Drugs.

VIPPS

Since 1999, NABP has successfully operated the Verified Internet Pharmacy Practice Sites™ (VIPPS®) accreditation program. VIPPS was developed in response to public concern about the safety of pharmacy practices on the Internet. A coalition of state and federal regulatory associations, professional associations, and consumer advocacy groups provided their expertise in developing the criteria which VIPPS-accredited pharmacies follow.

To be VIPPS accredited, a pharmacy must comply with the licensing and inspection requirements of its home state and each state to which it dispenses prescription drugs. In addition, pharmacies displaying the VIPPS seal have successfully completed the VIPPS licensure verification process, an on-site inspection, and have demonstrated to NABP compliance with VIPPS criteria including patient rights to privacy, authentication and security of prescription orders, adherence to a recognized quality assurance practices, and provision of meaningful consultation between patients and pharmacists.

NABP'S RESPONSE TO THE FDA'S TASK FORCE ON COUNTERFEIT DRUGS

The FDA is to be commended for its excellent report and efforts to combat counterfeit drugs. NABP strongly supports the recommendations of the FDA Task Force and is collaborating closely with FDA Officials to implement the Task Force's recommendations.

Specifically, NABP has revised its Model Rules for the Licensure of Wholesale Distributors (Attachment A) to assist states in revising requirements for state licensure and regulation of wholesale distributors, created and maintains a National Specified List of Susceptible Drug Products (Attachment B), has made operational its Verified-Accredited Wholesale Distributors (VAWD) program to provide states with the resources to combat counterfeit drugs and adopt a national standard for the regulation of wholesale distributors engaged in intra and interstate commerce, and established uniform data field elements for electronic pedigrees (Attachment C). Each of these efforts coincides with recommendations from the FDA Task Force report and involves significant interaction and cooperation with the FDA and industry stakeholders.

NABP's VAWD Program

The Verified-Accredited Wholesale Distributors™ (VAWD™) program provides assurance that the wholesale distribution facility operates legitimately, is validly licensed in good standing, and is employing security and best practices for safely distributing prescription drugs from manufacturers to pharmacies and other institutions. Applicants for VAWD accreditation undergo a criteria compliance review, licensure verification, an inspection, background checks, and screening through NABP's Clearinghouse. NABP has established and will operate and administer inspection services for the VAWD program. Inspections and inspectors will be managed and contracted directly through NABP.

VAWD was established in 2004 to help protect the public from the threat of counterfeit drugs affecting the US drug supply. NABP began developing VAWD after FDA requested that the Association update its Model Rules for the Licensure of Wholesale Distributors, which is part of the Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy. Members of NABP's resulting Task Force on Counterfeit Drugs and Wholesale Distributors, held in October 2003, revised the Model Rules and proposed the creation of an accreditation program and clearinghouse for wholesale distributors – a plan that was immediately supported by FDA – to further combat counterfeit drugs.

The Model Rules for Licensure of Wholesale Distributors are just now being adopted by the states and NABP will take this into consideration as it evaluates applicants' documents and operations for purposes of VAWD accreditation. Bearing this in mind, provisional VAWD accreditation may be awarded to qualifying wholesale distributors. Throughout the creation of VAWD, NABP involved key stakeholders such as wholesale distributors, state boards of pharmacy, and other state and federal regulators to ensure that the program addresses the concerns of all interested parties.

CONCLUSIONS

NABP and the state boards of pharmacy consider the problem of counterfeit drugs a significant concern that must be addressed immediately and effectively. The present regulatory safeguards, which have been changed and strengthened in response to the FDA's Report on Counterfeit Drugs, require additional resources and support from state and federal legislatures to ensure that the US medication distribution system is not compromised. Adoption of NABP's Verified Internet Pharmacy Practice Sites (VIPPS) program, Model Rules for the Licensure of Wholesale Distributors and the Verified-Accredited Wholesale Distributors (VAWD) programs are necessary to provide uniformity across the states and to ensure that "safe-havens" are not created for those entities that will seek to avoid regulation and operate illegally.

The cooperation among the states and the FDA is also critical to the success of any effort to maintain the integrity and security of the US medication distribution system. The collaborations between the FDA, NABP, and the state boards of pharmacy to combat the threat of counterfeit drugs have been exemplary and continue to grow as new challenges are faced and new strategies developed. If state and federal regulatory agencies are supported by Congress in these efforts through increased resources and legislation, the efforts to maintain the integrity and security of the US medication distribution system will be successful. If however, the illegal importation of drugs is encouraged and not halted and the US medication distribution system opened to the vagaries and dangers of an international counterfeit and diversion network that has already compromised the medication distribution systems of other countries, then little can be done to protect US citizens from peril.

Thank you for the opportunity to present this information to the Subcommittee.

Mr. SOUDER. Thank you.
Mr. Dahl.

STATEMENT OF JAMES A. DAHL

Mr. DAHL. Mr. Chairman and members of the committee, thank you for the opportunity to testify today on this important issue.

I appear before you as a private citizen but one with considerable knowledge on this topic. I retired from the FDA Office of Criminal Investigations just 1 month ago today. In my brief remarks today and in my more thorough submission for the record, I hope to represent the interests and opinions of the 185 special agents of FDA's Office of Criminal Investigations who are the true experts on counterfeit drugs and related pharmaceutical crimes.

The wholesale drug distribution system in this country is easily corrupted through the introduction of diverted, stolen, misbranded, illegally repackaged, expired, previously dispensed, counterfeit or otherwise suspect drugs. Substandard, dangerous or unapproved and sometimes counterfeit drugs are frequently sold via largely anonymous and unregulated Web sites. Small parcels containing unknown, misbranded, unapproved and counterfeit drugs are flooding our borders. Couple all that with the possibility for terrorist exploitation of our vulnerabilities, and one can easily see we have an enormous problem on our hands.

So what should we do? First, fully implement the PDMA regulations requiring a pedigree on wholesale distribution of prescription drugs. Although the underlying law has some loopholes, the pedigree regulations as currently written would help control unscrupulous wholesalers and provide evidence and information useful to OCI in its criminal investigations. OCI has recommended to the greater FDA the full implementation of the pedigree rules since it was originally proposed in 1999, and it is now time for Congress and the American public to demand that the stay on those regulations be lifted.

Second, call for new legislation that would help OCI and others in their criminal investigations. I'd like to highlight just a few needs. Administrative subpoena authority for use by OCI agents in their felony investigations should be authorized. This is a very effective tool commonly used by a number of other agencies, including the IRS and the Bureau of Immigration and Customs Enforcement and every inspector general in the Government. If a HUD agent can use an administrative subpoena to collect documentary evidence concerning false statements on a mortgage application, I'm sure the American public would agree that an OCI special agent should be able to use a similar tool to gather evidence concerning criminal organizations that would deliver substandard or counterfeit drugs to an unsuspecting patient in a hospital.

Title 18 of the United States Code needs to be amended to make the Food, Drug and Cosmetic Act felonies predicate offenses under the racketeering statutes and specified unlawful activities for money laundering. Most offenses are committed for economic gain. OCI needs these tools to effectively attack the criminal enterprises that put public health at risk. In addition, Title 18 needs to be amended to allow upon conviction the direct forfeiture of the gross proceeds from felony violations of the Food, Drug and Cosmetic Act.

This not only helps punish the defendant for his illegal actions but is effective in dismantling the criminal enterprise that could otherwise continue to prey upon the public.

Title 21 of the U.S. Code needs to be amended to provide for higher maximum penalties for felony violations of the act. I would suggest that the penalties be linked to the actual or potential harm caused by the illegal conduct in a manner similar to that provided under the Federal Anti-Tampering Act. It does not make sense that a person risks up to a 10-year maximum sentence for counterfeiting a registered trademark but only up to 3 years for counterfeiting a drug.

Title 21 of the U.S. Code also needs to be amended to modernize and improve enforcement generally. For instance, the definition of what constitutes a counterfeit drug should be broadened. A provision making the attempted commission of a FD&C Act felony needs to be enacted. A sting provision needs to be included to improve on the effectiveness of undercover operations, and seizure laws at ports of entry need to be streamlined to allow efficient and effective seizures and disposition of violative products.

My third suggestion for dealing with counterfeit drugs and related pharmaceutical crime is one of resources. OCI's operational budget for fiscal year 2005 was only $3.96 million, yet at any given time during that year, OCI had an inventory of 800 to 900 open and active investigations, many addressing the priority issue spoken of today along with others involving such diverse and important matters as consumer product tampering, medical device crimes, false statements to the agencies, illegal trade in human tissue for transplant, adulterated biologics, etc. Yet it appears to me that OCI has become a victim of its own success. I believe OCI provides the agency with its biggest bang for buck yet it is being asked again to do more with less. OCI simply needs more operational funding and more people to adequately address the increasingly complex criminal cases that appear on the horizon each day.

Resources are always a sensitive issue, but the time has come that we must confront this crime problem with real solutions. As a start, a mere million dollars in operational funding, along with a couple dozen of fully funded FTE's would go a long way to addressing these issues. In conclusion, I would like to compliment the men and women of OCI and the U.S. attorneys offices around the country for their continued dedication and resourcefulness in investigating and prosecuting pharma crime. Every day, they are out there doing interviews, conducting surveillance, testifying in courts and making arrests and much, much more. Without their continued good work, this country would be facing even greater problems.

I also believe that we need to remember that FDA's overall mission is extremely important and complex, but the problem of criminal attacks against the pharmaceuticals we all rely on cannot be solved with a status quo Office of Criminal Investigations. The FDA must confront drug counterfeiting as a law enforcement problem. It must continue to seek and seriously consider advice from the true experts within and outside the agency and adopt a political will to provide law enforcement with the tools and resources it needs.

[The prepared statement of Mr. Dahl follows:]

Written Statement of James A. Dahl

SUBMITTED TO THE COMMITTEE ON GOVERNMENT REFORM

SUBCOMMITTEE ON CRIMINAL JUSTICE, DRUG POLICY AND HUMAN RESOURCES

UNITED STATES HOUSE OF REPRESENTATIVES

November 1, 2005

Mr. Chairman and members of the committee, thank you for the opportunity to testify today on this important issue. I appear before you as a private citizen, but one with considerable knowledge on this topic. In my remarks today and in my submission for the record I hope to represent the interests and opinions of the 185 special agents of the FDA Office of Criminal Investigations who are the true experts on counterfeit drugs and related pharmaceutical crime.

I would like to first comment on the scope of the problem. Too often some tend to isolate the issue of counterfeit drugs from the broader but related range of pharmaceutical crime which includes wholesale and street level diversion schemes, illicit internet sales, and an enormous influx of foreign small parcel shipments containing unapproved, misbranded, adulterated, and/or counterfeit drugs (or components thereof). All of these issues are related, and all present significant public health concerns.

That said, I believe the most serious threat to unsuspecting patients today is the corruption of what should be, but is not, a highly regulated pharmaceutical supply chain. In fact our drug distribution network is being corrupted through the introduction of counterfeit and diverted prescription drug products. As I try to recall the myriad of counterfeit drug cases over the years I cannot think of a single case in which counterfeit products entered the "legitimate" marketplace without the aid of an existing diversion infrastructure. Couple that with the fact these illicit diversion networks not only distribute drugs obtained by fraud, but also traffic in drugs which are misbranded, stolen, expired, previously dispensed, illegally re-packaged, or otherwise suspect, and you can see we have a huge problem on our hands – a problem that endangers every American consumer.

The availability of drugs from unregulated and virtually anonymous foreign and at times domestic internet sites also presents an unacceptable level of risk. Small foreign originating parcels arriving via commercial carriers and the mail give criminal distribution organizations a smooth flow of inventory, with little chance of significant interruption, and even less risk of criminal prosecution.

I do want to praise those states that, despite a lack of any significant federal leadership on this issue, have moved forward with new laws to regulate wholesale drug distribution. In particular I applaud the efforts of the NABP and its Model Act, which promotes the more secure wholesale distribution of prescription drugs.

The problems described above become even more alarming when one considers something that OCI has always said - drugs are at least as susceptible to terrorist attack as foods. Yet the resources directed to food security within the FDA and throughout government are significantly disproportionate from those devoted to pharmaceuticals. Existing criminal infrastructures along with others continuing to be formed and the inherent weakness of our current distribution system certainly present opportunities for delivery of select agents to targeted patient populations. Such action could have a potentially catastrophic impact on public health and consumer confidence. Moreover, the huge illegal profits enjoyed by pharmaceutical crime organizations can be used to provide material support to terrorist organizations. We must increase the level of vigilance and resources in vulnerability analysis, threat assessment and criminal investigative response if we are to prevent such catastrophic events.

While the FDA and others primarily focus on public health awareness, suggestions for others, voluntary compliance, and published studies without formally calling for new legislation, the agency neglects some available regulatory options and an enhanced criminal enforcement approach that could provide better results.

So what should we do?

First, fully implement the PDMA regulations requiring a pedigree on wholesale transactions of prescription drugs (21 CFR 203.50). Although the underlying law has some loopholes that need attention, the pedigree regulations as currently written would help control unscrupulous wholesalers and would provide evidence and information useful to OCI in its criminal investigations. OCI has recommended full implementation of the pedigree rule ever since it was originally proposed in 1999. It is now time for Congress and the American public to demand that the stay on these regulations be lifted.

