# POINT, CLICK, SELF-MEDICATE: A REVIEW OF CONSUMER SAFEGUARDS ON INTERNET PHARMACY SITES

## HEARING

BEFORE THE

## COMMITTEE ON GOVERNMENT REFORM

## HOUSE OF REPRESENTATIVES

ONE HUNDRED EIGHTH CONGRESS

FIRST SESSION

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# POINT, CLICK, SELF-MEDICATE: A REVIEW OF CONSUMER SAFEGUARDS ON INTERNET PHARMACY SITES

**THURSDAY, MARCH 27, 2003**

HOUSE OF REPRESENTATIVES,
COMMITTEE ON GOVERNMENT REFORM,
*Washington, DC.*

The committee met, pursuant to notice, at 10:26 a.m., in room 2154, Rayburn House Office Building, Hon. Tom Davis of Virginia (chairman of the committee) presiding.

Present: Representatives Davis of Virginia, Burton, Platts, Putnam, Duncan, Miller, Murphy, Turner, Janklow, Waxman, Towns, Sanders, Maloney, Cummings, Kucinich, Tierney, Watson, Lynch, Van Hollen, Ruppersberger, and Bell.

Staff present: Peter Sirh, staff director; Melissa Wojciak, deputy staff director; Ellen Brown, legislative director and senior policy counsel; Scott Kopple, deputy director of communications; Teresa Austin, chief clerk; Joshua E. Gillespie, deputy clerk; Susie Schulte, legislative assistant; Corinne Zaccagnini, chief information officer; Anne Marie Turner, counsel; Phil Barnett, minority chief counsel; Josh Sharfstein, minority professional staff member; Earley Green, minority chief clerk; Jean Gosa, minority assistant clerk; and Cecelia Morton, minority office manager.

Chairman TOM DAVIS. Good morning. The committee will come to order.

I want to welcome everybody to today's oversight hearing on the domestic sale of drugs on Internet pharmacy sites.

The sale of consumer products over the Internet has grown exponentially over the last 10 years. Clearly, access to prescription drugs via online pharmacies can provide benefits to consumers, including convenience and reduced cost. But, while many online pharmacies operate in the same manner as traditional brick-and-mortar drug stores and comply with the standards of State licensing authorities, not all pharmacies practicing over the Internet are legitimate sites.

The Internet creates an easy environment for illegitimate sites to bypass traditional regulations and established safeguards for the sale of prescription drugs. Public health and consumer safety issues arise when the sale of prescription drugs occurs without a valid prescription or adequate physician supervision. It is now very simple to obtain virtually any medication online without ever seeking or speaking with a physician. All a consumer has to do is type the name of the drug into a search engine, quickly identify a site sell-

ing the medication, and then click to purchase. Although some sites require the consumer to fill out a health questionnaire to be reviewed by a physician prior to the prescription, consumers can easily manipulate their medical history on some questionnaires to be approved for the drug they desire. On other sites, no questionnaire is even required.

I think all of us here today have opened our in-boxes only to find dozens of e-mails advertising medications at low cost with no prescription required. The most popular of those drugs sold online are so-called "lifestyle" drugs, including Viagra and Propecia. After September 11th there was a sharp rise in the sale of Cipro over the Internet without a prescription. The risks of this kind of self-medicating can include adverse reactions from inappropriately prescribed medications, dangerous drug interactions, and use of counterfeit or tainted products.

I think it is important to note that several of these illegitimate sites fail to provide information about contraindications, potential adverse effects, and efficacy.

Regulating these Internet pharmacies can be a challenge for Federal and State enforcement capabilities. Authorities have trouble tracking down Internet sites that fail to comply with State licensing requirements and standards. Many don't disclose identifying information, change their names and appearances often, and sometimes disappear without a trace. Accountability is impossible when the violators cannot be identified and located.

Another regulatory challenge is the application of State regulations across multiple jurisdictions by multiple State and Federal authorities. Historically, States have been the primary enforcement authority with respect to the practice of medicine and dispensing of prescription drugs; however, the Food and Drug administration and the Federal Trade Commission also have a role to play.

We will hear the testimony from several witnesses to discuss the regulatory challenges created by the domestic sale of prescription drugs over the Internet. I want to thank all of our witnesses for appearing here with us today.

I would now like to yield to Mr. Waxman for an opening statement.

[The prepared statement of Chairman Tom Davis follows:]

**Opening Statement of Chairman Tom Davis**
**Hearing on "Point, Click, Self-Medicate: A Review of Consumer Safeguards on Internet Pharmacy Sites"**
**Committee on Government Reform**
**March 27, 2003, following 10:00a.m. Business Meeting**
**Room 2154 Rayburn House Office Building**

Good morning, I would like to welcome everyone to today's oversight hearing on the domestic sale of drugs on Internet pharmacy sites. The sale of consumer products over the Internet has grown exponentially over the past 10 years. Clearly, access to prescription drugs via online pharmacies can provide benefits to consumers, including convenience and reduced costs. But, while many online pharmacies operate in the same manner as traditional brick-and-mortar drug stores, and comply with the standards of state licensing authorities, not all pharmacies practicing over the Internet are legitimate sites. The Internet creates an easy environment for illegitimate sites to bypass traditional regulations and established safeguards for the sale of prescription drugs.

Public health and consumer safety issues arise when the sale of prescription drugs occurs without a valid prescription or adequate physician supervision. It is now very simple to obtain virtually any medication online without ever seeing or speaking with a physician. All a consumer has to do is type the name of the drug into a search engine, quickly identify a site selling the medication, and then click to purchase. Although some sites require the consumer to fill out a health questionnaire to be reviewed by a physician prior to the prescription, consumers can easily manipulate their medical history on some questionnaires to be approved for the drug they desire. On other sites, no questionnaire is even required.

I think all of us here today have opened our inboxes only to find dozens of emails advertising medications at low cost, with no prescription required. The most popular of those drugs sold online are so-called "lifestyle drugs" including Viagra and Propecia. After September 11$^{th}$, there was a sharp rise in the sale of Cipro (an antibiotic used to treat anthrax exposure) over the Internet without a prescription. The risks of this kind of self-medicating can include adverse reactions from inappropriately prescribed medications, dangerous drug interactions, and use of counterfeit or tainted products. I think it is important to note that several of these illegitimate sites fail to provide information about contraindications, potential adverse effects, and efficacy.

Regulating these Internet pharmacies can be a challenge for Federal and state enforcement capabilities. Authorities have trouble tracking down Internet sites that fail to comply with state licensing requirements and standards. Many do not disclose identifying information, change their names and appearances often, and sometimes disappear without a trace. Accountability is impossible when the violators cannot be identified and located.

Another regulatory challenge is the application of state regulations across multiple jurisdictions by multiple state and Federal authorities. Historically, states have been the primary enforcement authority with respect to the practice of medicine and the dispensing of prescription drugs; however, the Food and Drug Administration and the Federal Trade Commission also have a role to play. We will hear testimony from the following witnesses to discuss the regulatory challenges created by the domestic sale of prescription drugs over the Internet.

Mr. William Hubbard is here from the FDA and Mr. Howard Beales will be testifying on behalf of the Federal Trade Commission. We will also hear testimony from Dr. Jim Thompson of the Federation of State Medical Boards, Mr. Carmen Catizone of the National Association of Boards of Pharmacy, and Connecticut Attorney General, Mr. Richard Blumenthal.

Mr. WAXMAN. I would like to thank Chairman Davis for holding this hearing today on the proliferation of domestic Web sites that sell medications without a valid prescription. These Web sites occupy a dark and dangerous corner of the U.S. health care system. With the simple click of a mouse, consumers can purchase virtually any prescription medication without knowing who is hosting the Web site, who is writing the prescription, or who is dispensing the drug. On these sites, no prescription from your doctor is required. On the basis of a cursory medical questionnaire or no questionnaire at all, an anonymous physician prescribes medication that can be lethal.

This practice has been rejected as substandard care by the State medical boards, and for good reason. Without a real visit with a physician that explores the risks and benefits of a prescription drug, a consumer can wind up suffering severe and unnecessary side effects. Children can order drugs online without their parents' or their doctor's knowledge.

There is also concern among experts that easy access to antibiotics like Cipro through Internet pharmacies fosters drug resistance and therefore threatens us all.

One reason for the persistence of Web sites selling drugs without valid prescriptions is a gap in consumer safeguards and Government enforcement. On one side of this gap are Federal agencies that are charged with protecting consumers. Federal law prohibits false and misleading advertising and requires certain drugs only be dispensed with a prescription. However, while Federal agencies have taken action against Web sites when there is a clear consumer fraud, the Federal Government has generally deferred to States on the central question of what is a valid prescription.

On the other side of the gap are State agencies, including boards of medicine and pharmacy, and the attorneys general. Many States would like to shut these sites down, but often lack the legal authority to do so. For example, if one attorney general gets an injunction against one Web site, that injunction applies only in one State. It should not be necessary to require 50 separate lawsuits to shut down every dangerous Internet site.

Today we will hear from the key agencies and organizations on both sides of this gap. I look forward to hearing about existing efforts to protect consumers and to discussing possible solutions to this ongoing problem.

I want to thank all the witnesses for appearing today.

Thank you, Mr. Chairman.

[The prepared statement of Hon. Henry A. Waxman follows:]

Statement of Rep. Henry A. Waxman
Ranking Minority Member
Committee on Government Reform
Hearing on
"Point, Click, Self-Medicate: A Review of Consumer Safeguards on Internet Pharmacy Sites"

**March 27, 2003**

I would like to thank Chairman Davis for holding this hearing today on the proliferation of domestic web sites that sell medications without a valid prescription. These web sites occupy a dark and dangerous corner of the U.S. health care system. With the simple click of a mouse, consumers can purchase virtually any prescription medication without knowing who is hosting the web site, who is writing the prescription, or who is dispensing the drug. On these sites, no prescription from your doctor is required. On the basis of a cursory medical questionnaire, or no questionnaire at all, an anonymous physician prescribes medication that can be lethal.

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Today, we will hear from the key agencies and organizations on both sides of this gap. I look forward to hearing about existing efforts to protect consumers and to discussing possible solutions to this ongoing problem. I thank the witnesses for appearing today.

Chairman TOM DAVIS. Thank you very much.

Any additional statements? Mr. Burton.

Mr. BURTON. Mr. Chairman, thank you very much. I agree with what Representative Waxman and you just said. Those who are selling drugs without prescriptions over the Internet should be prosecuted to the full extent of the law; however, 10 years ago very few people owned a personal computer and the Internet was only used by the military and scientific communities. Ten years ago the Internet was available to most Government agencies and the corporate world, and today every desk in every office of the country has a computer hooked up to the Internet, and a majority of American homes have at least one computer and Internet access.

Americans can read the Congressional Record the day it is printed. We as a population buy books, music, video games, furniture, flowers, clothing, and airline tickets online. At the same time, Americans' dependence on prescription drugs has risen dramatically: 75 percent of Americans between the ages of 50 and 64 are on at least one prescription drug; 14 percent of women age 65 are on five prescription drugs in any given weeks. And I have friends who spend $600 or more a month on prescription drugs. Anyone with a chronic health condition likely is in the same situation.

The price of prescription drugs in the United States is the highest of any country on Earth—highest of any country on Earth. In fact, in these troubled economic times the pharmaceutical industry is thriving. Several companies had 10 to 15 percent growth just last year and their bottom line is unbelievable, the profits they are making. Many Americans—in particular, our senior citizens—are looking for legitimate ways to buy their needed prescriptions at lower prices. Other Americans prefer the convenience of having their prescriptions delivered directly to their home.

The technology highway, once a rough dirt road, has become a multi-lane superhighway intersecting with Americans' avenue of need for lower-priced prescription drugs.

As Federal officials looking at this emerging field of Internet pharmacies, we must move forward cautiously in determining what type of traffic controls, if any, we place on the intersection between consumers and the lawful Internet pharmacy. The roads and intersection already exist. Americans should have the right to lawfully purchase prescription drugs through licensed Internet pharmacies both in the United States and Canada, as long as those prescriptions are valid and given to the pharmaceutical Internet businesses.

Those who violate the law by operating illegal pharmacies should be prosecuted. Those wholesalers who provide drugs to non-licensed pharmacies should also be prosecuted. The jurisdiction of parts of these roads is not that of the Federal Government. The regulation of pharmacies and the practice of medicine both are managed by State governments. I am a firm believer in States' rights and do not wish for the Federal Government to co-opt State regulatory authority.

I'm also a strong proponent of the free enterprise system that is the underpinning of our democracy; therefore, I believe that anything we decide to do at the Federal level must respect rights of the State governments, the rights of lawful businesses to operate,

and the rights of Americans to use the Internet to buy prescription drugs for which they have a legitimate prescription at the best price available.

I look forward to hearing from our witnesses today. Today's hearing is focused on domestic Internet pharmacies. We have another problem relating to Internet pharmacies that we will be addressing in a subcommittee hearing next Thursday, and that is the ability for Americans to maintain access to lower-priced prescription drugs through Canadian online pharmacies.

I have cosponsored legislation with Congressman Sanders and 50 other legislators at this time—and I fully believe we will have maybe over 100 very shortly—that will institute monetary fines on pharmaceutical companies that reduce access of Americans to lower-cost drugs online from Canadian pharmacies.

Thank you, Mr. Chairman.

[The prepared statement of Hon. Dan Burton follows:]

TOM DAVIS, VIRGINIA
CHAIRMAN

HENRY A. WAXMAN, CALIFORNIA
RANKING MINORITY MEMBER

ONE HUNDRED EIGHTH CONGRESS

Congress of the United States

House of Representatives

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*Statement of Congressman Dan Burton (R-IN)*
*Chairman*
*Subcommittee on Human Rights and Wellness*

*At the Committee on Government Reform Hearing*
*"Point, Click, Self-Medicate: A Review of Consumer Safeguards on Internet Pharmacy Sites."*

*March 27, 2003*

*2154 Rayburn House Office Building*
*10:00 am*

Thank you Mr. Chairman for calling this hearing today. When I came to Congress, very few people owned a personal computer. The Internet was only used by the military and scientific communities.

Ten years ago, the Internet was available to most Government agencies and the corporate world.

Today, every desk in every office in the country has a computer hooked up to the Internet. And a majority of American homes have at least one computer and Internet access.

Americans can read the Congressional Record the day it is printed. We as a population buy books, music, video games, furniture, flowers, clothing, and airline tickets online.

At the same time, Americans' dependence on prescription drugs has risen dramatically. Seventy-five percent of Americans age 50 to 64 are on at least one prescription drug. Fourteen percent of women aged sixty-five are on five prescription drugs in any given week. I have friends who spend $600 dollars or more a month on prescription drugs. Anyone with a chronic health condition, likely is in the same situation.

The price of prescription drugs in the United States is the highest of any country on the planet. In fact, in these troubled economic times, the pharmaceutical industry is thriving. Several companies had 10 to 15 percent growth last year.

Many Americans, in particular our senior citizens, are looking for legitimate ways to buy their needed prescriptions at lower prices. Other Americans prefer the convenience of having their prescriptions delivered directly to their home.

The technology highway, once a rough dirt road has become a multi-lane superhighway intersecting with Americans' avenue of need for lower price prescription drugs.

As Federal officials looking at this emerging field of internet pharmacies, we must move forward cautiously in determining what type of traffic controls, if any, we place on the intersection between consumers and the lawful Internet pharmacy.

The roads and intersection already exist. Americans should have the right to lawfully purchase prescription drugs through licensed Internet Pharmacies both in the United States and Canada.

Those who violate the law, by operating illegal pharmacies should be prosecuted. Those wholesalers who provide drugs to non-licensed pharmacies should also be prosecuted.

The jurisdiction of parts of these roads is not that of the Federal Government. The regulation of pharmacies and the practice of medicine both are managed by state governments. I am a firm believer in state's rights and do not wish for the Federal Government to co-opt state regulatory authority.

I am also a strong proponent of the free enterprise system that is the underpinning of our democracy.

Therefore, I believe that anything we decide to do at the Federal level must respect the rights of the state governments, the rights of lawful businesses to operate, and the rights of Americans to use the Internet to buy prescription drugs for which they have a legitimate prescription.

I look forward to hearing from our witnesses today.

Today's hearing is focused on domestic Internet pharmacies. We have another problem related to Internet pharmacies that we will be addressing in a Subcommittee hearing next Thursday. That is the ability for Americans to maintain access to lower-priced prescription drugs through Canadian online pharmacies.

I have co-sponsored legislation with Congressman Sanders and fifty other legislators that will institute monetary fines on pharmaceutical companies that reduce access of Americans to lower cost drugs online from Canadian pharmacies.

Chairman TOM DAVIS. Thank you very much.

Any other opening statements? Mr. Towns.

Mr. TOWNS. Thank you very much, Mr. Chairman, for holding this oversight hearing on safeguards on Internet pharmacy. I would like to commend you and Ranking Member Waxman for shedding light on this issue.

Today's Internet technology has revolutionized the purchase and delivery of goods and services, so it should come as no surprise that many people are utilizing this technology to purchase prescription drugs, as well. However, what is surprising and often frightening is the ease of which it can be done.

The purchase of prescription drugs through the Internet raises some very troubling safety concerns. For starters, there is a legitimate question of whether a doctor or other medical professionals are actually involved in the prescription drug transaction. Even if there is a doctor, the consumer has no assurances of the medical professional's credentials or how thoroughly he or she reviews the medical information supplied. A brief online questionnaire may miss essential information on whether a specific drug is safe for a patient.

Additionally, children may try to use the Internet to get potentially dangerous prescription drugs. Although the FDA has the authority to take action against the sale of prescription drugs without a valid prescription, the agency has left it up to States to determine what is a valid prescription.

Since a person in New York can buy a prescription drug through an Internet site based in Texas, it seems to me that the regulatory scheme is inadequate.

I'm not in favor of shutting down all Internet pharmacy sites; however, it appears that better oversight and control is definitely needed. Purchasing drugs through the Internet can offer consumers incredible benefits. It offers improved access for home-bound patients and increases privacy for a person who has a disease that may carry a social stigma, but we must make sure that a licensed medical practitioner is involved in all prescription drug transactions.

I look forward, Mr. Chairman, to hearing from the witnesses. This is a very important hearing.

On that note I yield back.

Chairman TOM DAVIS. Thank you very much.

Any other opening statements over on this side? Mr. Janklow.

Mr. JANKLOW. Mr. Chairman, I am going to be brief. Thank you very much for conducting this hearing. It is obvious one of the major problems we have in this country is people just cannot get prescription drugs at a price that they can afford to pay for them, and, given the utility value of the Internet, they are able to very quickly lower the cost. It is not always just a case of people trying to circumvent the system as much as it is a lot of people trying to find adequate drugs.

We talk about the Canadian situation. The fact of the matter is this Congress passed statutes that were signed into law by the President of the United States, and the last two Secretaries of Health and Human Services have both refused to do the necessary documentation that the law required to deal with the importation

of drugs into the United States. For some reason, they've chosen just not to comply with the law.

We talk about using the courts for civil actions to close people down. The fact of the matter is a contested civil case in America takes longer from start to finish than World War II did. There isn't any way that we have an efficient adjudicatory process in this country. Someone can get an injunction on the front end, but by the time it is finished on the back end it is several years later. And there are hundreds of these cases that could be brought.

This is one of those rare times when, under the U.S. Constitution, where it was envisioned that Congress would regulate commerce between the States. This is something that's within the unique framework of the national Government to deal with.

Mr. Chairman, I think you have shown great insight in moving forward on this particular issue, and I really look forward to the testimony as to what people think we can do, as opposed to all the brilliant things they are doing.

Thank you.

Chairman TOM DAVIS. Thank you very much.

Mr. Sanders.

Mr. SANDERS. I apologize for jumping ahead of my colleague here.

Chairman TOM DAVIS. You can yield at the end of your 5 minutes and we can get more in. That's fine. You are recognized for 5 minutes.

Mr. SANDERS. Thank you, Mr. Chairman. Mr. Chairman, thank you for holding this important hearing. The issue of prescription drugs is something that I have been heavily involved in not only in my 12 years in Congress but in years before that, as well. As my friend, Mr. Janklow indicated, the reason for my concern is that the American people pay by far the highest prices in the world for prescription drugs. There are millions of senior citizens in this country who are unable to afford prescription drugs and suffer—and in some cases die—as a result of that reality.

Year after year the pharmaceutical industry leads every other industry in the profits that they make while millions of Americans are unable to afford prescription drugs. Many of these companies pay their CEOs extravagant compensation packages. And let us be honest and bring the real world into this room: the pharmaceutical industry is the most powerful lobby in the United States. In the last several years, Mr. Chairman, the pharmaceutical industry has spent hundreds and hundreds of millions of dollars in campaign contributions to the vast majority of the Members of Congress, to both political parties, especially the Republican party. The pharmaceutical industry has spent huge sums of money on lobbying. There are over 600 paid lobbyists from the pharmaceutical industry who descend on this institution any time that any Member comes up with an idea to lower the cost of prescription drugs.

Now, the reality of what is going on in America today—and I know, Mr. Chairman, this is a little bit divergent from your discussion, important issues that you are raising today—but the reality is that approximately 1 million Americans are now going to Canada in order to buy prescription drugs because the same exact med-

icine sold in Canada is sold for a fraction of the price that it's sold in the United States.

Mr. Chairman, several years ago I became the first Member of Congress to take a group of citizens from the State of Vermont over the Canadian border. Let me tell you one story. Mr. Chairman, I know that you are aware of the very serious problem of breast cancer in this country and how many women are struggling for their lives. Timoxaphin is one of the most widely prescribed breast cancer drugs in this country. The women who went with me over the border were able to purchase timoxaphin—the same, exact product, not a generic, Mr. Chairman—for one-tenth the price, 10 percent of the price that they're paying here in the United States.

Now, what is going on is that in the last several years—and I'm proud to have been an active player in that process—about 1 million Americans are either going over the border to purchase prescription drugs in Canada or else they are increasingly using the Internet.

Obviously, the pharmaceutical industry, which contributes so much money in the political process, is putting a great deal of pressure on the FDA and on Members here to say, "No, let the old people suffer. Let them die, because we have to protect our profits. Don't let them go to Canada," although there has not been one indication that the regulatory system in Canada is any inferior to what we have here, not one indication, to the best of my knowledge, that one medicine, one prescription coming over the border has caused anybody any problems.

So, Mr. Chairman, let me go on record right now as saying to the FDA and to Mr. Hubbard and those other people here that we are going to fight you and we are going to try everything that we can to prevent you from forcing people in this country to suffer and die so that the pharmaceutical industry can continue to rake up huge profits and provide campaign contributions to Members of the Congress.

Thank you very much, Mr. Chairman.

Chairman TOM DAVIS. Any other statements? Mr. Bell.

Mr. BELL. Thank you, Mr. Chairman. I want to thank you and the ranking member for focusing attention on what I think is a very important issue, and I look forward to hearing the testimony here today.

As the number of people accessing Internet pharmacy sites has increased from 45 million in 1999 to an estimated 320 million by the year 2005, it is imperative that the Federal Government lead the way to ensure that these sites are safe for consumer use. While I don't completely disagree with my colleague, Mr. Sanders, that I do think that consumers should have access to affordable prescription drugs, we need to make sure that it is safe.

Although law-abiding Internet pharmacies benefit modern health care in numerous ways, some Internet pharmacies conduct illegal and unsafe prescribing and dispensing practices that can endanger the health of their patients. Because many online pharmacies offer a variety of drugs, including controlled substances, and do not adhere to ethical guidelines to protect patients, the potential for harm to consumers is massive. These pharmacies present a significant

danger to health care consumers and pose a regulatory nightmare that I'm sure we'll hear more about today.

Mr. Chairman, I'm concerned that the Federal Government is merely playing catch-up and stands to lose this race if we don't take immediate action.

I thank you again for calling this hearing and I look forward to working with the committee to find a plausible solution.

Thank you, Mr. Chairman.

[The prepared statement of Hon. Chris Bell follows:]

**Statement of Congressman Chris Bell**
**House Committee on Government Reform**
**"Point, Click, and Self-Medicate: A Review of Consumer Safeguards on Internet Pharmacy Sites"**
**March 27, 2003**

I would like to thank the Chairman and Ranking Member for their leadership on this important issue.

As the number of people accessing Internet pharmacy sites increase from 45 million in 1999 to an estimated 320 million in 2005, it is imperative that the federal government lead the way in ensure that these sites are safe for consumer use.

Although, law abiding Internet pharmacies benefit modern healthcare in numerous ways, some Internet pharmacies, however, conduct illegal and unsafe prescribing and dispensing practices that can endanger the health of its patients.

Because many online pharmacies offer a variety of drugs, including controlled substances and do not adhere to ethical guidelines to protect patients, the potential for harm to consumers is massive. These pharmacies present a significant danger to healthcare consumers and pose a regulatory nightmare.

Mr. Chairman, I am concerned that the federal government is merely playing catch up and stand to loose this race if we don't take immediate action. I thank you again for calling this hearing and look forward to working with the Committee to find a plausible solution.

Chairman TOM DAVIS. Thank you.

Mr. Ruppersberger.

Mr. RUPPERSBERGER. Yes. Today we are going to discuss online pharmacies. The cost of prescription drugs are on the rise and everyone is looking to save money, and my concern today though is for the consumer. I think there are certain issues and questions that we need to discuss, and hopefully you will discuss them in your testimony.

Are these sites secure? Are these sites protecting the privacy of individuals who choose to purchase their prescription drugs online? Are there verification systems in place to make sure a prescription is legitimate and real? Are the prescriptions that are sold valid, safe, and healthy?

I'm also concerned about these Web sites because I'm concerned that the proper precautions and safeguards are not in place to protect consumers.

While the growth of the Internet has allowed many Americans to save money and experience real convenience, we have to question the safety of these Web sites.

Thank you, Mr. Chairman.

[The prepared statement of Hon. C.A. Dutch Ruppersberger follows:]

Congressman C.A. Dutch Ruppersberger
Committee on Government Reform
Internet Pharmacies
March 27, 2003

A few years ago the Internet helped to facilitate a tremendous economic boom. It gave rise to some innovative ideas and helped to push technology forward and brought most of us into the information age. I am concerned about the cost of prescription drugs. It is almost immoral that seniors have to pay more for prescription drugs as opposed to food and rent.

Today's hearing we are going to discuss on-line pharmacies. The cost of prescription drugs are on the rise and everyone is looking to ways to save money. My concern is for the consumer. Are these sites secure? Are these sites protecting the privacy of individuals who choose to purchase their prescriptions on-line? Are there verification systems in place to make sure a prescription is legitimate and real? Are the prescriptions that are sold valid, safe, and healthy?

I am concerned about these websites. I am concerned that the proper precautions and safe guards are NOT in place to protect consumers.

While, the growth of the Internet has allowed many Americans to save money and experience real convenience. We have to question the safety of these websites.

Mr. Chairman I thank you for calling this very important hearing and I look forward to hearing from the panels and learning more about the issue.

Thank you.

Chairman TOM DAVIS. Thank you very much.

Any other opening statements? Mr. Tierney.

Mr. TIERNEY. Thank you, Mr. Chairman.

I'd just ask for unanimous consent to enter my remarks in the record and essentially adopt much of what Mr. Sanders said. As much as we need to make sure that we have good regulatory practices in place, we ought to be very careful to make sure that we're not at the same time taking away from consumers and people that need affordable prescription drugs and alternatives. I would rather see us use this hearing as an effort to make the system work so that they can, in fact, get affordable prescription drugs, as opposed to one that's shutting the door on them in that regard.

[The prepared statement of Hon. John F. Tierney follows:]

**Testimony of Congressman John F. Tierney (MA-06)**
**Committee on Government Reform**
**"Point, Click, Self-Medicate, A Review of Consumer Safeguards on Internet Pharmacy Sites"**

I share many of the concerns raised by the Chairman and Ranking Member on this issue.

I very much agree with the premise that internet pharmacies must be equipped with the necessary safeguards to protect our constituents' health as well as their consumer safety.

Throughout this regulatory process, however, we must be careful not to completely undercut nor ignore the utility of internet pharmacies.

Let's keep in mind that on-line pharmacies do have quality controls – this service can be a safe, viable alternative to consumers – and consumers are in need of this alternative.

I asked the Special Investigations Division of the Democratic staff of the Government Reform Committee to examine the extent of price discrimination in my district. The results were staggering. Seniors in my district pay, on average, more than twice as much for the five most popular drugs as purchasers in foreign countries.

What really bothers me is that this debate could easily become a back door attack on re-importation of prescription drugs, primarily from Canada, by seniors who face ever-escalating drug prices here in the United States.

According to a recent Wall Street Journal article, in order to purchase prescription drugs from one of these Canadian pharmacies, consumers must first fax or mail a prescription from their doctor to the company running the website. In addition, they must provide medical history including other prescription drugs they are currently taking.

A Canadian doctor then reviews the personal information and prescription. If everything seems to be in order, then the doctor co-signs the prescription and the order is fulfilled and mailed to the U.S. customer.

It appears that, in Canada, safeguards do exist.

I must say it is very unfortunate that Congress has yet to pass a meaningful prescription drug plan that would allow seniors in my district and across the country to purchase drugs at a reduced cost.

In the meantime, we should endorse – not exclude – options that will save U.S. consumers money and serve their health.

I hope that we continue to approach this issue with that in mind.

Thank you, Mr. Chairman, and I look forward to the witnesses' testimony.

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Chairman TOM DAVIS. Thank you.

Any other comments?

[No response.]

Chairman TOM DAVIS. If not, we're going to move to our first panel of witnesses. We have Mr. William Hubbard here from the FDA. Mr. Howard Beales will be testifying on behalf of the Federal Trade Commission.

Mr. Taylor, you are accompanying him; is that correct?

Mr. TAYLOR. Yes.

Chairman TOM DAVIS. So you may be testifying. Why don't we all rise? It is the policy of the committee to swear in witnesses.

[Witnesses sworn.]

Chairman TOM DAVIS. Thank you very much.

We have a timer in front of you. When it is green, you keep going. When it is orange, you have a minute to sum up. When it turns red, we would appreciate your summing up, because your total statements will be in the record.

Let's start, Mr. Beales, with you, and then Mr. Hubbard. We thank you very much for being with us. As you can see, there's a lot of interest among Members on this subject.