Second, enact new legislation that would assist OCI and others in their criminal investigations. I'd like to highlight just a few of the changes needed:

- Administrative subpoena authority for use by OCI agents in their felony investigations needs to be authorized. This is a very effective tool commonly used by a variety of other agencies including the IRS, Bureau of Immigration and Customs Enforcement (ICE), and every Inspector General in the federal government. OCI desperately needs to have such a tool at its disposal; a tool that would call only for the production of documentary evidence (and not testimony). If a HUD OIG agent can use an administrative subpoena to collect evidence of false statements on a mortgage application, I am sure the American public would agree that an OCI special agent should be able to use a similar tool to gather evidence concerning criminal organizations that would deliver substandard or counterfeit drugs to an unsuspecting patient in a hospital.
- Title 18 of the U.S. Code needs to be amended to make Food Drug and Cosmetic Act felonies predicate offenses under the racketeering statutes (18 USC 1961) and specified unlawful activities for money laundering (18 USC 1956). Most FD&C Act

offenses are committed for economic gain. Like so many other federal agencies OCI needs these tools to effectively attack the increasingly sophisticated criminal enterprises that put the public health at risk.

- In addition, Section 982 of Title 18 United States Code needs to be amended to allow upon conviction the direct forfeiture of the gross proceeds from felony violations of the FD&C Act. This not only helps punish the defendant for his illegal actions, but also aids in effectively dismantling the criminal enterprise that could otherwise continue to prey upon the public.
- Title 21 of the U.S. Code needs to be amended to provide for higher maximum penalties for felony violations of the FD&C Act. I would suggest that penalties be linked to the actual or potential harm caused by the illegal conduct in a manner similar to that provided under the Federal Anti-Tampering Act (18 USC 1365). It does not make sense that a person risks up to ten years in prison for counterfeiting a registered trademark (18 USC 2320), but only three years for counterfeiting a drug. On a related note OCI and the FDA Office of Chief Counsel have been working for several years to improve the sentencing guidelines for FD&C Act offenses. If new legislation is enacted it should include a provision calling for the U.S. Sentencing Commission to immediately consider increases in the sentencing guidelines for all FD&C Act felonies.
- Title 21 of the U.S. Code also needs to be amended to modernize and improve enforcement generally. For instance, the definition of what constitutes a counterfeit drug needs to be broadened; a provision making the "attempted" commission of FD&C Act felonies a crime needs to be enacted; a "sting" provision needs to be included to improve the effectiveness of undercover operations; and seizure laws at ports of entry need to be streamlined to allow the Bureau of Customs and Border Protection (CBP) and the FDA to efficiently and effectively seize and dispose of violative products.

My third suggestion for dealing with counterfeit drugs and related pharmaceutical crime is one of resources. OCI's operational budget (less salaries, benefits and real estate expenses) for FY 2005 was a paltry $3.96 million. Yet at any given time during fiscal year 2005 OCI had an inventory of approximately 800 to 900 open and active investigations, many addressing the priority issues spoken of today, along with others involving such diverse and important matters as consumer product tampering, drug application fraud, medical device crimes, false statements to the agency, illegal trade in human tissue for transplant, adulterated biologics, etc. Yet it appears to me that OCI has become a victim of its own success. I believe OCI provides the agency with its biggest bang for the buck, yet it is again being asked to do more with less. OCI simply needs more operational funding and more people to adequately address the increasingly complex and sophisticated criminal cases that appear on the horizon each day. For instance, an influx of appropriate resources through supplemental appropriation and/or re-deployment of existing FDA/HHS resources would allow OCI:

- To conduct a more thorough strategic and tactical analysis of the counterfeit drug, internet distribution, and drug importation problems,
- To place investigative analysts in field offices where they could directly assist working agents,

- To expand an international strategy that includes active participation in various law-enforcement conferences, training and meetings around the world; and to develop effective law enforcement relationships and strategies so that more prosecutions and preventative actions could be brought in foreign countries and in the U.S.
- To initiate a more proactive approach to addressing pharmaceutical crimes without a decrease in investigative capability
- To hire, train and deploy additional agents and support personnel throughout the country to more effectively confront the criminals of the 21st century.

Resources are always a sensitive issue, but the time has come that we must confront this crime problem with real solutions. As a start, a mere million dollars in operational funding along with a couple dozen fully funded FTEs would go a long way to addressing these issues.

In conclusion, I would like to publicly compliment the men and women of OCI and the United States Attorneys Offices around the country for their continued dedication and resourcefulness in investigating and prosecuting pharmaceutical crime. Every day they are out there doing interviews, recovering evidence, conducting surveillance, serving search warrants, seeking indictments, making arrests, testifying in court, and much much more. Without their continued good work this country would be facing even greater problems. I also believe we need to remember that FDA's overall mission is extremely important and at times overwhelmingly complex. But the problem of criminal attacks against the pharmaceuticals we all rely on cannot be solved with a status quo Office of Criminal Investigations. The FDA must confront drug counterfeiting and pharmaceutical crime as a law enforcement problem. It must continue to seek and seriously consider advice from the true experts within and outside the agency, and adopt a political will to provide law enforcement with the tools and resources needed for a solution.

Mr. SOUDER. Thank you.
Mr. DeKieffer.

STATEMENT OF DONALD DEKIEFFER

Mr. DEKIEFFER. Mr. Chairman, I'm going to depart from my prepared testimony to address some of the issues that have been raised in the hearing today.

As we've all heard, the counterfeit drug problem in the United States is very severe, and it's getting worse, but it's not as severe as it is in many other countries, including countries all over Europe. The European market right now has approximately five times the number of counterfeits that we do, so the mere fact that a country has lower drug prices does not mean it will have axiomatically lower counterfeits.

There are three major sources of counterfeit drug supplies in the United States though: cross border imports, the Internet and diversion. I really don't want to spend too much time on talking about the import question today. As you mentioned, Mr. Chairman, that's maybe a topic for another day. The Internet itself could take up hearings all by itself. The fact is, though, the diversion has been the source of all of the counterfeit drugs that have entered the legitimate drug supply chain in this country in the last 5 years. I'm not talking about drugs that are purchased over the Internet. I'm not talking about drugs that are purchased by people that are going to Mexico and bringing back drugs across the border, people that are buying in back alleys. I'm talking about people going to legitimate pharmacies expecting to get legitimate drugs. In every case that we've seen in the last 5 years that we've seen counterfeits, it's because of diversion.

Now in the case of the sources of diverted drugs and where do these come from, well, there are about seven major sources: samples, stolen products, re-imports, own-use pharmacy fraud, Medicare and Medicaid fraud, complicity and conspiracy with pharmaceutical representatives, and so-called surplus medications. Now the problem is the supply chain is not controlled by the manufacturers, and it's not supervised by any regulator nationally.

Now when we talked today, we used the words "the industry" in kind of an umbrella here. The drug supply going from the manufacturer to the retailer is not one industry; it's three and arguably up to five different industries. So each of these industries, if you will, has slightly different interests. So when we heard today that the industry opposes this particular proposal or the industry supports this particular approach, we have to be very careful in what industry specifically we're talking about.

The diversion pipeline itself, once you open that diversion pipeline, from one of the sources I mentioned, stolen products, re-imports, own-use pharmacy fraud, whatever, once the pipeline is opened to get into the legitimate supply chain, that is where all of the counterfeits that have entered that chain have gotten in. That's the way they get into the stores, the shelves of CVS and Rite Aid and that sort of thing. So if you attack diversion and cut that out, you reduce the likelihood to near zero of counterfeit drugs getting on legitimate pharmacy shelves.

Consumers themselves really are defenseless. They can't tell what legitimate packaging is or what it isn't because, as we know in this country anyway, we don't get drugs in packages; we get them in little amber bottles. Maybe there's an amber bottle producers association out there making sure they don't have packaging in anything else aside from an amber bottle. In Europe, as you pointed out, unit dose is ubiquitous and has been for the past 10 years. That creates some of its own problems, but by and large, they have had far fewer instances because of that packaging than we have. And that certainly is one of the things that can be done. Because the kinds of marketing that you're talking about, Congressman, RFID among others, as RFID is only one of the solutions, is much easier to do if you have packaging that actually reaches the pharmacist and ultimately the consumer. Right now, that entire process is in the middle of the supply chain.

Evidence is destroyed during the process of consumption, too, so there's no way that a consumer or even OCI can tell whether the incident of counterfeiting is increasing or not.

There are a number of solutions that I have recommended in my written statement. Let me just mention a couple more. One, I would like to underscore what Mr. Dahl said: We have fewer than 200 agents in FDA OCI as our defense against counterfeit drugs in the entire United States, with an operating budget of less than $3 million. Some gas stations have bigger operating budgets than that. It's a scandal and a disgrace. It is something not brought before this committee or I dare say any other committee before because the FDA budgetary process doesn't permit it.

The other recommendations that I have, though, are in my written testimony. I'd be more than happy to answer questions about them in the question and answer session, and I thank you again for the opportunity to testify.

[The prepared statement of Mr. DeKieffer follows:]

Statement of Donald deKieffer

DeKieffer & Horgan
Washington, D.C.

BEFORE THE COMMITTEE ON GOVERNMENT REFORM

SUBCOMMITTEE ON CRIMINAL JUSTICE, DRUG POLICY AND HUMAN RESOURCES

UNITED STATES HOUSE OF REPRESENTATIVES

November 1, 2005

The regulatory system upon which Americans have relied for over 50 years to assure a safe and effective drug supply is broken, and is rapidly becoming irrelevant. The massive influx of counterfeit and substandard drugs has simply overwhelmed the regulators – and rendered current laws and regulations farcical.

I do not say this for shock value. It is simply true. Few observers are in a position to discuss this matter dispassionately. The regulators themselves, of course, need to defend their turf and to hew to Administration policy. Pharmaceutical companies are reluctant to criticize their own regulators or in today's environment, almost anyone in the government. And the counterfeiters are hardly likely to seek an opportunity to appear before this committee.

The collapse of the barriers against counterfeits has been on the horizon for many years, but only in the past five has it seriously breached the regulatory levees. The U.S. is being flooded with fake drugs as I speak. It is uncertain whether the system can be repaired, or whether it will have to be entirely abandoned. As in the case of New Orleans, once a portion of the levee collapses, the balance of the dikes, while undamaged, become little more than quaint relics.

Counterfeits in the U.S. Drug supply

There are three major sources for counterfeit prescription drugs in the U.S.: "personal" imports, Diversion and the Internet. [i] The size of the counterfeit problem from these sources is impossible to measure with precision, but the evidence is overwhelming that the amount of bogus drugs in this country vastly exceeds the rather modest estimates of only a few years ago.[ii]

- In 2004, the FDA, Office of Criminal Investigation initiated 58 counterfeit drug investigations. In 2000, they opened only 6 cases. Their resources have not changed much in that period, just their workload.
- In 2000, fewer than two dozen people were indicted for dealing in counterfeit drugs. *Just so far* in 2005, more than 200 indictments have been handed up.

- In 2000, seizures of fake pharmaceuticals accounted for fewer than 100,000 doses. By 2004, more than 3 *million* fake medications were seized.[iii]
- Despite several high-profile busts in the past two years, Internet pharmacies have proliferated. More than 1000 sites offer prescription drugs *without a prescription or examination by a physician.*
- As Internet pharmacies have expanded, so has mail-order fulfillment of orders. Every day, over 100,000 packages arrive by U.S. mail from overseas pharmacies. Spot inspections of these shipments reveals that 88% if them are not in compliance with U.S. standards.[iv]
- "Personal" imports of pharmaceuticals, especially from Mexico, are essentially unregulated by any governmental authority. Because of this, a lively *commercial* trade has developed along the border through which millions of doses of fake drugs enter the U.S. market. [v]
- Terrorist threats to the U.S. pharmaceutical supply have been taken seriously by the FDA and terrorism experts. In several studies, counterfeit drugs were identified as a likely vehicle which could be used by terrorists to attack the United States. [vi]

"Personal Imports"

U.S. drug regulations currently permit the importation of prescription pharmaceuticals for the personal use of the traveler.[vii] These are nominally restricted to a 90-day supply. These restrictions are so seldom enforced, however, as to invite bulk importation of thousands of drugs purchased in Mexican Farmacias into the U.S. It is reliably estimated at up to 1/3 of these drugs are fakes.[viii] Although the practice of "personal imports" has been touted as a money-saving alternative to high drug costs in the United States, it has served as a superhighway for criminals profiting from the maladies of America's seniors.

Since 9/11, the Customs Service (CBP) has focused primarily on terrorist threats and controlled substance interdiction. Tourists carrying trunkfulls of prescription meds, however, are routinely waved through the border checkpoints. A considerable number of these "tourists" are in fact entrepreneurs who take ample advantage of the virtually non-existent enforcement to import huge caches of drugs which they distribute with impunity.

Diversion

Drug diversion is one of the principal methods by which counterfeits enter the legitimate market. The pharmaceutical supply chain is particularly vulnerable to this practice since it is not controlled or regulated by any single entity – private or governmental.

Unlike most products, manufacturers generally do not control drug distribution much beyond their loading docks. Drugs may go through a dozen or more middle-men's hands before they are finally consumed by a patient. Drugs intended for certain markets, such as African AIDS sufferers, for example, are routinely re-routed back to the U.S. and sold for much higher prices by greedy and cynical market manipulators. Once the supply chain is breached in this manner, it is a simple matter to substitute fake products for the clandestinely diverted legitimate goods. In fact, *every single case* of counterfeit drugs investigated by the FDA in the past five

years where the fakes were found in legitimate pharmacies has involved diversion as an entry point.

In other cases, diverters exploit the weaknesses in the supply chain by inserting drugs which have been acquired by fraud or simply stolen. These drugs are often relabeled with fake packaging and sold to unwary customers. This, for example, is what happened in the famous Lipitor case in which more than 50 people have now been implicated. Thousands of Americans ingested (or injected) these fakes, unaware of the tampering, sometimes suffering life-threatening (or ending) consequences.[ix]

While the government has arrested scores of people for this sort of activity, arrests to date represent a tiny fraction of the scams that are in play. Remember, these kinds of violations are not (or should not be) difficult to detect. The perpetrators are selling their goods in plain sight – not in some back alley. The problem is that the regulatory framework—and the resources necessary to make it work – are so antiquated and miniscule respectively as to make the law itself irrelevant.

It has been suggested that the diversion problem is being addressed by the wholesale distribution industry itself, as well as by improvements in state regulations. The problem, however, persists. The recent attention to the issue by the industry and state officials has resulted in a complex patchwork of regulations, self-imposed "standards" and conflicting laws. Ironically, this mosaic of rules has made the identification of counterfeit pharmaceuticals even more complex and difficult.

Internet

The growth of the Internet has spawned a new class of villain who preys on the weak and the vulnerable. Aside from the 17 or so Internet pharmacies certified by the VIPPS program, the vast majority of these are either highly questionable or downright criminal.[x]

The studies which have been made of Internet "prescribing" and fulfillment of orders are virtually unanimous in concluding that this activity is rife with fraud and the wholesale delivery of substandard and counterfeit drugs. Companies such as ICG of Princeton, NJ, track these pharmacies on an around-the-clock basis and can attest to the sinister and altogether illegal activities which are the norm in this industry.

Generally, Internet pharmacies ship orders to their customers through the U.S. mail or through such companies as FedEx, UPS and others. They collect payment through the same types of credit cards most of us carry every day. None of these "choke points" for the delivery of counterfeit medicine has been used by the government to interdict fake drugs. This is not because they could not do so. The FDA, for example, has conducted spot checks of mail facilities, and found massive evasion of their regulations in almost every package.[xi] There is no regulatory authority for the FDA or the CPB to merely return suspect packages to the sender, so millions of doses of potentially lethal drugs enter the U.S. under the very noses of law enforcement every day.

Remedial Measures

The choice facing the Congress in this matter is straightforward: either repair the obsolete laws and regulations that are failing, or abandon the pretense of protecting the American public from bogus drugs altogether. I certainly hope that the latter solution is not adopted, but it would be preferable to the charade of "enforcement" as it now exists.

What can be done? Several rather simple steps could be taken which would have an immense impact on the effectiveness of law enforcement to interdict counterfeit medications:

- Adopt "Pedigree" rules for Rx pharmaceuticals. The FDA proposed such rules more than ten years ago, but they *still* have not been adopted. [xii] Pedigree rules would enable law enforcement, manufacturers and retailers to confirm that counterfeit drugs had not entered the supply chain. The absence of pedigrees for drugs has enabled unscrupulous wholesalers to substitute fakes for legitimate products with near impunity.

- Adopt federal minimum standards for drug wholesalers. Although the FDA has elaborate rules for prescribing drugs, there are few federal requirements as to who may handle prescription medications in the supply chain – this issue is almost totally a matter of state regulation. In some states, even convicted felons are permitted to distribute huge quantities of drugs with only minimal oversight.[xiii] Rogue wholesalers have been largely responsible for the epidemic of counterfeit drugs entering the supply chain through the diversion "leaks" noted previously.

- Give the FDA power to require "prior approval" of drug repackagers to ensure that process does not compromise the quality of any drug. Drug repackagers should be subject to the same requirements regarding overt and covert counterfeit-resistant technologies as original manufacturers.

- Strictly enforce the PDMA restrictions on "personal use" imports.[xiv]

- Specifically authorize the FDA and CBP to return suspect drugs to the sender if they are detected during the screening process that is already in place in international mail facilities. Repeal any requirement that each shipment be individually tested. This measure will effectively shut down rogue offshore Internet "pharmacies", and is much more cost-effective than attempting to identify and prosecute the website operators.

- Require the CPB to notify the legitimate manufacturer within 5 days of a detention of suspected counterfeit drugs bearing their name or trademark.

- Grant the FDA Office of Criminal Investigation the authority to issue administrative subpoenas *at least* in drug or medical device counterfeiting investigations.[xv]

- Permit the FDA Office of Criminal Investigations to retain seized assets of drug counterfeiters, smugglers and diverters. Currently, such asset seizures are routed to the Justice Department's Assets Forfeiture Fund or the Treasury's General Fund.

- Require more explicit manifest requirements – including precise descriptions – of products subject to FDA oversight. Currently, only the most general descriptions are required on Customs forms. Counterfeits routinely slip by CPB because their descriptions are so generic.

- Increase penalties for drug counterfeiting including making such activities a *specific* predicate for both civil and criminal RICO charges. Treat Rx drug counterfeiters no less harshly than those convicted of dealing in controlled substances by increasing the maximum penalty for drug counterfeiting to 20 years..

- Require that the FDA (rather than merely CPB) be instructed by the U.S. International Trade Commission to enforce ITC orders in affirmative Section 337 cases that involving articles (including drugs) which fall under the jurisdiction of the FDA. [xvi]

- Apply the moiety provisions such as those of 19 U.S.C. § 1619 to drug counterfeiting cases whether or not the counterfeits were imported. This would expand the investigative reach of law enforcement almost overnight, without any net cost to the government.[xvii]

- Reallocate resources within the FDA to bolster the law enforcement functions of the agency. The FDA spends more than 20 times as much money on inspecting legitimate suppliers than it does on investigating blatant criminal conduct. This is akin to ticketing jaywalkers while a bank robbery is occurring 10 feet away.

I appreciate your attention and will be pleased to expand upon any subject mentioned in my remarks.

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[i] There are, of course, many counterfeit drugs offered on the black market and sold along with controlled substances. In these cases, however, consumers usually are aware that they are purchasing illicit substances. My remarks focus on counterfeit drugs sold to consumers who may have no reason to doubt that they are buying legitimate products.
[ii] In 2003, the World Health Organization and the FDA estimated that counterfeits made up 10% of the global medicines market and were present in both industrialized and developing nations. It was estimated that up to 25% of all medicines in developing countries are counterfeit or substandard. By last month (September) the WHO revised its estimates of counterfeit drugs in Europe *alone* to be 10% of the market – up from zero only a decade ago. I
[iii] Source: EDDI, Inc. Includes both federal and state seizures in the United States.
[iv] Statements of John M. Taylor III, Associate Commissioner for Regulatory Affairs, FDA before the Permanent Subcommittee on Investigations, Committee on Governmental Affairs, July 22, 2004 and Statement of William K. Hubbard, Senior Associate Commissioner for Policy, Planning and Legislation, FDA before the Subcommittee on Consumer Affaires, Foreign Commerce and Tourism, Senate Committee on Commerce, Science and Transportation, September 5, 2001.

[v] See e.g. Statement of Dr. Marv Shepard, College of Pharmacy, University of Texas before the Subcommittee on Health, Committee on Energy and Commerce, U.S. House of Representatives, July 25, 2002 and other publications by Dr. Shepard.

[vi] See, e.g An Analysis of Terrorist Threats to America's Medicine Supply, Global Options, Inc. 2003. In that year, the FDA formed two Working Groups for the evaluation of Counterfeiting and Tampering vulnerabilities and security solutions for foods, pharmaceuticals and biological products (Product Surety Task Forces). These were composed of industry representatives, government officials, and experts in product track/trace and authentication technologies. Their reports were submitted to the FDA in 2004.

[vii] The Food, Drug, and Cosmetic Act (21 U.S.C. 331) prohibits the interstate shipment of unaproved drugs inclduing drugs approved in the U.S. but manufactured abroad. In general, it is legal for US residents to import medications from outside the US provided the following conditions are met:

A) The product was purchased for personal use and does not exceed a 3 month supply.
B) The product is not for resale.
C) The intended use of the product is appropriately identified.
D) The patient seeking to import the product affirms in writing that it's for the patient's own use.
E) The patient provides the name and address of the doctor licensed in the U.S. responsible for his or her treatment with the product.
F) The medication is not a controlled substance, e.g. sleeping pills, Valium, narcotics. Etc.
These restrictions are seldom, if ever enforced.

[viii] See Note 4 Id.

[ix] The actual number of victims is unknown. This is because the counterfeits are extremely difficult to track and detect. In most cases, the evidence has been destroyed by the customer by the simple act of taking the drug. In others, ill effects have gone undiagnosed since the patient was ill in the first place, and failure to recover is one of the predictable consequences of life-threatening diseases – medications or no. Counterfeits are not suspected as a cause until it is too late, and then it is often impossible to prove the link.

[x] To be VIPPS (Verified Internet Pharmacy Practice Site) certified, a pharmacy must comply with the licensing and inspection requirements of their state and each state to which they dispense pharmaceuticals. In addition, pharmacies displaying the VIPPS seal have demonstrated to National Association of Boards of Pharmacy compliance with VIPPS criteria including patient rights to privacy, authentication and security of prescription orders, adherence to a recognized quality assurance policy, and provision of meaningful consultation between patients and pharmacists.

[xi] See Note 3 *supra*

[xii] In 1994, the FDA issued a proposed rule implementing the Prescription Drug Marketing Act (PDMA). In December, 1999 the Agency published final regulations in 21 CFR part 203 implementing the provisions of the PDMA. As of today, this rule has still not been implemented.

[xiii] Michael Carlow, for example, had previously been convicted on two occasions for dealing in controlled substances and violating numerous statutes concerning drug wholesaling, , but was able to secure controlling interest in numerous licensed pharmaceutical wholesalers in Florida. Dozens of similar instances have been documented in the past five years which can be provided to the Committee Staff upon request.

[xiv] See Note 5 *supra.*

[xv] Administrative subpoenas may already be issued in cases involving Federal health care offenses (18 U.S.C. 3486), but these subpoena powers are not available to the very agency charged with enforcing the law (i.e. the FDA).

[xvi] 19 U.S.C. 1337

[xvii] A moiety concept might be combined with the *qui tam* provisions of 31 U.S.C. §§ 3729-3733 to induce disclosures from insiders when any counterfeit drugs are directly *or indirectly* supplied under any government program.

Mr. SOUDER. Thank you all for your testimony.

One thing I have been confused about today is the multiplicity of possible conspiracies here. It's unclear to me who favors what. On the one hand, a couple of my colleagues are suggesting that this whole idea of counterfeit drugs is something that the pharmaceutical companies are proposing.

What I thought I heard Mr. Catizone imply was that there's a danger that—I thought you were saying that the pharmaceutical companies or others were opposing regulation. Is that what you were in effect saying?

Mr. CATIZONE. I need to clarify that. There's been opposition to different aspects of regulation. In regard to title control over the wholesale distributors, the pharmaceutical industry and particularly Pfizer has taken a lead role in this regard. But in regard to the chips and the RFID technology, there's some confusion as to which, in industry, support that and which don't. I think overall, in this instance, the manufacturers are very supportive because they want to protect their products and make sure the right products are reaching consumers. The wholesale industry is the one opposing the regulation that we've been pushing at the State level.

Mr. SOUDER. You're concerned that if Congress passes a bill, that the wholesale industry would weaken it so that it wouldn't be implemented and undermine strict State laws?

Mr. CATIZONE. That's one of our concerns. We've had recent discussion with the industry that's assured us this won't occur. But if you look at some of the facts and some of those that were in Katherine's books, the wholesale industry says this represents less than 1 percent of their business. They're going to stop doing business with the secondary markets. If that's the case, why is there so much resistance to any regulation?

Second, now that the States have gained momentum and are passing regulations and creating uniformity, why aren't they coming forth for Federal legislation? We've also not heard the wholesalers support Representative Israel's bill at the Federal level but want to introduce their own bill.

We have over 100 field investigators that are ready to inspect and soon will have over 200 ready to move in to any State at a moment's notice. We think that the industry realizes that the States have taken this seriously, and the States are not going to back down, and so now there's an attempt to say, let's try something federally to weaken what the States have done.

Mr. SOUDER. Mr. Dahl, how would you characterize the types of investigations you are doing? Would you say CSI? That's a TV show.

Mr. DAHL. OCI. We don't have a TV show yet.

Mr. SOUDER. If we give you that much money, you'll maybe have a TV show.

At OCI, were these—let me ask you two questions. Do you believe that the investigations were driven by the pharmaceutical companies' desire on the import question or do you believe that they're driven more by how we've had a rise in counterfeiting and the types of threats of counterfeiting? In other words, did you chase down people buying pills on the Internet because of the cost, or were you focusing on broader investigations that might have been

more threats to safety or a little bit of both, protecting international patents and so on and some of its safety questions? And then the second question I wanted you to take that one; it's a pretty big question.

Mr. DAHL. It's a little bit of both. Certainly, we had criminal investigations involving illegal Internet sales. There is no crime of selling drugs by the Internet, but if you sell a defective product, illegal product, you commit certain crimes. So certainly we have had criminal investigations there. We certainly have had some criminal investigations with small parcels and large parcels being smuggled in from foreign countries, and we certainly have had criminal investigations involving wholesale distribution of counterfeit or misbranded or stolen or illegally repackaged drugs. We have not had any criminal investigations on little old ladies crossing into Canada buying drugs. We are not focusing on that. We are not bringing cases like that.

Mr. SOUDER. Do you sense, and is there any peremptory type of looking at or should this be part of the variable of—I don't know how to say this. In other words, how would you prioritize investigations? One would suggest, if there's a big price gap, smuggling operations are going to occur, as well as high-risk terrorist type actions. Are we doing sampling on vaccinations or things that are vulnerable, a little bit more proactive rather than reactive? Are there some drugs where they become essential to life where an adulterated drug has a different threat than an aspirin, although any drug totally tampered with can be a threat? How would you address that, Mr. Dahl, and then Mr. DeKieffer?