**STATEMENTS OF J. HOWARD BEALES, DIRECTOR OF THE BUREAU OF CONSUMER PROTECTION, FEDERAL TRADE COMMISSION; AND WILLIAM HUBBARD, SENIOR ASSOCIATE COMMISSIONER FOR POLICY PLANNING AND LEGISLATION, FOOD AND DRUG ADMINISTRATION**

Mr. BEALES. Thank you, Mr. Chairman and members of the committee. I am Howard Beales, the Director of the Federal Trade Commission's Bureau of Consumer Protection. I'm pleased to be here today to present the FTC's testimony and to work with the committee on these important issues.

For many years the Commission has actively attacked false and misleading health care advertising, no matter the medium. In the last 5 years, alone, the Commission has brought 105 health and safety cases. In most of those cases, some part of the marketing occurred online.

We have been particularly concerned about fraudulent claims on the Internet. The Commission's "Operation Cure All" targets Web sites that deceptively promote products or services that purportedly treat or cure serious and life-threatening diseases. Since June 1999, the FTC has filed 18 "Operation Cure All" cases and sent warning letters to hundreds of Web sites.

Of course, success would not be possible without the efforts of our many law enforcement partners, including the FDA and several State attorneys general.

The sale of prescription drugs on the Internet raises special law enforcement challenges. Prescription drugs available online offer consumers convenience and value. Many online pharmacies appear to operate the same way traditional pharmacies do; however, as this committee well knows, the practices of some online pharmacies that file prescriptions without adequately reviewing a consumer's medical history or dispense unapproved drugs from overseas have significant potential to injure consumers.

Historically, the States have regulated the practice of medicine and pharmacy. In the last few years, a number of States have brought actions against online companies that dispense prescription drugs without a valid prescription or have initiated professional disciplinary actions.

On the Federal level, the FDA is the principal agency with both scientific expertise and statutory authority to oversee online prescription sales, including the authority to take action against the dispensing of a prescription drug without a valid prescription.

The Commission can assist these agencies by bringing cases against Web sites that engage in false and deceptive practices. For example, in one case the Commission charged an online pharmacy with falsely representing that consumers received care by a clinic with physicians and an onsite pharmacy. There were no physicians, no onsite pharmacy.

Following the anthrax outbreak in 2001, the Commission investigated the possible sale of counterfeit Cipro on the Web. Working with FDA, our staff ordered product samples from both foreign and domestic Web sites and had them tested. No counterfeit Cipro was discovered and no actions were filed. We provided information about the foreign Web sites to the FDA.

Prescribing and dispensing drugs online may be illegal, but unless it is deceptive or unfair it falls outside of the FTC's authority and expertise.

We will continue to work closely with the FDA and other Federal and State agencies and assist them when we can. We will also continue to monitor the Internet for deceptive and misleading product claims and to bring cases when appropriate under our jurisdiction.

Thank you for this opportunity to present the Commission's views. I look forward to responding to your questions.

Chairman TOM DAVIS. Thank you very much.

[The prepared statement of Mr. Beales follows:]

**Prepared Statement of**

**the Federal Trade Commission on**

# "The Internet Sale of Prescription Drugs From Domestic Websites"

**Before the**

**Committee on Government Reform**

**United States House of Representatives**

**Washington, D.C.**

**March 27, 2003**

Mr. Chairman and members of the Committee, I am Howard Beales, Director of the Bureau of Consumer Protection of the Federal Trade Commission. I am pleased to have this opportunity to discuss the Commission's consumer protection activities relating to the online marketing of health products and specifically prescription drugs.[1]

The Commission is charged by Congress with preventing deceptive or unfair acts or practices in commerce, pursuant to Section 5 of the Federal Trade Commission Act ("FTC Act").[2] This morning I will describe some of the Commission's enforcement efforts and other activities to protect the online consumer from the deceptive marketing of health care products generally, and outline how the FTC's role relates to that of other federal and state authorities with respect to online prescription drugs specifically. As I will explain, there are significant limitations on the Commission's ability to address the online prescribing and sale of prescription drugs over the Internet.

**I. Protecting Consumers Against Deceptive Online Marketing of Health Products.**

The Internet offers significant consumer benefits in the form of greater and easier access to detailed health information, as well as more convenient access to health care products and services. Use of the Internet to obtain health information has grown dramatically, from

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[1] This written statement presents the views of the Federal Trade Commission. Responses to questions reflect my views and do not necessarily reflect the views of the Commission or any Commissioner.

[2] 15 U.S.C. § 45(a). In addition, Section 12 of the FTC Act prohibits the false advertisement of "food, drugs, devices, services, or cosmetics." 15 U.S.C. § 52.

approximately 22.3 million adult users in 1998[3] to over 70 million by October 2002.[4] Moreover, it is clear that consumers are turning to the Internet not just for health information but to purchase health care products as well. Unfortunately, the online medium also provides an easy opportunity for irresponsible marketers to prey on sick or vulnerable consumers with false or deceptive claims that can cause potentially serious consequences to consumers' pocketbooks and, potentially, their health.

Pursuant to its broad authority to prevent unfair and deceptive practices, the Commission actively monitors Internet commerce. In health care, as in many other areas, the Commission takes a lead in enforcing existing laws to ensure that advertising claims are not misleading or deceptive. Moreover, in the area of Internet commerce, the Commission has been sensitive to concerns that Internet advertising be treated the same as advertising in other media.

*Operation Cure.All* is an integral part of the Commission's campaign against the marketing of fraudulent health-related products on the Internet. The initiative began in 1997 in response to rising concerns about the proliferation of questionable marketing claims for health products on the Internet. *Operation Cure.All* is an on-going, coordinated law enforcement and consumer/business education initiative targeting deceptive and misleading Internet promotion of products and services that promise to cure or treat serious diseases or conditions such as cancer, HIV/AIDS, arthritis, diabetes, multiple sclerosis, and heart disease. The FTC works with numerous law enforcement partners including the Food and Drug Administration ("FDA"),

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[3] Cyberdialogue, Inc. (June 1999).

[4] Pew Internet & American Life Project, *Counting on the Internet: Most Expect to Find Key Information Online, Most Find the Information They Seek, Many Now Turn to The Internet First* (Dec. 29, 2002).

Health Canada, the Competition Bureau of Industry Canada, Procuraduria Federal del Consumidor of Mexico, the Secretaria de Salud of Mexico, several state Attorney General offices, and several state health departments.

As part of the agencies' effort to identify appropriate law enforcement targets, *Operation Cure.All* partners periodically conduct Internet surfs.[5] To date, the FTC and partners have conducted three international surfs, in 1997, 1998 and 2002,[6] and a number of narrowly targeted surfs focused on specific types of diseases or products such as anthrax. The three international surfs identified thousands of sites making questionable treatment claims for serious diseases. Although some of these questionable sites marketed therapies and devices, most sold dietary supplements.

After each surf, the FTC sends email alerts to those websites that make questionable claims and for which email addresses could be obtained, warning them that any health claims they make must be substantiated by competent and reliable scientific evidence. The Commission urges the websites to review their claims to make sure that they complied with the law. In addition, the Commission provides the sites with a list of resources they could consult for

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[5] In an Internet surf, participants use search engines to find relevant Internet sites based on a set of predetermined search terms, for example, "cancer cure." Once a site is identified it is forwarded to a central collection center, where the site is reviewed again to ascertain that it satisfies the selection criteria. In the three health claims surfs the FTC organized, the selection criteria were whether the site appeared to be making questionable claims that the product or service being offered was effective in the treatment, prevention, or cure of cancer, arthritis, heart disease, HIV/AIDS, diabetes, or multiple sclerosis.

[6] FTC and FDA led the 2002 surf. In addition to the numerous government agencies and private organizations in the United States, three foreign countries also participated in the surf – Canada, Ireland, and Mexico. This surf focused specifically on sites that sold products and services that promised to cure, treat, or prevent cancer, HIV/AIDS, or arthritis.

additional guidance. Websites that fail to take corrective action may then become targets for law enforcement actions.

Efforts to achieve industry compliance are most effective when they are backed up by traditional law enforcement. The FTC has filed 18 *Operation Cure.All* cases since June 1999. The challenged products include comfrey,[7] cat's claw,[8] shark cartilage,[9] cetylmyristoleate

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[7] *Western Botanicals, Inc., et al.*, Civ. Action No. CIV.S-01-1332 DFL GGH, (E. D. Cal., filed July 13, 2001) (Stipulated Final Order) and *Christopher Enterprises, Inc., et al.*, Civ. Action No. 2:01 CV-0505 ST (D. Utah, filed Nov. 29, 2001) (Stipulated Final Order). In both matters, the orders prohibit the defendants from, among other things, marketing any comfrey product for ingestion, for use as a suppository, or for external use on open wounds, unless they have evidence that the product is free of pyrrolizidine alkaloids and that it is safe. The defendants also are required to place a warning disclosure in any ad, promotional material, or product label for any comfrey products intended for topical use.

[8] *Body Systems Tech., Inc.*, Dkt. No C-3895 (Sept. 7, 1999) (consent). Cat's claw was promoted primarily as an effective treatment for cancer, HIV/AIDS, and arthritis.

[9] *Lane Labs-USA, Inc.*, Civ. Action No. CV-00-3174 (D. N.J, filed Jun. 28, 2000) (Stipulated Final Order); *Cartilage Consultants, Inc.*, Civ. Action No. CV-00-3174 (D. N.J, filed Jun. 28, 2000) (Stipulated Final Order); Body Systems Tech., Inc., Dkt. No. C-3895 (Sept. 7, 1999) (consent).

(CMO),[10] Essiac tea,[11] colloidal silver,[12] Chitosan,[13] ephedra,[14] St. John's Wort,[15] anti-aging supplements,[16] electronic devices,[17] magnetic therapies,[18] and unproven cancer therapies

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[10] *John Sneed and Melinda Sneed d/b/a Arthritis Pain Care Center*, Dkt. No. C-3896 (Sept. 7, 1999) (consent); *CMO Distribution Centers of America,* Dkt. No. C-3942 (May 16, 2000) (consent); *EHP Prods., Inc.*, Dkt. No. C-3940 (May 16, 2000) (consent). These products were marketed for the treatment and cure of arthritis.

[11] *Michael D. Miller, d/b/a Natural Heritage Enters.*, Dkt. No. C-3941 (May 16, 2000) (consent). This product was promoted for the treatment of cancer.

[12] *Robert C. and Lisa M. Spencer, d/b/a Aaron Co.*, Dkt. No. C-4019 (July 30, 2001) (consent). The respondent made false and unsubstantiated safety and efficacy claims for Colloidal Silver, and Chitosan, with Vitamin C; and unsubstantiated claims that "Ultimate Energizer," a product containing ephedra (ma huang), was safe and had no side effects. The Order required warning labels on products containing ephedra.

[13] *Id.*

[14] *Id.*

[15] The two matters in this area are *Panda Herbal International, Inc., et al.,* Dkt. No. C-4018 (July 30, 2001) (consent) and *ForMor, Inc., et al.*, Dkt. No. C-4021 (July 30, 2001) (consent). These respondents sold numerous products to treat a number of serious diseases. Among other claims, they claimed that those with HIV or AIDS could use St. John's Wort as a safe treatment for the disease. Not only were these claims unsubstantiated, St. John's Wort is known to interfere with proven HIV/AIDS medications. The orders, among other prohibitions, require that the respondents place a disclosure warning in advertisement, promotional materials, or product labels regarding the potential dangerous interactions between St. John's Wort and some prescription drugs.

[16] *MaxCell BioScience, Inc., et al., d/b/a Oasis Wellness Network*, Dkt. No. C-4017 (July 30, 2001) (consent). This case involved an anti-aging product containing, among other ingredients, the hormone DHEA, and an at-home urine test to gauge overall health and youthfulness.

[17] *Western Dietary Products Co., et al.*, Civ. Action No. CO1-0818R (W.D. Wash., filed Dec. 26, 2001) (Stipulated Final Order) and *Dr. Clark Research Assoc., et al., d/b/a Dr. Clark Zentrum*, Civ. Action No. 1:03CV0054, (N.D. Ohio, filed Jan. 8, 2002) (complaint for permanent injunction and other equitable relief). Among other products, the defendants sold an electrical unit called the "Zapper" for the treatment and cure of cancer, Alzheimer's, diabetes, arthritis, and HIV/AIDS. Another device case was *Michael Forrest, d/b/a Jaguar Enterprises of Santa Ana,*

(continued...)

delivered in Mexico.[19] Copies of all *Operation Cure.All* cases are available on the Commission's website at www.ftc.gov. Overall, the Commission has brought 105 cases in the last five years challenging deceptive and misleading health-related claims in advertising.

Consumer education is the third critical component of *Operation Cure.All*. The FTC uses each case as another opportunity to get consumers the information they need to protect themselves. For example, the Commission, in conjunction with the FDA, published a consumer education brochure, *Miracle Health Claims: Add a Dose of Skepticism*, and an online consumer feature, *Health Claims on the Internet: Buyer Beware*. These publications have been widely disseminated.[20] In addition to reaching consumers through these materials, the agency also has

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[17](...continued)
*a/k/a Jaguar Enters.*, Dkt. No. C-4020 (July 30, 2001) (consent). The respondents claimed that their electronic therapy devices known as, among others, the "Black Box," "Magnetic Pulser," "Beck-Rife unit," and "Portable Rife Frequency Generator," would cure or prevent cancer and other serious diseases. The defendants also sold a number "Miracle Herbs," for the treatment of cancer, AIDS, and bacterial and viral infections.

[18]*Magnetic Therapeutic Techs., Inc.* Dkt. No. C-3897 (Sept. 7, 1999) (consent) and *Pain Stops Here! Inc.* Dkt. No. C-3898 (Sept. 7, 1999) (consent). The respondents marketed magnetic devices to treat or alleviate numerous medical problems and diseases, including cancer, liver disease, arthritis, and high blood pressure.

[19] *Biopulse International, Inc., et al.*, Civ. Action No. C023511 (N.D. Cal., July 23, 2002) (Stipulated Final Order). Biopulse was a U.S.-based company offering its purported treatments in a clinic in Tijuana, Mexico. The defendants used two "therapies" in this clinic: (1) the so-called "insulin-induced hypoglycemic sleep therapy" which involved injecting insulin into cancer patients to "starve" cancer tumors, among other things, and which typically cost up to $39,900; and (2) the so-called "Acoustic Lightwave Therapy" which was based on the so-called "Rife machine" technology (allegedly worked by emitting frequencies that purportedly destroyed cells or organisms that caused arthritis, candida yeast, diabetes, flu, headaches, parasites, lyme disease, pneumonia, and some cancers).

[20] Nearly fifty thousand copies of the *Miracle Health Claims* brochure was distributed in FY02. The online English version of this brochure was accessed 28,366 times during FY02, and (continued...)

set up a "teaser" site which mimics a website selling a product to treat arthritis.[21] Teaser sites attract and then educate consumers who may be lured by questionable claims on commercial sites.

In addition to *Operation Cure.All*, the Commission also has conducted an initiative targeted at the marketing of bioterrorism-related products on the Internet. Shortly after the tragedy of September 11 and subsequent events, the FTC executed this initiative with the assistance of the FDA, several State Attorney General offices,[22] and the California Department of Health Services. As a result of the project, the FTC sent fifty warning letters to website operators marketing health-related products, such as dietary supplements, advising them to stop making unsubstantiated bioterrorism representations. All but three of these sites are now in compliance, or under investigation by other agencies. Prompt FTC enforcement action also prevented the marketing of a home test kit for anthrax that did not work, and stopped a seller of colloidal silver products from claiming that it cured 650 diseases, including anthrax and ebola.

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[20](...continued)
the Spanish version has been accessed 1,305 times since May 2002. The *Buyer Beware* online consumer feature was accessed 3,526 times during FY02. In May 2002, the FTC also launched a special website for this initiative, called *Operation Cure.All*. Between October 2002 and March 2003, the website was accessed 26,920, and between May and September 2002, 9,515 times.

[21] This teaser site was visited 1,112 times in FY02.

[22] The Attorney General offices of Alaska, Arizona, Arkansas, California, Connecticut, Florida, Illinois, Iowa, Kansas, Kentucky, Maryland, Massachusetts, Michigan, Minnesota, Missouri, Nevada, New Jersey, New York, North Carolina, North Dakota, Ohio, Oregon, Pennsylvania, South Carolina, Tennessee, Texas, Vermont, Virginia, Washington, Wisconsin, Wyoming, and the District of Columbia Office of the Corporation Counsel, participated in this project.

## II. The Benefits, Risks, and Challenges Presented by Online Pharmacies

Like other health care promotions on the Internet, the availability of prescription drugs via online pharmacies can offer benefits to consumers, including convenience and value. Many online pharmacies appear to operate like, and compete with, traditional "brick and mortar" or mail order pharmacies.[23] Some online pharmacies and some physicians who provide online prescription services, however, are not so scrupulous. As documented by prior Congressional hearings and State and Federal enforcement actions, consumers can easily obtain online access to prescription drugs, often by completing a basic online questionnaire that receives cursory, if any, review before the drugs are dispensed. Significant potential for injury exists when prescriptions are issued without adequate review of the consumer's medical history or when unapproved drugs are sold to consumers over the Internet by overseas pharmacies.[24]

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[23] Robust competition between emerging Internet firms and incumbent "brick and mortar" firms offers many potential benefits to consumers. In October 2002, the Commission hosted a three day public workshop to examine effective strategies for balancing competition and regulatory priorities in the e-commerce context. *See* Federal Trade Commission, Public Workshop, *Possible Anticompetitive Efforts to Restrict Competition on the Internet* (Oct. 8-10, 2002), *available at* <http://www.ftc.gov/opp/ ecommerce/anticompetitive/index.htm>.

[24] Leading health associations have condemned the practice of online prescribing based solely on answers to online questionnaires. The American Medical Association has taken the position that "Web sites that offer a prescription solely on the basis of a simple questionnaire" do not meet appropriate standards of care for issuing a prescription. *See* Statement of the American Medical Association before the Subcommittee on Oversight and Investigations, Committee on Commerce, U.S. House of Representatives, *Drugstores on the Net: The Benefits and Risks of On-Line Pharmacies*, Presented by Herman I. Abromowitz, M.D., July 30, 1999 <www.ama-assn.org/ama/basic/article/0,1059,177-486-1,00.html>; American Medical Association, Report of the Board of Trustees, *Internet Prescribing*, 35-A-99. In addition, the Federation of State Medical Boards believes that the "prescribing of medications by physicians based *solely* on an electronic medical questionnaire clearly fails to meet an acceptable standard of care and is outside the bounds of professional conduct." Federation of State Medical Boards, *Report of the Special Committee on Professional Conduct and Ethics*, Section IV (April 15, 2000).

**III. State and Federal Regulation of Online Prescription Drug Practices**

Historically, states have regulated pharmacies and the practice of medicine. Accordingly, a number of states have challenged online companies that dispense prescription drugs without a valid prescription. Kansas,[25] Missouri, Illinois, and Michigan have been particularly active.[26] Except where specific statutes permit such practice, a physician engaging in online prescribing for consumers residing in states where the physician is not licensed to practice could be charged with the unlicensed practice of medicine.[27] State enforcement actions have been based on violations of state consumer protection statutes as well as state medical and pharmacy laws. In addition, professional disciplinary actions have been initiated in more than a dozen states.[28] For example, an Oregon physician was sentenced to ten-years probation and fined $5,000 for prescribing drugs online without an examination of the patient.[29]

As the Committee is aware, the rapid growth in online sales of prescription drugs and the increase in the practice of online prescribing, both of which are taking place across state and even international borders, present significant technological and logistical challenges to the traditional

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[25] *See, e.g., State ex rel. and Kansas B. of Pharmacy v. Focus Med. Group, Inc.*, Civ. Action No. 99C749 (Shawnee Cty. Dist. Ct., filed June 9, 1999).

[26] Testimony of Kansas Attorney General Carla J. Stovall before the Health, Education, Labor, & Pensions Committee, Hearing on E-Drugs: Who Regulates Internet Pharmacies, March 21, 2000.

[27] *See, e.g., Illinois v. Express Today, Inc.*, Civil Action No. 99 CH 0452 (D. Ill., Sangamon Co.), filed Oct. 21, 1999.

[28] U.S. GENERAL ACCOUNTING OFFICE, INTERNET PHARMACIES: ADDING DISCLOSURE REQUIREMENTS WOULD AID STATE AND FEDERAL OVERSIGHT, GAO-01-69 (2000), Appendix II.

[29] *Internet Viagra*, PITTSBURGH POST-GAZETTE, Apr. 2, 2000, at A-12.

regulatory framework.[30] In the past, state medical and pharmacy boards have expressed concerns that their existing enforcement tools are not adequate to police the online medium.[31] In many cases it can be difficult, without extensive investigation, to identify the name, location, and state of licensure or registration for the physicians, pharmacies, and website operators involved in these practices. Even when parties can be located, it can be difficult and costly for a state medical board or a state pharmacy board to pursue law enforcement action against an out-of-state physician or pharmacy prescribing or dispensing prescription drugs inappropriately via the Internet.

The principal federal agency with authority in this area is the FDA. The FDA has primary jurisdiction to regulate labeling and advertising claims made by the manufacturer, distributor or

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[30] *The Electronic Frontier: The Challenge of Unlawful Conduct Involving the Use of the Internet: A Report of the President's Working Group on Unlawful Conduct on the Internet*; Appendix D Internet Sale of Prescription Drugs and Controlled Substances (Mar. 2000) <http://www.usdoj.gov/criminal/cybercrime/append.htm>.

[31] *See, e.g.*, Letters from the Connecticut Medical Examining Board, dated March 19, 1999 ("the difficulties of exercising jurisdiction over an out-of-state physician who does not have a Connecticut license in these circumstances are substantial"); Louisiana State Board of Medical Examiners, dated January 29, 1999 ("Regrettably, our investigations have revealed that those individuals who have advertised and dispensed Viagra® without physical examination, have been physicians licensed in states other than Louisiana and located beyond our jurisdictional reach."); Board of Medical Licensure & Supervision of the State of Oklahoma, dated February 19, 1999 ("Oklahoma law does require establishment of valid doctor/patient relationship and proof of medical necessity for any type of treatment but obviously this Board has no jurisdiction across state lines."); Tennessee Board of Osteopathic Examination, dated March 10, 1999 ("Having jurisdiction over the issue is one thing; practically enforcing the situation is quite another issue."); and State of Wisconsin Department of Regulation & Licensing, dated February 12, 1999 ("Wisconsin does not have the ability to police this kind of activity all around the country.").

packer of prescription drugs.[32] In addition, the FDA has the authority to take action against the dispensing of a prescription drug without a valid prescription.[33]

In contrast to the states and the FDA, the Commission's role in this area is limited to protecting consumers from unfair or deceptive practices by online pharmacies. The FTC Act prohibits deceptive or unfair acts or practices in commerce. The marketing of prescription drugs online is deceptive in violation of FTC law if it involves a material misrepresentation or omission likely to mislead consumers acting reasonably under the circumstances to their detriment. Thus, the Commission has authority to bring an enforcement action where an online pharmacy makes false or misleading claims about the products or services it provides.[34] The online prescribing and dispensing of prescription drugs that does not involve a deceptive or unfair practice, however, does not fall within the agency's scope of authority.[35]

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[32]*See* 21 U.S.C. § 351 *et seq.*

[33]*See* 21 U.S.C. §§ 353(b)(1); 331(a), and 333.

[34]*See* Deception Policy Statement, appended to *Cliffdale Associates, Inc.*, 103 F.T.C. 110, 174 (1984). The Commission also has authority under its unfairness jurisdiction to regulate marketing practices that cause or are likely to cause substantial consumer injury, which is not reasonably avoidable by consumers, and not outweighed by countervailing benefits to consumers or to competition. *See* Unfairness Policy Statement, appended to *International Harvester Co.*, 104 F.T.C 949, 1070 (1984); 15 U.S.C. § 45 (n).

[35] The Commission, however, can address situations where medical professionals have made false or misleading claims in advertising or other promotional literature distributed to potential consumers about the efficacy, safety, cost or other benefits of the services or products they provide. *See Dr. Scott M. Ross*, 115 F.T.C. 54 (1992) (consent agreement resolving misrepresentations of safety, recovery period, discomfort of liposuction).

*FTC v. Rennert* exemplifies the Commission's authority to address deceptive online claims in this arena.[36] There the Commission alleged that the defendants misrepresented the services they provided. The defendants' website contained statements such as:

> Focus Medical Group is a full service clinic with a full time staff dealing with the treatment of sexual dysfunction. The clinic's licensed medical physicians network with an organization of physicians throughout the United States and Internationally . . . . All of our prescriptions are filled on premises.

Based on these statements, among others, the Commission alleged that the defendants falsely represented that customers were served by a clinic with physicians and an on-site pharmacy. In fact, the defendants' customers were not served by a medical clinic or an on-site pharmacy. The defendants employed one physician in another state to review customers' medical questionnaires. For this service, customers were charged $75.00 if the prescription was approved. The doctor was paid $10.00 for each of the first 50 prescriptions he approved per week and $7.50 for each additional approved prescription request. The stipulated final order enjoined the defendants from misrepresenting their services and required certain disclosures, including the name, address and phone number of the physician and the states where the physician is licensed or authorized to practice and the states from which the entity will accept orders.

The Commission's most recent intensive look at online prescribing and dispensing practices involved the drug Cipro.[37] In the weeks following press reports of anthrax contamination and related deaths in the fall of 2001, a large number of Internet websites started aggressively marketing Cipro, an antibiotic used in the treatment of anthrax. In an effort to

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[36] *FTC v. Rennert* Civ. Action No. CV-S-00-0861 JBR (D. Nev., filed July 6, 2000).

[37] "Cipro" is Bayer Corporation's trade name for the drug ciprofloxacin.

protect consumers from counterfeit Cipro products, the Commission staff, in conjunction with the FDA, reviewed online Cipro sites. In the course of these investigations, the staff ordered product samples from both foreign and domestic websites and had them tested. No counterfeit Cipro was discovered and no actions were filed. The staff forwarded information about foreign sites to the FDA.[38]

Because there are many federal and state authorities with specific roles in the regulation of physicians and pharmacies, it is critical that the various agencies coordinate closely. For example, because the FTC and the FDA have closely related and partially overlapping authority over a number of products, including prescription drugs, the two agencies coordinate closely pursuant to a longstanding liaison agreement.[39] Also, on April 26, 1999, an interagency working group, comprised of the FTC, FDA, the Department of Justice, the Drug Enforcement Agency, and other federal and state agencies, was organized to coordinate enforcement and regulatory activity in this area. The working group meets on roughly a quarterly basis to share information and discuss

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[38] Congress has enacted specific provisions to deal with the distribution of counterfeit drugs. These provisions give the FDA and the Department of Justice a broad panoply of remedial powers, including the power to stop the import of counterfeit products, seize products already in the country, and file injunctive and criminal action in appropriate cases. Moreover, the FDA, which has traditionally dealt with counterfeit drug issues, has the expertise to enforce prohibitions against the marketing of counterfeit drugs. On November 1, 2001, the FDA announced that it had issued warnings to eleven Internet vendors of unapproved foreign ciprofloxacin. One foreign order of ciprofloxacin the FTC received was identified on custom forms as cosmetics.

[39] Working Agreement Between FTC and FDA, 3 Trade Reg. Rep. (CCH) ¶ 9,859.01 (1971). Under this longstanding formal liaison agreement, the FDA has primary responsibility to regulate claims made in the labeling and advertising of prescription drugs if those claims are made by a manufacturer, packer, or distributor. The agreement establishes the basic division of responsibilities of the two agencies with respect to the regulation of foods, drugs (both over-the-counter and prescription), cosmetics and devices. With the exception of prescription drugs, the FTC regulates advertising of these products, while the FDA regulates labeling.

interagency coordination.[40] In addition, the FTC assists other federal and state authorities in their investigatory work.

**VI. Conclusion**

The Federal Trade Commission will continue to do its part to combat deceptive practices by online pharmacies and to assist other authorities in their investigative work. For the most part, however, the practices that present the greatest concern and risk of consumer injury are those involving the prescribing and dispensing practices of individual physicians and pharmacies, which are outside of the Commission's traditional authority.

Thank you for this opportunity to present the Commission's views. I will be happy to respond to your questions.

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[40]These meetings provide a regular forum for exchange of information about ongoing activities and problems.

Chairman TOM DAVIS. Mr. Hubbard, thank you for being with us.

Mr. HUBBARD. Thank you, Mr. Chairman.

As you said earlier, I am accompanied by John Taylor, our Chief Enforcement Official at FDA. We have a written testimony. I'll make just a few remarks, if I may.

One of the best things Congress ever did for consumers in our view, Mr. Chairman, is to create a modern drug approval system. Drugs are tested for safety and efficacy and manufactured to exacting specifications overseen by the FDA. American patients can be almost totally certain when they go to a licensed pharmacy that they are getting a safe and effective drug.

The emergence of these illegal Internet sites poses a fundamental threat to that safety/assurance system. We note, of course, that there are legitimate Internet sites that are licensed by the States and can properly dispense drugs and, in fact, provide a public service, but let me show you a site. I believe the committee may have a printout of a site that we are looking at. I've taken off the name of this site to perhaps protect the guilty. But this site, as you can see from the information—it's also on the poster over here—a consumer can go on and fairly easily buy some relatively serious drugs. Some of these drugs have serious side effects and need to be taken under the guidance of a physician, and some are, in fact, controlled substances. We believe this is a very fundamental threat.

Now, the patient that buys these drugs on the Internet site has no way of knowing what they are getting. This offers particular drugs. If I order any of these drugs, I have no idea that I'm going to get that drug or it is going to be the real drug or it is going to be a safe and effective drug. In fact, there are cases in which people have ordered drug A and gotten drug B.

I'll last say that this site that I have given you we have begun to look at. This site looks like an American doctor and nurse or doctors or whatever. It looks very normal. When we checked, this site is actually in Thailand, and the drugs that are coming from this site are from some place we don't know, but I doubt they are from the United States. These sites have sprung up continuously in recent years and they challenge the ability of State and Federal authorities to combat them.

Now, FDA and other agencies in the States have taken a number of steps to fight these rogue sites. We have been educating consumers. We have many brochures and information on our Web site and other things to warn people about these. We have partnership agreements with the State medical and pharmacy regulators to jointly attack these sites in many cases. We and the FTC, as Mr. Beales has said, have been working on a number of cases. FDA has enforced dramatically in this area. We've had over 300 cases of Internet sites since 2000, 150 arrests. We have 100 current investigations. And just today, this morning the State of Oklahoma is going to court to seek an injunction against an Internet site with the support of the FDA. That action is one that we are trying to do in concert with the States, and we believe that together the Feds and the State can have an impact here.