Mr. DAHL. OCI prioritizes its investigations based on harm to individuals. The economic fraud that may be present is always secondary. We will always compromise a criminal investigation in favor of public health, and we certainly have announced recalls and recoveries of products and given public warnings that would have in another agency not been done because the investigation was still underway. But we can't afford to risk the public health. So whether it's a counterfeit drug, a medical device that could have a serious impact on an individual, tissue for transplant, whatever it might be, the blood supply, we're always going to prioritize the public health, and I don't think that will ever change.

Mr. CATIZONE. Mr. Chairman, if I can respond. The risk of drug products we've prepared is based on criteria that address the high price pharmaceuticals, so they will counterfeit Epogen and Procrit versus an Amoxicillin. They're also based on limited distribution, specialized patient care like HIV/AIDS patients. That list has been compiled based on the facts and based upon some of the concerns which other Representatives have raised today.

Mr. DEKIEFFER. One of the major issues is, I think, a misunderstanding about what is likely to be counterfeited. The higher-priced item will be counterfeited first; that's almost never the case. The product will be counterfeited first whether it's drugs or almost anything else where the margin is the greatest. In other words, the opportunity to make the greatest markup, No. 1, and No. 2, the likelihood of being caught is the lowest. In other words, the ease with which you can pass the product off and the margin you can make will be the magnets for counterfeiting in almost any circumstance,

and it's particularly true with drugs. When certain States, for example, Florida made up lists of drugs a few years ago with a little bit more than 30 drugs they wanted to look at most carefully. They really didn't pick drugs that were most likely to be counterfeited. They picked drugs that were the most likely to have some effect on people. I think a combination of those two approaches, one, the most likely to be counterfeited, and second, the drugs most likely to cause harm if they are, is the correct way to go about it.

Mr. PITTS. Mr. Chairman, to that point as well, the drugs that are most likely not to be counterfeited are drugs that are going to do extreme damage to the consumer because that's basically killing off the business. When you see drugs such as Viagra or antidepressants pills, they're the least likely to be reported, for obvious reasons. So I think you're looking for counterfeiters who are looking to make as big a margin as possible for as long as possible. This is not a one-shot operation; it's big business, and they want to be in business for a long time.

Mr. SOUDER. Mr. Burton.

Mr. BURTON. Do any of you represent the pharmaceutical industry?

Mr. DEKIEFFER. My law firm provides data to about 50 different companies, and among them some are in the pharmaceutical industry. We provide data on diverters and counterfeiters internationally, and among some of our clients are pharmaceutical companies. About a third of our clients are pharmaceutical companies.

Mr. PITTS. Pacific Research accepts funding from pharmaceutical companies, but I'm funded from general funding.

Mr. DAHL. I'm unemployed.

Mr. BURTON. You know, let's say we pass the legislation to which you referred, and it sounds like to me that there is some real merit in a number of the things that you brought up today. I think I've already asked for a copy of the Indiana statute, so we may look at that as a model for Federal legislation if necessary. But what I wanted to find out is let's say we pass everything that you say we ought to pass and it becomes law. How do you deal with the people that buy pharmaceutical products from Canada or Mexico or France or Germany and buy them through the Internet?

Mr. DAHL. If I could speak to maybe the 185 OCI agents, we're not dealing with them at all. We're not worried about somebody buying a small parcel from a brick and mortar pharmacy, Winnepeg, we're worried about the 10,000 pills that come in a 75-pound package from Thailand with no labels on it at all that get put in other boxes and resold.

Mr. BURTON. OK. That's good. So then you really don't have opposition to individuals getting pharmaceutical products from Canada or——

Mr. DAHL. Let's face it, we have importation. There is probably 10,000 parcels that came in while we've been sitting in this room this afternoon, so we have it. If you want to pass a law to better regulate it, I think you should. If you don't, it doesn't matter, we're still going to have it. And the FDA knows that, and so does everyone else.

Mr. PITTS. Although, Mr. Burton, to your point, I think it's important not to send the wrong signals. Clearly when you tell people

that drugs from other countries are safe, and it's OK to get them from the Internet, with all the best intentions, some people aren't necessarily listening quite as carefully, and what they hear is it's OK to get drugs from nonregulated entities.

Mr. BURTON. We've had legislation in both the House and the Senate that got a lot of support, although we've never gotten them both together, and we continue to work on that. dThe legislation deals primarily with Canada, because they have pretty strict regulations on pharmaceutical products up there. And we keep getting opposition. Yet when Mr. Hubbard appeared before our committee, we asked him to give us a case where someone was damaged by pharmaceuticals imported from Canada, for instance, and he couldn't give us any.

Mr. PITTS. Well, there are five deceased Canadians in Hamilton, Ontario, from counterfeit drugs, so——

Mr. BURTON. There are five deceased Canadians?

Mr. PITTS. Yes, sir.

Mr. BURTON. From counterfeit drugs.

Mr. PITTS. Yes, sir. Norvasc.

Mr. BURTON. Well, what does it have to do with the importation into the United States from pharmacists up there?

Mr. PITTS. Well, you said that, you know, bringing in drugs from Canada, which is a safe and secure drug supply system, which they do——

Mr. BURTON. No, I understand. If there is counterfeit, regardless of where they come from, they can be contaminated and can kill people. But the problem is that the people that were importing, little old ladies and people like that, pharmaceutical products from Canada, they couldn't find any cases where there was any harm that had happened. We asked about that.

Mr. PITTS. A lot of times when you're taking medicine like for cholesterol or high blood pressure medication, as the earlier panel has mentioned, it isn't a question of taking the drug and keeling over, it's a question of not getting the therapeutic benefit from the drugs that you're taking.

Mr. BURTON. I understand.

How many people died from aspirin last year, or from Tylenol?

Mr. PITTS. How many?

Mr. BURTON. Do you know how many?

Mr. PITTS. No, sir.

Mr. BURTON. Well, it was in the thousands, from what I've been told, and other medications like that. But anyhow, that's another issue.

I guess the main question I had was how do you police importation of pharmaceutical products? And I don't know—no matter how many laws we pass that deal with the problem here in the United States, as long as people can buy those products over the Internet from outside the country, you still have a real policing problem.

Mr. PITTS. Oh, absolutely, no question about it. But I guess the point is not to exacerbate the problem by telling people that they should do it, because it allows people that are trying to take advantage of these people to sell more bad product.

Mr. BURTON. OK. I guess my last question would be, then, do you think that one of the inducements for people to go outside the coun-

try to buy these products is because things like tamoxifen cost four or five times as much as it does here than it does in Canada, and people who are dying from cancer want to be able to buy their product, and they can't afford it, and so they say, in desperation, "If I'm going to survive, I've got to get the product, I've got to split my pill?" Sometimes you have people that go to the pharmacy here in the United States that say, "I have to split my pill," and so the reason they do it is because of economics.

Mr. PITTS. Sure, people in this country do that; people in Europe do it as well. It is common practice that people want to get something less expensive, and especially something they need for their life. It simply becomes a question of what are the tradeoffs. If you want to have drugs, you need to have them available, and if you want to get a drug cheaper and you want to go outside the regulatory system that your government provides, then you take risks.

Mr. Chairman, to your point, it goes back to the whole issue of what is the job of the FDA, and to my former colleague at OCI, how can they be better funded to make sure that people can get the drugs that they need and that they're safe.

Mr. BURTON. Thank you, Mr. Chairman.

Mr. SOUDER. Thanks.

Mr. Gutknecht.

Mr. GUTKNECHT. Thank you. And just for the record, then, Mr. DeKieffer, your company does do work with the pharmaceutical industry, and, Mr. Pitts, your organization does receive significant funds from the pharmaceutical industry?

Mr. PITTS. I don't know what significant means, but they definitely do receive funding, yes. I wish it was significant.

Mr. GUTKNECHT. Would you submit for us a record of how much money you got from pharmaceuticals last year?

Mr. PITTS. It's a 501(c)(3), so those records are publicly available.

Mr. GUTKNECHT. All right, thank you.

Mr. Catizone, I just want to say that I agree with everything that you've said. I've been studying this issue now for 5 years. I often tell people I feel like the little boy who comes in and asks his mother a question. His mother is busy, and she says go ask your dad, and the little boy said, well, I didn't want to know that much about it. I sometimes feel that way. I think you've really hit the nail on the head. And my concern about whether it's this bill or this whole issue of counterfeiting, there are different motives by different groups. My real concern—and I do agree with you, that the pharmaceutical industry really doesn't want to solve this problem because the technology exists, too—in terms of solving, that's not really the right word, we can never solve any problem completely. We live in an imperfect world, and there are always going to be people who will take advantage of it.

But the truth of the matter is neither FDA nor the pharmaceutical industry has taken a particularly keen interest in solving this problem, and I believe—and I will just say this for the record—I believe the real reason is they know if they really solve this problem, all of a sudden, and somebody said the Internet has changed everything, and it is true, because until the Internet we didn't know how much more we paid for prescription drugs than people in Germany or Italy or France or Canada. In the informa-

tion age you can't keep those things secret anymore, and it has changed everything. Yet in the information age we still want to pretend that we can hire enough policemen, and with all due respect, I'm not sure you can hire enough enforcement people to ultimately change consumer behavior on this. You are correct, probably 10,000 packages arrived in Minnesota today, and some of them through the State-sponsored Web site so that people can buy their prescription drugs from Canada.

But I would love to work with people who are really sincere about resolving this, because I think if you go to the RFID tags, like these, or, as I say, the latest technology, which are microscopic taggants, all of a sudden, you know, then it becomes a world market. And we can track this product wherever it is, wherever it comes from, where it was produced, when it was produced.

But, Mr. Catizone, I think you're exactly right. I'm not sure the FDA or the pharmaceutical industry really wants to solve the problem because then it becomes a world market, and then they can't play the game where they sell some of these drugs for literally thousands of dollars more. You mentioned—I don't know who mentioned the AIDS drugs. It's almost shameless what they sell some of those drugs for, especially when you consider that most of the research was paid for by the American taxpayers. But those are all policy questions that we have to resolve, and I want to thank you all for coming because I think this has been a very interesting hearing.

And, Mr. Catizone, I really do want to thank you because I think you nailed exactly what the problem is.

I yield back.

Mr. SOUDER. I thank the gentleman.

And the other question I meant to ask that I didn't get done because it's something that's kind of confused me all day long here, and that is, if we get the pedigree, we solve the question of the grayness, the gray market and all that. But if we get a pedigree, does, in fact—if the pedigree includes black marketers, that just enables us, from law enforcement purposes, to go back and figure out how it got bad, right? Does it put—is another advantage to this that it puts pressure on individuals to have a shorter pedigree, that announcements like CVS did, or we heard Wal-Mart, bigger companies can figure out how to do this, they can buy directly from the manufacturer? In fact, they can probably hammer the price down at the manufacturing level.

What is a practical impact of a pedigree to an independent pharmacist in a small town who's buying wholesale?

Mr. CATIZONE. With a pedigree you track that product from a manufacturer throughout the distribution chain, and if you alert people to not accept any products where that pedigree doesn't exist, where the pedigree has been altered, where the pedigree has gone outside of that normal distribution, you have placed a major dent in the counterfeit drug market.

Mr. SOUDER. So first off, one would be the mere existence of a pedigree.

Mr. CATIZONE. Exactly.

Mr. SOUDER. The second thing is how would you know if you're a small pharmacist what is outside the chain?

Mr. CATIZONE. That's what the normal distribution has been from the manufacturer directly to the pharmacy, or from the manufacturer through one wholesaler that's been authorized or that's been accredited to the pharmacy. Anything outside of that is outside of normal distribution.

Mr. SOUDER. So what we're really looking for are very short pedigrees.

Mr. CATIZONE. Exactly.

Mr. SOUDER. And very tight. Otherwise this looks like an analysis of figuring out; after somebody's dead, you can go back and figure out how it got there, as opposed to how I was trying to sort through the prevention side.