So with those brief remarks, Mr. Chairman, I will say thank you and take questions.

Chairman TOM DAVIS. Thank you very much.

[The prepared statement of Mr. Hubbard follows:]

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

**STATEMENT OF**

**WILLIAM K. HUBBARD**

**ASSOCIATE COMMISSIONER FOR POLICY, PLANNING, AND LEGISLATION**

**BEFORE THE**

**COMMITTEE ON GOVERNMENT REFORM**

**U.S. HOUSE OF REPRESENTATIVES**

**MARCH 27, 2003**

FOR RELEASE ONLY UPON DELIVERY

**INTRODUCTION**

Mr. Chairman and Members of the Committee, I am William K. Hubbard, Associate Commissioner for Policy and Planning at the Food and Drug Administration (FDA or the Agency). Today I am accompanied by John M. Taylor III, FDA's Associate Commissioner for Regulatory Affairs. We are pleased to come before the Committee to discuss the benefits and risks of pharmaceutical sales over the Internet and what the Agency has been doing to address issues related to the sale of drugs via the Internet.

With greater and greater frequency, consumers are using the Internet to access health related information and products. Sales of consumer products over the Internet have grown rapidly, including the sale of drugs. The growth in online drug sales by reputable pharmacies has provided significant benefits to consumers. Many managed health care organizations are searching for ways to achieve cost savings and are turning to online prescription plans as a means of providing quality service at a lower cost.

Online drug websites, however, also present risks to purchasers and unique challenges to regulators, law enforcement officials and policy makers. FDA is concerned about the public health implications of Internet drug sales, and we are responding to these concerns as we develop and implement risk-based strategies to protect the public health. FDA monitors the Internet to evaluate the quality of information being provided, and we encourage consumers to remain vigilant about their purchases and to rely on reputable Internet sites.

Although other products regulated by the Agency, such as medical devices, medical diagnostics, foods, dietary supplements and animal drugs also are sold online, this testimony will focus on domestic online drug sales. We will discuss the advantages and risks of domestic online drug sales, outline FDA's authority and enforcement activities in this area, and describe initiatives we are taking to better respond to the regulatory challenges we face.

In the context of prescription drug sales over the Internet, the private sector also has an important role in promoting consumer education and in providing assurances to consumers about the quality of products and services they offer. Our challenge is to make sure that protection for consumers who purchase prescription drugs in cyberspace with the click of a mouse is just as strong as the protection consumers enjoy when they purchase drugs at their corner pharmacy. Rapid technological developments have magnified the challenges we face. We constantly struggle to design appropriate solutions to meet these challenges. As electronic commerce embraces global markets, we should strive for consistent policies that promote safety regardless of the jurisdiction in which a U.S. consumer resides or the location of the pharmacy.

Let me begin by providing an overview of FDA activities and concerns relating to drugs purchased on the Internet:

- **OUTREACH AND EDUCATION**: Consumers take genuine risks when they purchase drugs from Internet sites that dispense foreign drugs or are not licensed and operated under state pharmacy law. These outlets may dispense expired, subpotent, contaminated or counterfeit product, the wrong or a contraindicated product, an incorrect dose, or medication without adequate directions for use. Unsafe or inappropriate drugs put consumers at risk for dangerous drug interactions and serious health consequences. FDA continues to meet with organizations representing consumer health practitioners and industry. The Agency's website and brochures contain information for consumers on safely purchasing drugs online.

- **WORKING WITH STATES:** Last month, FDA hosted a nationwide call with 38 state boards of pharmacy, other state regulatory agencies and consumer groups to discuss current Internet drug sale practices. Some state laws are stronger than others, FDA has actively engaged with a number of states in jointly pursuing illegal Internet sites. FDA will continue to expand it's cooperative activities with states in order to effectively address the many challenges in this area of electronic commerce.

- **ENFORCEMENT**: Recent criminal and civil cases are evidence of the seriousness of the risks to public health that regulators uncover when responding to Internet drug sales. To date, FDA has initiated the following actions:

  - 372 Internet drug criminal investigations, 90 involve domestic Internet pharmacies.
  - 150 Internet-related drug arrests, 60 involve Internet pharmacies, and 92 convictions, 26 convictions involve Internet pharmacy cases;
  - 100 open Internet drug criminal investigations; 90 sites are under active review for possible regulatory or civil action;
  - Nearly 200 cyber warning letters have been sent to domestic and foreign online sellers;
  - 5 preliminary injunctions;
  - 15 product seizures;
  - 11 product recalls; and the voluntary destruction of 18 illegal products.

**BENEFITS OF ONLINE DRUG SALES**

The Internet is rapidly transforming the way we live, work, and shop in all sectors of the economy. In the health sector, tele-medicine allows people in remote areas to access the expertise of doctors in the nation's finest health centers. The Internet permits individuals to obtain extensive medical information to help them understand health issues and treatment options. Millions of Americans used the Internet last year to find medical information, either in documentary resources or through online discussions with health professionals. Conducting research regarding health concerns is the sixth most common reason that people use the Internet, according to the market research firm, Cyber Dialogue Inc.

The sale of most consumer products over the Internet has grown rapidly in recent years, including the sale of prescription medications. FDA is aware that many reputable Internet pharmacies provide consumers seeking prescription drugs with a measure of safety, privacy and convenience. They provide information on drug interaction, and may e-mail customers if the drug they ordered has been recalled, a cheaper generic version of the drug becomes available or to remind them of prescription renewals. Some sell drugs for less than traditional "brick-and mortar" pharmacies, which is particularly important for people with limited income or without insurance coverage.

Prescription drug sales over the Internet can provide tremendous benefits to consumers. These benefits are many and include:

- Access to drugs for the disabled or otherwise homebound, for whom a trip to the pharmacy can be difficult.
- The convenience of shopping 24 hours a day; a complete selection of pharmaceutical products.
- Privacy for those who don't want to discuss their medical needs in a public place.

Hyperlinks and search programs provide online customers with written product information and references to other sources of health information more easily than in the traditional storefront. Finally, as the use of computer technology to transmit prescriptions from doctors to pharmacies expands, a reduction in prescription errors may be possible.

While online pharmaceutical sales are important for some customers, brick and mortar pharmacies offer benefits and services that are often not available through the Internet, such as immediate access to prescription drugs needed for immediate treatment. These pharmacies will undoubtedly remain an essential component in the effective delivery of health care.

In matters relating to pharmaceutical sales over the Internet, the challenge for government at both the state and Federal level is to develop and implement policies that will allow legitimate electronic commerce to flourish while continuing to assure safety. Consumers must have confidence that protections for online consumers are equivalent to safeguards at brick and mortar pharmacies.

**CONCERNS ABOUT ONLINE SALES**

As beneficial as this computer technology can be, the Internet also creates a new marketplace for illegal activity such as the sale of unapproved new drugs, prescription drugs dispensed without a valid prescription, or products marketed with fraudulent health claims. Consumers may have difficulty identifying which sites sell legitimate products. As FDA considers the issues related to online drug sales, we recognize that there are various types of websites used for drug sales. Many sites focus on selling prescription drugs and are referred to by some as "Internet pharmacies." These sites offer for sale either FDA-approved prescription drug products, or in some cases, unapproved, illegal versions of prescription drugs. In many cases, FDA cannot provide consumers with any assurance that the drugs purchased over the Internet were manufactured under current good manufacturing practices (cGMP) requirements even if the website appears to be based in the U.S. The Internet sites of legitimate, properly licensed pharmacies provide genuine benefits to consumers. However, sites that are unlicensed or otherwise engaged in the illegal dispensing of prescription drugs pose a serious threat to the health and safety of American citizens. While the increase in "Internet pharmacy" sites engaged in illegal sales is seen by some as a particularly potent threat, FDA believes that some of the non-pharmacy sites are also harmful, We

have moved aggressively against those other drug sites unlawfully offering unapproved drug products, products making fraudulent health claims, or drugs for recreational use.

Consumers can, and should, be cautious when purchasing drugs online. There is no foolproof way of checking a site's reliability. Although there are legitimate sites that sell drugs, some sites do not employ licensed professionals and may not sell you the real drug. Consumers should check with their State Board of Pharmacy or the National Association of Boards of Pharmacy to see if the online pharmacy possesses a valid pharmacy license and has met state quality standards. In addition, consumers should use the same common sense they would apply to anyone they have never purchased a product from before: Does the site have a good reputation for the service it provides? Have people you trust used them and were they satisfied? If it's a site that cannot be verified – such as an overseas site – it may be best to avoid it. There is usually a local pharmacy that will have what the consumer needs.

**FDA AUTHORITY**

The unique qualities of the Internet, including its broad reach, relative anonymity, and ease of creating new or removing old websites, pose new challenges for the enforcement of the Food Drug and Cosmetic (FD&C) Act. FDA has found that many Internet sites are actually comprised of multiple related sites and links, thereby making investigations much more complex and resource intensive. The global nature of the Internet creates special problems for effective law enforcement. Different approaches to drug approval and marketing in foreign countries further complicate law enforcement issues for U.S. officials. FDA and other U.S. government agencies

need to work closely with foreign governments to share information and to develop mechanisms for cooperative law enforcement.

The types of unlawful conduct that can occur when drugs are sold over the Internet are similar to unlawful activities that occur in other contexts. Under the FD&C Act, FDA has the legal authority to take action against:

- The importation, sale, or distribution of an adulterated or misbranded drug;
- The importation, sale, or distribution of an unapproved new drug;
- Illegal promotion of a drug;
- The sale or dispensing of a prescription drug without a valid prescription; and
- Counterfeit drugs.

When the Internet is used for an illegal sale, FDA, working with the Department of Justice (DOJ), must establish the grounds for a case, develop the same charges, and take the same actions as it would if another medium, such as a storefront or a magazine, had been used. FDA has investigated and referred cases for criminal prosecution and initiated civil enforcement actions against online sellers of drugs and other FDA-regulated products, particularly sellers of drugs not approved by the Agency.

**STATE REGULATION OF THE PRACTICE OF MEDICINE, PHARMACY AND DISPENSING OF DRUGS**

The states have enacted laws regulating the practice of pharmacy and the practice of medicine to protect patients from harm resulting from the use of unsafe drugs, and the improper practice of

medicine and pharmacy. Under many of these laws, to receive a prescription drug, a patient generally must be examined by a licensed health care practitioner who determines the appropriate treatment and issues a prescription for an FDA-approved drug. The prescription may also authorize refills. The patient then has the prescription filled by a registered pharmacist working in a licensed pharmacy that meets state standards.

These safeguards are not always in place when drugs are purchased over the Internet. A consumer may not be examined by a health care practitioner prior to purchasing drugs online. A patient-doctor relationship, in many cases, is never established. Attempts to stop some U.S. doctors and online pharmacies from issuing online prescriptions without a physical examination have not always been successful. States face many obstacles when it comes to online pharmacies. State and state medical boards may have limited resources for enforcement and state regulations may currently address the Internet context, There is also the difficulty of prosecuting or taking legal action across state lines. Doctors may or may not be in the same state where the patient lives, so states may have difficulty prosecuting under their existing criminal or consumer protection laws. Only a handful of state legislatures have passed legislation to address issues that arise from online prescribing.

**USE OF INTERNET TO BYPASS REGULATORY SYSTEMS**

Even with these Federal and state systems in place, the Internet provides ample opportunities for circumventing established safeguards. The speed, ease, and anonymity of ordering products on the Internet can attract unscrupulous sellers. Individuals not licensed to sell prescription drugs can

easily create websites that appear to represent legitimate pharmacies. The fact that operators can quickly change the location and appearance of their Internet site makes enforcement all the more difficult. More than many other types of electronic commerce, the unauthorized sale of prescription and unapproved drugs poses a potential threat to the health and safety of consumers.

Patients who buy prescription drugs from an illegitimate site are at risk of suffering adverse events, some of which can be life threatening. These risks include potential side effects from inappropriately prescribed medications, dangerous drug interactions or drug contamination. Patients are also at risk because they often don't know what they are getting when they purchase some of these drugs. Although some patients may purchase genuine product, others may unknowingly buy counterfeit copies that contain inert ingredients, legitimate drugs that are outdated and have been diverted to illegitimate resellers, or dangerous sub-potent or super-potent products that were improperly manufactured. Moreover, consumers who are desperate for a cure to a serious medical problem may be more than willing to accept a product of unknown origin.

FDA is concerned about the proliferation of sites that substitute a simple online questionnaire for a face-to-face examination and patient supervision by a health care practitioner. According to the American Medical Association, a health care practitioner who offers a prescription for a patient he or she has never seen before, based solely on an online questionnaire, generally does not meet the appropriate medical standard of care. The Federation of State Medical Boards, Special Committee on Professional Conduct and Ethics, has found that "Prescribing of medications by physicians based solely on an electronic medical questionnaire clearly fails to meet an acceptable standard of care and is outside the bounds of professional conduct." This finding is especially

important in light of the primary responsibility of states in regulating the practice of medicine. FDA is also concerned that the use of such questionnaires may jeopardize the privacy of a patient's medical records. We will continue to play a role in the Administration's efforts with the private sector to implement appropriate protections for patient's medical information. We also will continue to distinguish legitimate online communications from unlawful conduct that poses risks to patients.

The Agency is equally concerned that in some Internet transactions there is an apparent absence of any health professional/patient relationship. This is a particular concern where a patient may be using a prescription drug for the first time or where the patient may be taking other medications. FDA is concerned that the selection of prescription drug products or treatment regimens for a particular patient should be made with the advice of a licensed health care practitioner who is familiar with the patient's current health status and past medical history. In situations where a customary physician-patient relationship does not exist, the patient may be practicing what amounts to self-diagnosis. Consequently, the risk of negative outcomes such as harmful drug interactions, contraindications, allergic reactions or improper dosing is greatly magnified.

**FEDERAL, STATE AND INTERNATIONAL JURISDICTION CHALLENGES**

Online drug sales pose unique challenges for regulatory and law enforcement agencies at the state, Federal and international level. Internet technology can obscure the source of the product as well as provide a degree of anonymity to those responsible for selling and shipping the product. The

parties to a transaction can be dispersed geographically and usually never meet. Thus, the regulatory and enforcement issues cross state, Federal, and international jurisdictional lines.

The sale of drugs to U.S. residents via foreign websites is an extremely challenging area. Some medications sold on the Internet may be legal in foreign countries but not approved for use in the U.S. Products not approved for sale in the U.S. often do not conform to the GMP and quality assurance requirements in U.S. laws and regulations, and it is illegal for a foreign pharmacy to ship such drugs into the U.S. Foreign sales pose the most difficult challenge for U.S. law enforcement because the seller is not within U.S. boundaries. Although FDA has jurisdiction over a resident in a foreign country who sells in violation of the FD&C Act to a U.S. resident, from a practical standpoint, the Agency has a difficult time enforcing the law against foreign sellers. FDA confronts the same obstacles facing other U.S. regulatory and law enforcement agencies seeking to hold foreign actors accountable for violations of U.S. law. FDA efforts are mostly limited to requesting the foreign government to take action against the seller of the product, or asking the Bureau of Customs and Border Protection (Customs) to stop the imported drug at a U.S. port-of-entry.

## FDA ACTIVITIES TO PROTECT PUBLIC HEALTH

### Public Outreach

Public outreach is an important tool that the Agency uses to inform consumers about dangerous or inappropriate drugs. FDA is expanding its public outreach about dangerous practices associated with Internet purchases. We are also conducting outreach to explain what compliance and

enforcement actions we already have taken. This effort includes FDA *Talk Papers*, articles in *FDA Consumer* magazine, and information on FDA's website to help educate consumers about safely purchasing drugs online. FDA's website also provides consumers with an opportunity to submit information to the Agency about sites that may violate the FD&C Act.

FDA remains committed to developing more effective education and enforcement strategies. With this goal in mind, FDA has created public education brochures and posters entitled, "*Things you should know about purchasing medications outside the United States*" to alert consumers to the health risks of buying medications outside the U.S. Outreach to consumers and the media continues, and new public material will be added to FDA's website.

In October 2000, the Division of Public Affairs in FDA's Center for Drug Evaluation and Research (CDER) launched an education campaign on the subject of buying prescription medicines online, entitled, "Shop Smart." This effort is part of FDA's "Buying Rx Drugs Online" education program. The centerpiece of this multi-media campaign is FDA's website: *http://www.fda.gov/oc/buyonline/default.htm* (launched December 1999) that can be accessed from FDA's home page. The website includes information for consumers, including tips and warnings, how to spot health fraud, frequently asked questions (FAQ's) and where to report suspected "rogue" sites. The website is one of the most frequently visited web pages on the FDA website.

Another central piece of our campaign is a brochure entitled, "Buying Prescription Medicines Online: *A Consumer Safety Guide*." The brochure was produced by the CybeRx-Smart Safety Coalition, a partnership of Internet companies, trade associations, health and consumer organizations and other government agencies. The brochure is available in hard copy from FDA,

the Federal Consumer Information Center and the National Council for Patient Information and Education (member of CybeRx-Smart). It is also posted on the FDA web site. The number of consumer complaints received by FDA has grown steadily with the circulation of the brochure.

In addition, the January/February 2001 issue of the *FDA Consumer* magazine included an article entitled, "Buying Drugs Online: It's Convenient and Private, but beware of 'Rogue Sites.'" The article is available online and thousands of reprints have been distributed at conferences and exhibits around the country. To date, the release has generated 644 newspaper articles in 35 different states. In addition, a 30-second radio public service announcement was produced and distributed to stations throughout the U.S. The release has been broadcast on 233 radio stations in 46 different states with an audience of almost 6 million. Two print public service announcements (one for medical devices and one for prescription medicines) were produced and sent to over 100 national magazines. Many Internet drug sites are unknowingly in violation of FDA's regulations, and the "about me" section of the release provides guidance on how to meet FDA requirements.

Promotional items, such as magnets and pens, with the message "Shop Smart when Buying Prescription Medicines Online" advertise our website and phone numbers. In addition, FDA's Public Affairs Specialists (PAS) located in district and regional offices around the country chose this topic as their National Education Campaign in 2001. In concert with this campaign, each PAS was responsible for spending at least twenty percent of his or her workday promoting the campaign. Their efforts ranged from doing an on-camera interview on the television program "Good Morning Dallas," to a front page headline on El Nuevo Herald, a large Spanish language newspaper.

In November 2001, FDA worked with the Federal Trade Commission (FTC) and the Centers for Disease Control to produce a National Association of Boards of Pharmacy (NABP) newsletter article on Cipro and the dangers of buying antibiotics to treat biological threats over the Internet. The article is an abbreviated version of the FTC alert, which was posted on its website in October 2001. FDA's website continues to update and post frequently asked questions (FAQ's), warning letters, talk papers, etc. on the subject of Cipro and other antibiotics.

The Agency will continue working with consumer groups, health care practitioner organizations, and industry to encourage all parties to keep their constituents and the public informed about safe practices for purchasing drugs online.

**Professional Outreach and Partnering**

At the February 1999 meeting of health professional organizations, FDA, the Federation of State Medical Boards of the United States, the NABP, the American Medical Association and the Association of Food and Drug Officials discussed the roles of each organization in regulating prescribing and dispensing medication via the Internet and how the various roles could better complement each other. At that meeting, the NABP announced its program to verify the legitimacy of Internet sites dispensing prescription drugs. The program, known as the Verified Internet Pharmacy Practice Sites, or VIPPS, provides a NABP "seal of approval" to sites who apply and meet state licensure requirements and NABP's standards. Over time, this seal of approval may help to assure consumers that the designated sites are offering FDA approved pharmaceuticals. The VIPPS program is voluntary and requires the applicant to pay a fee.

FDA continues to meet with organizations representing state regulatory and law enforcement bodies, consumers, health care practitioners and industry. The purpose of these meetings is to gather information on: 1) how issues relating to online drug sales should be addressed, 2) who should regulate and how they should regulate, 3) whether and what changes to the current law should be enacted, and 4) when to develop partnering arrangements. The organizations we are meeting with include:

- The National Association of Boards of Pharmacy
- The Federation of State Medical Boards
- The National Association of Attorneys General
- The American Medical Association
- The American Pharmaceutical Association
- The American Association of Retired Persons
- The National Consumers League
- The American Society of Health-Systems Pharmacists
- The National Association of Chain Drug Stores
- The National Community Pharmacists Association
- The Pharmaceutical Research and Manufacturers Association
- Pharmaceutical Security Institute

**Coordination with State and Federal Agencies**

Several Federal agencies, as well as the states, have the authority to regulate and/or enforce U.S. laws related to the sale of drug products online. Due to the growth of potential cases involving the Internet, there are instances when working with another agency or state yields a more effective enforcement result. Working closely with the states is essential to effectively regulate the sale of

drugs, as well as the sale of prescription drugs without a valid prescription over the Internet. FDA has established partnership agreements with several state bodies, including the National Association of Boards of Pharmacies and the Federation of State Medical Boards, to coordinate Federal and state activities aimed at questionable practices associated with the selling and prescribing of prescription drugs over the Internet.

Just last week, acting in conjunction with action by the Arkansas State Board of Pharmacy, FDA issued a warning letter to Rx Depot, a storefront operation. The letter put the firm on notice that FDA considers their operation to be illegal and a risk to public health. The Arkansas State Board of Pharmacy issued their own letter to the firm instructing them to cease violating state law immediately. Rx Depot and similar companies often state incorrectly to consumers that FDA condones their activities and even that their prescription medications are "FDA approved," which could lead consumers to conclude mistakenly that the prescription drugs sold by the companies have the same assurance of safety as drugs actually regulated by FDA. FDA believes that operations such as this one expose the public to significant potential risks associated with unregulated imported prescription medicines.

As this action indicates, FDA intends to work closely with its partners in the individual states in support of their efforts to curtain illegal and potentially dangerous operations, especially when they involve misleading claims about drug safety. FDA has been working closely with states on illegal Internet pharmacy issues over the past four year to protect the public health.

FDA has increased coordination with other governmental bodies and has met several times over the past year with other Federal agencies and state officials to share information, discuss the roles and responsibilities of the parties regarding online drug sales and identify opportunities for partnering in enforcement actions. FDA maintains strong working relationships with the DOJ, including the Drug Enforcement Administration (DEA) and Federal Bureau of Investigation (FBI), the U.S. Postal Inspection Service, Customs and other appropriate Federal and state agencies. FDA believes that cooperation among Federal agencies is particularly critical to address the sale of drugs to U.S. residents by foreign sellers. Customs, the U.S. Postal Service, FDA, and the DEA all have important responsibilities in countering the illegal importation of drugs.

FDA determines when and with whom to engage in joint enforcement activities based on the type and severity of conduct identified through various means, including Internet monitoring. Although FDA is expanding its own Internet monitoring capabilities, the Agency also is developing partnerships in this area with other agencies.

**Enhanced Enforcement Activities**

FDA has conducted investigation and enforcement activities relating to Internet drug sales by re-deploying FDA personnel, which necessarily results in a reduction of investigation and enforcement activity in other areas. The Agency has taken action because we believe that illegal online drug sales pose a significant public health risk. FDA has initially focused its online drug

sales-related enforcement activities in the following areas, particularly where there is a significant public health risk:[1]

- Unapproved new drugs;
- Health fraud; and
- Prescription drugs sold without a valid prescription.

FDA has increased its capability to monitor the Internet and identify sites that potentially violate the FD&C Act through the use of various search tools and by upgrading its data handling capabilities. These actions help the Agency to better understand the type and extent of unlawful conduct on the Internet and to more accurately assess whether its enforcement efforts have had an impact on illegal Internet behavior.

Over the last three years, in an attempt to better comprehend the universe of websites selling drugs, OCI has reviewed thousands of websites and identified hundreds involved in the sale of drug products. This review was based on an electronic search of websites, followed by a manual review of sites that appeared to involve the sale of drug products. Because new websites are launched everyday and old websites are taken down, the total number of these sites changes over time.

In June 1999, FDA established a case assessment or "triage" team with representatives from the Office of Enforcement and the Office of Criminal Investigation (OCI) within the Office of

1. A *significant public health risk* exists when a consumer is at risk for harm (1) from the use of the product, (2) as the result of not taking approved drugs for a specific disease or condition, or (3) by delaying medical treatment recognized as safe and effective for a specific disease or condition.

Regulatory Affairs (ORA), the Center for Drug Evaluation and Research (CDER), the Office of Chief Counsel (OCC) and the Office of Policy. Under the triage process, FDA obtains leads on sites that potentially violate the FD&C Act from internal Internet monitoring activity, state, other Federal or foreign law enforcement agencies, consumers, Congress, and the press. The triage team evaluates leads and decides whether they should be pursued through a civil or criminal investigation. Priority is given to cases involving unapproved new drugs, health fraud, and prescription drugs sold without a valid prescription and products with the potential for causing serious or life-threatening reactions. The triage team makes referrals, when appropriate, for FDA follow-up.

The triage process results in a better coordination of criminal and civil enforcement actions at the appropriate Agency components and reduces overlapping effort. This process helps to ensure that decisions are made in a timely way. The Agency seeks an appropriate balance in terms of achieving a maximum deterrent effect while taking action, if needed, to remove harmful products from the market. The team will continue to oversee Internet-related enforcement activities while they are being investigated, and will ensure that they are brought to appropriate conclusion. In addition, the scope of this group is being expanded to cover all FDA-regulated products.

OCI, working with OCC, is responsible for investigations of pharmacy sites and other Internet drug sites whose operations involve potential criminal activity. The Investigative Analysis Branch analyzes the information collected by OCI. After the suspect sites are researched, and possible violations are identified, the OCI field offices receive assignment for investigative work, which often includes undercover buys. Further investigation determines the bona fides of the

pharmacy and doctor(s), and examines the relationship between the patient and doctor and the doctor and pharmacy. OCI has ongoing cooperative relationships with Customs, DEA, FBI, the Postal Inspection Service and appropriate state law enforcement and regulatory agencies, and this has enhanced their investigative capabilities with regard to Internet drug sales.

To date, OCI has initiated 372 Internet drug investigations, 90 of which involve domestic Internet pharmacies, with each case involving a variable number of websites from 1 to 25 or more. These cases originated from multiple sources including interception at mail facilities, web-based research, consumer complaints, and a variety of other sources. OCI has effected 150 Internet-related drug arrests, 60 of which involve Internet pharmacy cases, and obtained 92 convictions, 26 of which involve domestic Internet pharmacy cases. OCI currently has approximately 100 open Internet investigations.

Currently, FDA has 90 sites under active review for possible regulatory or civil action. Warning letters have been sent to 55 domestic online sellers. In addition, FDA has sent 137 cyber letters to operators of Internet sites in many countries, including Canada, that offer to sell on-line prescription drugs or unapproved drugs. These sites may be engaged in illegal activity such as offering to sell prescription drugs to U.S. citizens without valid (or in some cases without any) prescriptions. Cyber letters are sent over the Internet to the suspect websites to warn the operators that they may be engaged in illegal activities, and inform them of the laws that govern prescription drug sales in the U.S. FDA also sends copies of its cyber letters to the home governments of targeted websites when the locations can be identified. However, follow-up depends on the

ability and willingness of the foreign regulatory bodies to investigate and take actions against website operators who are illegally shipping drugs to other countries.

In cooperation with DOJ, FDA has obtained five preliminary injunctions against the sale of illegal products, including one product marketed as a weight-loss aid containing a potent thyroid hormone that could cause heart attacks or strokes, and an unapproved cancer therapy. The Agency has also conducted 15 product seizures, 11 product recalls, and the voluntary destruction of 18 illegal products (generally pertaining to unapproved new drug products). Finally, FDA has been involved in numerous cases that involve rogue websites. A synopsis of many of these cases is attached to this testimony. (See Attachment) This attachment also lists a number of studies and surveys conducted by FDA to gather data on unapproved drugs coming into the U.S.

**CONCLUSION**

Mr. Chairman, online shopping for pharmaceutical products clearly provides many benefits for consumers. However, it also poses a number of significant risks. In addition, the nature of Internet technology presents law enforcement and policy makers with unique challenges. FDA is grappling with these challenges including our need to carefully balance consumer access to information and products with protecting the public health. We are using our existing compliance and enforcement tools to prevent consumers from obtaining adulterated and/or misbranded FDA regulated goods via the Internet and will continue to evaluate what changes in our procedures, regulations, or the law might be appropriate to enhance our efforts. Our goal is to ensure that the

protections afforded to consumers who purchase drugs from their corner drugstore also extend to consumers in the electronic marketplace.

We look forward to working further with Congress on this important issue, and I would be happy to answer any questions you may have.

**ATTACHMENT**

# FDA CASES AND STUDIES

**CASES**

Norfolk Men's Clinic

On February 16, 2002, a Federal jury in Alabama convicted Anton Pusztai and Anita Yates of charges arising out of the operation of the online pharmacy that illegally sold prescription drugs over the Internet to consumers. On June 18, Pusztai and Yates were sentenced respectively to more than 15 and 6.5 years. Pusztai, an Australian citizen, and Yates, a resident of Clanton, Alabama, were convicted of conspiracy to commit violations of the FD&C Act, conspiracy to commit money laundering, mail fraud, dispensing misbranded drugs, and operating a drug repackaging facility not registered with FDA. From fall 1998 to the summer of 2000, the defendants operated a website called *Viagra.au.com*, also known as Norfolk Men's Clinic, and related sites, that sold a variety of prescription medications.

In September 1999, OCI received information regarding the Norfolk Men's Clinic and the website. Based on this information, several covert purchases were made via the Internet. Search warrants were executed in October 1999 that resulted in the seizure of prescription drugs and business records. Based on these purchases and information gathered through numerous interviews, several individuals were indicted. In addition to defendants Pusztai and Yates, the president of a prescription drug wholesaler located in Miami, Florida, and the company itself, pled guilty to distributing misbranded drugs. The company also plead guilty to obstruction of justice. In conjunction with the indictment, a second search warrant was

executed in Clanton, Alabama, along with two search warrants in West Virginia. While most of the drugs sold in this operation were domestic product, some appeared to have originated in New Zealand.

Dr. Mario Alvarez-Valentin

On January 11, 2002, Dr. Mario Alvarez-Valentin was sentenced to 26 months imprisonment after pleading guilty to wire fraud in connection with the unlawful sale of Viagra over the Internet. Alvarez was a physician contracted with Internet websites for the purpose of authorizing prescriptions for Viagra to persons throughout the U.S. From April 2000 to January 2001, Alvarez, who was only licensed to practice in Puerto Rico, prescribed and caused to be prescribed more than 4,000 prescriptions for Viagra. In doing so, he violated the licensing laws of at least 20 states. United States v. Alvarez-Valentin, D.P.R.