Mr. DeKieffer, in fairness, you said you provided data to other companies as well. What other companies besides pharmaceutical companies do you provide——

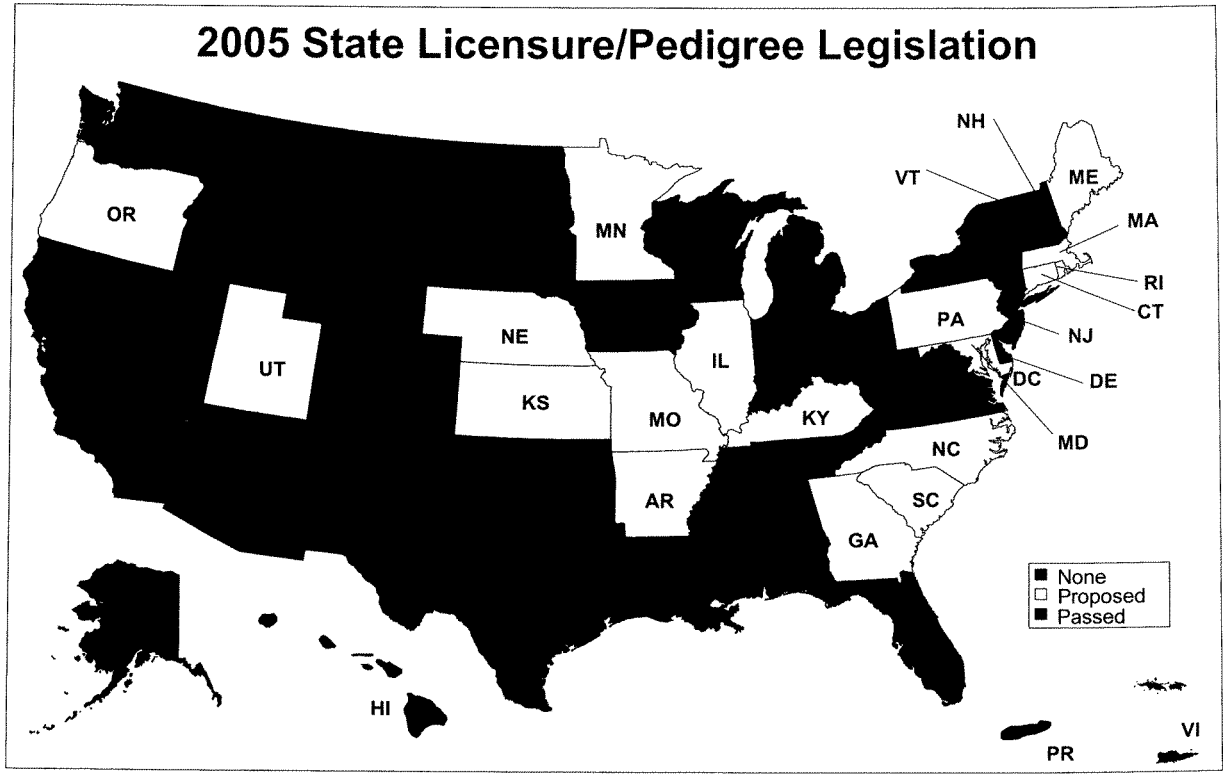
Mr. DEKIEFFER. Yes. We provide data to footwear industries, to apparel, to food industries, to high-tech electronics, because the same kinds of people who are diverting drugs are also involved in all kinds of other illicit black market and gray market activities. So we work with a number of clients in a number of different industries to try to identify leaks in the supply chain. And very often we find that the bad guys don't divide their industry the same way that legitimate companies do, and they will steal anything.

So, yes, we do have pharmaceutical clients. We also have clients that sell sunglasses.

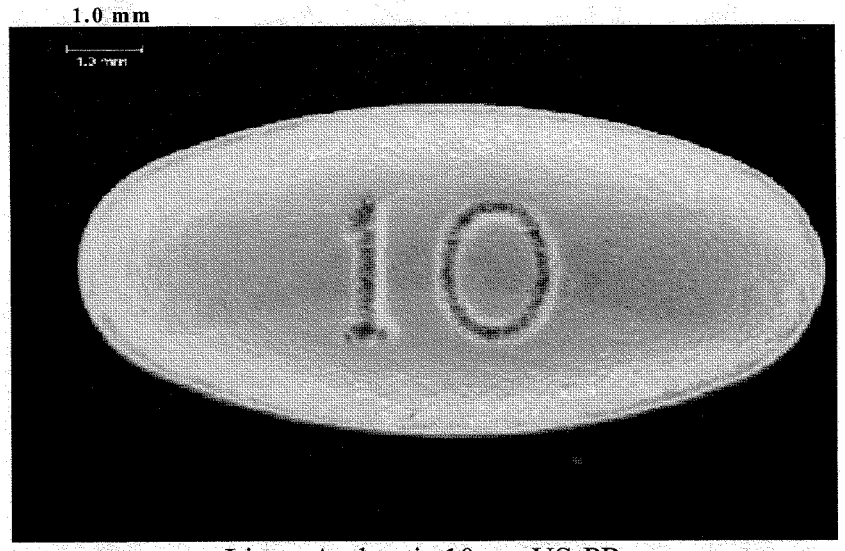
Mr. SOUDER. I thank you all for your testimony today. Thank you for your patience. It was a long hearing. With that, the subcommittee stands adjourned.

[Whereupon, at 5:08 p.m., the subcommittee was adjourned.]

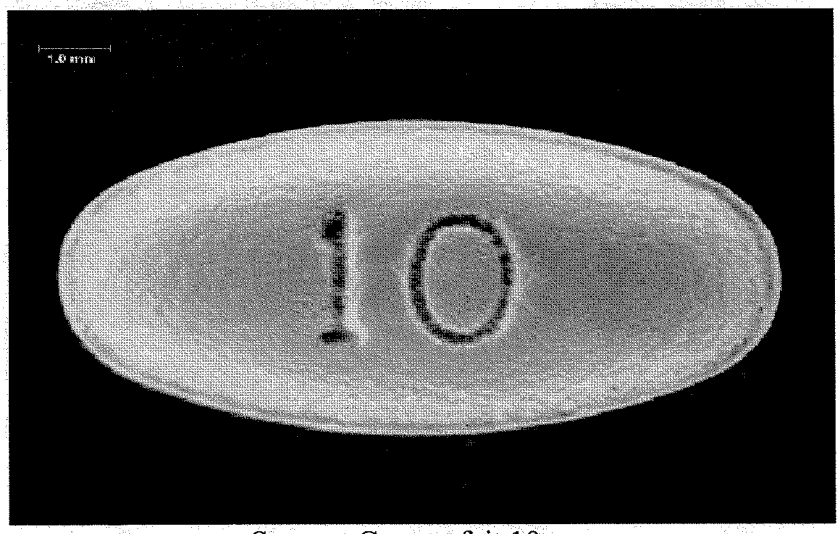
[Additional information submitted for the hearing record follows:]



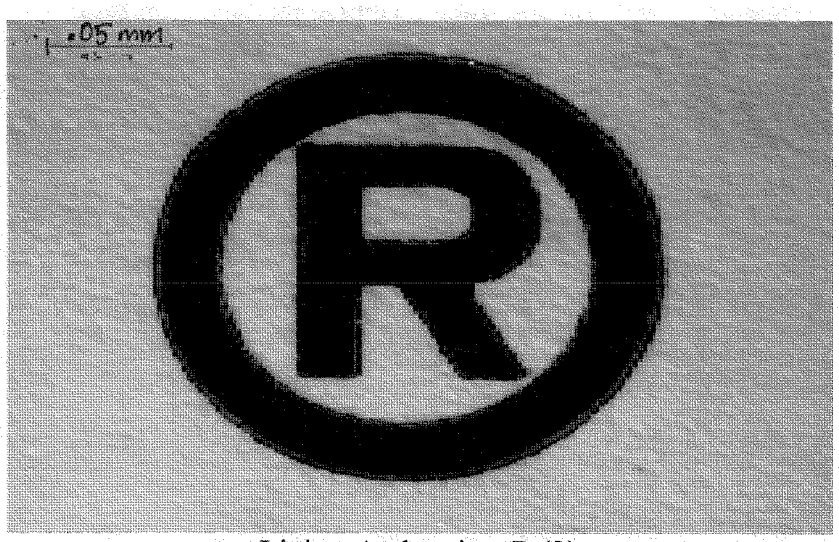
SOURCE: Healthcare Distribution Management Association



Liptor Authentic 10 mg US-PR



Suspect Counterfeit 10 mg



Lipitor Authentic – R (2)

Suspect Counterfeit – R – type 1

Pharmaceutical Drug Cost Comparison

Metropolitan Pharmacy, *Frankfurt, Germany*		Local Pharmacy *Rochester, Minnesota*
$35.72	Celexa *(30 tablets - 20 mg)*	$85.46
$60.25	Nexium *(30 tablets - 20 mg)*	$145.33
$19.31	Norvasc *(30 tablets - 5 mg)*	$54.83
$34.33	Zyrtec *(30 tablets - 10 mg)*	$73.02
$35.22	Prevacid *(30 tablets - 15 mg)*	$146.47
$23.83	Zocor *(30 tablets - 10 mg)*	$85.39
$50.62	Actos *(30 tablets - 15 mg)*	$116.64
$54.98	Zoloft *(30 tablets - 50 mg)*	$89.44
$102.67	Imitrex *(9 tablets - 50 mg)*	$166.40
$38.64	Clarinex *(30 tablets - 5 mg)*	$77.06
TOTAL=$455.57 Frankfurt, Germany		TOTAL=$1,040.04 United States of America

Americans pay 128% more on average!

Congressman Gil Gutknecht, R District, Minnesota
All prices in U.S. dollars. Prices effective February 7, 2005

AMERICAN FREE TRADE ASSOCIATION
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Written Testimony Presented to
United States House of Representatives'
Government Reform Committee
Subcommittee on Criminal Justice, Drug Policy and Human Resources

"Sick Crime: Counterfeit Drugs in the United States"
November 1, 2005

Thank you for the opportunity to offer this testimony on behalf of the American Free Trade Association (AFTA).

AFTA was formed over twenty (20) years ago in order to provide, among other things, an industry-wide voice to wholesale distributors in the secondary marketplace. In the context of this hearing, AFTA hopes to publicly address the concerns about counterfeit drugs shared by all legitimate pharmaceutical wholesalers and to ensure that the respected Subcommittee members are made aware of the ongoing, vigorous efforts by this industry's leaders to combat even inadvertent infiltration of illicit drugs into the American marketplace.

Background

AFTA has been and continues to be well-recognized and visible in the debate over secondary market issues. It has offered testimony to Congress, filed comments and met with federal agencies, and appeared as *amici curiae* in federal and state courts throughout the country, including the two leading Supreme Court cases on secondary market issues, albeit outside the context of prescription drug distribution: the 1988 **Kmart** decision and the 1998 **L'Anza** decision. AFTA has actively defended against challenges to laws so as to permit free competition through the secondary marketplace and it regularly provides its members with information and education regarding the laws governing secondary market trade and related regulations throughout the World.

AFTA's members uniformly support efforts to protect consumers against potentially unsafe or threatening merchandise (particularly counterfeit merchandise); however, the Association opposes any such campaigns that deny U.S. consumers the benefits of a freely competitive marketplace and unfettered access to unadulterated, safe and genuine consumer goods - especially prescription drugs. In that regard, the absence of any legitimate pharmaceutical wholesaler on today's panels of witnesses gives rise to understandable concern that this Subcommittee may not be aware of all that has been done through several industry trade associations – such as the Health Distributors Management Association (HDMA) and the Pharmaceutical Distributors Association (PDA) - to fight *against* counterfeit drugs while fighting *for* continued access of all Americans to affordable, brand name and generic pharmaceuticals.

It is also worthwhile to note that, perhaps for the first time in history, pharmaceutical drug manufacturers are facing substantive and measurable marketplace pressures as a result of the movement, supported by many members of this Congress, toward increased access to generic drugs. Because Congress is conspicuously concerned about even the perceived inability of our citizens to obtain the medicines they need at prices they can afford, it is paramount that the respected members of this Subcommittee remain confident that legitimate pharmaceutical wholesalers share their commitment and resolve to ensure a safe and competitive domestic marketplace.

While certain advocates may applaud announcements by drug manufacturers that drug distribution to American consumers will be limited to their appointed authorized distributors[1], there is little doubt that such practices and policies will further hinder this Congress' ability to guarantee American consumers access to much-needed, unadulterated, genuine and affordable drug supplies. In fact, any effort to deny secondary market wholesalers[2] the right to perform their critical role within the domestic pharmaceutical supply chain would necessarily frustrate this resurgence of such critical marketplace competition to the great detriment of United States' consumers.

But, of even more import, such policies and procedures are unnecessary limitations on free trade and competition. AFTA hopes to help the honored members of this Subcommittee learn more about efforts undertaken by the wholesale industry itself to distinguish between legitimate secondary market wholesalers and criminal counterfeiters.

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[1] Eban, K. "Dangerous Doses" Pages 341-342

[2] Secondary market wholesalers are, by definition, wholesalers without direct relationships to pharmaceutical manufacturers but who are uniquely able to provide American consumers with greater access to more affordable brand name drugs.

Testimony

Any discussion about efforts to protect the American drug supply must begin with the Prescription Drug Marketing Act ("PDMA"). The PDMA was enacted in 1988 because Congress found that inadequate controls existed within the American drug supply to prevent against distribution of adulterated and counterfeit pharmaceuticals. The PDMA was amended by the Prescription Drug Amendments of 1992 (PDA) and, on December 3, 1999, the FDA published its final rulemaking implementing the PDA. As a result of an unanticipated amendment of the definition of an Authorized Distributor of Record[3] (ADR), thousands of businesses throughout the country were immediately threatened with extinction[4] and advocates from the Small Business Administration to the manufacturers themselves[5] insisted that the final form of pedigree requirements was too onerous and ultimately unacceptable. As a result, the portions of the final rule demanding full pedigrees of all pharmaceutical products distributed by legitimate pharmaceutical wholesalers has been stayed until December 2006, in the hopes that voluntary RFID technology adoption will better enable compliance by all supply chain participants[6].

In May of this year, a Harvard student, Afia K. Asamoah, published a paper discussing the PDMA's pedigree requirement, debating the feasibility of relying on expensive and untried RFID technology as the "magic pill" to ensure compliance with the controversial pedigree requirements[7]. In her paper, Ms. Asamoah described the pharmaceutical wholesaler industry as follows: *The wholesaler industry consists of drug manufacturers, drug wholesalers or distributors, and retailers or dispensers, such as pharmacies that sell drugs to the American consumer. In short, drug wholesalers function as the middlemen between drug manufacturers and the retail drug dispensers. Wholesalers allow manufacturers to make bulk sales to one entity*

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[3] Subsequent to passage of the PDMA, FDA's guidance indicated that an ADR was a distributor having an ongoing business relationship with a manufacturer and that the existence of two transactions in a two-year period would be presumptive evidence of such a continuing relationship; the published FDA's Final Rule, however, indicated that an ADR must have a written agreement with a manufacturer for a specified term or pursuant to specific sales volume requirements.

[4] Small Business Association's letter to FDA, February 29, 2000; found at http://www.sba.gov/advo/laws/comments/fda00_0229.txt

[5] Eban, K. "Dangerous Doses" page 163.

[6] On May 12, 2005, Representative Steven Israel introduced H.R. 2345, "Tim Fagan's Law", which would require pedigrees back to the manufacturer even for ADRs and amends the definition of an ADR to a manufacturer-designated distributor whose name the manufacturer makes publicly available – deleting the PDA's final rule requirement that such designation only be possible through formal, written agreement. Technology based tracking systems are also included within this pending legislation, which, except for the hope that a grandfathering clause be included, AFTA generally supports in content and intent.

[7] [7] "Using RFID to Fulfill PDMA's Elusive Pedigree Requirement" found at http://leda.law.harvard.edu/leda/data/728/Asamoah05.html

while consolidating the drug purchase process for drug retailers. ***As such, drug wholesalers provide a cost-effective, efficient means for the purchase, delivery and sale of prescription drugs. According to the FDA, the wholesaler system ships more than half of the 14,000 approved prescription drugs in the U.S.***[8]

And, the 106th Congress heard testimony from Susan Winckler, Group Director of Policy and Advocacy for the American Pharmaceutical Association, that *"... alternative sources for drug purchases are vital to both the patient's and pharmacist's ability to acquire prescription drugs. The increase in drug prices [resulting if wholesalers are eliminated from the drug supply chain] will have a direct impact on patient access to drugs as fewer people are able to afford them. The closing of wholesale drug distributors may disrupt the distribution process, further restricting access."*[9]

There is simply no reason to doubt or minimize the important role played by legitimate pharmaceutical wholesalers in ensuring the integrity of the entire supply chain for the ultimate benefit of American consumers. It is critical that secondary market pharmaceutical wholesalers continue their valuable role in the domestic drug supply chain as a means of supplementing supplies of life-saving drugs within the United States and in order to maintain competitive pricing for the American consumer.

Wholesalers – like other legitimate businesses --- are hurt significantly by the distribution of counterfeit products. Industry trade associations, like AFTA and its business members, have very publicly supported federal and state efforts to increase penalties and more vigorously prosecute counterfeiters. In fact, the National Association of Boards of Pharmacy recently appointed a National Drug Advisory Council specifically committed to eradicating counterfeit drugs, on which the two leading industry trade associations representing pharmaceutical wholesalers are members --- the Health Distributors Management Association (HDMA) and Pharmaceutical Distributors Association (PDA).[10] Interestingly, despite this overt attempt by a federally recognized pharmaceutical association to join together all supply chain participants with interest in protecting American citizens against tainted product, merely because HDMA and PDA are associations advocating on behalf of drug wholesalers, both associations are conspicuously and repeatedly mischaracterized in Ms. Eban's book, "Dangerous Doses."

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[8] (quoting from Gardiner Harris, *The 'bar code that barks' Radio chip for pirated rugs has wider use,* INT'L HERALD TRIB., Nov. 16, 2004, at 1.)

[9] *FDA Part 15 Hearing: Prescription Drug Marketing Act*, 106th Cong. 9 (2000)

[10] Other members include representatives from the various states' boards of pharmacy, American Medical Association, National Association of Chain Drug Stores and even the Pharmaceutical Research and Manufacturers of America (|PhRMA).

Katherine Eban's book "Dangerous Doses" describes an intense, lengthy and costly investigation of certain Florida based pharmaceutical wholesalers that were ultimately found to be involved in complicated schemes facilitating the distribution of counterfeit drugs. Ms. Eban's passionate indignation over any individual or agency that even silently would support or enable such an illicit operation is understandable and shared by the members of the American Free Trade Association. However, Ms. Eban's disregard for the efforts made by federal and state agencies - as well as industry trade associations such as HDMA and PDA - to better regulate the industry, also invites - and in fact encourages - discrimination against the thousands of small and medium-sized businesses which, for many years, have just as passionately fought for uniform and effective regulation of legitimate pharmaceutical wholesalers.

With undisguised disdain, Ms. Eban writes that, in 2003, the Florida Bureau of Statewide Pharmaceutical Services in Tallahassee "*...launched an effort to overhaul existing legislation and turned to lobbyists for the wholesale industry to help them draft the changes. The series of sit-downs with the industry, which the local press got wind of, came to be known as "co-operation meetings." The group that met on a regular basis included....two lobbyists – one representing the largest wholesalers' trade group, the Healthcare Distribution Management Association (HDMA), and the other working for Salvatore Ricciardi's group of secondary wholesalers, the Pharmaceutical Distributors' Association (PDA). The group's efforts became so interconnected that the lobbyist for the PDA, Ross McSwain, openly referred to their work product as the "DOH/industry bill.*[11]"

The tone of the book's rhetoric clearly indicates that Ms. Eban believed the State to be in error by intentionally including the wholesale drug industry in its efforts to craft a comprehensive pharmaceutical wholesale licensing regulation that would sufficiently protect consumers against counterfeit drugs, while, at the same time, still enabling continued operations of legitimate, licensed drug wholesalers. Presumably, Ms. Eban would prefer that the State opt to wipe out the industry entirely – without hearing or giving consideration to the thousands of citizens lawfully employed by its members or of the many benefits provided by increased competition in even a highly regulated environment. This is, frankly, an unfair and insupportable position for a respected journalist like Ms. Eban to take and AFTA is confident this position is not one favored by the members of this Subcommittee.

In her rejection of the FDA's 2004 report on Counterfeit Drugs[12], Ms. Eban again illustrates an intolerance even for a well-regarded federal agency to include wholesalers as stakeholders in the United States' pharmaceutical industry. On page 336 of "Dangerous Doses" Ms. Eban indicates the following: *In February 2004, an FDA task force released its final report on the problem of*

[11] "Dangerous Doses", page 262
[12] "Combating Counterfeit Drugs: A Report of the Food and Drug Administration" found at http://www.fda.gov/oc/initiatives/counterfeit/report02_04.html

drug counterfeiting. Those looking for forceful direction, strengthened regulations or immediate solutions were disappointed. The report emphasized due diligence by those in the supply chain, the voluntary use of cost-effective technology and better education of the public. It also emphasized the need to reduce the "regulatory burdens' for "stakeholders" – which included the middlemen. Instead of blaming wholesalers, the report now blamed "illicit nationwide networks" that capitalized on the "inadequate due diligence" of those in the distribution chain – a problem that could be solved by the industry's adoption of voluntary standards.[13] While Ms. Eban may be understandably passionate in her distrust of the pharmaceutical wholesale industry, having reported of transgressions by bad actors that took place several years ago, her undeniable disregard for the FDA's efforts to fully assess the marketplace and report on shared responsibilities for past mistakes committed by participants throughout the entire supply chain undermines the credibility of her arguments..

On May 18, 2005 of this year, the FDA issued an update to its 2004 report[14] confirming that the FDA is committed to six critical areas to better protect Americans from counterfeit drugs. These include:

- Securing the actual drug product and its packaging
- Securing the movement of the product as it travels through the U.S. drug distribution chain
- Enhancing regulatory oversight and enforcement
- Increasing penalties for counterfeiters
- Heightening vigilance and awareness of counterfeit drugs
- Increasing international collaboration

The update confirms that, since the 2004 report was published, the FDA has worked with manufacturers, wholesalers, pharmacies, consumer groups, technology specialists, standard-setting bodies, State and Federal agencies and international governmental entities among other parties to advance these measures. The FDA's Office of Criminal Investigations has seen a significant increase in its initiation of counterfeit drug cases and focused on the need to adopt wide spread use of reliable track and trace technology. As the FDA continues its work to fine tune the implementing regulations necessary to standardize these efforts against counterfeit drugs, without debate wholesalers have been conspicuously involved and a part of such work. In that regard, particular recognition must be given to both HDMA and PDA – despite the publications by Ms. Eban that would have some believe otherwise.

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[13] Page 338 "Dangerous Doses"
[14] Found at http://www.fda.gov/oc/initiatives/countefeit/update2005.html

In November 2003, Dr. Paul Rudolf, Senior Advisor for Medical and Health Policy met with representatives of the PDA to exchange ideas on how to preserve small pharmaceutical wholesalers in the wake of the need for stronger controls against counterfeit drugs. In its responsive letter to Dr. Rudolf on December 1, 2003[15], the PDA confirmed its support for strong state licensure requirements and that State certification of pharmaceutical distributors to confirm distributor compliance with a proposed FDA Recommended Guidelines for Pharmaceutical Distribution Integrity would be a favorable development.

The Guidelines, in the form proposed by HDMA[16], set forth due diligence criteria and best practices for legitimate drug wholesalers, in order to better find and prosecute "suspect" traders. The recommended best practices drafted by the HDMA and provided to the FDA by the PDA, include the following:

- Initial Information Request from suppliers, including but not limited to copies of all state and federal licenses and registrations; most recent site inspection reports, procedures for reporting of counterfeit or stolen product; insurance limits; corporate officer information; detailed list of any and all disciplinary actions by state/federal agencies against the company; the number of employees and employment screening procedures; a full facility and warehouse description; description of drug import and export activities; description of the company's process for validation of its suppliers and purchases; and available financial and/or SEC filings.
- Certification of ADR status.[17]
- Background check of any prescription drug wholesaler with which it conducts business, both civil and criminal of all officers, owners, principals and management; drivers license and social security verification of all officers, management and owners; credit history; national database of licensed prescription drug wholesalers; [18] and verification and verification of corporate status
- Physical Site Inspection prior to initial purchase from any prescription drug wholesaler, including review of training and hiring procedures; building security and climate control; and operational policies to confirm compliance with PDMA requirements
- Seller Qualification to include written contracts confirming PDMA compliance and compliance with all applicable state and federal laws
- Ongoing PDMA Compliance Review

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[15] Found at http://www.fda.gov/ohrms/dockets/dailys/03/dec03/120303/03n-0361-psa0001-01-vol7.pdf
[16] Found at http://www.healthcaredistribution.org/gov_affairs/anti.asp
[17] The HDMA Recommended Guidelines include a revised definition of an ADR to include either a written agreement and/or a manufacturer verifiable account number with minimal transaction requirements measured by annual sales volumes or numbers of individual purchase transactions
[18] As of the date HDMA drafted these Guidelines, no such national database exists

HDMA's Recommended Guidelines are now routinely followed by all legitimate pharmaceutical wholesalers known as such by HDMA, PDA and AFTA's Board of Directors. In fact, Supreme Distributors, a company affiliated with Purity Wholesale Grocers - whose president Sal Ricciardi, serves as President of PDA and a Board Member of AFTA - sent a memo to all of its customers in late 2003/early 2004, including both the HDMA Guidelines and its own customized implementation plan of those exact principles and policies. This public notice to customers throughout the country – from a major independent, pharmaceutical wholesaler - clearly confirms the Industry's commitment to diligently work with Congress (through the PDMA) and the FDA (through anticipated Guidance publications), as well as with various States' health agencies to ensure that brand name pharmaceuticals are purchased only from legitimate, compliant, lawful and robust business operations.

Respectfully, this Subcommittee may have faltered in its attempts to comprehensively understand - and fairly address - the counterfeit drug issues facing its honored members and their constituents. While there is no doubt that receiving testimony from federal agency overseers and authors of books detailing a frightening investigation into a tangled counterfeiting network is important for the Subcommittee to consider, it is similarly critical that Congress understand and appreciate the ongoing and vigorous efforts of legitimate drug wholesalers to strengthen federal and state oversight of their industry.

Since the events described in Ms. Eban's book took place, industry initiatives, state legislative and regulatory efforts have substantially and laudably addressed many of the regulatory problems and shortcomings Ms. Eban conspicuously brought to the attention of the American consumer. Legitimate pharmaceutical wholesalers, particularly those in the secondary marketplace, are eager for federal legislation making uniform the hodgepodge of state licensing requirements and AFTA urges the Subcommittee's further review of the HDMA's Recommended Guidelines as at least a starting point in that direction. These Guidelines, which PDA and others have urged the FDA to mimic in the form of an Agency published Guidance document, set forth stringent, standardized and critical criteria pursuant to which distinctions may be easily made between legitimate pharmaceutical wholesalers and criminal counterfeiters. Only through such federal standardization exercises will it be possible to prevent against illicit operators selecting more lenient state regulations under which to operate and will all supply chain participants be held fully accountable to the American consumer.

Without a doubt, the stories told in "Dangerous Doses" should make us all scared - very scared. But they should also make all of us determined, through a collective and concerted effort, to further strengthen federal and state efforts to protect American consumers from adulterated and counterfeit drugs. On February 16, 2005, John M. Gray, President of HDMA, presented testimony to the Senate Committee on Health, Education, Labor & Pensions during a hearing

entitled "Drug Importation: The Realities of Safety and Security"[19] During that hearing, Mr. Gray confirmed the following: *Patients in the United States expect that when they receive a prescription from their medical provider, the medication will be available for dispensing upon their arrival at a pharmacy. They expect and deserve authentic medicine that has been handled and stored properly. Each member of the supply chain – from the manufacturer, to the distributor, to the pharmacy – has an important role and we must work in tandem to ensure a safe and reliable supply of prescription drugs for patients."* AFTA agrees with Mr. Gray and trusts that the members of this Subcommittee do as well.