Kwikmed

On October 1, 2002, a Federal Grand Jury in Arizona returned a 198 count indictment against Kwikmed, Inc., Cymedic Health Group, Inc., four owners of these corporations, and two physicians associated with the corporations. The indictment alleges that defendants operated Internet websites, two of which include *kwikmed.com and cymedic.com*, through which they sold prescription drugs, including Viagra, Celebrex, Xenial, and Propecia. The websites did not require a consumer to have a prescription before receiving the drugs. Instead the customers were required to complete a questionnaire, which the website told customers would be reviewed by a physician.

Customers were charged a fee for this purported medical consultation. The indictment alleges, however, that for the overwhelming majority of applications, no medical reviews, consultations, or physical examinations by a physician took place before drugs were shipped to customers. The indictment also alleges that defendants repackaged drugs obtained from a drug wholesaler, even though defendants were not a registered manufacturer or a licensed pharmacy, and that there was never a licensed pharmacist in any way involved. The indictment also alleges that the drugs dispensed were adulterated because of the defendants' failure to follow cGMP in packaging, holding, and labeling of the drugs. The indictment alleges that during the course of the conspiracy the defendants and others generated sales in excess of $28 million, which was billed to consumers as charges for prescription drugs, doctor consultations, and shipping. These sales resulted from the defendants' distribution of at least 48,816 new orders for prescription drugs and 41,817 refills of those orders. The indictment charges defendants with several violations of the FD&C Act, as well as conspiracy, mail fraud, and money laundering. The charges were the result of an investigation by FDA and the U.S. Postal Inspection Service.

United States v. Carl David Roberts, (E.D. Tenn.).

On January 15, 2003, Roberts was sentenced to a prison term of 57 months. Roberts was chief administrator of an Internet business that used sophisticated technology to sell prescription drugs, including Schedule II narcotics, without any medical supervision. He had directed an organization that sold drugs from within the U.S., and from abroad. His organization included drug suppliers from Mexico, the Netherlands, and Ecuador. In September 2002, he pled guilty to distribution of controlled substances and conspiracy to violate the FD&C Act.

United States v. Kimball, (11th Circuit).

On May 14, 2002, the Eleventh Circuit affirmed the district court's sentence. Kimball received a 13-year sentence for violating the FD&C Act. Kimball was found guilty after trial of putting prescription drugs into commerce without a prescription. His marketing efforts included use of the Internet.

Medications Express

On June 7, 2001, Gerald Bevins was convicted in U.S. District Court for the Southern District of California of conspiracy to defraud the U.S. and commit offenses against the U.S. by introducing misbranded drugs into interstate commerce and smuggling. On September 4, 2001, Bevins was sentenced to serve twenty-four months in prison. The case was initiated on information received from Customs concerning an Internet website called Medications Express. Bevins sold Mexican prescription pharmaceuticals from this website and claimed that no doctor's prescription was necessary. He continued to sell Mexican prescription pharmaceuticals through the mail from Sun City, California, even after discontinuing the Medications Express website. Bevins, his wife and daughter would receive orders via mail, travel to Tijuana, Mexico, to purchase the pharmaceuticals, and smuggle them back into the U.S. The three packaged the pharmaceuticals into commercial courier boxes and shipped them to customers around the U.S. The drugs supplied by Bevins were labeled in Spanish.

Canadian Drug Store, Inc.

On May 14, 2002, the Ontario College of Pharmacists, a Canadian government agency, filed charges under Ontario law against The Canadian Drug Store, Inc., for unlawfully operating an

unlicensed pharmacy and using an un-registered pharmacist in filling prescriptions for U.S. residents. The College also filed charges against a licensed pharmacist, pharmacy, and physician in Ontario for helping to facilitate the delivery of prescription and non-prescription drugs to U.S. residents. A drug wholesaler was charged with supplying medications to a non-licensed pharmacy.

According to a statement released by the College, there are many websites selling prescription and non-prescription medicines that have not been accredited as legitimate pharmacies by pharmacy regulators in either Canada or the U.S. Some websites presenting themselves as online "pharmacies" or "drugstores" may be operating without a pharmacy license and dispensing prescriptions without the oversight of a licensed pharmacist.

Total Remedy/Prescription Center II

According to news accounts, a Los Angeles pharmacy and two pharmacists were assessed penalties of almost $90 million in a California Board of Pharmacy proceeding in May 2002 for filling more than 3,500 illegal prescriptions over the Internet. The case was brought under a state law that creates a requirement to fill a prescription pursuant to a good-faith medical examination. The Internet site concentrated on filling prescriptions for lifestyle drugs such as Viagra and Propecia (Associated Press, 5/29/02).

Pillbox Pharmacy

In March, 2002, a Texas pharmacist, three doctors, two corporations and an individual were charged in a Federal indictment alleging that they conspired to illegally dispense drugs in

connection with an Internet pharmacy operation. The indictment charged one pharmacist, three physicians and two corporations, the S&H Script Shop and the Pillbox Medical Center, with conspiring to illegally dispense controlled substances and commit money laundering. According to the indictment, between January 1, 2000, and June 12, 2001, the defendants grossed more than $7.7 million from the Internet sales of just two drugs alone. The indictment alleges the doctors would issue prescriptions without establishing a patient history, performing a mental or physical exam, using appropriate diagnostic or laboratory testing, or providing any means to monitor medication response. The charges were the result of an 18-month investigation by FDA, DEA and IRS, working with the U.S. Attorney's office. In April, the pharmacist and two corporations pled guilty to illegally dispensing controlled substances, and agreed to forfeit $1 million.

**STUDIES**

**Carson mail study**

In early 2001, FDA and Customs conducted a survey of imported drug products entering the U.S. through the Carson City, California mail facility (the Carson pilot). The purpose of the Carson pilot was to examine incoming mail shipments of pharmaceutical products over a specified time frame to identify both the volume and the types of drug products entering the U.S. We also wanted to better assess the level of effort and human resources required to handle drug importations at a mail facility, and to better understand the public health implications these importations may have for U.S. consumers.

The Carson pilot ran for a five-week period, with FDA inspectors present for 40 hours per week, a much higher staffing level than is normally possible. Although Customs took a

baseline sample which indicated they could have set aside for FDA review an estimated total of 16,500 international packages (650 packages per day), FDA was able to examine only 1,908 packages during the five-week pilot, or an average of 381 packages per week. Unexamined packages were sent on to the addressees. Of the 1,908 packages examined by FDA, 721 parcels (38 percent of the total) originating in 19 countries were detained and the addressees notified that the products appeared to be unapproved for use in the U.S., misbranded and/or a drug requiring a doctor's prescription.

Analysis of the Carson Pilot Drug Parcels

FDA's Center for Drug Evaluation and Research (CDER) reviewed listings of the products detained during the Carson pilot to define better the nature of the risk to public health from the types of products coming into the U.S. through personal importation. CDER's review demonstrates that there are serious public health risks associated with many of the 721 drug shipments (composed of 197 different drugs) detained at Carson. There are primarily two types of risks that consumers of these drugs would face. The first risk arises when consumers take drugs of unknown origin or quality. Second is the very significant risk associated with taking many of these drugs without first obtaining a physician's prescription and without the continued oversight of the physician.

In general, FDA has no information to establish where these drugs were actually manufactured and whether current GMP requirements were followed. There is also no assurance that the drugs were packaged and stored under appropriate conditions to avoid degradation or contamination. Approximately eight percent of the shipments contained drugs that could not

be identified because they contained no labeling; some of these contain only foreign language labeling. Most of these drug shipments were contained in plastic bags; one shipment contained drugs taped between magazine pages.

Several drugs do not appear to correspond with any FDA-approved drugs and therefore the risks associated with the products are difficult to assess. One drug had been reviewed for FDA approval but was rejected because its efficacy could not be demonstrated. Several shipments contained three drugs that were once approved by FDA but have been withdrawn from the market.

The vast majority of the shipments were identified as containing prescription drugs. A number of controlled substances were also identified. Importation of these drugs containing controlled substances violates criminal provisions of the Controlled Substances Import and Export Act, including 21 U.S.C. 960 (unregistered importer/declared importation). These drugs have the potential for abuse, addiction or risk of life-threatening overdose. A physician's prescription and oversight are essential for managing these risks. Additionally, drugs to treat diseases including diabetes, hypertension and serious infection were included in the Carson shipments, as were many drugs with serious contraindications and/or possible drug or food interactions.

Many of the drugs identified in the Carson pilot are intended to treat conditions that only physicians can properly diagnose. Consumers who bypass physician diagnosis and prescribing may be exposing themselves to risks and toxicities that cannot be justified by offsetting

**Three Surveys**

Within the last two years, FDA has conducted three surveys at U.S. borders to gather data on drug products carried by individuals entering the U.S. While these border surveys involve land traffic rather than mail importation, the results show some similarities to the findings from the Carson mail pilot, but also some significant differences.

Southwest Border Survey (August 2000)

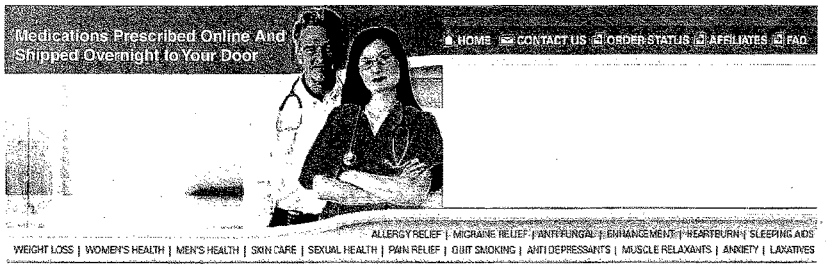
A survey of prescription drugs being brought by pedestrians into the U.S. at eight ports-of-entry along the 2,000-mile border with Mexico was conducted by FDA's Southwest Import District (SWID) with the assistance of other agencies. The survey looked at activity during four hours on a Saturday (August 12, 2000) at eight border ports in California, Arizona, and Texas. The purpose of the survey was to determine what specific types of products are being imported, and who is importing these products. The data collected from over 600 interviews indicated that the most common importers were bringing back primarily antibiotics or pain relievers. Prescriptions were held by 63 percent of the persons interviewed (59 percent U.S. prescriptions while 41 percent were Mexican). While many of these products are already available as FDA-approved drugs in the U.S., some are unapproved for sale in this country.

Canadian Border Survey

On January 6, 2001, in cooperation with Customs, FDA conducted a survey to obtain a snapshot of prescription drug products being brought into the U.S. from Canada via passenger vehicles. During the eight-hour survey at three ports-of-entry in New York, Michigan and Washington, a total of 10,374 passenger vehicles and 58 buses crossed into the U.S. Of these, 33 passenger vehicles (35 individuals) were referred by Customs to be interviewed. These individuals brought in a total of 47 containers of drug products from Canada. The largest group of products was pain medicines. The next largest group of products was herbal products, with the reason for importation being that the products were not available in the U.S. Some of these drugs are unapproved foreign versions of FDA-approved drugs, although some approved for sale as prescription drugs in the U.S. are sold as over-the-counter medications in Canada.

Southwest Border Survey (April 2001)

On April 11, 2001, FDA, Customs, and other agencies conducted a survey of prescription drugs being brought into the U.S. at seven ports-of-entry along the U.S./Mexican border. During the four hour survey, a total of 586 persons imported in a total of 1,120 drugs. Approximately 56 percent had a prescription for the medicines (61 percent were U.S. prescriptions, 39 percent were Mexican). As in the earlier survey, many of these products are already available as FDA-approved drugs in the U.S., while some are unapproved for sale in this country.




**Weight Loss**
Adipex
Bontril
Didrex
Ionamin
Meridia
Phentermine
Tenuate
Xenical
Phendimetrazine
SlimPro
Fattache

**Muscle Relaxants**
Cyclobenzaprine
Skelaxin
Soma
Flexeril
Zanaflex

**Men's Health**
Propecia
Viagra

**Women's Health**
Ortho Tri-Cyclen
Vaniqa
Nordette 28
MenoPro
Ortho Evra patch
Triphasil
Diflucan
Estradiol
Ovral

**Sexual Health**
Acyclovir
Valtrex
Viagra

## PHENTERMINE *for weight loss*

Phentermine is used as an appetite suppressant. It is used in conjunction with an overall diet plan to reduce weight.

Phentermine is best taken on an empty stomach one-half hour before breakfast. Because this medication may cause sleeplessness, avoid taking a dose late in the day. Take Phentermine as prescribed.

Buy It Now - Click on Desired Medication Below:

| | | |
|---|---|---|
| 1 Month Supply (30 pills) of Phentermine 37.5mg Tablets | $99.00 | buy now! |
| 3 Month Supply (90 pills) of Phentermine 37.5mg Tablets | $199.00 | buy now! |
| 2 Month Supply (60 pills) of Phentermine 37.5mg Tablets | $149.00 | buy now! |
| 1 Month Supply (30 pills) of Phentermine (Blue) 30mg Capsules | $89.00 | buy now! |
| 3 Month Supply (90 pills) of Phentermine (Blue) 30mg Capsules | $169.00 | buy now! |
| 2 Month Supply (60 pills) of Phentermine (Blue/Clear) 30mg Capsules | $139.00 | buy now! |
| 1 Month Supply (30 pills) of Phentermine (Yellow) 30mg Capsules | $79.00 | buy now! |
| 3 Month Supply (90 pills) of Phentermine (Yellow) 30mg Capsules | $149.00 | buy now! |
| 2 Month Supply (60 pills) of Phentermine (Yellow) 30mg Capsules | $129.00 | buy now! |
| 1 Month Supply (30 pills) of Phentermine 15mg Capsules | $89.00 | buy now! |
| 3 Month Supply (90 pills) of Phentermine 15mg Capsules | $169.00 | buy now! |
| 2 Month Supply (60 pills) of Phentermine 15mg Capsules | $139.00 | buy now! |

**Enhancement**
BustPro
V-Pro
Formula HGH
HGH15
MindPro
MoodPro

**Anti-Depressants**
Paxil
Prozac
Zoloft
Effexor
Elavil
Fluoxetine
Wellbutrin
Sarafem
Celexa

**Skin Care**
Retin A
Renova
Genie Smoother

# Medical Request Form

The information requested allows the Medical Doctor to review your request for prescription medication. Information will be treated confidentially and will not be released to third parties. For additional information on how we protect your privacy, please review our privacy statement.

All information requested must be completed.

**Section 1:** customer account information

**First Name:** (Complete First Name - No Initials)
**Last Name:**
**Email Address:** (Like yourname@aol.com)
**NOTE:** Notifications of your order status will be sent via email.
**Date of Birth:** Month / Day / Year
**Gender:** --Select--

**Section 2:** shipping/contact information

**Shipping Method:** Next Day - $18 (Non-continental US - $30)
**NOTE:** When the package is delivered, an adult must be present to receive the shipment.

**Shipping Address:**
**Street Address:** (No P.O. Boxes)
**City:**
**State:** --Select--
**Province:** (Non U.S. use only)
**Zip Code:**
**Country:** U.S.A.
**Day Time Phone:** ( ) - Ext.
**Evening Phone:** ( ) - Ext.

**Section 3:** payment method

**Payment Method:** --Credit Card Type--
**Card Holder:** (Exact Name on Credit Card Bill)
**Card Number:**
**CVV2:** (The 3 digit number on the back of your card) More Info
**Expiration Date:** --Select-- --Select--
**Billing Address:**
☐ Same as Shipping Address
**Address:**
**Address 2:**
**City:**
**State:** --Select--
**Province:** (Non U.S. use only)
**Zip Code:**
**Country:** U.S.A.

**Section 4:** your medication selection

**Please select the medication that you would like to order:**

**Medication:** Celebrex 200mg ( 50 pills) - $249.00

**Section 5:** medical questionnaire

**Please select your Height:** Height

**Please enter your Weight in pounds:** Lbs.

NOTE: Customers must have a body mass index of 25 or greater to request a weight loss medication

**Your Calculated Body Mass Index (BMI):**
(Automated calculations, please click on box)

---

**1. I agree not to take this medicine if I have any history of liver or kidney disease.**

O I Agree O I DISAGREE If you disagree, please explain why:

**2. I agree not to take this medication if I am pregnant, breast-feeding, or trying to get pregnant.**

O I Agree O I DISAGREE If you disagree, please explain why:

**3. I agree not to take this medicine if I have any history of heart failure, fluid retention, or uncontrolled hypertension.**

O I Agree O I DISAGREE If you disagree, please explain why:

**4. I agree not to take this medicine if I have any history of asthma or allergic-type reactions to aspirin or non-steroidal compounds.**

O I Agree O I DISAGREE If you disagree, please explain why:

**5. I agree not to take this medicine if I have had any adverse reactions to sulfa-containing compounds.**

O I Agree O I DISAGREE If you disagree, please explain why:

**6. I agree not to take this medicine if I have any history of ulcer disease, bleeding, or symptoms of gastrointestinal disease such as gnawing or burning stomach pain, black or tarry stools or vomiting. I also agree to notify my health care provider if I exp**

O I Agree O I DISAGREE If you disagree, please explain why:

**7. I agree to notify my health care provider of any untoward side effects while taking this medication (including, but not limited to any bleeding, skin rash, unexplained weight gain or edema, itching, yellow jaundice, nausea or fatigue).**

O I Agree O I DISAGREE If you disagree, please explain why:

**8. Please list all current medical conditions. Enter "NONE" if none.**

O None O I will specify

**9. Is there anything in your medical history that you consider to be relevant? If yes, please specify. Enter "NONE" if none.**

O None O I will specify

**10. Please list all over-the-counter and prescription medications that you are currently taking and the length of time for each. Enter "NONE" if none.**

○ None ○ I will specify

**11. Please list all medications that you plan to take while on this program. Enter "NONE" if none.**

○ None ○ I will specify

**12. Please list all past or present allergies including allergies to any medications. Enter "NONE" if none.**

○ None ○ I will specify

**13. Please list all past surgeries and provide details including the condition that was treated with each surgery. Enter "NONE" if none.**

○ None ○ I will specify

**14. Please explain the specific medical reason for ordering this medication. The physician must know the exact nature of your medical problem in order to prescribe this medication. This cannot be left blank.**

**Section 6:** customer agreements

To request prescription mediation, your agreement to the Customer Responsibility and Informed Consent Statements are required.

**Having read and understood the Statement, I Agree with the** Customer Responsibility Statement --Select--

**Having read and understood the Statement, I Agree with the** Informed Consent Agreement --Select--

**Please update me on new site features, specials, and promotions.** --Select--

Review and Confirm Order

Click **"Review and Confirm Order"** to continue.
Credit Card will be billed by Medline Financial.

Chairman TOM DAVIS. I'm going to start the questioning with Mrs. Miller. The gentlelady from Michigan is recognized.

Mrs. MILLER. Thank you, Mr. Chairman.

I'm particularly interested in this issue, as we are talking about these various Internet sites and the kinds of problems that we are having. I live in Michigan, obviously a border State to Canada, and our seniors—I'm not sure if they are on the Internet. They just get on the bus and go across the Bluewater Bridge or the Ambassador Bridge and they're purchasing their drugs in Canada. You can't hardly blame them, certainly.

It has been interesting for me to listen to your testimony here today. I notice that you said that you send out initial warning letters to some of the sites that are illegitimate or what have you. It is my understanding that what is happening with many of the seniors, whether they are purchasing these drugs over the Internet or whether or not they're just traveling there personally, they do have to have a script from a Canadian doctor. My understanding is that they'll go there with a script from an American doctor and then have to have it re-scripted by Canadian doctors.

How are you interacting not only with the States but with the Canadian Government? Are you having any success in writing these letters? You just mentioned that you only had one lawsuit and you had another this morning with Oklahoma. Are you having good cooperation with the local law enforcement from the States, as well as the Canadian Government, on weeding out some of these illegalities that are happening?

Mr. HUBBARD. I will take that as my question. I certainly think we are having good success. As I said, we have agreements with the States in which we are attempting to coordinate our actions. In terms of Canada, we have been in regular contact with Canadian regulatory officials and they recognize that these sites are illegal and are working at their end of the border on them.

As far as patients coming across from Canada, the American citizens, we try to warn them and tell them that they're taking risks in buying these drugs.

We do not, of course, prosecute or otherwise take action against individual consumers who go to Canada to purchase drugs.

Mrs. MILLER. I mean, it is a huge cottage industry immediately across the various bridges that I have talked about in our State, and I'm not sure if these Canadian doctors are licensed or what is happening, but that's what my seniors are telling me—that they just take these scripts and they are re-scripted over by the Canadian doctors and they come back with their drugs.

Mr. HUBBARD. Well, the Canadian officials tell us that the Canadian regulatory officials who oversee the practice of medicine in Canada are very concerned about Canadian physicians co-signing these prescriptions, and they are trying to make that point to their physicians that they should not be doing that. They do not consider it a good practice of medicine.

Mrs. MILLER. Thank you.

Chairman TOM DAVIS. Thank you very much.

The gentleman from Texas.

Mr. BELL. Thank you, Mr. Chairman.

Mr. Hubbard, I want to talk to you for a moment about the definition of a valid prescription. The FDA allows States to determine the definition for valid prescription, correct?

Mr. HUBBARD. That's correct. The Federal law says that a prescription drug must be dispensed pursuant to a valid prescription, but it does not define that, so FDA relies on the State definition of valid prescription.

Mr. BELL. Is that part of the problem?

Mr. HUBBARD. It certainly has been said by many that is a problem; that if the individual State does not have a definition of valid prescription that covers these Internet sites, then that is viewed as a weakness.

Let me ask Mr. Taylor to say more about that.

Mr. TAYLOR. Sure. I can expand upon that.

It poses two challenges, one in the context of our own statute, which basically says that if a product is dispensed and there isn't a valid prescription, the drug product is misbranded. So if there isn't a clear definition on the State level as to what constitutes a valid prescription in the context of the Internet, it is difficult for us to make a misbranding charge.

In the criminal context, the challenge comes because in order to show intent to establish a criminal violation, it is difficult to establish intent if, again, the standard as to what constitutes a valid prescription is not clear.

So, to the extent we have had success in building criminal cases, it is often in those States where there, indeed, is a clear definition as to what constitutes a valid prescription in the context of the Internet.

Mr. BELL. From a regulatory standpoint, isn't it somewhat of a nightmare, because you could be looking at 50 different definitions for valid prescription, couldn't you?

Mr. TAYLOR. Indeed. And when we started working on the Internet in 1999, both on the State level and the Federal level, our statutes really never contemplated the use of the Internet, quite frankly, as a means of conveying drug products, and so I think both on the State level and the Federal level we have tried to apply our laws in a way that allows us to address this problem.

But you are right: in the context of the States, you have 50 different definitions, and therefore when we are putting together cases or when we are investigating sites we have to factor that in as a part of our strategy, and so that does pose a great challenge to us.

Mr. BELL. Would it be your recommendation to try to come up with one definition?

Mr. TAYLOR. Well, I don't think the administration has a position on that; however, as I said, it has been a longstanding concern to us because our inability to build the cases we would like in certain circumstances.

Mr. BELL. And, just so we'll have a better understanding of what is going on out there, I assume there are some folks that are operating in a legitimate fashion?

Mr. TAYLOR. Absolutely. Absolutely. And I think one of the programs that we think is very positive is NABP's Verified Internet Practice Pharmacy Site program [VIPPS]. We also think that is an

excellent program because it allows consumers to look at the seal and realize that they are getting a drug that is pursuant to a valid prescription under State law, and also that they are getting a drug that is FDA approved. So yes, there are definitely legitimate sites. The Internet definitely provides great benefits, including anonymity, convenience to those who are homebound, as well as cheaper prices in some cases, but that's not the case across the board.

Mr. BELL. Thank you, Mr. Chairman.

Chairman TOM DAVIS. Thank you very much.

Mr. Duncan.

Mr. DUNCAN. Thank you, Mr. Chairman, and thank you for calling a hearing on this very important topic.

Mr. Hubbard, as Congresswoman Miller said, you can't blame these people for trying to get lower prescription drug costs almost any way that they can—going to other countries or over the Internet or something. But I've read several times in the Wall Street Journal over the last few years that it costs they estimate an average of $650 million to $800 million and 10 to 12 years to get a drug approved by the FDA. And then I remember reading also in the Wall Street Journal a few years ago about a small company in Illinois that had a breast cancer detection pad that they had sold many, many thousands in other countries and they had gotten approved in every industrialized nation within weeks or months, but they had been, I think, at that point 9 years dealing with the FDA. They had several doctors quoted in that article saying thousands of women have died because the FDA had been so slow and bureaucratic.

What I'm wondering about is why does it take so much longer to get drugs approved here than in any other industrialized nation in the world, and what are you doing now or have you done some things to try to bring down those costs and those time constraints to help, because that would do more than anything to bring down the prices of prescription drugs in this country.

Mr. HUBBARD. Mr. Duncan, in fact, in the 1970's and 1980's drugs did occasionally reach the U.S. patients last in some cases because of—allegedly because of FDA requirements. However, I would say that Congress stepped in on this issue about a decade ago——

Mr. DUNCAN. Right.

Mr. HUBBARD [continuing]. And created new legislation that has resulted in drugs now being approved as fast or faster in the United States than anywhere in the world, so our patients do get the drugs faster than anywhere else.

It's very expensive to——

Mr. DUNCAN. I was here when we passed that legislation and I remember that, and we did try to step in. But I still read these articles in the Wall Street Journal and other places that says FDA still—that the big drug giants can get things approved real quickly, but some of these small companies don't have a chance.

Mr. HUBBARD. Well, when Congress passed that legislation it gave us very strict review times, and we'd be glad to share the data with you. We, in fact, meet those review times as directed by Congress.

Mr. DUNCAN. So you are saying that we are now faster than most other industrialized nations?

Mr. HUBBARD. Than all other industrialized nations.

Mr. DUNCAN. All right.

Mr. Beales, how many people are buying drugs over the Internet, as best as you can tell? And has the FTC—have you received complaints about these drugs being fake in some way, or can you tell us, do you know of anybody that has been hurt by any of these drugs? I'm wondering about the scope of the problem here.

Mr. BEALES. We don't have a specific estimate of how many people purchase drugs over the Internet. I mean, there are an enormous number of people who make various health-related purchases over the Internet, but I can't narrow that down to pharmaceutical products.

We do get complaints about products that are ineffective. They are—those don't tend to be complaints about prescription drugs, but what most of the complaints we get from online pharmacies—that concern online pharmacies are non-delivery kinds of complaints and those kinds of issues.

We don't know of particular instances of cases where somebody has tried to buy a drug that turned out not to work or to be the wrong thing. That is what we were concerned about in looking at Cipro, and we have in the past brought cases against home test kids for AIDS that were sold online and, in fact, did not work. So we know that problem is out there, but we don't know of specific instances in prescription drugs.

Mr. DUNCAN. All right. Thank you very much.

Chairman TOM DAVIS. Thank you very much.

Mr. Waxman.

Mr. WAXMAN. Thank you, Mr. Chairman.

Mr. Beales, one possible model of addressing the Internet pharmacy issue could involve shared response authority, shared authority between FDA and the States. Shared enforcement already exists within FTC law in the Telemarketing Act. Can you explain how the Federal Government and States share enforcement of the Telemarketing Act? And does this work in the case of telemarketing?

Mr. BEALES. Certainly. The way the Telemarketing Sales Act is set up is the FTC writes rules that govern telemarketing to define deceptive and abusive practices and specify requirements, and then the FTC can enforce those rules, but States also have the ability to go into Federal court to enforce the Federal rule. There is a right of first refusal, if you will. States have to tell us to go to Federal court, and if we want to take over the case we can.

What that structure does is to preserve a uniform Federal set of rules and Federal authority over what the rules will be and remain, but it allows for individual States to go into Federal court to obtain a national injunction to stop a particular practice.

By and large, that scheme has worked well. We find that mostly States prefer still to go into State court under their own State laws, but there have been about 50 or so cases where States have gone to Federal court in order to stop particular telemarketing practices.

Mr. WAXMAN. Thank you. You testified that FTC has noticed a large number of false or misleading claims made about dietary supplements. After the death of Oriole's pitcher Steve Bechler several weeks ago, a great deal of attention is focused on ephedra products. Can you give us examples of statements made by Web sites about ephedra that FTC considers false or misleading? And let me also ask: if a company asserts that an ephedra product is safe, is that considered misleading by the FTC?

Mr. BEALES. We have, in four cases so far, going back to 1997, challenged claims that ephedra was safe or had no side effects as unsubstantiated. We don't think there is sufficient scientific evidence to establish safety or to establish the lack of side effects. And we have been successful in those four cases that we have brought. We have other investigations involving ephedra products, and there will be more cases that are in the pipeline.

Mr. WAXMAN. Well, if a company asserts that an ephedra product is safe, is that considered misleading by the FTC?

Mr. BEALES. Yes, it is. We think that a claim is misleading if it is false or it is misleading if there is not sufficient scientific evidence to substantiate the claim, and in either case we can and do go to Federal court in order to stop it.

Mr. WAXMAN. Mr. Taylor, some have suggested that there should be a single Federal standard for what is valid prescribing over the Internet. With a clear Federal standard, would enforcement be easier?

Mr. TAYLOR. Indeed, it would, simply because, instead of dealing with the standards of 50 States in terms of looking at whether to bring a civil or criminal case, we would be dealing with one unified standard for what constituted a valid prescription.

Mr. WAXMAN. Thank you.

Thank you, Mr. Chairman. I yield back.

Chairman TOM DAVIS. Thank you very much.

Mr. Janklow.

Mr. JANKLOW. Thank you very much, Mr. Chairman.

Mr. Taylor, if I could ask you, give us an example of two States that have different laws that define a prescription.

Mr. TAYLOR. You mean specific States or specific fact patterns?

Mr. JANKLOW. Either one, because I just need an example of two States that have a definition of "prescription" that's different.

Mr. TAYLOR. Sure. There are some States that specifically address, for example—if you notice up on the easel there is essentially what is called an "online questionnaire." There are some States that specifically state that an online questionnaire, filling out that online questionnaire does not fall within the standard for the practice of medicine and does not fall under the standard of what constitutes a practice of pharmacy and therefore a valid prescription. There are other States, however, that don't address the question of whether or not an online questionnaire falls inside or outside the proper standard of medical care or inside or outside the standard for the practice of pharmacy or what constitutes a valid prescription. That's two concrete examples of how an online questionnaire is dealt with different in two different States.

Mr. JANKLOW. But, sir, your second example that you gave, you said they don't say one way or the other, so I don't know how that

is a different example. One State may say that an online fill-out is not a prescription, the other State is silent. That doesn't mean it is.

Mr. TAYLOR. Well, actually, here's the difference. The difference, in the context of a criminal case, is that if you are going to bring a criminal case and you are going to go to a U.S. Attorney's office, and as part of a statute in a criminal case you need to establish intent, you're able to go to the U.S. Attorney and say definitively that this type of conduct falls outside what constituted a valid prescription, and by this kind of conduct, the filling out of a questionnaire falls clearly outside of what constituted a valid prescription within that State, and therefore it is easier to establish that someone has intentionally violated State and thereby Federal law.

In the context of a State where it is unclear whether it does or does not constitute a valid prescription, it is difficult to show that someone, you know, willfully intended to violate the law because they may not know, themselves, that——

Mr. JANKLOW. But, sir, as a practical matter, you can file charges against somebody that should be determined. I mean, what we're doing is making subjective judgments on cases that we don't file, as opposed to filing an action where we believe there is a violation and letting it be determined by judges through the appellate chain.

Mr. TAYLOR. Well, in some cases where there is ambiguity we've gone to the States to get an advisory opinion as to whether or not the online questionnaire falls under a valid prescription of medicine, but we have not, quite frankly——

Mr. JANKLOW. Let me ask you, if I can, this, sir.

Mr. TAYLOR. OK.

Mr. JANKLOW. Do you know of any State that says an online questionnaire fulfills a prescription requirement?

Mr. TAYLOR. Not off the top of my head, but that doesn't mean——

Mr. JANKLOW. OK. Mr. Hubbard, if I can ask you, you talked about this case in Arizona [sic] that is being filed today. How long has that case been being worked?

Mr. HUBBARD. I don't know how long Oklahoma—it's Oklahoma. I don't know how long Oklahoma has been working it, but we spent a few, the last few weeks on it.

Mr. JANKLOW. Pardon?

Mr. HUBBARD. We've spent the last few weeks on it. We are reacting to the claims they are making to their Web site and to the actual sales that they are making.

Mr. JANKLOW. And are there thousands of these sites out there?

Mr. HUBBARD. There are certainly hundreds. We have learned that in many cases a given Web site is part of a larger business that runs several Web sites, so it could be if you see Web site A, there is also B, C, D, E all run by the same company with different looks on the Internet.

Mr. JANKLOW. Do you have any estimate as to the number of cases globally that have been filed in America, what percent are civil, what percent are criminal?

Mr. HUBBARD. As I said in my testimony, we have done over 300 at FDA. The States have done some number more, but I do not have that number. Perhaps the next panel will know more.

Mr. JANKLOW. Are you aware of many instances where someone has been shut down civilly where they have reopened under another name or another operation?

Mr. HUBBARD. Absolutely.

Mr. JANKLOW. So the civil law really doesn't work very well, does it?

Mr. HUBBARD. Well, I think that could also be true of the criminal. If you don't catch the criminal and he has moved on to another State or another country, just because you have targeted them doesn't mean you have successfully put them out——

Mr. JANKLOW. I understand that, but, I mean, as a practical matter there is less likelihood someone will be dealing with the criminal law violations as a matter of choice than civil law violations.

Mr. HUBBARD. Let me ask John to answer that.

Mr. TAYLOR. Not in all cases.

Mr. JANKLOW. I said as a practical matter. I didn't say in all cases.

Mr. TAYLOR. Not even in—I can't even say it is a practical matter, because there might be some instances where a Web site is disseminating a product that is so dangerous that it is, quite frankly, more advantageous to try and move with the civil case—for example, an injunction or seizure—that removes the product from the marketplace quickly. Some of our criminal cases are so complex that, quite frankly, it takes a certain amount of time to put them together, and during that time in some cases products could still be—the pharmacy could still be dispensing products to consumers. So it really is a fact-based analysis.

If you may, I just want to expound upon what Oklahoma is doing today. One of the unique facets of the Oklahoma action is this involves a storefront pharmacy which is accepting prescriptions, sending the prescriptions to Canada, and then obviously products are then distributed to consumers.

The reason why this particular storefront was of interest both to the State of Arkansas and the State of Oklahoma is because, as Mr. Hubbard said, the company was making misleading claims about the FDA-approved status of their products, which raises safety concerns that are troubling to us.

Part of, I think, the driving force for trying to address this problem is to ensure that the American public has products that, indeed, are FDA approved and that, indeed, are safe and effective, and that's one of the reasons why the State of Oklahoma moved the case.

Mr. JANKLOW. My time is expired. Thank you.

Chairman TOM DAVIS. Thank you very much.

Mr. Ruppersberger, and then Ms. Watson.

Mr. RUPPERSBERGER. First, after listening to a lot of the testimony and questions, it seems to me that clearly the problem isn't getting any better and there's a lot of ambiguity within different States and that we really do need to establish some Federal standard. Would you agree with that premise?

Mr. HUBBARD. Well, certainly we're getting that advice from several points. Understand that there are significant policy decisions around doing that because FDA does not regulate the practice of pharmacy or the practice of medicine.

Mr. RUPPERSBERGER. What policy decisions? If you were sitting here, what would you suggest that we do to resolve and try to help this situation?

Mr. HUBBARD. Obviously, the advice you will get is that there be a national Federal standard for a valid prescription, but, as I was saying, there is a certain States rights issue and federalism issue around whether you want to empower the Federal Government to define what States traditionally have done. Obviously, that's Congress' choice to make, not FDA's.

Mr. RUPPERSBERGER. But isn't it true that State boards of medicine, State boards of pharmacy, States Attorneys General are all asking for this type of legislation?

Mr. HUBBARD. And from their points of view it is a very legitimate request.

Mr. RUPPERSBERGER. And, you know, the issue is a Federal issue. I mean, it's Internet, it's not within State.

Let me ask you this. I think, Mr. Taylor, you referred to VIPPS. It is my understanding that VIPPS is a voluntary program that certifies Web sites; is that correct?

Mr. TAYLOR. That's correct.

Mr. RUPPERSBERGER. Well, it seems to me that's a very simple issue, a very simple program. What would you think of making VIPPS mandatory? What would be the down side of making VIPPS mandatory?

Mr. TAYLOR. The administration does not have a position; however——

Mr. RUPPERSBERGER. Do you have a position?

Mr. TAYLOR. I don't have a position, either.

Mr. RUPPERSBERGER. As an enforcer.

Mr. TAYLOR. However, obviously I think one of the reasons why VIPPS is so good and one of the reasons why the agency embraces it and tries to spread the word is because it does provide consumers with good advice about the products that they are seeking and it allows consumers to discern whether or not they should be choosing from a site with the VIPPS seal versus all the other sites that are proliferating out there on the Internet.

Mr. RUPPERSBERGER. Do we really think that by answering a few questions a physician is in a position to prescribe medicine?

Mr. TAYLOR. Well, I think the American Medical Association has said that it is important to have a real doctor/patient interaction, and that merely asking and having a few questions answered does not fall within what they believe to be the proper standard.

Mr. RUPPERSBERGER. And what kind of actions do we have that we can take against medical professionals that blindly prescribe drugs?

Mr. TAYLOR. Well, on the State level there have been instances where we have worked with medical boards who have taken actions to disqualify a doctor based on their interactions with a patient. We have, quite frankly—we had one criminal case that we brought against a doctor who was not only prescribing but also owned an Internet site and was disseminating prescription—excuse me, disseminating drugs without a valid prescription. So there are some actions that can be taken on both the State and Federal level. But

the practice of medicine, as Mr. Hubbard said, does rest primarily with the States.

Mr. RUPPERSBERGER. Well, from sitting here and listening to the testimony, it seems to me that a very practical solution might be to encourage that VIPPs be changed to some type of mandatory certification. That might be the first step for getting the camel's nose under the tent. So I would hope that you would take that back to your policymakers in the administration.

Mr. TAYLOR. Fair enough.

Chairman TOM DAVIS. Thank you very much.

Mr. Turner, any questions?

Mr. TURNER. Thank you, Mr. Chairman.

Mr. Taylor, I was fascinated by one comment you made. You said that if they violated State law they thereby violated Federal law with respect to the issuance of a prescription. In your discussions from the whole panel on the issues of foreign Web sites where people are logging on and buying prescriptions and may not even know where they are buying them from, is there any State that doesn't require that a valid prescription be issued by a U.S.A. or State-licensed doctor?

Mr. TAYLOR. Yes. All the States require a valid prescription. The key is—well, there are two keys. One is that what constituted a valid prescription is not necessarily consistent from State to State.

Mr. TURNER. That's why I ask you is there a State that doesn't require that a prescription be written by a licensed doctor?

Mr. TAYLOR. Not that I know of. No, sir.

Mr. TURNER. So these sites that are foreign or where there doesn't appear to be any regulation that's going on, it would seem that you would not have to wonder whether or not Federal law is being violated and whether or not it satisfies all 50 States' regulations if you can determine or ascertain that a U.S.A.-licensed medical doctor is not participating in the transaction.

Mr. TAYLOR. That's correct.

Mr. HUBBARD. And can I say, Mr. Turner, that for the foreign sites it is almost irrelevant whether it's a valid prescription because the drugs, themselves, are unapproved and shouldn't be imported into this country.

Mr. TURNER. And to what extent, then are you taking action on those that are just foreign?

Mr. TAYLOR. Well, in the context, just using Canada as an example, we have shared with the Canadian Government recently 45 Web sites that came to our attention, based on our own domestic work, and we have asked for them to evaluate those Web sites and to let us know whether or not they can take action on their side of the border.

In the context of the action that Mr. Hubbard just talked about, which involves Rx Depot, which is an action that was brought not only by the State of Arkansas but also by the State of Oklahoma, the Canadian—the province Manitoba has issued a statement saying that they were going to take steps to notify Rx Depot that the importation of products from Canada were not only not in compliance with U.S. law, but was not in compliance with the law in the province of Manitoba.

So, to make a long story short, what we try to do is increase our contact with foreign governments and working closely with them. Obviously, it poses a number of challenges, one being products can appear to come from Canada but in some cases they do not. And so one challenge is trying to figure out exactly where the products come from.

The other challenge is, quite frankly, the fact that different foreign governments, as well as the United States, are becoming acquainted with this problem and we're all at different places in terms of coming up with tools that can best address what is now a global issue, as opposed to an issue that is impacting specific countries.

Mr. TURNER. Turning to domestic sites, then, to what extent do you work to verify that a licensed doctor is participating? You have the issue in all 50 States to what extent the questionnaire is enough or not enough, but are you verifying whether or not, as they state, that there is a doctor at all involved in the transaction?

Mr. TAYLOR. Yes, we do. As a matter of fact, when the Internet first—in 1999 and 2000 when the Internet first became a very popular medium for the dissemination of these products, there was a perception that most of these sites did not have any doctor involvement.

What we found subsequent to that was that there are some where there indeed is no physician involved; however, there are others that do have physicians involved. And then the question becomes whether or not the physicians, based on online questionnaire or based on the interaction, are really interacting with the patient in a way that again is consistent with the standard for medical care and is consistent with what, indeed, is a standard for a valid prescription. So yes, we do try and determine that as a part of our investigations, because that is going to be an important fact in determining not only what charges apply but what remedies we want to use in order to deal with the conduct if it is violative.

Mr. TURNER. Thank you.

Chairman TOM DAVIS. Thank you very much.

Ms. Watson.

Ms. WATSON. Thank you so very much, Mr. Chairman, for holding this hearing.

I have been following this issue for many, many years. I was chair of the California Senate's Health and Human Services Committee. There are a couple of things that I want to address, I guess to Mr. Hubbard and then to you, Mr. Taylor.

First, dealing with the foreign Web sites and the prescriptive drugs that can be available, I have tremendous concerns because the ingredients in a particular product vary from country to country, No. 1. So many of these prescriptions might be counter-indicative, depending on the ethnic group that is using them, and so there is a tremendous danger.

I'd like you to comment first, Mr. Hubbard, on what you are doing to look at the prescriptive drugs that can be ordered without a doctor's assistance or without a doctor being in relationship with the patient.

Mr. Taylor, could we have a national standard that says any kind of prescriptive drugs that are ordered off the Internet dealing

with foreign pharmaceutical groups will be prohibited if there is not a doctor related? Can we do that as a national standard?

Mr. Hubbard, and then you think about your response.

Mr. HUBBARD. To answer the question to me, you are absolutely right that there is a great risk that drugs purchased over the Internet from foreign countries could have variability in ingredients and content, they can be contaminated, they might not even be the drug you think you're getting, so that is a very serious issue and we have been trying to essentially stop those drugs from coming in by taking some enforcement action, by asking foreign governments from where those drugs are coming to step in, and by warning our consumers who buy those drugs that they are taking great risk.

I'll let Mr. Taylor answer the other question.

Ms. WATSON. Could we have a Federal standard as it addresses the foreign pharmaceuticals?

Mr. TAYLOR. Again, the administration doesn't have a position on a Federal standard; however, to the extent that there were going to be policy discussions on the issue, I think it would certainly be wise to try and, with whatever standard, whether it be a Federal or State standard, try to come up with a standard that addresses the myriad of fact patterns that we're seeing in relation to these Internet sites, including the one maybe that you just posed as part of your hypothetical.

Ms. WATSON. Well, I understand that FDA has intervened when there is no doctor or prescription involved at all, and in terms of trying to set a national standard, as has been mentioned here before, could we not start there with the foreign pharmaceuticals? Would that not make sense?

I know each State has a board and they set their own standards for practice, but this seems to be—since we are dealing with the Internet, international, wouldn't it be in the best interest of our Federal authority to prohibit the ordering of a prescriptive drug if there has been no patient/doctor contact?

Mr. TAYLOR. In the context of the foreign sites, quite frankly, as Mr. Hubbard alluded to earlier, the issue of valid prescriptions is just really one piece of the puzzle. I mean, in regards to the foreign sites, there certainly are steps that the agency could take to not only address the patient/physician interaction, but, quite frankly, could take to address the actual products, themselves, that are being sold on these sites.

I mean, one of the over-arching concerns that the agency has once again is that, you know, we certainly are cognizant and sensitive to the fact that people are purchasing products from these sites because of their cost, but the over-arching concern that we have is that we, quite frankly, don't know a lot about the manufacturer of these drugs, we don't know a lot about the storage condition of these drugs, we don't know whether these drugs are counterfeit. We don't know, quite frankly, as to whether or not these drugs are originating in Canada or have been trans-shipped from other countries. We have had recent evidence that there are Web sites where the product reports it came from Canada but, indeed, comes from——

Ms. WATSON. Would you yield, Mr. Taylor?

Mr. TAYLOR. Yes. Sure.

Ms. WATSON. To cut to the chase, couldn't we start there? Since you have all these questions——

Mr. TAYLOR. Sure.

Ms. WATSON [continuing]. And we are looking for a national standard, would that not be the place to begin in terms of a national, all 50 States?

Mr. TAYLOR. It is certainly——

Ms. WATSON. Since we have all these questions.

Mr. TAYLOR. It is certainly something I am willing to take back.

Ms. WATSON. OK. Thank you.

Mr. BURTON [assuming Chair]. The gentlelady's time has expired.

Mr. Janklow.

Mr. JANKLOW. Thank you very much, Mr. Chairman.

Mr. Taylor, when the gentleman from Maryland asked you the question "what's the down side if we had a, so to speak, national registry, if we required them to be registered," you said the administration didn't have a position and you didn't have a position. Do you know of a down side if we had a—I don't care about a position. Do you know of a down side if there were a national registration requirement?

Mr. TAYLOR. Well, I mean, I guess one down side would be that on some level it takes away from the States the discretion to pick the standard that they feel is best within their State.

Mr. JANKLOW. OK. Anything else that you know of for a down side?

Mr. TAYLOR. Not off the top of my head. I don't know if Mr. Hubbard has any——

Mr. JANKLOW. Mr. Hubbard, do you know of a down side, sir?

Mr. HUBBARD. I will simply say that the way the Federal/State relationships have evolved for 200 years in this country is that the practice of medicine and practice of pharmacy are inherently State responsibilities, and FDA is not being granted the authority to regulate the practice of medicine except in one limited area called a mammography program, so it would be, to some extent, saying to FDA, "You now have a more substantial role in regulating the practice of medicine."

Mr. JANKLOW. Sir, let's pursue that if we can for a second. We have an FDA, don't we, and it is national?

Mr. HUBBARD. Right.

Mr. JANKLOW. And the FDA, part of its national responsibility is to be concerned about the quality of the drug, of prescription drugs?

Mr. HUBBARD. Right.

Mr. JANKLOW. And part of it has to be concerned with the efficacy of what people may take those drugs for. That's also a concern, isn't it?

Mr. HUBBARD. Right, but the decision to give the drug to the patient is a physician's decision, so he is really the one deciding that this drug will work in this patient.

Mr. JANKLOW. But the FDA has a legitimate concern. I assume you have a concern and you have exercised it with respect to the fact that where a physician isn't in the loop, people having access to drugs which you approve?

Mr. HUBBARD. Well, if there is no physician at all, that is clearly a violation of our act.

Mr. JANKLOW. OK. Well, it appears we have several kinds of problems with the Internet, and I think—at least myself, I have been mixing them. One, we have a foreign problem with importation into this country. Two, we have a problem with respect to the ability for myself to order drugs over the Internet without going through a physician. And, three, we have a problem of me being able to order over the Internet where I have—where there is some physician in some other State that is approving it. At least the fourth one is I have a valid prescription, I feel I can get it cheaper some place other than locally, and so I am ordering it over the Internet with a valid prescription.

Can we agree we've got four different scenarios? Do you know of any others that we're concerned with?

Mr. HUBBARD. I think those are reasonable, although, as I said, if there is no physician at all both the States and the FDA can very clearly act in that circumstance.

Mr. JANKLOW. No, no. My question is: do you know of any other scenarios other than the ones I've put forth? In my questions, I'd like to deal with scenarios separately because we intermingle them.

Mr. HUBBARD. Sure.

Mr. JANKLOW. Do you know of any others?

Mr. HUBBARD. None come to mind, but there may be some more. But I think you have summarized well some of the dilemmas.

Mr. JANKLOW. OK. Sir, now eliminating the foreign issue and eliminating the one where I've got a valid prescription from a doctor in my State and I'm shopping for the best price, be it in Canada or some other State, and I'm filling out a questionnaire that is read by a doctor—that I send it from here, this community, and it is read, it is seen by a doctor in some other State, and on the basis of that I am sent a prescriptive drug, do you know of any place in America where that is the legitimate practice of medicine?

Mr. HUBBARD. Certainly the medical practitioners have advised us that they believe that is not legitimate practice of medicine.

Mr. JANKLOW. OK. So you don't know of any place where it is.

Do you, Mr. Taylor, know of any place where that is called the legal practice of medicine?

Mr. TAYLOR. Sir, I can't think of a place off of the top of my head. That doesn't mean that it doesn't—I just can't think of a place.

Mr. JANKLOW. OK. So, with respect to that issue, that ought to be something that the FDA could move forward on now, isn't it?

Mr. HUBBARD. Well, again, let's say you've got a patient in North Dakota——

Mr. JANKLOW. A what, sir?

Mr. HUBBARD. A patient.

Mr. JANKLOW. Sir, I'm hard of hearing. I wear a hearing aid.

Mr. HUBBARD. Let's say you have a patient in North Dakota who goes on a Web site that is located in South Dakota.

Mr. JANKLOW. OK.

Mr. HUBBARD. And the physician who writes that prescription based on this sort of questionnaire is in South Dakota.

Mr. JANKLOW. Yes.

Mr. HUBBARD. And North Dakota comes to FDA and says, "Will you go after this site?" And we would ask the question of North Dakota, "Is that prescription that physician in South Dakota is writing a valid prescription under your law?" And if they say, "Well, our law doesn't deal with that. We don't have an answer for you," then FDA is pretty much out of the game.

Mr. JANKLOW. Correct. Sir, do you know of any instance where a State has ever done that, where they've said that a—let's take your example—where a North Dakota, for example, has said that a physician who is not licensed in the State of North Dakota, has no nexus with the State of North Dakota, who fills prescriptions for residents who are ordering them from North Dakota based on some Internet document that's filled out, do you know of any scenario where a State has ever said that's not the practice—that's something that we don't have laws that cover, or that it's not the practice—it is the practice of law in our State?

[No response.]

Mr. JANKLOW. They don't.

Chairman TOM DAVIS [resuming Chair]. The gentleman's time is expired, but we'll give him a chance to answer. Any response?

Mr. TAYLOR. I believe initially in the State of Florida there was, quite frankly, a situation similar to that. What the State of Florida has done since then is it has actually tried to come up with a stronger definition as to what constitutes a valid prescription, but we did have some situations with the State of Florida where there was some ambiguity as to whether or not——

Mr. HUBBARD. I believe the next panel will have more information because they are the folks that are much more in touch with that particular State issue.

Chairman TOM DAVIS. OK. Thank you. Thank you very much.

Mr. Lynch.

Mr. LYNCH. Thank you, Mr. Chairman. I just want to thank the witnesses for appearing here and helping the committee with its work. I have a general question, and that is I know from past experience in dealing with e-commerce, if you will, with the European Union, that they had stricter guidelines with e-commerce in Europe, not necessarily dealing with the United States but internally. Are there any models out there to deal with this problem from the European Community?

Mr. TAYLOR. Well, actually, I went to Geneva a couple of years ago to meet with many of the European regulators. Interestingly enough, there really isn't a good model because in some respects the practice of Internet pharmacies is—their practice is lagging behind ours, and so they are wrestling with some of the same issues that we are wrestling with. I know that there are some countries, particularly Germany, that are taking a very aggressive stance, but, like the United States, there is sort of a patchwork of approaches based on the fact that this, too, is a new arena for them.

Mr. LYNCH. OK. Thank you, Mr. Taylor. Thank you, Mr. Chairman. Nothing further.

Chairman TOM DAVIS. I thank the gentleman.

Mr. Burton.

Mr. BURTON. Mr. Hubbard, can a prescription written by a U.S. physician be lawfully filled by a Canadian pharmacy?

Mr. HUBBARD. As I understand it, the way Canadian law works—and I am not an expert in that—is that there needs to be a Canadian physician's signature on that prescription before it is filled by a Canadian pharmacy, although I do understand that sometimes they are co-signed. It will actually be the same piece of paper, and then the Canadian physician will sign his name to it, as well.

Mr. BURTON. I think that is the practice. I think that when a legitimate prescription from an American doctor goes up there, they have it reviewed by a Canadian physician, and he either writes a separate prescription that is identical or he initials that in some way, so it is double checked.

How many times has there been drugs from Canada that have come across the border and harmed American citizens, other than it would harm an American citizen if it was even purchased here in the States?

Mr. HUBBARD. We have very little information of harm.

Mr. BURTON. But to your knowledge how many times?

Mr. HUBBARD. From Canada, I know of none.

Mr. BURTON. We don't either, and we have been checking on it.

GlaxoSmithKline has gone to the pharmacists up there who sell over the Internet and they've said that if they continue to sell into the United States that they're going to stop giving them drugs from their company. Many of us believe they are the stalking horse for a lot of pharmaceutical companies in the United States who charge double, triple sometimes the amount for drugs in the United States that they charge in Canada. Now, you just talked about the European Union and England. Isn't GlaxoSmithKline a European company?

Mr. HUBBARD. Originally the parent company was originally English, yes. I think their headquarters now for the domestic operation is in North Carolina.

Mr. BURTON. No, but they still are pretty much controlled out of England, aren't they?

Mr. HUBBARD. I don't really know their corporate structure that well.

Mr. BURTON. Well, we'll check that out when we have our subcommittee hearing. But you don't know of any cases where the pharmaceuticals coming from Canada have caused any unusual problems?

Mr. HUBBARD. Of course, there is no system to recognize that. Those are not legal drugs, so therefore the medical system doesn't track them.

Mr. BURTON. Well, but an American doctor writes a prescription. It's got to be double checked by a Canadian doctor. Then they issue a prescription. It sounds like a pretty good check and balance. The only difference to me, it sounds like, is the cost is maybe double or triple down here.

Mr. HUBBARD. Well, you'd certainly have a check in the sense that it sounds like in that scenario you give the patient has been adequately diagnosed by a physician and he's written a prescription he believes to be appropriate.

Mr. BURTON. Let me ask——

Mr. HUBBARD. But we don't know what the actual drug is that is being ordered.

Mr. BURTON. You are inferring that the Canadians don't police that and it might be an adulterated pharmaceutical product?

Mr. HUBBARD. The Canadians tell us that if the drug is intended for the U.S. market they do not regulate that.

Mr. BURTON. They don't regulate that, but they have a doctor that double checks the prescription and has—but you don't know of any adverse impact of pharmaceuticals from Canada?

Mr. HUBBARD. The Canadians inform us that a Canadian physician should not be co-signing these prescriptions because that physician has not seen the U.S. patient.

Mr. BURTON. Yes. Let me ask you a question. If you take a product that is sold here in the United States by GlaxoSmithKline or any other pharmaceutical company and it costs two to three times what it does in Canada or maybe any other country in the world, what do you think about that?

Mr. HUBBARD. I think, first of all, it's not that the drug necessarily is priced higher here; it's priced lower in countries that have price controls. That's the reason for the price difference.

Mr. BURTON. You're indicating then that they don't make a profit on the pharmaceuticals they sell in Canada?

Mr. HUBBARD. They may well, but that's not really FDA's purview. Our concern is the safety of the drugs.

Mr. BURTON. I know, but the point is that the pharmaceutical companies and the FDA seem to be in lock step on trying to control the flow of drugs out of Canada, and people are saving a ton of money by buying their pharmaceuticals from Canada. Over a million people do it right now, and there has been no claim that there has been any problem.

It seems to me unbelievable, especially since we have passed NAFTA and we are supposed to have free trade, as long as those prescriptions are double checked the Americans ought to benefit from the lower cost of those pharmaceuticals just like the Canadians do.

Mr. HUBBARD. Well, your argument is certainly one we hear a lot, Mr. Burton.

Mr. BURTON. But the pharmaceutical companies, who are making a very, very large profit worldwide, are making a profit in Canada, they are making a profit in other countries where they're selling them at half the price they are here in the United States, so what they are doing is they are loading the price of U.S. pharmaceuticals so they can make a bigger profit. You wouldn't agree with that though, would you?

Mr. HUBBARD. Well, I don't think that's my job to agree or disagree with that.

Mr. BURTON. Your job is to make sure that they are of the purity and that they are not going to harm American citizens.

Mr. HUBBARD. That's correct.

Mr. BURTON. What about a reciprocity agreement with the Canadians? Would you——

Mr. HUBBARD. Well, there are exemptions from the free trade statutes, I understand, that allow each country to set its own public health standards, and in this case drugs are approved for safety

and efficacy in the United States and there has not been a program in place to approve drugs made in other countries unless they are formally shipped in and——

Mr. BURTON. Mr. Chairman, let me just make sure he answers this question. Would it be a problem if there was reciprocity between the United States and Canada?

Mr. HUBBARD. Certainly there is a concept called "equivalence" that has been adopted by some agencies to say that products from one country can more freely come in. That's something we are looking at. But there is not currently a reciprocity agreement in place with Canada on drugs.

Mr. BURTON. Thank you.

Chairman TOM DAVIS. Thank you. I think the reality is in most cases it doesn't take that much to make the pill; it is the research and development that goes into it, and you make a profit whether you sell it in Mexico, Canada, or the United States. You make more, you know, greater areas. That's really not your purview, though.

Mr. HUBBARD. That's right.

Chairman TOM DAVIS. You are to make sure they are safe, and you deal on that basis.

Mr. HUBBARD. That's right.

Chairman TOM DAVIS. And you can understand the frustration of a lot of Members when it looks like the United States is paying more——

Mr. HUBBARD. Yes.

Chairman TOM DAVIS [continuing]. Than consumers in other places. And so this is all about safety, but I think it shows us, as some of the opening statements from some of our other Members indicated, the frustration of Americans who are paying higher prices and in some cases finding it not affordable.

We appreciate your input in this.

We have another panel to get to. Mr. Sanders, I can recognize you, but we want to get to the next panel.

Mr. SANDERS. I missed Mr. Burton's comments, but I understand that they were similar to some of my original comments and I want to go on record in supporting him.

Mr. Hubbard, in terms of the regulatory system in Canada, in your judgment is it inferior in protecting the Canadian people than the system in the United States?

Mr. HUBBARD. I certainly don't think that's my judgment to make.

Mr. SANDERS. But you told us earlier that you communicate with Canadian authorities.

Mr. HUBBARD. Right.

Mr. SANDERS. I presume you communicate with your counterparts in Canada.

Mr. HUBBARD. That's correct.

Mr. SANDERS. They have a system similar to the FDA. My understanding is that it is as strong or stronger. Do you disagree with that?

Mr. HUBBARD. They tell us that they have a similar system to ours. In terms of its resources, its people, it is less robust than the

FDA's system. They only have, for instance, 100 inspectors for their entire country.

Mr. SANDERS. Yes, but their country is a lot smaller than our country. Have you heard of problems in Canada where people are becoming ill with adulterated medicine?

Mr. HUBBARD. No. We don't have the evidence——

Mr. SANDERS. This is something that I mentioned earlier when I raised some questions, that you warn Americans about the potential dangers of buying medicine in Canada. About a million Americans, to the best of my knowledge, do buy medicine in Canada. You warn them, but have any of them become sick?

Mr. HUBBARD. No. Again, we don't have the evidence, but let me point out that a big part of the concern is that even if the Canadian drugs today are just fine—and, you know, we don't know, but if this practice were legitimized, Canada could become strictly a trans-shipment point for Third World countries to send drugs to.

Mr. SANDERS. Not if we develop laws, as we did. Mr. Janklow made the point that there was reimportation legislation passed several years ago in cooperation with the FDA which had very, very strong safety elements. In fact, we spent too much money, but I supported that. You're not suggesting for a moment that, with the resources of the United States of America, we cannot develop a safety mechanism with our Customs people, with the FDA, to make sure that every medicine that came into this country was absolutely safe?

Mr. HUBBARD. Well, you'll recall that when that statute passed that there was a provision for the Secretary of Health and Human Services to certify that it could be safely implemented. Secretary Donna Shalala refused to do that certification and Secretary Thompson refused.