Enabling counterfeit drugs to filter into the United States is indeed a "Sick Crime" as suggested by the title of today's hearing. Many legitimate pharmaceutical wholesalers, such as those serving on AFTA's Board of Directors[20] or as may exist within the hundreds of legitimate secondary market traders they, PDA or HDMA represent are making incredible strides and are continuing their efforts to work hand in hand with federal and state governments to strengthen our country's laws against counterfeiters and to cleanse the industry of illicit operators. It is sincerely hoped that future efforts by this Subcommittee to comprehensively learn more about the American pharmaceutical marketplace include representatives from recognized industry trade associations such as the Health Distributors Management Association, the Pharmaceutical Distributors Association and/or the American Free Trade Association. Subcommittee members are invited to contact AFTA's General Counsel, Gilbert Lee Sandler, Esq. directly or any of its Board Members, each of whom would be pleased to contribute to any effort to eliminate domestic distribution of counterfeit drugs.

We thank you for providing us with this opportunity to have our testimony made a part of the record of today's hearing.

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[19] Found at http://help.senate.gov/testimony/t192_tes.html

[20] AFTA's Board of Directors include Alfred R. Paliani of QK Healthcare, Inc., Sal Ricciardi of Purity Wholesale Grocers and Steven Schmidt of Alliance Medical Systems.

Congress of the United States.

Testimony.

Name of Witness: Graham Satchwell

Before: Subcommittee on Criminal Justice, Drug Policy & Human Resources – United States House of Representatives.

Title of hearing: Sick Crime: Counterfeit Drugs in the United States

Date of hearing: November 1st. 2005.

Mr. Chairman and Members of the Committee

It is an honour to be asked to speak before you.

I have been involved in the business of investigating product counterfeiting and other intellectual property crime, and its links to organised crime, for many years.
In addition-

- In 2004, on behalf of the Stockholm Network, a European based organisation, I completed the writing of a book entitled 'A Sick Business – Counterfeit Medicines & Organised Crime'. It has been widely reported upon and Interpol have linked it to there internet site.
- I was a detective superintendent for many years in the UK;
- I am a member of UK Government's Patent Office Investigative Strategy Group.
- For several years to 1999, I was the official spokesperson (on counterfeiting of branded goods) for Association of Chief Police Officers (ACPO) England & Wales.
- Prior to leaving the Police Service I received personal thanks from four UK Government Ministers. Those thanks included comments from the UK Trade & Industry Secretary in relation to work in anti-counterfeiting of branded goods.
- During my investigative work I have been officially commended by HM Judges, chief constables, the Director of Public Prosecutions and The Lord Lieutenant of London for successful major investigations.
- I have successfully led international and politically sensitive major corporate investigations into counterfeiting, illegal diversion and fraud including the massive re-importation of anti-retroviral drugs from Africa to Europe.
- I was the chief architect and author of the 1999 UK 'Memorandum of Understanding' between all police forces in UK, Customs authorities and other law enforcement agencies, brand-owners and industry groups on the investigation of counterfeiting of branded goods.
- For 3 years I was Director of Security (Europe, Middle East & Africa) for GlaxoSmithKline and took the lead on anti-counterfeiting and unlawful diversion.
- Three years ago I created and led an anti-counterfeiting investigative forum in Europe involving the world's leading pharmaceutical companies.
- Between 1994 & 1999 I was the Metropolitan Police 'Joint Action Group' leader in relation to counterfeiting of branded goods.
- I am currently providing both anti-counterfeiting and diversion strategic input and operational investigations to several major pharmaceutical corporations and doing research into these subjects for another book on that subject
- I have had items published on counterfeiting, diversion and other crime issues in UK and USA.

I should also mention that I am an Honours Law Graduate.

It is about 10 years since the first case involving counterfeit pharmaceuticals came my way. I have specialised in that area for the last five years.

It is my understanding that I can most help this hearing by focusing on-

1. The extent of counterfeiting of medicines,
2. How these are imported into Western nations,
3. The involvement of organised crime
4. Any potential or actual known connections to terrorism.
5. Terrorism, counterfeiting of medicines- delivering a terrorist blow.

First I should say a few words about the meaning of terms.

In different circles 'counterfeiting', 'substandard medicines' and pharmaceuticals that are dangerously mislabelled are not always clearly distinguished. This is no doubt because the criminal who deals in one is likely to deal in the others. However, in this statement, and in my oral testimony, I will use the World Health Organisation's (WHO) definitions of counterfeit medicines and substandard medicines, most of the other meanings of terms as given are my own–

Counterfeits:
Counterfeits are deliberately and fraudulently mislabelled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products and counterfeit medicines may include products with the correct ingredients
but fake packaging, with the wrong ingredients, without active ingredients or with insufficient active ingredients'.
The WHO defines 'counterfeit medicines' as a sub-set of 'substandard medicines. Usually, and for all practical purposes in trying to protect the US citizen from harm, it is advised that the broader term of substandard medicines should be considered.

Substandard medicines:
The WHO says "Substandard medicines are products whose composition
and ingredients do not meet the correct scientific specifications and which are consequently ineffective and often dangerous to the patient. Substandard
products may occur as a result of negligence, human error, insufficient human and financial resources, or counterfeiting. Counterfeit medicines are part of the broader phenomenon of substandard pharmaceuticals".

The free movement of goods across the world, the basis of most successful economies, is an essential part of discussions of these topics. The'phrase 'diversion' is often seen.

Diversion
Diversion is the movement of branded goods across international markets, contrary to the wishes and legal rights (sometimes the word 'grey' is used to describe
diverted products) of the brand-owner. However, no brand-owner would use the word 'diversion' to describe such activity for the movement of goods across nations within Europe. The word 'diversion' cannot be used for the unwanted (by the brand-owner) movement of goods within the European Union since the E.U is legally and emphatically a single market.

Parallel Trade

Parallel trade (known as re-importation in the USA) occurs when products protected by patent, trademark or copyright are first placed into circulation in one market, then (re-)imported into a second market by a person other than the original owner of the intellectual property rights and against the original owner's interests. A variety of products are traded in this way, including pharmaceuticals, automobiles, clothing, perfume and other consumer goods. Parallel trade is legal within the European Union.
The European experience on parallel trade is of significance to this hearing for the lessons it can reveal in relation to the dangers that accompany the importation of foreign medicines.

Organised Crime
The term 'organised crime', like counterfeiting is variously defined; the UK National Criminal Intelligence Service would accept the following description. Organised crime refers to the activities of any group which comes together to commit serious crime (serious crime in this context means crime for which the offenders could expect to receive at least three years' imprisonment). In some instances such groups consist of permanent members (each with a distinct role, and within a hierarchy in which there are clear lines of command and communication), but the term also includes loose networks, whose members undertake particular criminal ventures of varying complexity, structure and duration. In the latter instance some of the criminals may not think of themselves as being members of an organised
crime group.

1. The Extent of Counterfeiting of Medicines.

No one knows the extent of the problem of counterfeiting of medicines. The WHO, which is known to be conservative in its approach, estimates 8% of world trade in medicines in counterfeit. The FDA has estimated similarly and other international groups seem to give figures roughly in accordance.
However, it is clear that no one truly knows. The figures are based on current reporting systems and these are far from scientific or comprehensive.

Current research is inadequate (many countries – where there is a known counterfeiting problem- fail to report any incidents, whilst others like the USA seem to be reporting fully yet have totally inadequate means of measuring the problem).

Current research is less than thorough (The Pharmaceutical Security Institute takes reports only from its membership – large Pharma companies – but fails to gather information from generic manufacturers) and many smaller brand manufacturers.

Current research lacks standardisation (the conclusions reached on the global picture take account of 'national market is testing' – but the market surveys are conducted by different bodies using different methods and with different motives).

As awareness of the risks of counterfeit medicine increases in political, legislative, judicial, enforcement, media and public circles, so too will the data upon which research and analysis can be conducted. This will enable more accurate conclusions to be drawn.

In the meantime there is certainty that this is a substantial and growing threat to the health of all.

More than 100,000 people die annually from counterfeit medicines in China, thousands die in Africa, and we have more recently seen deaths in Canada. Those deaths in Canada might yet prove to be but a tragic warning.

It is important to note that North America and Western Europe provide the best return on investment for those involved in the international supply of counterfeit medicines simply because North America & Western Europe are the most expensive markets and therefore provide the highest profits for substandard medicines masquerading as the genuine article.

In North America and in Europe there is currently no effective method of identifying counterfeited pharmaceuticals before they are dispensed.

2. How these are imported into Western nations

There are 3 main methods of importing counterfeit drugs –

a) By bulk commercial shipment
b) By showering of small commercial shipments
c) By supplying direct to consumer via the Internet

a) Bulk commercial shipments.
The extent of world trade and the international movement of cargo by container vessel means that the vast majority of products go unchecked when entering our ports.

At best Customs authorities can check all paperwork. Only a small percentage of containers are physically inspected, even more rare is any investigation into goods that appear to be less than harmful (e.g. not suspected of being explosives, firearms, narcotics or pornography).

The movement of containers from China and elsewhere in Asia (the origin of most counterfeit medicines) is a sophisticated matter. Containers are often unloaded in 'free ports' such as Jeb Al Ali in Dubai where there true origins are disguised before onward movement into Europe and elsewhere.

The wholesale and blatant international shipment by container of dangerous medicines is well illustrated by the experience of the Nigerian authorities.

b) By 'showering' of small commercial shipments.
The sending of whole container loads does not pose a significant risk to the counterfeiter but, should the shipment be discovered (Customs seizure) it can mean a very significant loss of profit. In addition the discovery of a container of fake product can provide a relatively easy means for the authorities to 'track back' to the point of illicit manufacture.

For those reasons counterfeiters also use a system of sending bulk consignments broken down into many small packages.

These can be posted into the country and the method avoids any possibility of total loss. This method also provides greater anonymity.

c) By supplying direct to consumer via the Internet.
The Internet is not only a threat to the unwary online customer but also a ready marketplace from which the unscrupulous Western pharmacist or wholesaler can buy.

As is well known, there are now many, many thousands of internet sites actively soliciting sales from consumers. Any prescription drug can be bought without prescription or question and in any quantity. One piece of recent American research indicated that 25% of medicines bought by this means were counterfeit.

Claims of guarantees provided by well sounding associations are often fatuous and merely add to the fraud and the danger.

The internet provides an unstoppable market that can, and is, taken advantage of by private and commercial purchasers of firearms, narcotics, pornography, fraudulent deals and all sorts of consumer goods. It cannot be stopped nor easily regulated. Governments make increasing resources available to control the adverse elements of online trading and given that individuals in the USA, UK and elsewhere will buy access to goods and services that are harmful to themselves and others, it is apparent that the Internet market needs to be regulated like any conventional one. Of course such regulation must be commensurate with the level of harm that the particular transaction could be expected to cause.

An important distinction therefore needs to be made between the private individual buyer and the commercial importer; the former risks harming himself, the latter risks harming many others. It seems obvious that regulations on business-to-business transactions should be much more tightly controlled.

Of course wherever the Western dealer buys counterfeit product from, and usually such dealers will not want to believe that the goods they have purchased at bargain price are counterfeit, they have to be sold on in order to make profit.

Getting the counterfeit product to market takes two forms. Either the product is sold direct (the importer might run a pharmacy or sell 'online' themselves) to the consumer, or the importer will sell it into the legitimate distribution chain. This is as easy as selling legitimate product and goes unnoticed.

Re-Importation - the lessons from Parallel Trade

I have no doubt that most parallel traders (importers) are law-abiding, but as in any other occupation there will be those that are not. Certainly, the special nature of their chosen business – dealing wholesale in lifesaving and potentially death-causing products – means that extra care needs to be taken, by legislators, regulators and by parallel traders themselves.

It seems to me right and fair that those who suffer from the highest prices (USA and Northern Europe) should be able to enter into free-trade with those in less developed countries, to the benefit of both parties and as a result of the differentiation in pricing structures which are imposed, to that extent no fair-minded person would object to parallel trade (or importation).

However, it must be abundantly clear that in matters such as medicine, special care needs to be taken. It is one thing to buy substandard footwear but quite another to buy substandard and potentially life-threatening medicines.

I have read from time to time comments such as, 'it can be difficult for the layman to identify counterfeit drugs' or 'it would need a trained doctor to examine the package to know whether

the drugs were genuine'. Such comments completely miss the point and show a lack of experience in handling counterfeit medicines.

The truth is that counterfeit medicines often appear so like the genuine product that no one, not the best specialist can tell the genuine packaging from the counterfeit. And no one, not the best specialist can tell the genuine product from the counterfeit unless the product is subjected to chemical analysis. The result is that everyone, poor, ignorant, rich and smart, all are at risk from counterfeit or sub-standard products – and they probably won't recognise them when they and if they see them.

The threat is not restricted to those of a certain income, intelligence, or to those who suffer from a particular disease.

The UK now receives some 140 million parallel traded medicines per annum. This is more than 20% of the entire consumption of the British National Health Service. The UK receives much more parallel traded product than any other European country; the reason is obvious – the UK is an expensive market in which parallel traded goods offer the best return for any European importer.