Mr. SANDERS. Actually, I do know it because we wrote it. So let's be clear about what happened with Secretary Shalala. What happened in the process is at the very end in the Senate there were loopholes put in. What that provision said is the Secretary has got to say, as a result of that legislation, that the American people would be paying lower prices and that the safety element will be preserved. In fact, because of those loopholes the Secretary could not appropriately enough say the prices would be lower because what was in those loopholes is what Glaxo is doing today. But the bottom line is you're not going to suggest that, with the resources of this country, we cannot develop a regulatory system to make sure that all medicine coming in—we get beef from Canada, we get vegetables from Mexico. How would we not be able to make sure that we could protect Americans who buy prescription drugs?

Mr. HUBBARD. We certainly could think of provisions that would ameliorate the safety risks from foreign imported drugs. We do not believe such provisions could be crafted in a way that they would not lower the current safety standard, which is very high in this country.

Mr. SANDERS. In terms of safety, let me ask you this. You're very concerned about safety. How many Americans are dying in this country today because they can't afford a medicine?

Mr. HUBBARD. I have no idea.

Mr. SANDERS. Do you think that's an important issue to pursue?

Mr. HUBBARD. Absolutely. My own 90-year-old mother cannot afford her drugs, Mr. Sanders.

Mr. SANDERS. For the record, Mr. Chairman—and I'll end, and I thank you for allowing me to ask these questions—they talk about safety, but he has just told us that not 1 American out of 1 million, we think, has become sick by importing medicine from Canada. He will not tell us how many thousands may suffer because they cannot afford the medicine that their doctors are prescribing. In my State doctors tell us, "Why waste our time writing out a prescription when a person can't afford to fill it?"

I would like to see you do a study and tell us how many people are dying in America because they can't afford medicine and are getting sick, and that number will be 1,000 times higher than anybody from Canada who is becoming ill.

Thank you very much, Mr. Chairman.

Chairman TOM DAVIS. Thank you. I don't think he was prepared to answer those questions today, but the gentleman wants to initiate a study and try to get that information, I would be happy to—thank you all for being with us.

I'm going to ask just one question. I had one question I wanted to ask. Mr. Hubbard, is it true that all enforcement authority here today can take the same kind of action against these illegal domestic Internet pharmacy sites under existing law?

Mr. HUBBARD. Can you repeat the question, sir, just to make sure I get it?

Chairman TOM DAVIS. Can you take—the enforcement authority you have today, can you take action against these illegal domestic Internet pharmacy sites under existing law?

Mr. TAYLOR. We can take actions under existing law; however, as I described earlier, there are challenges, and one of the challenges is being able to use our full set of tools in those instances where it is difficult to discern whether or not—where it is difficult to discern what, indeed, is the standard for a valid prescription in each State.

Chairman TOM DAVIS. Right. So additional tools would be very helpful at this——

Mr. TAYLOR. Well, to the extent that, you know, there are challenges posed by the fact that there, indeed, is a difference in the standard of what constitutes a valid prescription. I mean, we have—and let me be clear here. Under the act there is a provision that allows us to make a misbranding charge if there is—if the product is dispensed without a valid prescription, so we have the tool, we have the authority. It's just that in order to meet that definition under the act we are dealing with standards that vary from State to State. So, in terms of statutory tools and statutory language, we have the ability to address these situations; however, from a practical standpoint it is difficult to do so because, indeed, there is a different definition as to what constitutes the standard of prescription in each State.

Chairman TOM DAVIS. I've got you. All right. Thank you all.

Let me say to all of you thank you very much.

Anything else you wanted to add?

[No response.]

Chairman TOM DAVIS. Thank you very much for being with us.

We have our second panel today. We have Jim Thompson of the Federation of State Medical Boards, Carmen Catizone of the National Association of Boards of Pharmacy, and Connecticut Attorney General Mr. Richard Blumenthal. We appreciate all of you bearing with us through the first panel.

It's the policy of the committee we swear the witnesses in, so, if you would, stand up with me and raise your right hand. Do you solemnly swear that the testimony you are about to give will be the truth, the whole truth, and nothing but the truth?

Mr. THOMPSON. I do.

Mr. CATIZONE. I do.

Mr. BLUMENTHAL. I do.

Chairman TOM DAVIS. Thank you all very much. You may be seated.

We'll have the timers in front of you—green, yellow with a minute to go, and then red. Your entire statements are in the record. Your questions will be based on this.

Dr. Thompson, why don't we start with you and end up with General Blumenthal.

Thank you all for being with us.

**STATEMENTS OF DR. JAMES THOMPSON, M.D., EXECUTIVE VICE PRESIDENT, CHIEF EXECUTIVE OFFICER, FEDERATION OF STATE MEDICAL BOARDS; CARMEN CATIZONE, EXECUTIVE DIRECTOR, NATIONAL ASSOCIATION OF BOARDS OF PHARMACY; AND RICHARD BLUMENTHAL, ATTORNEY GENERAL, STATE OF CONNECTICUT, ON BEHALF OF THE NATIONAL ASSOCIATION OF ATTORNEYS GENERAL**

Dr. THOMPSON. Good morning, Mr. Chairman and members of the committee. I am Dr. Jim Thompson. I am executive vice president and chief executive officer of the Federation of State Medical Boards of the United States. I will refer to us as the Federation.

The Federation is a national nonprofit association established in 1912 which serves as a collective voice for 70 member State medical licensing and disciplinary boards. The Federation's primary mission is to improve the quality, safety, and integrity of health care by promoting high standards for physician licensure and practice, as well as supporting and assisting State medical boards in their protection of the public.

The Federation has been recognized as a national leader on the issue of telemedicine regulation and has published model telemedicine license legislation and guidelines for Internet prescribing and medical practice. In our guidelines, the Federation recommends that Internet prescribing or practice be based on—and I quote from that text—"a documented patient evaluation including history and physical evaluation adequate to establish diagnosis and identify underlying conditions and/or contra-indications to the treatment recommended and provided, and must be obtained prior to providing treatment, including issuing prescriptions electronically or otherwise."

The Federation's key concern with respect to Internet pharmacies is that there must be an appropriate relationship between the patient and the physician before a prescription is written and dispensed. In addition to our guidelines, the Federation has aggres-

sively sought to identify Internet pharmacies that dispense drugs based on prescriptions that do not meet minimal standards.

In September 2000, the Federation of State Medical Boards established the National Clearinghouse on Internet Prescribing. This was designed to collect and disseminate information on rogue Internet sites offering prescribing and dispensing services for prescription drugs to consumers. A major goal of the Clearinghouse is to facilitate communications among all entities that play a role in regulating Internet pharmacy operations and the physicians associated with them.

Regulatory efforts of State medical boards and other agencies have been complicated by a number of factors, including: one, the inability to identify the physical location of the business or pharmacy; two, anonymous physicians approving prescriptions; and, three, the lack of licensing information on such physicians and the pharmacies.

In addition, because online pharmacies operate in multiple States, lack of formal lines of communication has resulted in the duplication of efforts and missed opportunities for cooperation among regulatory jurisdictions.

The Federation strongly supports State-based regulation of the practice of medicine. With regard to Internet prescribing, State medical boards have the authority to discipline licensed physicians prescribing and dispensing medications inappropriately. Many boards have already taken actions against licensees, adopted rules and policies, or introduced legislation to clarify this authority. These efforts have been effective in closing several Internet sites and causing a number of physicians to cease their affiliation with questionable operations.

The Federation believes that there are at least three areas in which there is a need for Federal legislation to protect patients ordering prescriptions over the Internet.

First, the patient should know with whom they are dealing. They should know the name and location of the pharmacy that is dispensing the drug, and they should know the name of the physician who will be providing a medical consultation that will be the basis of that prescription. This information should be disclosed on the Internet pharmacy Web site.

Second, States are currently not able to enforce injunctions against Internet pharmacies beyond their State jurisdiction. Nationwide injunctive power would greatly enhance enforcement capabilities and reduce the tremendous duplication of efforts currently taking place.

Third, I noted in my testimony that State licensing boards currently have the authority to discipline physicians who are prescribing and dispensing drugs over the Internet inappropriately.

Federal authorities have indicated the need for clarification of certain issues, such as what constitutes an appropriate physician/patient relationship, in order to facilitate Federal enforcement actions. The Federation believes that it is possible to define an appropriate physician/patient relationship narrowly solely for the purpose of enforcing a Federal law regulating Internet pharmacies without affecting the autonomy of the State boards to regulate the

practice of medicine. We would be interested in pursuing this course of action with this committee.

Thank you for the opportunity to testify today. I will be glad to answer questions at the appropriate time.

I have attached to my testimony the Federation's model guidelines for the appropriate use of the Internet in medical practice.

Thank you.

Chairman TOM DAVIS. Thank you very much.

[The prepared statement of Dr. Thompson follows:]

**Statement of the**
**Federation of State Medical Boards of the United States**
**Committee on Government Reform**
**United States House of Representatives**

**Presented by James N. Thompson, M.D.**
**Executive Vice President and CEO**

**Re: Domestic Sales of Prescription Drugs over the Internet**

**March 27, 2003**

Good morning Mr. Chairman and members of the Committee. I am Dr. Jim Thompson, Executive Vice President and CEO of the Federation of State Medical Board of the United States or FSMB. The Federation is a national non-profit association established in 1912, which serves as a collective voice for 70-member state medical licensing and disciplinary boards. The Federation's primary mission is to improve the quality, safety, and integrity of health care by promoting high standards for physician licensure and practice, as well as supporting and assisting state medical boards in the protection of the public. The Federation is uniquely positioned as an authoritative leader in policy development and dissemination relating to emerging issues affecting state regulation of the practice of medicine.

**Early Interest in Use of Internet for Practice of Medicine**

The Federation was recognized as a national leader on the issue of telemedicine regulation when it published *A Model Act to Regulate the Practice of Medicine Across State Lines* in 1996. This role was expanded with the subsequent publication of guidelines for Internet prescribing in 2000 and *Model Guidelines for the Appropriate Use of the Internet in Medical Practice* in 2002, one of the first national standards established for Internet medical practice.

Those guidelines, which the Federation recommends to state medical boards, include a key provision:

> "A documented patient evaluation, including history and physical evaluation adequate to establish diagnoses and identify underlying conditions and/or contraindications to the treatment recommended/provided, must be obtained prior to providing treatment, including issuing prescriptions, electronically or otherwise."

This has been the key interest of the Federation with respect to Internet pharmacies. There must be an appropriate relationship between the patient and the physician before a prescription is written and dispensed.

**Internet Clearinghouse**

In addition to issuing these guidelines, the Federation has aggressively sought to identify Internet pharmacies that appeared to be dispensing drugs on the basis of prescriptions written by health care providers whose relationship with the patient did not appear to meet minimal standards. In September 2000, the Federation of State Medical Boards established The National Clearinghouse on Internet Prescribing, to collect and disseminate information on "rogue" Internet sites offering prescribing and dispensing services for prescription drugs to consumers.

The Federation is uniquely qualified to coordinate information between regulatory and enforcement entities because of its formal relationship with all state medical boards in the U.S. and its territories and its well-established lines of communication with state and federal regulatory agencies, including the Department of Justice (DOJ), the Drug Enforcement Agency (DEA), the Food and Drug Administration (FDA), and the Federal Trade Commission (FTC); national associations such as the National Association of Boards of Pharmacies (NABP), the National Association of Drug Diversion Investigators (NADDI), and the National Association of Attorney Generals (NAAG); representatives of the pharmaceutical industry, and the media.

A major goal of the Clearinghouse is to facilitate communications among all entities that play a role in regulating Internet pharmacy operations and the physicians associated with them. Regulatory efforts of state medical boards and other agencies have been complicated by a number of factors including (1) the inability to identify the physical location of the business/pharmacy, (2) anonymous physicians approving prescriptions, and (3) the lack of licensing information on such physicians and the pharmacies. In addition, because online pharmacies operate in multiple states, regulatory authorities experience difficulty in tracking, monitoring, and enforcing actions. This lack of a formal vehicle for communication has resulted in the duplication of efforts and missed opportunities for cooperation among regulatory jurisdictions.

**Results of Clearinghouse Activities**

Clearinghouse efforts will ultimately yield a safer Internet pharmacy environment where consumers can benefit from the convenience and accessibility of Internet commerce while enjoying the protection afforded by appropriate regulation. Additionally, eliminating "rogue" Internet pharmacy sites will permit legitimate operations to compete on a level playing field where market share is determined by such issues as price and quality of service. To date, the Clearinghouse has supplied information leading to investigation of and disciplinary action against physicians in several states.

**Enforcing the Law**

The Federation strongly supports state-based regulation of the practice of medicine. With regard to Internet prescribing, state medical boards have the authority to discipline licensed physicians prescribing and dispensing medications inappropriately. Several boards have already taken actions against licensees, adopted rules/policies or introduced legislation to clarify this authority. In addition, state medical boards are communicating among themselves regarding physicians licensed in more than one state. These cooperative efforts have been effective in closing several Internet sites and causing a number of physicians to cease their affiliation with questionable operations.

**Need for Federal Legislation**

The Federation believes that there are at least three areas in which there is a need for federal legislation to protect patients ordering prescriptions over the Internet.

First, patients should know with whom they are dealing. They should know the name and location of the pharmacy that is dispensing the drug and they should know the name of the physician who will be providing a medical consultation that will be the basis of a prescription. I should point out that almost without exception, a state would find that such physician would have violated licensure standards if he or she writes a prescription on the basis of an online questionnaire without having any preexisting relationship with the patient. Therefore, disclosure will not only be beneficial to patients, but will allow medical licensing boards to identify individuals against whom they can take disciplinary action.

Second, State attorneys general are currently not able to enjoin the operations of an Internet pharmacy that affect citizens in their particular states if that pharmacy is operated out of another state. Many of our member boards have indicated that they believe that a number of Internet sites that dispense drugs in an inappropriate manner could be shut down if the attorneys general had nationwide injunctive powers as well as the ability to pursue other civil remedies including damages, restitution or other compensation across state lines.

Third, I noted in my testimony that state licensing boards currently have the authority to discipline physicians who are prescribing and dispensing drugs over the Internet inappropriately, and that many boards have taken such action. But it is not the role of licensing boards to take actions against operators of Internet sites that dispense drugs. If federal legislation is enacted making the operation of an Internet pharmacy unlawful under certain conditions, it will be necessary that those conditions be clearly defined. One of the conditions that should make the operation of an Internet pharmacy unlawful is the lack of an appropriate relationship between the patient requesting the drug and the physician writing the prescription.

While all state licensing boards believe that the law and regulations governing the physicians in their state are clear as to what constitutes an appropriate physician-patient relationship for purposes of writing a prescription, some courts and prosecutors believe that certain state laws and regulations appear to be somewhat ambiguous in this regard. We understand that, because of that ambiguity, prosecutors have not pursued certain actions. The Federation believes that it is possible to define an appropriate physician-patient relationship narrowly, solely for the purpose of enforcing a federal law regulating Internet pharmacies, without affecting the autonomy of the state boards to regulate the practice of medicine. We would be interested in pursuing that course of action with this Committee.

Thank you for the opportunity to testify today. I will be glad to answer any questions. I have attached to my testimony the Federation's *Model Guidelines for the Appropriate Use of the Internet in Medical Practice.*

# REPORT OF THE SPECIAL COMMITTEE ON PROFESSIONAL CONDUCT AND ETHICS

**Introduction**

In April 2000, the Federation's House of Delegates adopted 15 recommendations issued by the Special Committee on Professional Conduct and Ethics focusing on physician behaviors and practices which negatively impact (1) patient safety and welfare, and/or (2) the physician-patient relationship. The recommendations pertain to physician activities in five specific areas:

- Disruptive behavior by physicians
- The sale of goods from physician offices
- Boundary issues and patient surrogates
- Participation in business or contractual relationships
- Regulation of Internet prescribing

Recommendation Nine of the Special Committee's Report called for the Federation of State Medical Boards to study the practice of medicine via the Internet as to the impact on public health and safety and develop guidelines for state medical boards to use in educating licensees as to the appropriate use of the Internet in medical practice. Then Federation President George C. Barrett, MD, extended the charge of the Special Committee on Professional Conduct and Ethics to fulfill the adopted recommendation.

In developing the guidelines that follow, the Committee evaluated current and projected use of the Internet in the delivery of health care services and identified two distinct areas of e-health: health information and delivery of patient care. The Committee focused the guidelines on the latter due to its direct impact on patient safety and welfare and the physician-patient relationship.

## MODEL GUIDELINES FOR THE APPROPRIATE USE OF THE INTERNET IN MEDICAL PRACTICE

**Section I. Preamble**

The Internet has had a profound impact on the practice of medicine and offers opportunities for improving the delivery and accessibility of health care. Studies show a growing number of physicians are utilizing the Internet to some degree in their practices and patients want to receive certain medical services online[1]. However, patient safety concerns, especially as related to providing medical services via the Internet, including prescribing and dispensing medications, have created complex regulatory challenges for state medical boards in protecting the public.

The (name of board) recognizes that the Internet offers potential benefits in the provision of medical care. The appropriate application of this technology can enhance medical care by facilitating communication with physicians and other health care providers, refilling prescriptions, obtaining laboratory results, scheduling appointments, monitoring chronic conditions, providing health care information and clarifying medical advice. However, it is the expectation of the Board that e-mail and other electronic communications and interactions between the physician and patient should supplement and enhance, but not replace, crucial interpersonal interactions that create the very basis of the physician-patient relationship.

The Board has developed these guidelines to educate licensees as to the appropriate use of the Internet in medical practice. The (name of board) is committed to assuring patient access to the convenience and benefits afforded by the Internet while promoting the responsible practice of medicine by physicians.

It is the expectation of the Board that physicians who provide medical care, electronically or otherwise, maintain a high degree of professionalism and should:

- Place the welfare of patients first
- Maintain acceptable standards of practice
- Adhere to recognized ethical codes governing the medical profession
- Properly supervise physician extenders
- Protect patient confidentiality

**Section II. Parity of Professional and Ethical Standards**
There should be parity of ethical and professional standards applied to all aspects of a physician's practice. Related to the use of the Internet in a physician's practice, the Board expects the following ethical standards to be observed:

**Candor:**
Physicians have an obligation to disclose clearly information (financial, professional, or personal) that could influence patients' understanding or use of the information, products or services offered on any Web site offering health care services or information.

**Privacy:**
Physicians have an obligation to prevent unauthorized access to or use of patient and personal data and to assure that "de-identified" data cannot be linked back to the user or patient.

**Integrity:**
Information contained on Web sites should be truthful and not misleading or deceptive. It should be accurate and concise, up to date, and easy for patients to understand. Physicians associated with medical Web sites should strive to ensure that information provided be supported by current medical peer review literature, emanates from a recognized body of knowledge, and conforms to minimal standards of care. It should clearly indicate whether it is based upon scientific studies, expert consensus, professional experience or personal opinion.

**Informed Consent:**
Delivery of medical services via the Internet requires expanded responsibility on the part of the physician in informing and educating the patient. A patient has the right to know what personal data may be gathered and by whom. The physician must obtain material and informed consent from the patient to collect, share or use personal data. It should be clearly explained to patients when online communication should not take the place of a face-to-face interaction with a health care provider.

**Accountability:**
Physicians have an obligation to provide meaningful opportunities for patients to give feedback about their concerns and to review and respond to those concerns in a timely and appropriate manner.

**Section III. An Appropriate Physician-Patient Relationship**
The health and well-being of patients depends upon a collaborative effort between physician and patient.[2] The relationship between physician and patient is complex and is based on the mutual understanding between physician and patient of the shared responsibility for the patient's health care.

Although the Board recognizes that it may be difficult in some circumstances, particularly in an online setting, to define precisely the beginning of the physician-patient relationship, it tends to begin when an individual seeks assistance from a physician with a health-related matter for which the physician may provide assistance. However, the relationship is clearly established when the physician agrees to undertake diagnosis and treatment of the patient and the patient agrees, whether or not there has been a personal encounter between the physician (or other supervised health care practitioner) and patient.

The physician-patient relationship is fundamental to the provision of acceptable medical care. It is the expectation of the Board that physicians recognize the obligations, responsibilities and patient rights associated with establishing and maintaining an appropriate physician-patient relationship whether or not interpersonal contact between physician and patient has occurred.

**Section IV. Definitions**
For the purpose of these guidelines, the following definitions apply:

"**Medical Practice Site**" means a patient-specific Internet site, access to which is limited to licensed physicians, associated medical personnel and patients. It is an interactive site and thus qualifies as a practice location. It requires a defined physician-patient relationship.

"**General Health Information Site**" means a non-interactive Internet site that is accessible by anyone with access to the Internet and intended to provide general, user non-specific information or advice about maintaining health or the treatment of an acute or chronic illness, health condition or disease state.

"**Personal Health Information**" means any personally-identifiable information, whether oral or recorded in any form or medium, that is created or received by a physician or other health care provider and relates to the past, present or future physical or mental health or condition of an individual, the provision of health care to an individual, or the past, present, or future payment for the provision of health care to an individual.[3]

"**Physician-patient e-mail**" means computer-based communication between physicians (or their medical personnel) and patients within a professional relationship in which the physician has taken on an explicit measure of responsibility for the patient's care.[4]

"**Passive tracking mechanism**" means a persistent electronic file used to track Web site navigation, which allows the Web site to record, and retain user-specific navigation information whenever the user accesses the Web site. Examples include "cookies," "clear gifts" or "Web bugs."[5]

"**Web site**" means an electronic source of health information content, commerce, connectivity and/or service delivery.[6]

**Section V. Guidelines for the Appropriate Use of the Internet in Medical Practice**
The Board has adopted the following guidelines for physicians utilizing the Internet in the delivery of patient care:

**Evaluation of the Patient**
A documented patient evaluation, including history and physical evaluation adequate to establish diagnoses and identify underlying conditions and/or contra-indications to the treatment recommended/provided, must be obtained prior to providing treatment, including issuing prescriptions, electronically or otherwise.

**Treatment**
Treatment and consultation recommendations made in an online setting, including issuing a prescription via electronic means, will be held to the same standards of appropriate practice as those in traditional (face-to-face) settings. Treatment, including issuing a prescription, based solely on an online questionnaire or consultation does not constitute an acceptable standard of care.

**Electronic Communications**
Written policies and procedures should be maintained for the use of patient-physician electronic mail. Such policies and procedures should address (1) privacy, (2) health care personnel (in addition to the physician addressee), who will process messages, (3) hours of operation, (4) types of transactions that will be permitted electronically, (5) required patient information to be included in the communication, such as patient name, identification number and type of transaction, (6) archival and retrieval, and (7) quality oversight mechanisms. Policies and procedures should be periodically evaluated for currency and be maintained in an accessible and readily available manner for review.

Sufficient security measures must be in place and documented to assure confidentiality and integrity of patient-identifiable information. Transmissions, including patient e-mail, prescriptions, and laboratory results must be secure within existing technology (i.e., password protected, encrypted electronic prescriptions, or other reliable authentication techniques). All patient-physician e-mail, as well as other patient-related electronic communications, should be stored and filed in the patient's medical record.

Turnaround time should be established for patient-physician e-mail and medical practice sites should clearly indicate alternative form(s) of communication for urgent matters. E-mail systems should be configured to include an automatic reply to acknowledge message delivery and that messages have been read. Patients should be encouraged to confirm that they have received and read messages.

**Informed Consent**
A written agreement should be employed documenting patient informed consent for the use of patient-physician e-mail. The agreement should be discussed with and signed by the patient and included in the medical record. The agreement should include the following terms:

- Types of transmissions that will be permitted (prescription refills, appointment scheduling, patient education, etc.)
- Under what circumstances alternate forms of communication or office visits should be utilized
- Security measures, such as encrypting data, password protected screen savers and data files, or utilizing other reliable authentication techniques, as well as potential risks to privacy
- Hold harmless clause for information lost due to technical failures
- Requirement for express patient consent to forward patient-identifiable information to a third party
- Patient's failure to comply with the agreement may result in physician terminating the e-mail relationship

**Medical Records**
The medical record should include copies of all patient-related electronic communications, including patient-physician e-mail, prescriptions, laboratory and test results, evaluations and consultations, records of past care and instructions. Informed consent agreements related to the use of e-mail should also be filed in the medical record.

Patient medical records should remain current and accessible for review and be maintained in compliance with applicable state and federal requirements.

**Compliance with State and Federal Laws and Web Standards**
Physicians should meet or exceed applicable federal and state legal requirements of medical/health information privacy. Physicians are referred to "Standards for Privacy of Individually Identifiable Health Information" issued by the Department of Health and Human Services (HHS).[7] Guidance documents are available on the HHS Office for Civil Rights Web site at www.hhs.gov/ocr/hipaa.

Physicians who treat or prescribe through Internet Web sites are practicing medicine and must possess appropriate licensure in all jurisdictions where patients reside.[8]
Physicians are encouraged to comply with nationally recognized health Web site standards and codes of ethics, such as those promulgated by the American Medical Association, Health Ethics Initiative 2000, Health on the Net and the American Accreditation HealthCare Commission (URAC).

**Disclosure**
Physician medical practice sites should clearly disclose:

- Owner of the site
- Specific services provided
- Office address and contact information
- Licensure and qualifications of physician(s) and associated health care providers
- Fees for online consultation and services and how payment is to be made
- Financial interests in any information, products or services
- Appropriate uses and limitations of the site, including providing health advice and emergency health situations
- Uses and response times for e-mails, electronic messages and other communications transmitted via the site
- To whom patient health information may be disclosed and for what purpose
- Rights of patients with respect to patient health information
- Information collected and any passive tracking mechanisms utilized

**Accountability**
Medical practice sites should provide patients a clear mechanism to:

- access, supplement and amend patient-provided personal health information
- provide feedback regarding the site and the quality of information and services
- register complaints, including information regarding filing a complaint with the applicable state medical board(s)

**Advertising/Promotion of Goods or Products**
Advertising or promotion of goods or products from which the physician receives direct remuneration, benefits or incentives is prohibited.

**Links**
Physician Web sites may provide links to general health information sites to enhance patient education; however, the physician should not benefit financially from providing such links or from the services or products marketed by such links. When providing links to other sites, physicians should be aware of the implied endorsement of the information, services or products offered from such sites.

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[7] Federal Register, December 28, 2000.
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Chairman TOM DAVIS. Dr. Catizone.

Mr. CATIZONE. Thank you, Mr. Chairman. I'd also like to thank the Representative for his earlier comments on the VIPPS program.

I am the executive director of the National Association of Boards of Pharmacy [NABP], which was founded in 1904 and represents all the pharmacy regulatory and licensing jurisdictions in the United States, Puerto Rico, the Virgin Islands, eight provinces of Canada, three Australian states, New Zealand, and South Africa. Our purpose is to assist the States in developing, implementing, and enforcing uniform standards for the purpose of protecting the public health.

Internet pharmacies serving patients in the United States provide valuable and innovative services to the patients. It is unfortunate that the benefits of these legitimate pharmacies are often overshadowed by the activities of rogue sites whose concerns do not rest with the best interest of the patient or compliance with State and Federal laws.

Over the past 6 years, NABP has assumed an active role in differentiating legitimate pharmacy sites from rogue Internet sites that illegally sell or distribute drugs. During that time we've worked with the State Boards of Pharmacy and Medicine, the FDA, and State legislatures to develop regulatory strategies to manage this emerging area and provide consumers with information needed to distinguish between legitimate pharmacy, Internet sites, and rogue sites. Our efforts have helped millions of consumers and resulted in the closing of rogue sites and the prosecution of pharmacists and physicians involved with those rogue sites.

In NABP's opinion the FDA has worked with the States not to avoid taking action but to construct an effective enforcement process that respects States' authority and affords due process. Undoubtedly, the issue of importation of medications from Canada is a complex issue. It is fueled by price differences, but it is an issue that cannot be resolved by allowing illegal activities to occur. Oversight on both the State and Federal level is needed to bring the system into compliance or to enforce the laws that presently exist.

Our research has found that rogue sites create several Web pages around their primary operations. The objective of this operation is to capture as many consumers as possible and deceive them into believing that the Web pages are independent operating sites and can deliver drugs.

The information posted on these rogue sites is often purposefully misleading and in some cases purposely fraudulent so as to lure consumers to these sites and engage them in the illegal purchase and distribution of drugs.

The VIPPS program which was mentioned earlier combines State regulation and licensure with consumer empowerment. NABP conducts an intensive onsite review of all sites in adherence to a 19-point criterion that looks at all standard licensure requirements, as well as special Internet applications.

The VIPPS program was implemented with wide consumer acceptance and support. Information about the VIPPS program has appeared on national local news media and consumer information specials. The exposure included programming on CNN, ABC World

News Tonight, NPR Radio, NBC News, CBS News, Fox News, and other local media outlets. Articles, stories, and consumer advice recommending the VIPPS programs have also appeared throughout the print media in local newspapers across the country as well as in Time Magazine, Newsweek, Ladies Home Journal, Consumer Reports, USA Today, the Wall Street Journal, the New York Times, the Washington Post, and other national publications. NABP estimates that more than 10 million consumers have heard, watched, or read about the VIPPS program.

The States have determined that Internet sites offering prescription medications are engaged in the practice of pharmacy and therefore must abide by the same laws and rules that presently apply to traditional brick-and-mortar pharmacies. Internet pharmacies, although unique in their structure and environment, essentially represent the operations of non-resident or mail order pharmacies.

Any Internet legislation that seeks to address consumer need or consumer information should include verified information. NABP applauds the objective to separate rogue from legitimate pharmacy sites, but believes disclosure without some outside, independent assessment or verification will only deceive the consumers further. If this has not occurred, then rogue sites will engage in illegal activities with a new marketing tool—Government-mandated but unverified disclosures.

It is NABP's position that without this validation of information, rogue sites will post fraudulent information to mislead and confuse the public without any regard for the possible penalties or actions for engaging in such conduct.

We appreciate the opportunity to be here today, and I will be glad to answer any questions.

Chairman TOM DAVIS. Thank you very much.

[The prepared statement of Mr. Catizone follows:]

Prepared Statement of the National Association of Boards of Pharmacy
Before the Committee on Government Reform
Regarding
The Domestic Sale of Prescription Drugs Over the Internet

Presented by Carmen Catizone, M.S., R.Ph., D.Ph.
Executive Director

I thank the Committee on behalf of the Executive Committee and member state boards and jurisdictions of the National Association of Boards of Pharmacy (NABP) for the opportunity to discuss the issue of state regulation of Internet pharmacies. I am Carmen Catizone, executive director of NABP and secretary of the Association's governing body, the Executive Committee. NABP was founded in 1904 and represents all of the pharmacy regulatory and licensing jurisdictions in the United States, Puerto Rico, 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 its member boards and jurisdictions in developing, implementing, and enforcing uniform standards for the purpose of protecting the public health.

The Internet is a remarkable medium that offers phenomenal opportunities for improving how we live and how pharmaceutical care can be delivered to patients. The legitimate Internet pharmacies serving patients in the US are providing valuable and innovative services to their patients. It is unfortunate that the benefits of these legitimate pharmacies are often overshadowed by the activities of rogue sites whose concerns do not rest with the best interest of the patient or compliance with state and federal laws. Over the past six years, NABP has assumed an active role in differentiating legitimate Internet pharmacies from rogue Internet sites that illegally sell or distribute drugs.

During that time we worked with the state boards of pharmacy and state legislatures to develop regulatory strategies to manage this emerging area and provided consumers with the information needed to recognize legitimate Internet pharmacies from rogue sites. Our efforts have helped millions of consumers and resulted in the closing of rogue sites and the prosecution of pharmacists and prescribers involved with those rogue sites. The data we have compiled and collect daily concerning the rogue sites and their operations is a source of information for other Congressional Committees, federal and state agencies, and consumer outreach programs.

NABP is often queried about the number of sites operating on the Internet. Estimates have ranged anywhere from 400 to 1,000 sites. The anonymous design of the Internet and desire by rogue operators to hide from detection, significantly limit the ability of regulators and consumers to identify the source of an Internet site or the practitioners affiliated with that site. NABP believes that there are some 500 independent sites on the Internet offering to distribute prescription medications. The most prevalent rogue sites remaining today and based in the United States are sizeable operations well financed and organized to exploit the loopholes in federal and state regulations. These sites often

create several web pages around their primary operations: medical questionnaire and cyberspace consultation areas; distribution centers; and credit card processing systems. The objective of this design and operation is to capture as many consumers as possible and deceive consumers into believing that the web pages are independent sites operating and offering to deliver drugs. The appearance of a multitude of sites offering prescription medications also helps to persuade a high percentage of consumers that such activities are legal and acceptable practices. The information posted on these rogue sites is often purposely misleading and, in some cases, purposely fraudulent so as to lure consumers to these sites and engage them in the illegal purchase and distribution of drugs.

Historical Background

Our involvement in the Internet and the delivery of drugs began in late 1997 with the startling observation that Internet web sites were offering prescription medications in direct violation of state and federal laws and regulations. At first, it appeared that such activity was an aberration or the misguided aspirations of uninformed entrepreneurs who viewed the distribution of medications in the same light of opportunity as books and compact discs. However, subsequent research into this emerging area of e-commerce indicated otherwise. NABP detected in the increasing number of Internet sites appearing on the web a clear pattern of lawlessness and disregard for the legal safeguards in place for the practices of pharmacy and medicine.

The numbers of web sites grew steadily in 1998 and soon were present in all areas of the web. Data compiled by NABP, the FDA and other state and federal agencies presented a growing area of concern and potential compromise of the US medication distribution system and public health protections. In 1999, a coordinated effort between NABP, state agencies (state boards of pharmacy and medicine) and the FDA, and the introduction of NABP's Verified Internet Pharmacy Practice Sites Program (VIPPS) increased consumer awareness about the dangers of rogue or illegal sites, and helped to close a number of rogue sites. Those efforts were making significant progress in ceasing the operations of the rogue sites when the September 11 attack occurred and provided an unfortunate opportunity for the rogue sites to reinvent themselves and again proliferate.

The resurgence in rogue sites that occurred shortly after September 11can be directly attributed to the nation's fears that terrorists would inflict a bioterrorism attack on major US cities. Preying on consumers' fears and anxiety, rogue sites began a substantial campaign to offer for sale products promoted as approved treatments for anthrax exposure. The number of sites on the Internet and operating outside of the law increased dramatically at this time. Fortunately, the threat of an anthrax attack dissipated in the early months of 2003 and subsequently, the number of sites selling these and similar drugs began to diminish.

In mid 2002, there appeared an unprecedented increase in the number of Internet web sites offering American consumers lower priced medications from Canada and other foreign sources. Sites involved in this illegal activity crammed the Internet, deluged consumers with advertisements and solicitations at every turn and click, and aggressively

lobbied senior citizen groups and other special interest groups for Congressional support to protect their activities. NABP spoke out against these sites and prepared a position paper outlining the problem, identifying the illegal acts, and noting the possible dangers to public health (Attachment A). We have commented extensively on the need to close these sites and end their illegal operations and worked with states and the FDA to identify these sites and support enforcement actions to cease their activities. The illegal distribution of drugs from foreign-based web sites must be a major concern of any effort to regulate Internet sites. Although not the primary focus of the proposed legislation before the Committee today, such rogue sites must not be ignored.

The VIPPS Program

In early 1999, working with federal and state regulators, consumers, and the legitimate Internet pharmacy industry, NABP developed the Verified Internet Pharmacy Practice Sites (VIPPS) program. The VIPPS program fashioned traditional regulation and consumer empowerment into a thorough and successful verification and authentication system. The VIPPS process developed by NABP encompasses compliance with state and federal laws governing the practice of pharmacy and the direct verification of licensure of the Internet pharmacy with all states where licensure or registration is required. VIPPS certifies, through on-site inspections and the meticulous analysis of the site's operations and submitted written information, compliance with an 18-point criterion. The VIPPS Criteria (Attachment B) combine current licensure requirements in all of the US states and territories with additional criterion that concentrate on the distinctions of Internet practice such as the transmission of prescription information and patient data, confidentiality of patient records, and quality improvement and monitoring of prescription processing and patient interactions.

The VIPPS program was implemented with wide consumer acceptance and support. Information about the VIPPS program has appeared on national and local news media programs and consumer information specials. The exposure included programming on CNN, ABC World News Tonight, NPR Radio, NBC News, CBS News, and Fox Special Report. Articles, stories and consumer advice recommending the VIPPS program have also appeared throughout the print media in local newspapers across the country as well as in Time, Newsweek, the Ladies Home Journal, Consumer Reports, USA Today, Wall Street Journal, New York Times, Washington Post, and other national publications. NABP estimates that more than 10 million consumers have heard, watched, or read about the VIPPS program. Government agencies such as the Food and Drug Administration (FDA) and the Center for Medicare and Medicaid Services also reference and recommend that consumers refer to the VIPPS program. Professional organizations such as the Federation of State Medical Boards (FSMB), American Pharmaceutical Association (APhA), and the American Medical Association (AMA) have also referenced and recommended consumers to the VIPPS program to consumers.

Regulatory Challenges by Practicing Pharmacy Across State Lines

The Internet changed pharmacy practice in a revolutionary manner by allowing for the electronic transmission of prescriptions and patient data, enhanced access to health care information and treatment, improved communications among health care practitioners, and distant care treatment occurring in real time. These advances have also brought new challenges to practitioners and regulators; challenges that question traditional enforcement provisions. For state boards of pharmacy the regulation of US-based sites, although exigent is not impossible. The physical presence of a building (pharmacy or wholesale operation) or person (pharmacist or prescriber) in a state or US territory provides state regulators with the information and access needed to identify these entities and successfully prosecute them. In fact, the combined regulatory actions of states and the FDA have resulted in the disciplining of practitioners, the closing of sites, the restriction of sites from operating in certain states, and multi-million dollar fines.

NABP believes and is on record noting that the state boards of pharmacy and other state regulatory agencies, working with the FDA and other federal agencies, can be effective in monitoring and regulating US-based sites offering prescription medications over the Internet. All states have in place laws and regulations governing the practice of pharmacy. These laws and regulations ensure that the provision of pharmaceuticals and pharmacist care meet accepted standards of practice and protect the public from harm. The various practice acts and regulations also establish the criteria for licensing pharmacists and pharmacies, operating a pharmacy to dispense medications to patients, and disciplining those pharmacists and pharmacies who violate state laws and regulations and endanger the health and safety of the citizens of the states.

The states have determined that Internet sites offering prescription medications are engaged in the practice of pharmacy and therefore must abide by the same laws and rules that presently apply to traditional brick and mortar pharmacies. Internet pharmacies, although unique in their structure and environment, essentially represent the operations of non-resident or mail order pharmacies. The basic construction of these systems involves the receipt of prescription orders from patients who do not physically deliver the prescription orders to the pharmacy and the delivery of prescription medications to patients who reside in locations different than where the pharmacy is located. All activities between these beginning and end points involve the practice of pharmacy and require adherence to present state laws and regulations. Only five states have enacted additional regulations for Internet pharmacies. The additional regulations enacted in these states reinforce that Internet pharmacies are regulated by the states and establish some notification requirements. The additional regulations are in accord with the regulatory framework for non-resident or out of state pharmacies and do not present any additional burden or restraint of competition.

All but a handful of states require that non-resident or out of state pharmacies license or register with them and comply with their applicable laws and statutes. These laws and regulations have been in place for almost 20 years, effectively protecting the citizens of the states and fostering cooperation among the states. What the various laws and regulations governing the practice of pharmacy and Internet sites have restricted is the

operation of illegal sites seeking to bypass the regulatory system. State laws and regulations recognize the advantages of the Internet and allow for the practice of telemedicine and telepharmacy. Specific provisions of the majority of state laws and regulations allow for the electronic transmission of prescriptions, shared data bases, electronic patient profiles, and other advantages offered through the Internet and other electronic means. These laws and regulations transfer existing and accepted standards for patient care from traditional activities to the new, non-traditional activities of the Internet.

Assessment of H.R. 4990

The legislation being proposed, HR 4990, seeks to address the need to provide consumers with identifying information about a web site or the prescriber involved with that site. NABP applauds the objective of the bill to "improve the ability of Federal and state oversight officials to eliminate 'rogue' interstate Internet web sites illegally selling prescription drugs ..." NABP's VIPPS Program provides and validates directly with the appropriate state licensing jurisdiction all of the information H.R. 4990 proposes to require as well as the actual license number in the various states, contact information for the state agency holding the license, indication if the pharmacy has any disciplinary actions against the license, services offered, and corporate information including the name of the CEO (Attachment C).

Although NABP supports H.R. 4990 in concept we respectfully request that the bill strongly suggest to the Secretary that regulations authorized to be promulgated include an independent means for verifying the authenticity and veracity of the information required to be posted by the Internet pharmacies. It is NABP's position that without this validation of information, rogue sites will post fraudulent information to mislead and confuse the public without any regard for the possible penalties or actions for engaging in such conduct.

NABP is anxious to assist the sponsors and supporters of H.R. 4990 in achieving the stated objective and subsequently assisting the Secretary in the development of, and implementation of, regulations to achieve the desired outcomes of the bill. Thank you for the opportunity to appear before this Committee and offer our perspective on this important public health issue.

ATTACHMENT A

**National Association of Boards of Pharmacy**
**Position Paper on the Importation of Foreign Prescription Drugs**

**March 2003**

Patients in the United States are facing a crisis. Access to affordable medications is driving patients outside of the US regulatory system into unidentified and unregulated areas. Purchasing medications from unknown and illegal sources via the Internet and other means is compromising the US medication distribution system and making US citizens vulnerable to bioterrorism attacks. Data collected by NABP indicates that the importation of drugs from foreign countries is fast becoming a concern for state and federal regulators. The US Food and Drug Administration (FDA) estimates that approximately two million parcels containing FDA-regulated products for personal use enter this country annually through international mail facilities.[1] Other sources estimate that nearly 70 pharmacies in Canada (40 in Manitoba) shipped almost $500 million dollars worth of prescriptions into the US in 2002.[2] Fueling this mass exodus from US pharmacies to foreign outlets, particularly Canadian pharmacies, are US prescription drug prices and weak foreign currencies. These two factors allow for substantial savings by US patients on their prescription medications.

As an organization whose primary concern is assisting its member state boards of pharmacy in protecting the public health, the National Association of Boards of Pharmacy (NABP)[3] is concerned that, while some Americans are choosing between purchasing their prescription medications and purchasing other staple necessities, others are ignoring the possible dangers associated with the unregulated importation or reimportation of prescription medications. The distribution by unregulated drug outlets of expired, contaminated, subpotent, superpotent and counterfeit drugs is a significant potential danger linked to foreign medications. Foreign dispensers may provide patients with incorrect or contraindicated medications, incorrect strengths, or medications without adequate directions for use. Absent regulation from the state boards of pharmacy, foreign drug outlets may not have implemented the appropriate standards and safeguards to prevent such occurrences. The "rewriting" of American prescriptions by foreign prescribers introduces another whole host of problems. Foreign prescribers often lack information regarding the patient's medical and medication history and "unauthorized" therapeutic substitutions and transcription errors have been reported.

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[1] *Drug Importation: Hearing before the House Subcommittee on Health*, 107th Cong., 2d Sess. (July 25, 2002) (statement of William K. Hubbard, Senior Associate Commissioner for Policy, Planning, and Legislation, FDA).
[2] Joel Baglole, Getting the Gray Out, Wall Street Journal, February 13, 2003.
[3] NABP is the professional organization that represents state boards of pharmacy in all regions of the United States, the Virgin Islands, Puerto Rico, eight provinces of Canada, four states in Australia, South Africa, and New Zealand. NABP was established in 1904 to develop uniform standards and procedures for pharmaceutic licensure and for the transfer of licensure. Since its inception, NABP has been repeatedly called upon to develop programs and services to assist the state boards in their charge to protect the public health, safety, and welfare.

Most importantly, in all such instances, patients may never know there is a problem. Even if a problem is discovered by a patient, there is little or no recourse, since the actual dispenser or prescriber may not be known, there may be no legal authority to which a complaint may be submitted and action taken, and, oftentimes, patients have waived their right to sue[4].

The potential for harm exists even with medications obtained from Canada. Canadian drugs, like all foreign drugs, are outside the realm of the US Food and Drug Administration (FDA) approval process and oversight systems, including those manufactured here in the US and exported. FDA officials maintain that once these products leave the US and control of the manufacturer, there is no way to verify where they have been, the conditions under which they have been stored, and whether or not they have been tampered with or contaminated. In light of threatened terrorist attacks, the risk of tampering seems to be one of great significance.

An added concern is that foreign brand-name drugs, including Canadian drugs, are not necessarily the same as their US counterparts. Different dosages and dosage forms exist and drugs often have different proprietary names, further adding to the confusion. Many generic drugs sold in Canada are even not available here in the US, are not manufactured in FDA-approved facilities, and have completely bypassed the FDA approval process.

Of utmost concern is the lack of ability to determine the actual country of origin. An order for what is purported to be a Canadian drug may never be filled by a legitimate Canadian pharmacy with a Canadian drug or even be filled in Canada. The well-known risks that all consumers take when purchasing over the Internet, where, for example, an anonymous company may be "here today and gone tomorrow" or an illicit business is disguised as a legitimate organization, are heightened when purchasing foreign drugs.

The newest twist to Canadian drug importation involves prescription "facilitators," services that take prescription drug orders from patients then transmit them to Canadian pharmacies for dispensing. Although these operations, which range from Internet sites to store fronts, do not stock or dispense drugs, it is the position of NABP that they are conducting the practice of pharmacy and must be appropriately licensed by the state board of pharmacy.

**Scope of the Problem - Study Results/Statistics**

*FDA/US Customs Service Studies*

In an effort to more definitively identify the risks to the public from the drug products being shipped into the US, as well as the level of effort and resources required to handle drug importations at a mail facility, in early 2001, the FDA and US Customs Service conducted a survey of imported drug products entering the US through the Carson City, California mail facility.[5] Over a period of five weeks, it was estimated that approximately 16,500 packages (650/day) could have been set aside for FDA review. Actually reviewed were 1,908 packages (72/day), with 721 packages containing 197 different drug products from 19 foreign countries detained. Addressees were notified that the package contents appeared to be unapproved for use in the US, misbranded, and/or a drug requiring a prescription.

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[4] In fact, NABP has discovered that most if not all Canadian Internet pharmacies require US, but not Canadian, patients to waive their right to sue if a medication error occurs.

[5] *Drug Importation*, *supra* note i.

Eight percent of the packages contained drugs that could not be identified due to the lack of labeling or labeling in a foreign language. Most of the drugs were packaged in plastic bags and one shipment contained drugs taped between magazine pages. Several samples did not appear to correspond with any FDA-approved drugs. One package contained a drug denied FDA approval due to lack of efficacy data and cardiac risks. Several shipments contained three drugs withdrawn from the market due to safety concerns. Several controlled substances were identified, including lorazepam, codeine sulfate, chlordiazepoxide, chloral hydrate, and diphenoxylate.

Many of the drugs found were intended to treat conditions that only a physician can properly diagnose, and have potentially serious side effects, contraindications, and drug/food interactions. These drugs included antibiotics (nearly 10 percent) and steroids. The great majority of products were suspected of being issued without a prescription because less than four percent of addressees responded to detention notices by providing evidence of prescription or practitioner oversight. Overall, the FDA concluded the primary risks to patients were those associated with 1) taking drugs of unknown origin or quality, and 2) taking prescription drugs without prescriber supervision.

Similar border surveys conducted by the FDA at points of entry from Mexico and Canada revealed comparable results.[6] A survey at the Mexican border, conducted at eight border points in California, Arizona, and Texas over four hours on August 12, 2000, found the following:

- Over 600 persons, mostly older Caucasian males, were found carrying prescription drugs across the border.
- Sixty-three percent of the persons interviewed had prescriptions for the medications they were bringing into the country (59 percent US prescriptions and 41 percent Mexican prescriptions).
- The most common drugs were amoxicillin, Glucophage (metformin), Premarin (conjugated estrogens), Vioxx (rofecoxib), Retin-A (tretinoin), Tafil (alprazolam), Celebrex (celecoxib), penicillin, Viagra (sildenafil), carisoprodol, and Dolo Neurobion (a vitamin supplement not available in the US that contains metamizole, a substance that is banned in the US due to potentially fatal agranulocytosis).

A second survey at the Mexican border, conducted at seven ports of entry over four hours on April 11, 2001, again found analogous results:

- 586 persons brought 1,120 prescription drug products into the US.
- Fifty-six percent had a prescription for the medications (61 percent US prescriptions and 39 percent Mexican prescriptions).
- The most common drugs imported were amoxicillin, Premarin, Claritine (loratidine), Terramicina (oxytetracycline), ampicillin, ibuprofen, penicillin, Vioxx, Tafil, Dolo Neurobion, Glucophage, Celebrex, naproxen, Retin-A, Ventolin (albuterol), and Valium (diazepam).

On January 6, 2001, the US Customs Services detained for the FDA 33 passenger vehicles (of a total of 10,374 passenger vehicles and 58 buses) crossing the Canadian border over eight hours at

[6] *Drug Importation, supra* note i.

three ports of entry in New York, Michigan, and Washington. Interviews of the passengers found:

- Thirty-five persons carrying 47 containers of medications.
- The most common reasons given for import was that the products were available without a prescription and cost less than in the US.
- Most of the drugs were pain medications, primarily A-222 (acetaminophen, caffeine, and codeine).
- The next largest group of products found was herbal products not available in the US.
- Other products included Tobradex (tobramycin/dexamethasone), Claritin, Allegra (fexofenadine), and Sibelium (flunarizine HCl, a calcium channel blocker).

Researchers at the University of Texas conducted a survey of declaration forms submitted to Customs over 84 days, between July 1994 and June 1995, to assess the prevalence of patients purchasing medications from Mexico. Again, it revealed great concern regarding the importation of controlled substances.[7] The most common drugs declared were Valium, Rohypnol (flunitrazepam, commonly known as the "date rape drug"), Tafil, Tenuate Dospan (diethylpropion), Neopercodan (propoxyphene), Diminex (mazindol), Asenlix (clobenzorex, an anorexiant), Tylox (oxycodone/acetaminophen), Nubain (nalbuphine), Qual (diazepam, propoxyphene, acetaminophen), Halcion (triazolam), Ritalin (methylphenidate), Ativan (lorazepam), and Somalgesic(naproxen/carisoprodol), with all except Somalgesic being controlled substances.

*NABP Information*

Between October 2002 and February 2003, NABP received seven complaints from consumers regarding contacts with what appeared to be foreign pharmacies. Three patients indicated they had been defrauded in that they paid for an order and never received it.[8] Two patients reported having received what appeared to be counterfeit drugs.[9] Another person, apparently testing the integrity of the Canadian-US system, complained that she was able to receive prescription medications without a prescription.[10] Yet another patient from Great Britain reported receiving Meridia from Thailand loose in a baggie.[11]

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[7] McKeithan EK, Shepherd MD, *Pharmaceutical products declared by US residents on returning to the United States from Mexico*, 18 Clin Ther, 1242 (1996).

[8] www.1medsource.com, which sells foreign versions of a variety of prescription medications, including controlled substances, and sells online prescriptions to those who need them, is registered to an address in Mexico; www.pharma-international.com, which sells both controlled and non-controlled substances seemingly without a prescription, appears to be based in Pakistan; www.overseas-prescription.com, which focuses on selling lifestyle medications and controlled substances, no prescription required, appears to be based in the US but links consumers to foreign medications supplied by unknown sources.

[9] www.Rx-Phy.com, which sells lifestyle drugs, is registered to an address in Namibia; www.ltmc.net, which appears to sell only Viagra (with no Pfizer markings, according to the complainant), posts an address in Florida, but is registered to an address in Isreal.

[10] This person, an employee of a US prescription drug manufacturer, received drugs without a prescription from www.canadapharmacy.com, which sells lifestyle drugs but no controlled substances, and is apparently based in Washington and Vancouver. The drugs were reportedly shipped from Canada.

[11] www.1drugstore-online.com, www.1onlinepharmacy.com sells a variety of prescription drugs, including Meridia.

A February 2003 survey of state boards of pharmacy by NABP found that at least six boards have received complaints regarding foreign pharmacies. The Nevada Board of Pharmacy reported complaints about delayed deliveries, the receipt of incorrect product, and a Sri Lankan "bait and switch" scheme.[12] The New York Board of Pharmacy received a complaint about drugs labeled in a foreign language, and the South Dakota State Board of Pharmacy reported complaints about drug "switching" (Zoloft v. Paxil). The Minnesota Board received a complaint about not receiving $300 worth of drugs that had been charged to the patient's credit card. The Oregon Board of Pharmacy received a complaint about a medication error where a breast cancer patient received lisinopril instead of tamoxifen and took the lisinopril for three months before the error was discovered. The Board is currently consulting with that state's attorney general on action that may be taken. The North Dakota Board of Pharmacy reported incidents of duplicate therapy, one due to slightly different names of Canadian and US drugs and the other due to the filling of two different drugs in the same therapeutic category for the same condition, one at a US pharmacy and the other at a Canadian pharmacy.

**Legal Assessment**

New drugs marketed in the US must be approved by the FDA based upon demonstrated safety and efficacy and must be produced in manufacturing plants inspected and operated in conformance with FDA's current Good Manufacturing Practices. In addition, their shipment and storage must be appropriately documented and subject to inspection. This "closed" system has been successful in preventing unapproved, adulterated or misbranded drugs from entering interstate commerce. With this in mind, the importation or reimportation of prescription drugs from foreign countries generally violates one or more of the following sections of the Federal Food, Drug, and Cosmetic Act (the Act):[13]

- 21 USC § 355, which makes it illegal to introduce or deliver into interstate commerce unapproved drugs. Foreign versions of US approved drugs are considered unapproved because FDA approvals are manufacturer-specific, product-specific, and include such factors as manufacturing location, formulation, source and specifications of active ingredients, processing methods, manufacturing controls, container/closure system, and appearance (21 CFR § 314.50). Even if the drug is originally manufactured in the US, foreign versions of US approved drugs are usually classified as unapproved because the versions produced for foreign markets usually do not meet all the requirements listed above.
- 21 USC § 353(b)(2), which makes it illegal to dispense a drug without proper labeling.
- 21 USC § 353(b)(1), which requires a valid prescription for dispensing prescription drugs.
- 21 USC § 331(a), (d), (i), which prohibit the introduction or delivery into interstate commerce of misbranded, adulterated, or counterfeit drugs.
- 21 USC § 381(d)(1), which makes it illegal for anyone other than the manufacturer to reimport a drug.

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[12] This involved a scenario where the "pharmacy" advertised Canadian drugs but contacted the patient to encourage the acceptance of a drug manufactured in Sri Lanka. The Sri Lankan drugs were much less expensive than the Canadian drugs and the business apparently made more money on the Sri Lankan transaction.

[13] Letter from William K. Hubbard, Associate Commissioner for Policy and Planning, FDA to Robert P. Lombardi, Esq., The Kullman Firm (February 12, 2003)(on file at NABP).

The liabilities associated with violations of the Act can be found in the following sections of the US Code[14]:

- 21 USC § 332, which allows a court to enjoin violations of the Act.
- 21 USC § 333, which states a person can be held criminally liable for violations of the Act.
- 21 USC § 333(a)(1), which states a misdemeanor violation of the Act is a strict liability offense [see also *United States v. Dotterweich*, 320 US 277, 284 (1943)].
- 21 USC § 333(a)(2), which says a violation that is committed with intent to defraud or mislead or after a prior conviction for violating the act is a felony.
- 21 USC §§ 333(b)(1)(A), 381(d)(1), which states it is a felony to knowingly import a drug in violation of the reimport prohibition.
- 21 USC § 331, which says those who can be found civilly and criminally liable include all who cause a prohibited act.
- 18 USC § 2371, which says those who aid and abet a criminal violation of the Act, or conspire to violate the Act, can also be found criminally liable.

**Personal Use Exemption**
According to the FDA, under certain defined circumstances, the agency allows patients and physicians to import small quantities of unapproved drugs for the treatment of a serious condition. This policy has been applied to products that do not present an unreasonable risk and for which there is no known commercialization and promotion to patients in the US. It is not intended to allow the importation of foreign versions of US approved drugs. This policy outlines the FDA's enforcement priority and guides the FDA in their enforcement discretion with respect to imports by individuals of drugs for their personal use. It does not change the law and does not give license to individuals to import or export foreign medications into the US.

**State Law**
Currently, 43 states require non-resident pharmacies to register with state boards of pharmacy if they are shipping prescription drug products to citizens of that state.[15] These requirements allow state boards of pharmacy to order non-resident pharmacies to stop shipping product into the state. Within the US, such orders can be enforced by the board of pharmacy where the violation took place, or by mutual action by the board of pharmacy in the state where the pharmacy is located.

An August 2002 survey of the state boards of pharmacy conducted by NABP indicated that nine jurisdictions found their state laws and regulations to be broad enough to allow them to register foreign pharmacies;[16] however, the dichotomy of providing legal recognition to an entity violating federal law is one that has prevented any state from registering foreign pharmacies[17].

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[14] *Id.*
[15] National Association of Boards of Pharmacy. Survey of Pharmacy Law 45-47 (2002-2003).
[16] National Association of Boards of Pharmacy, *Canadian Drug Imports to the United States*, 31NABP Newsletter, 97 (2002).
[17] Although reports received by NABP on March 12, 2003, indicate that the Rhode Island legislature is considering such action, a moved opposed by the Rhode Island Board of Pharmacy.

Additionally, the enforcement of a state action or the initiation of a mutual action by a foreign licensing body is virtually unheard of, making it difficult, if not impossible, for state actions to have any effect on foreign pharmacies.

**Drug Importation Legislation**
NABP believes that recent efforts by Congress to placate the swelling numbers of constituents seeking prescription drug price relief will cause more harm than good. One proposal would allow pharmacists and wholesalers to import drugs from Canada[18]. It is our position that such activities would put at risk the "closed" system currently guarded by federal, and to some extent, state authorities. Without jurisdiction over foreign sellers, it is and will continue to be impossible to ensure the products being sent to the US are approved, safe, effective, and not adulterated, contaminated or counterfeit.

Another proposal seeks to fine drug manufacturers for refusing to ship medications to Canadian pharmacies that dispense to US patients[19]. We cannot support legislation that penalizes anyone for complying with the laws and regulations of the US. Our members believe that existing laws and regulations prohibiting the importation of unapproved drugs must be obeyed and enforced or changed to incorporate these products and pharmacies into the federal and state regulatory system. Access to medication through illegal means does not resolve the problem of access but only increases the chances of US patients being harmed by unregulated entities.

A third proposal would disallow certain tax deductions and credits for pharmaceutical manufacturers that "discriminate" against Canadian pharmacies that sell prescription drugs to US patients.[20]

**Canadian Regulators**
Several provincial authorities have advised federal and state regulatory agencies and NABP of their support on this issue and have identified or issued various laws, regulations, or standards of practice in keeping with this position.

*Manitoba Pharmaceutical Association*
The Standards of Practice of the Manitoba Pharmaceutical Association prohibit a pharmacy from breaking a law in the jurisdiction where the patient resides.[21] Upon documentation of violation of state law, Manitoba advises its pharmacies to comply with that state's law.[22]

*Ontario College of Pharmacists*
The Ontario College of Pharmacists has stated that US prescriptions are not legal per Ontario and Canadian law, and the filling of prescriptions for US patients in Canada does not correspond with a safe standard of practice, because pharmacies are not providing counseling and other patient care services. In early 2003, the Council of the Ontario College of Pharmacists adopted a policy

[18] S. 7, 108th Cong., 1st Sess. (2003).
[19] H.R 847, 108th Cong.., 1st Sess. (2003).
[20] S. 477, 108th Cong., 1st Sess. (2003).
[21] The Manitoba Pharmaceutical Association, *Internet Pharmacy Standards* (July 2001).
[22] Letter from Ronald F. Guse, Associate Registrar, Manitoba Pharmaceutical Association to James T. Carder, Executive Director, Wyoming Board of Pharmacy (June 4, 2002)(on file at NABP).

that prohibits the participation in agreements with physicians to co-sign or rewrite prescriptions for foreign patients, and prohibits waivers of patient care standards.[23]

*Newfoundland Pharmaceutical Association*
The Newfoundland Pharmaceutical Association recently adopted Internet standards of practice that say a pharmacist shall not knowingly fill prescriptions that are issued in a manner contrary to normal practice standards, and uses as an example the countersigning of prescriptions written by a physician in another country if the physician has not seen and examined the patient.[24]

*College of Physicians and Surgeons of British Columbia*
In June 2002, the College of Physicians and Surgeons of British Columbia issued a policy that declares Internet prescribing based on a mailed, faxed, or electronically transmitted questionnaire, and the countersigning of prescriptions issued by other physicians without direct patient contact to be activities that fall outside acceptable medical practice standards.[25]

*NAPRA*
In 2002, the National Association of Pharmacy Regulatory Authorities (NAPRA) in Canada partnered with NABP to launch the Verified Internet Pharmacy Practice Sites (VIPPS)[26] program

[23] Ontario College of Pharmacists, *New Policy Respecting Out of Country Prescriptions Approved*, Pharmacy Connection (Jan/Feb 2003). The full text of the policy reads: "Pharmacists shall not facilitate or enter into agreements with physicians for the purposes of co-signing or rewriting prescriptions for out-of-country patients. If a prescription is filled in Ontario, the Standards of Practice for pharmacists and pharmacies for Ontario must be met, regardless of where the patient resides and these Standards cannot be waived through any agreements or contracts. The Council considers that pharmacists who knowingly facilitate the practice by any Ontario prescriber to co-sign/authorize prescriptions where no established physician/patient relationship exists are acting unethically and fall below a standard of practice of our profession."