The difficulties surrounding parallel trade manifest in Britain in several ways, and valuable lessons can be applied in the USA:

- The very necessary requirements that medicines marketed in Britain must be packaged in the English language and contain a patient information leaflet in English language means that foreign medicines need to be repackaged. The repackaging process is often undertaken.
- Repackaging standards are not uniformly high and Patient Safety Groups in UK provide many examples of patients being dispensed medicines that 'don't look right' or have accompanying patient information that is incomplete, dangerously translated or otherwise different in effect.
- Repackaging is often conducted in the exporting country or some intermediate country. In such cases the UK regulators are blind to the conditions under which these processes are conducted.
- Repackaging is labour intensive. It is often not a mechanised process. The result is that repackaging is often done in those countries with the cheapest labour. It is just such countries of course that often cannot afford proper regulatory control, spend least on hygiene, and frankly, worry least about U.S or UK concerns.
- During the repackaging process original packaging is removed, blister packs emptied by hand or cut up (a month's supply in Continental Europe is usually 30 days worth, in UK a month's supply is 28 days worth, traders regularly manually remove 2 days supply from each 30 and put them by to create further packs)
- One survey in 2004 revealed that of 300 parallel traded medicines examined, 25% should have failed on 'safety reasons', 50% because of poor quality of product. In addition 80% failed on legal grounds such as IPR infringement.
- The removal of the product from the brand owners packaging destroys original batch numbering and anti-counterfeiting features. This in itself provides an ideal opportunity for sub-standard medicine, counterfeit or otherwise to enter the chain.
- The empty original packaging is ideal material in which to place counterfeit products destined first for a foreign market.
- Of course much parallel trade and repackaging is conducted properly according to law. However, those who choose to buy out of date, counterfeit or otherwise substandard medicines and to have them repackaged or stored in totally inappropriate conditions, can do so in Europe with very low risk of detection.

- One potential risk that has not been adequately researched on either side of the Atlantic, is the potential for counterfeiters to copy lawfully repackaged product. This is a low cost and perhaps the most anonymous method of introducing counterfeit in the chain with lowest risk of detection.
- Parallel trade is conducted by those who hold licenses that are extremely easy to obtain and then go largely unsupervised.

The nonsensical position in Europe is that it is very easy to become a pharmaceutical trader. Once trading you can buy from anywhere in Europe, and in many countries the regulatory regime is all but absent. In order to verify the bona fides and professional certification of the foreign party with whom you are dealing you are expected to obtain a copy of the other party's certification. This, if obtained, will usually come by fax- and of course be in any one of more than twenty different European languages.

3. The involvement of organised crime

The UK National Criminal Intelligence Service (NCIS) provides annually a description of the main threats to the UK from Organised crime. They have reported that,
" ....intellectual property crime offers potentially lucrative opportunities for serious and organised criminals. ...

Technical know-how is required to crack the security features, but thereafter production and distribution calls for largely non-technical criminal methods and infrastructures. Distribution may involve traditional forms of smuggling. However, pirated goods are increasingly marketed and distributed via the internet.

"... the ready consumer market for pirated goods, low chance of detection and low penalties attracted by such offences following conviction all serve to make intellectual property crime attractive to organised criminal groups.

...Intellectual property crime is taking place on a vast scale globally. Advances in technology have facilitated its growth, by enabling the speedy reproduction of high quality counterfeit goods, the best of which are difficult to differentiate from the genuine articles".

....the counterfeiting of all types of goods from designer clothes to **pharmaceuticals** is (also) rife. Many serious and organised criminals are involved, either in the manufacture of counterfeit products, or in their distribution, attracted by the high profits and the low risk of detection, and no doubt conscious of the fact that the penalties for intellectual property crime offences are rarely more than minimal. Meanwhile, there remains a public perception of intellectual property crime as a victimless crime, despite the fact that certain counterfeit products, such as car or aircraft parts, **pharmaceuticals** and alcohol, pose a direct risk to the public.....

...Although most of the largest importers of heroin and cocaine tend to concentrate on one or other drug, many drugs traffickers appear largely unconcerned about the different types of drugs they handle and, by inference, the different penalties they face should they be caught. The pattern of poly-drug use provides an obvious incentive for traffickers to engage in multidrug trafficking, rather than limiting themselves to one commodity. The key concerns are opportunity, capability, and profit. Therefore, if they have access to them, can handle the logistics of importation, and can buy and sell at a profit, some smugglers of Class A drugs will readily smuggle cannabis (which remains the most widely used drug in the UK), amphetamine (the market for which appears to be in decline) **or pharmaceuticals**

(such as Viagra and its various copies, the market for which is strong), importing the drugs in 'cocktail' loads or consecutively."

I am not suggesting for one moment that traditional organised crime families are controlling counterfeit medicines from manufacture, through the distribution and into pharmacies being run by the same gang. At various points in that process, criminals do business with other criminals who do business with shady businessmen who do deals with those who turn a blind-eye. Invariably by the time the substandard medicine reaches the point of final sale, the seller has no knowledge that the medicine is counterfeit.

Nevertheless individuals involved in the chain may associate with, buy from and even pay a percentage of their profits to an organised crime group unknowingly.
Perhaps less obviously, in the process of that business, organised crime types rely not only on other criminals, but also on professionals such as solicitors, accountants and pharmacists, whom they draw into their criminal enterprises to facilitate and protect them, and to launder their criminal profits.

There are now several cases in the UK that could be described as 'organised crime' cases. Several involving the UK, the Far East, and the Americas are currently ongoing.

One early case (1995) in the UK case involved imported pharmaceutical products product from Italy that had been produced by the Naples-based organised crime group, the Camorra, the investigation uncovered a clandestine manufacturing facility.

In 2000, approximately 250,000 doses and two tons of raw material (valued at US$1 million) originating from India and China were seized during another investigation into organised crime. The goods were being repackaged in Europe for resale in the Americas.

Over the last three years substantial cases have come to light in the USA, not least of all the Lipitor case.

4. Counterfeiting links to terrorism

I have seen articles written by American writers who pour scorn on the suggestion of a link between counterfeiting of pharmaceuticals and terrorism. It seems that anyone who might suggest terrorist involvement is open to ridicule. But it would selling this hearing short not to bring your attention to certain facts.

In the course of my anti-counterfeiting of pharmaceuticals investigations over a number of years I have become aware on at least two occasions that government agencies had linked the matter being investigated to known or suspected terrorist groups.

I am by no means alone in that, and not the only person to have gone on record to that effect-

The Italian government has disclosed that links between Islamic terrorist groups and the Camorra, that Italian crime gang behind the case I refer to above.

In addition, this issue has been the subject of debate in Brussels under the chair of the Directorate General of Internal Justice and Affairs, who is leading a forum for the prevention of organised crime. It has declared,
"The greater involvement of criminal organisations and sometimes even of terrorist groups in major international trafficking of counterfeits and pirated goods is evidence

of the particularly lucrative nature of these activities and of the increased sophistication of methods of fraud. This new threat, because of its scale, requires the setting up of new instruments within the (European) Union".

No lesser figure than the Director General of Interpol, Mr Ron Noble has publicly linked counterfeiting of branded goods to particular terrorist organisations.
In 2004 the head of Interpol gave public testimony to the effect that 'Terrorist financing is the generation of funds to a terrorist organisations.
He said, "The link between organised crime groups and counterfeit goods is well established. But Interpol is sounding the alarm that Intellectual Property Crime is becoming the preferred method of funding for a number of terrorist groups".

He continued, "... because of the growing evidence that terrorist groups sometimes fund their activities using the proceeds, it must be seen as a very serious crime with important implications for public safety and security".

5. Terrorism & the potential that counterfeiting of medicines- delivering a terrorist blow.

It must be apparent that once a connection to terrorism is shown the potential to inflict massive injury is clear. What more simple method could there be for the terrorist to cause

- massive loss of life,
- shatter the Healthcare Delivery System, and
- shake confidence that Government can adequately protect its people,

than simply introducing a noxious substance into our most frequently used drugs, or conducting germ warfare by introducing an agent via a counterfeit injectable product.

Of course providing adequate and reasonable measures to prevent the realisation of such a terrible act is easier said than done, but difficulty in planning should not be an excuse for ignoring the risk.

Currently there is a general lack of understanding and perhaps some wilful blindness about the nature and extent of the trade in dangerous pharmaceuticals.
This environment provides both a threat to general safety and ongoing opportunities for unscrupulous businessmen and organised crime and terrorism.

I hope my testimony is of some value to you.

Graham Satchwell
28 October, 2005.

John M. Gray, President & Chief Executive Officer

November 8, 2005

The Honorable Mark Souder
Chairman
Subcommittee on Criminal Justice, Drug Policy
and Human Resources
B-377 Rayburn House Office Building
U.S. House of Representatives
Washington, DC 20515

Dear Mr. Chairman:

The issue of counterfeit prescription drugs entering the domestic marketplace is a very serious one and the Healthcare Distribution Management Association (HDMA) commends you for convening the hearing held by the Subcommittee on Criminal Justice, Drug Policy and Human Resources on November 1, 2005, entitled "Sick Crime: Counterfeit Drugs in the United States." HDMA was pleased to work with your staff to provide background information on the pharmaceutical distribution industry and our ongoing efforts to address this very important topic. Regretfully, several statements made at the hearing need clarification and I request that you make this letter part of the official hearing record.

Who the Healthcare Distribution Management Association (HDMA) Represents
Several references to HDMA were made during the hearing and there appeared to be some confusion by some Subcommittee members and panelists regarding who HDMA represents.

HDMA is the national trade association representing the country's primary, full-service pharmaceutical and healthcare product distributors. These distributors, representing more than 90 percent of the distribution system, are responsible for ensuring that billions of units of medication are safely delivered to tens of thousands of retail pharmacies, nursing homes, clinics and providers in all 50 states. For more than 125 years, HDMA and its members have been the vital link in the healthcare system that is responsible for medicine safety, quality, integrity and availability in the marketplace.

HDMA Advocates Multi-Pronged Approach to Combating Counterfeit Drugs, Including Stronger Regulation, Increased Criminal Penalties, Adoption of New Anticounterfeiting Technologies, Comprehensive Best Practices Implementation
It was suggested by a witness that the "industry" is opposed to regulation and is not willing to work with regulators and other key stakeholders. I am not sure to whom the "industry" is meant to refer, but HDMA has a long track record of proactively working with state and federal policymakers and regulators, as well as private sector organizations, to continuously improve supply chain practices and businesses processes to aggressively combat counterfeit drugs.

As you cited in your opening statement, HDMA has most recently come forward to call for uniform federal licensing of prescription drug distributors. As highlighted at the hearing, in an era of increasingly sophisticated domestic and international threats to the nation's prescription drug supply, the current state-by-state licensing structure cannot provide the strong and consistent regulation of pharmaceutical

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distribution necessary to further secure the supply chain and protect the safety of the public. Several years ago, HDMA developed a state model bill and has since vigorously worked for its uniform adoption in the states. However, our experience in this effort is that while some states are very interested in reforming distributor licensure laws and have taken constructive steps, others have voiced frustration over lack of resources and an inability to properly regulate out-of-state distributors.

By no means is federal, uniform licensure of distributors the "silver bullet." HDMA believes that constant vigilance is required and that there is no single solution to ensuring product integrity. Given the increasing sophistication and frequency of product counterfeiting, it is imperative that our nation remain vigilant and constantly seek new approaches to further secure the domestic prescription drug supply. These ongoing efforts include: strengthening government regulation, oversight and enforcement; adopting new technologies; increased criminal penalties for those who counterfeit or traffic in counterfeit products; and developing and implementing industry best practices. Finally, each member of the supply chain – manufacturers, distributors and pharmacies – must work in partnership to ensure a safe and reliable supply of prescription drugs for patients.

HDMA Supports an Enhanced, Modernized "Pedigree"

Some Subcommittee members and witnesses argued that "industry" has opposed utilization of a pedigree system to track prescription drugs.

The fact is that a mandatory pedigree system has been in place for all distributors not authorized by the manufacturer to handle and sell their products since the enactment of the Prescription Drug Marketing Act (PDMA) in 1988. States are required to follow PDMA as a "baseline," but can mandate additional requirements. Some states have not acted beyond the baseline requirements, some have called for paper-based pedigrees and others plan to implement "electronic pedigrees."

HDMA has strongly recommended modernizing and improving the pedigree system to build on current and emerging electronic track and trace technologies, such as radio frequency identification (RFID), which was widely discussed at the hearing.

Paper pedigrees have not proven to be an effective deterrent against counterfeiting. Today, pharmaceutical products are not serialized with unique numbers or other identifiers that can be used to track, trace and authenticate individual items. As a result, no one in the supply chain, including the distributor generating the pedigree and the pharmacy that receives it will be able to verify with 100 percent accuracy that the paper pedigree accompanying the product unit is a real and accurate reflection of that unit's transaction history.

Many counterfeit drugs have been discovered to have had fraudulent paper pedigrees, chiefly because a paper pedigree is easier to counterfeit than the drug. Indeed, according to the FDA's study on counterfeit drugs, "paper records can be easily forged." Paper pedigree is a dated, inefficient and ineffective way to prevent criminal activity; it is a 1980s solution for at 21st Century problem.

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HDMA on the Verified-Accredited Wholesale Distributors (VAWD) Program
At the hearing, VAWD was described as a program that "…by default has set a national standard for the licensure and accreditation of wholesale distributors because very few wholesalers operate only in Indiana."

VAWD is a very new commercial endeavor recently created and managed by a private, third-party trade association. In fact, the first VAWD inspection took place just days before this hearing.

We believe that government authorities, not private interests, should ensure that distributor licensure standards are implemented and aggressively enforced. As currently structured, VAWD does not provide the appeals or confidentiality protections that are standard components of government-run licensure programs. Furthermore, VAWD will evaluate distribution facilities against standards that are not even part of the validly enacted Indiana law.

If the government decides that accreditation/licensure inspections should be outsourced, HDMA believes that the public interest would be best served by a competitive program in which licensure applicants have a choice of government-authorized accreditation vendors who would have to periodically demonstrate their competency and qualifications to the satisfaction of the government health authority, and who would be inspecting against validly enacted laws and regulations.

In closing, HDMA again commends you in your efforts to bring attention to the issue of counterfeit prescription drugs. HDMA remains committed to working with you and other Members of Congress who share our desire to strengthen the security of the nation's pharmaceutical supply chain and protect the American public.

Sincerely,

John M. Gray
President & CEO

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