[24] Newfoundland Pharmaceutical Association, *Standards of Pharmacy Practice, The Provision of Pharmacy Services via the Internet* (April 12, 2002).

[25] College of Physicians & Surgeons of British Columbia, *Policy Manual, Prescribing Practice/ Countersigning, Prescriptions/Internet Prescribing* (June 2002). The full text of the policy reads: "Prescribing for a patient solely on the basis of mailed or faxed information, or an electronic questionnaire, or countersigning a prescription issued by another physician, without direct patient contact, is not an acceptable standard of medical practice. The provision of a prescription to a patient is a medical act. It is the result of a clinical decision made by a physician subsequent to a comprehensive evaluation of the patient by that same physician. This evaluation should be based on a face-to-face encounter with the patient which includes the usual elements of clinical assessment such as the taking of a history, conducting a physical examination and any necessary investigations, and reaching a provisional diagnosis. Patient records should clearly reflect that the pertinent elements of the patient evaluation have been completed and documented. In situations where the patient is known to the physician, and where he or she has current knowledge of the patient's clinical status from previous encounters, a prescription may be provided on the basis of a more focused clinical evaluation. If the physician is part of a group practice or a call group, he or she may choose to accept a previous patient evaluation by an associate as the basis for further prescribing. However, under such circumstances, the prescribing physician would retain the professional responsibility for the prescription that he or she has written. If a medication is prescribed, physicians have a responsibility to advise the patient about such matters as, drug effects and interactions, side effects, contraindications, precautions, and any other information pertinent to their use of the medication. There is an obligation for the prescribing physician to arrange appropriate follow-up, either personally or with the most responsible physician."

[26] NABP's VIPPS program and its accompanying VIPPS seal of approval identifies to the public those online pharmacy practice sites that are appropriately licensed, are legitimately operating via the Internet, and that have successfully completed a rigorous criteria review and inspection. To be VIPPS 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 NABP compliance with VIPPS criteria

in Canada. This program will certify validly licensed, legitimately operating online Canadian pharmacies that meet the program's criteria. The Canadian VIPPS program will assist Canadian consumers in identifying legitimate Canadian pharmacies serving Canadian residents, and will aid the boards of pharmacy and patients by excluding those Canadian pharmacies that ship prescription medications to US patients.

In February 2003 NAPRA convened a forum to discuss the international sale of prescription drugs from Canada, focusing on issues related to professional regulation, public protection, and compliance with professional standards of practice. Participating in the forum were approximately 50 representatives from Canadian and US government and pharmacy organizations, including NABP.[27]

**NABP/Boards of Pharmacy**

On February 26, 2003, NABP, in a letter to the US Department of Health and Human Services and the FDA, urged the FDA to enforce US laws addressing the importation of drugs from outside the US.[28] In addition to declaring its opposition to efforts to allow a system of drug

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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. VIPPS pharmacy sites are identified by the VIPPS hyperlink seal displayed on their Web site. By clicking on the seal, a visitor is linked to the NABP VIPPS site where verified information about the pharmacy is maintained by NABP. Accessing the VIPPS site at www.nabp.net allows visitors to search for a VIPPS Internet pharmacy.

[27] Alberta College of Pharmacists, *NAPRA hosts forum on international sale of prescription drugs from Canada*, http://www.altapharm.org/college/Home/DetailsPage.cfm?ID=3787 (March 5, 2003).

[28] Letter from Carmen A. Catizone, Executive Director/Secretary, NABP, to Tommy G. Thompson, Secretary, US Department of Health and Human Services, and Mark B. McClellan, Commissioner, FDA (February 26, 2003) (on file at NABP). The letter reads:

> I am writing to you today on behalf of the National Association of Boards of Pharmacy (NABP) to urge you to enforce the law(s) of United States with regard to the importation of drugs from outside the U.S. Allowing unlicensed practitioners to dispense non-FDA approved medicines without regard for patient health and safety sets a dangerous precedent that puts Americans at risk. We should ensure that Americans have appropriate access to affordable medicines from within the protections of the health care system in the United States - not by sending them to purchase medicines from across the border. I would further urge you, therefore, to also call for passage of a Medicare prescription drug benefit in Congress.
>
> The National Association of Boards of Pharmacy (NABP), whose membership includes all of the state boards of pharmacy in the United States, provincial authorities in Canada, state boards of pharmacy in Australia, New Zealand and South Africa believes as the FDA has said in Congressional testimony, "...Consumers are exposed to a number of risks when they purchase drugs from Internet sites that are not licensed and operating within [U.S.] state pharmacy laws or [from] sites that dispense foreign drugs."
>
> The state boards of pharmacy and NABP have partnered with the FDA to formalize cooperative efforts to enforce applicable acts and statutes in regard to the Internet and strongly maintain that federal-state cooperation is essential to policing these activities. NABP also supports the information on the FDA's own website (http://www.fda.gov/oc/buyonline/faqs.html#faqs1) which advises consumers:
>
> > Patients who buy prescription drugs from Websites operating outside the law are at increased risk of suffering life-threatening adverse events, such as side effects from inappropriately prescribed medications, dangerous drug interactions, contaminated drugs, and impure or unknown ingredients found in unapproved drugs.
>
> While recognizing that access to affordable medications is an important concern for U.S. citizens, NABP believes that existing laws and regulations prohibiting this activity need to be obeyed and enforced to allow for the safe and regulated supply of drugs and medications. Allowing the practice of cross-border Internet trade of medicines to continue and expand opens up the U.S. population to those who would take full advantage of the lack of regulatory enforcement to increasingly prey on American patients.

importation that cannot guarantee the quality and safety of the products imported, NABP's Verified Internet Pharmacy Practice Sites (VIPPS) program stands as the only information and enforcement aid to regulatory authorities and consumers. Implemented in 1999, the VIPPS Program identifies legal and safe pharmacies and, through information and empowerment, creates a partnership between state and federal regulators and the public. Through the VIPPS web site, NABP also operates a "Report-A-Site" feature for consumers to use to file complaints about on-line pharmacies. NABP shares the reported information with state and federal regulatory authorities.

Attempts by states to take action against foreign pharmacies have been minimal, primarily due to the lack of jurisdiction the boards have over such entities. Information obtained by NABP indicates that at least four boards have attempted to contact Canadian pharmacies by mail and/or phone to advise them of the illegality of their actions. [29]

At least six boards have taken some action against local businesses that facilitate the transmission of prescriptions to Canada.[30] The most recent action involved a collaborative effort between the Arkansas State Board of Pharmacy and the FDA, with the Board issuing a "Cease and Desist" letter and the FDA issuing a warning letter to Rx Depot, Inc., charging them with various violations of state and federal laws and regulations[31]. In its warning letter, The Arkansas Board lists the violations, including practicing pharmacy with out a license[32] and using pharmacy

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> Access to medications through illegal means does not resolve the problem of access, but only increases the opportunity that U.S. citizens will be harmed by unregulated entities. I urge you to do what is necessary and right to protect the American public. We should not wait until increasing numbers of Americans are injured or die before our government acts on their behalf.

[29] Dennis Jones, executive secretary of the South Dakota Board, reported personally calling Canadian pharmacies to request a visit but received no response, and he reports notifying them that it is illegal to ship prescription medications to South Dakota from a foreign country. He has also contacted local newspapers that publish advertisements for these pharmacies explaining their potential liability for encouraging persons to participate in an illegal activity. Don Williams, executive director of the Washington State Board of Pharmacy, reported having sent several letters to Canadian pharmacies advising them not to ship prescriptions into the state. Kendall Lynch, executive director of the Tennessee Board of Pharmacy, has sent a "Cease and Desist" letter to CanadaDiscountRx, which has run full-page ads for Canadian prescription drugs in *The Tennessean*. Howard Andersion, executive director of the North Dakota Board of Pharmacy, has sent "Cease and Desist" letters to Canadian pharmacies, with copies to the provincial authority, the FDA, and the US Customs Service. Rebecca Deschamps, executive director of the Montana Board of Pharmacy, reports having sent "Cease and Desist" letters to five foreign pharmacies advertising in Montana.

[30] The Pennsylvania Board, the South Dakota Board, and the Washington State Board of Pharmacy all report having met with and/or taken some sort of action against prescription facilitators. The North Dakota Board reports contacting the facilitators and asking them to stop their activities on the basis they are operating without a valid license and aiding and abetting an illegal activity. They have also asked local newspapers and radio and television stations not to run their advertisements, since the businesses are operating illegally. The Montana Board sent a "Cease and Desist" letter to Gary Moffitt and Club MedzRx, saying that by "implementing prescriber orders and assisting patients in procuring drugs from RealFast Drugstore, a Canadian mail order pharmacy," Mr Moffitt and Club MedzRx are practicing pharmacy without a license and aiding and abetting a pharmacy not licensed in Montana, unlawfully using the "Rx" symbol, acting as unlicensed pharmacy technicians, among other violations. Letter from Rebecca H. Deschamps, Executive Director, Montana Board of Pharmacy to Gary Moffitt, ClubMedzRx (March 10, 2003) (on file at NABP).

[31] Letter from David J. Horowitz, Director, Office of Compliance, CDER, FDA to Harry Lee Jones, Store Manager, Rx Depot, Inc. (March 21, 2003) (on file at NABP); Letter from Charlie S. Campbell, Executive Director, Arkansas State Board of Pharmacy to Harry Lee Jones, Store Manager, Rx Depot, Inc. (March 21, 2003) (on file at NABP).

[32] Ark. Code Ann. § 17-92-401 et seq.

related wording in its advertising and signage[33]. The FDA states in its letter that Rx Depot violates federal law by causing shipments of prescription drugs from Canada into the US[34] and that it makes misleading statements about the legality of drug importation and drug safety.

The Oregon Board of Pharmacy sent a letter to the College of Pharmacists of British Columbia notifying them that pharmacies in that province are dispensing prescriptions to citizens of Oregon in violation of state and federal laws, and urged the College to instruct its licensees to "refrain from providing drugs and other professional services into Oregon in violation of US and Oregon law."[35] The College responded saying their understanding of the situation was that US laws were violated when US citizens import the drugs, not when their licensees export the drugs. The College has taken a provisionally-focused position stating "it is the responsibility of the individual US jurisdictions to monitor for the shipment of drugs from foreign countries and for compliance by foreign pharmacies with the laws of their jurisdictions" and that they "did not support the notion that it is our College's responsibility to enforce other jurisdictions' legislated requirements." The College did state that the pharmacies that they know of that ship drugs to the US have been determined to be in full compliance with all provincial laws and standards of practice, and that they have advised such pharmacies that many states require non-resident pharmacy registration.[36]

**FDA**

In addition to the warning letter mentioned above, the FDA has issued warning letters to a number of foreign pharmacies requesting that they stop shipping prescription medications to US residents.[37] Although it has been reported that certain foreign pharmacies have heeded these warnings, many have not. The FDA has also published several documents for consumers aimed at educating them on the dangers of importation.[38] Additionally, FDA has responded to numerous inquiries clarifying the illegal status of drug importation, including those from active and associate NABP member boards of pharmacy.[39]

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[33] Ark. Code Ann. § 17-92-404(b).

[34] 21 USC § 331.

[35] Letter from Gary A. Schnabel, Executive Director, Oregon Board of Pharmacy to Linda Lytle, Registrar, College of Pharmacists of British Columbia (August 22, 2002) (on file at NABP).

[36] Letter from Linda Lytle, Registrar, College of Pharmacists of British Columbia to Gary A. Schnabel, Executive Director, Oregon Board of Pharmacy (September 19, 2002) (on file at NABP).

[37] http://www.fda.gov/bbs/topics/ANSWERS/ANS01001.html

[38] FDA Drug Importation Web sites:

- Testimony: July 25, 2002, Statement of William K. Hubbard before the House Subcommittee on Health: http://www.fda.gov/ola/2002/drugimportation0725.html
- FDA Consumer Magazine: Imported Drugs Raise Safety Concerns: http://www.fda.gov/fdac/features/2002/502_import.html
- Looks Can Be Deceiving (brochure): http://www.fda.gov/cder/consumerinfo/border.pdf
- Buying Prescription Medicine Online: A Consumer Safety Guide: http://www.fda.gov/cder/drug/consumer/buyonline/guide.htm
- Consumer Information: http://www.fda.gov/cder/consumerinfo/DPAdefault.htm
- Buying Medicines and Medical Products Online: http://www.fda.gov/oc/buyonline/default.htm
- "FDA Strengthens Controls, Issues Consumer Alert on Importing Certain Prescription Drugs (press release), December 9, 2002

[39] *E.g.*, Letter from David J. Horowitz, Acting Director, Office of Compliance, CDER, FDA to Ronald F. Guse, Registrar, The Manitoba Pharmaceutical Association (April 12, 2002)(on file at NABP); Letter from David J. Horowitz, Acting Director, Office of Compliance, CDER, FDA to DJ Eriksen, Assistant Registrar, Saskatchewan

Efforts to seize parcels containing imported prescription drugs are hampered by current regulations that require the FDA to issue notice to an addressee that his parcel has been detained and provide an opportunity to respond with reasons why the parcel should be allowed entry. If an inadequate or no response is received, the FDA must return the parcel to the sender. These detention, notice, and return requirements are time consuming and require significant resources unavailable to the FDA.[40] With this in mind, either the regulations governing the seizure of packages at the border must be simplified, or the FDA must be provided with additional resources to search and seize foreign drugs at US mail facilities. Illegal activities should not be allowed to continue due to inefficient regulatory systems and rules that were developed at a time when huge problems such as the one we are currently experiencing could not have been foreseen. Further, the lack of resources for enforcement must be addressed prior to a complete compromise of the US drug distribution system, and subsequent patient injury or death.

**Conclusion**

Regardless of the obvious illegality of these activities, particularly distressing is the blatant disregard for the law by those in positions of authority: politicians sponsoring bus trips to Canada and Mexico for constituents to purchase foreign medications and introducing legislation to penalize anyone for taking action that support current federal laws and regulations, as well as US insurance companies or pharmacy benefit managers offering or even mandating the use of foreign pharmacies by patients. These activities are particularly distressing to state and federal regulators charged with enforcing the law and protecting patients. It is this dichotomy of messages that is being sent to the American public, the support for illegal activities by entities of authority, which is making this a difficult situation.

While the price of prescription drugs obviously is of concern to US patients, it should not be the driving force behind their importation. The practice of importing drugs from foreign jurisdictions is illegal and has been made so to support the overriding purpose of the law, namely the protection of the public health and welfare. Until there is equity in the pricing of prescription medications, it may be impossible to completely stop US patients from obtaining medications from Canada, Mexico, and other countries. Notwithstanding the illegalities associated with importing unapproved medications, we are deeply concerned that illegitimate pharmacy Web sites could be a front for criminals seeking to introduce adulterated medications, counterfeit drugs, or worse, to the American public. Considering current world events, we believe it is dangerous to purchase medications from abroad. As regulatory authorities in the US and other countries grapple with this important issue, educating the American public on the danger and illegality of purchasing prescription medications abroad is a necessary component of any solution to the problem. If the laws need to be changed to recognize the globalization of pharmacy practice, then licensure of legitimate foreign pharmacies by US state boards of pharmacy may help to ensure that US patients receive appropriate medications and care.

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Pharmaceutical Association (April 3, 2002)(on file at NABP); Letter from John M. Taylor, Senior Associate Commissioner for Regulatory Affairs, FDA to Howard C. Anderson, Jr., Executive Director, North Dakota Board of Pharmacy (September 10, 2002)(on file at NABP).

[40] *Drug Importation*, *supra* note 1.

**ATTACHMENT B**

## VIPPS® Criteria

### Licensure and Policy Maintenance

**Qualifying VIPPS Pharmacies (see definitions) must:**

1) Provide NABP with the information necessary to verify that the VIPPS pharmacy is licensed or registered in good standing to operate a pharmacy and/or engage in the practice of pharmacy with all applicable jurisdictions;

2) Provide NABP with the information necessary to verify that all persons affiliated with the site, including those affiliated through contractual or other responsible arrangements, that are engaging in the practice of pharmacy are appropriately licensed or registered and in good standing in all applicable jurisdictions;

3) Maintain and enforce a comprehensive policy and procedure that documents how the pharmacy's policies and procedures are organized, authorized for implementation, revised, retired and archived; and

4) Comply with all applicable statutes and regulations governing the practice of pharmacy where licensed or registered, and comply with the more stringent law or regulation as determined by conflicts of law rules. VIPPS pharmacies must maintain and enforce policies and procedures that address conflicts of law issues that may arise between individual states or between state and federal laws and regulations. Said policies and procedures must assure compliance with applicable laws including generic substitution laws and regulations, and must prohibit unauthorized therapeutic substitution from occurring without necessary patient or prescriber authorization and outside of the conditions for participation in state or federal programs such as Medicaid.

### Prescriptions

**Qualifying VIPPS Pharmacies, in accordance with applicable state and federal laws and regulations, must:**

5) Maintain and enforce policies and procedures that assure the integrity, legitimacy, and authenticity of the Prescription Drug Order and seek to prevent Prescription Drug Orders from being submitted, honored, and filled by multiple pharmacies. Maintain and enforce policies and procedures that assure that prescription medications are not prescribed or dispensed based upon telephonic, electronic, or online medical consultations without there being a pre-existing patient-prescriber relationship that has included an in-person physical examination.

### Patient Information

**Qualifying VIPPS Pharmacies, in accordance with applicable state and federal laws and regulations, must:**

6) Maintain and enforce policies and procedures ensuring reasonable verification of the identity of the patient, prescriber, and, if appropriate, caregiver, in accordance with applicable state law;

7) Obtain and maintain in a readily accessible format, patient medication profiles and other related data in a manner that facilitates consultation with the prescriber, when applicable, and counseling of the patient or caregiver;

8) Conduct a prospective drug use review (DUR) prior to the dispensing of a medication or device in accordance with applicable state law; and

9) Maintain and enforce policies and procedures to assure patient confidentiality and the protection of patient identity and patient-specific information from inappropriate or non-essential access, use, or distribution while such information is being transmitted via the Internet and while the pharmacy possesses such information. [The NABP Guidelines for the Confidentiality of Patient Health Care Information as It Relates to Patient Compliance and Patient Intervention Programs can serve as a useful resource for addressing the confidentiality and security of patient data.]

## Communication

**Qualifying VIPPS Pharmacies, in accordance with applicable state and federal laws and regulations and VIPPS program criteria must:**

10) Maintain and enforce policies and procedures requiring pharmacists to offer interactive, meaningful consultation to the patient or caregiver;

11) Maintain and enforce policies and procedures establishing a mechanism for patients to report, and the VIPPS Pharmacy to take appropriate action regarding, suspected adverse drug reactions and errors;

12) Maintain and enforce policies and procedures that provide a mechanism to contact the patient and, if necessary, the prescriber, if an undue delay is encountered in delivering the prescribed drug or device. Undue delay is defined as an extension of the normal delivery cycle sufficient to jeopardize or alter the patient treatment plan;

13) Maintain and enforce policies and procedures establishing mechanisms to inform patients or caregivers about drug recalls; and

14) Maintain and enforce policies and procedures establishing mechanisms to educate patients and caregivers about the appropriate means to dispose of expired, damaged, and unusable medications.

## Storage and Shipment

**Qualifying VIPPS Pharmacies, in accordance with applicable state and federal laws and regulations and VIPPS program criteria, must:**

15) Ship controlled substances to patients via a secure and traceable means; and

16) Assure that medications and devices are maintained within appropriate temperature, light, and humidity standards, as established by the United States Pharmacopeia (USP), during storage and shipment.

## Over-the-Counter Products

**Qualifying VIPPS Pharmacies must:**

17) Comply with all applicable federal and state laws regarding the sale of Over-the-Counter Products identified as precursors to the manufacture or compounding of illegal drugs.

## Quality Improvement Programs

**Qualifying VIPPS Pharmacies must:**

18) Maintain a Quality Assurance/Quality Improvement Program.

## Reporting to NABP

**Qualifying VIPPS Pharmacies must:**

19) Notify NABP within thirty (30) days of any change of information provided as part of the verification process, including change in pharmacist-in-charge, or involving data displayed on the VIPPS Web site. VIPPS pharmacies shall notify NABP in writing within ten (10) days of ceasing operations. The written notification shall include the date the pharmacy will be closed, and an affirmation that all VIPPS Seals and references to the VIPPS program have been removed from the Web site and wherever else they are displayed.

**ATTACHMENT C**

drugstore.com
www.drugstore.com

Corporation
drugstore.com, inc.

Phone
425-372-3200

Address
13920 SE Eastgate Way, Suite300
Bellevue, WA 98005

CEO
Kal Raman

State of Incorporation
DE

Experience Operating a Pharmacy
since Feb.1999

**Dispensing Pharmacies**

| Pharmacy Name | Address | Click for Details |
|---|---|---|
| drugstore.com | 13920 SE Eastgate Way, Suite 300<br>Bellevue, WA 98005 | |
| Rite Aid Pharmacy #777 | 407 Heron Drive<br>Swedesboro, NJ 08085 | |

To report medication / device problems:

Click www.drugstore.com or call 800-drugstore

To report business compliance problems:

Click www.drugstore.com or call 800-drugstore

| Original VIPPS Certification Date | Next Verification Date |
|---|---|
| September 10, 1999 | September 10, 2003 |

Additional Details for Drugstore.com available to consumers.

drugstore.com
www.drugstore.com

Pharmacy Name
drugstore.com

Web Business Name
drugstore.com

Address
13920 SE Eastgate Way, Suite 300
Bellevue, WA 98005

Phone
800-drugstore

Pharmacist in Charge
Christopher A. Pierce

| State of Licensure | State License Number | State Board Website | Disciplinary Actions |
|---|---|---|---|
| AK | 165 | www.dced.state.ak.us | No |

| | | | |
|---|---|---|---|
| AL | 111510 | www.albop.com | No |
| AR | X01345 | www.state.ar.us | No |
| CA | NRP312 | www.pharmacy.ca.gov | No |
| CO | 5136 | www.dora.state.co.us | No |
| CT | 223 | www.ctdrugcontrol.com | No |
| DC | Not Required | None Available | No |
| DE | A9251 | www.professionallicensing.state.de.us | No |
| FL | PH0016400 | www.doh.state.fl.us | No |
| GA | Not Required | www.sos.state.ga.us | No |
| HI | PMP-129 | www.state.hi.us | No |
| IA | 3227 | www.state.ia.us | No |
| IL | 054-014057 | www.dpr.state.il.us | No |
| IN | 64000141 | www.state.in.us | No |
| KS | 1549 | www.ink.org | No |
| KY | WA505 | www.state.ky.us | No |
| LA | 4208 | www.labp.com | No |
| MA | Not Required | www.state.ma.us | No |
| MD | PO2324 | www.dhmh.state.md.us | No |
| ME | MO40000212 | www.maineprofessionalreg.org | No |
| MI | 5302032549 | www.michigan.gov | No |
| MN | 261662-5 | www.phcybrd.state.mn.us | No |
| MO | PS006538 | www.ecodev.state.mo.us | No |
| MS | 04477-09DB | www.mbp.state.ms.us | No |
| NC | 7334 | www.ncbop.org | No |
| ND | 368 | None Available | No |
| NE | 182 | www.hhs.state.ne.us | No |
| NH | NR0077 | www.state.nh.us | No |
| NJ | Not Required | www.state.nj.us | No |
| NM | PH00001981 | www.state.nm.us | No |
| NV | PH1367 | glsuitewww.glsuite.com | No |
| NY | Not Required | www.nysed.gov | No |
| OH | 02-1134700 | www.state.oh.us | No |
| OK | 99-300 | www.pharmacy.state.ok.us | No |
| OR | 1698 | www.pharmacy.state.or.us | No |
| PA | Not Required | www.dos.state.pa.us | No |
| RI | NRP9188 | None Available | No |
| SC | 60004660 | www.llr.state.sc.us | No |

| | | | |
|---|---|---|---|
| SD | 400-0098 | www.state.sd.us | No |
| TN | 3449 | www.state.tn.us | No |
| TX | 19468 | www.tsbp.state.tx.us | No |
| UT | 375795-1708 | www.commerce.state.ut.us | No |
| VA | 0214000334 | www.dhp.state.va.us | No |
| VT | Not Required | www.vtprofessionals.org | No |
| WA | CF 00056247 | wws2.wa.gov | No |
| WI | Not Required | www.badger.state.wi.us | No |
| WV | MO059274 | None Available | No |
| WY | 49-26602 | pharmacyboard.state.wy.us | No |

Services Offered

Cosmetics and Toiletries
Dispense Medical Devices
Dispense Over-The-Counter Medications
Dispense Prescription Medications
Herbals and Homeopathics
Offer Next Day Delivery
Provide General Medical / Pharmaceutical Information On Site
Vitamins and Nutritionals

Chairman TOM DAVIS. General Blumenthal, thanks for being with us.

Mr. BLUMENTHAL. Thank you, Mr. Chairman, and thank you for your leadership on this issue in holding a hearing and for the very perceptive and insightful questions that have been asked about this problem which surely requires Federal intervention at this point to strengthen the role of State oversight, as well as Federal scrutiny in an area that, unfortunately, is rife with abuse, deception and health damage.

The Internet offers enormous promise, as I've indicated in my testimony, for consumers to save very hard-earned dollars and scarce dollars that they need to buy prescription drugs.

In a survey that my office will release just next week, probably, we surveyed six Internet pharmacies and compared them to bricks-and-mortar stores and found that consumers can realize very, very significant savings, not just pennies or dollars, but literally hundreds of dollars in using certified—that is, VIPPS-approved—Web sites to buy drugs that they purchase pursuant to valid prescriptions.

I think that the abuses here come when the Web sites are used with questionnaires, without legitimate prescriptions, without any prescriptions at all, without any diagnosis from a licensed doctor, and that is where the remedies ought to come.

If I may outline some of the areas that I think are particularly appropriate and important for this committee to address, as Dr. Thompson has said, I would recommend that Congress require all Internet Web sites to provide information about the location of the pharmacy, the legal entity owning it, a contact person for consumer complaints, a list of employees and State licenses—in short, the kind of information that will enable consumers and State enforcers, as well as Federal regulators, to pinpoint responsibility and hold them accountable.

I would disagree with the implication that there needs to be a national standard for prescriptions. I think each of the States now has such standards. I don't object as a matter of principle to there being a national standard, but I think it may divert energy and attention away from the areas that do need fundamental reform.

For example, I think Congress ought to require all Internet pharmacies to dispense pharmaceutical drugs only when the prescription meets the standards of the State where the resident who is buying the pharmaceutical drug actually lives. Requiring them, for example, to meet Connecticut standards would mean they need the address of the practitioner who is prescribing the drug, the name of the drug, the dosage, the strength—basic information that is contained in every prescription in every State across the country.

And then also very importantly I think that Federal law ought to require Internet pharmacies to require that prescriptions be done by a health care provider who meets the State licensing requirements. If I were to go to Indiana or Virginia or South Dakota or New York and receive the prescription from a licensed doctor, I wouldn't have questions about the basic credentials and abilities of that doctor. The point is to require a prescription that meets the State standards from a practitioner who meets the State standards.

And let me just say that the issue here very often does become one of enforcement, as Mr. Janklow implied. States need the ability to go to a Federal court. We need Federal jurisdiction for national injunctions, not just in the State where we try to shut down one of these rogue Internet sites. In Connecticut, for example, we did so against a number of the sites and the physicians and we are still in court on issues of jurisdiction, procedural kinds of tangents, because we are in our State court rather than Federal court, and so we do need Federal jurisdiction and the power to seek national injunctions.

And, finally, we need tougher penalties so that the fines and the monetary punishments are not just regarded as the cost of doing business but offer a real sanction against some of these online outlaws.

I think that these sites can offer real benefits for consumers. The VIPPS program has been working very well. I commend the NABP for its efforts in that regard. There is a real potential here, as long as we avoid the possible abuses.

I might just close—and I thank you for giving me a couple of extra moments—by making a suggestion about the foreign jurisdictions. If there is a threat from Internet pharmacies based in foreign countries, I might suggest that the Congress could ban the use of any financial instruments such as checks, money orders, and electronic transfers, in payment for those kinds of prescriptions that come from foreign-based Web sites. I realize they are tough to reach, even under the Federal jurisdiction, but in cutting off the financial air supply, so to speak, we can reach those kinds of foreign-based Web sites. The analogy would be to Internet gambling, where a similar suggestion has been made under Federal law to ban certain kinds of Internet gambling from foreign-based Web sites. I think the same kinds of remedies would be effective here. Thank you, Mr. Chairman.

Chairman TOM DAVIS. Thank you very much.

[The prepared statement of Mr. Blumenthal follows:]

***TESTIMONY OF***
***RICHARD BLUMENTHAL***
***ATTORNEY GENERAL OF CONNECTICUT***
***BEFORE THE COMMITTEE ON GOVERNMENT REFORM***
***MARCH 27, 2003***

I appreciate the opportunity to speak on the issue of the domestic sale of prescription drugs over the Internet.

The Internet is an instrument of untapped promise and peril -- tremendous benefits and pitfalls -- especially for unwary, unaware consumers. It can enhance worker efficiency, and speed communication but also furnish fertile soil for scams and fraud.

Prescription drug Internet sales are a case in point -- fraught with risks of deception and health damage. Prescription mistakes, under-filling, or adulteration can cost money and cause serious or even fatal injury. Unlicensed pharmacies and doctors are online outlaws -- rogue medical merchants who advertise, sell, and deliver very popular and powerful prescription drugs that are readily and commonly abused. Their sales of drugs like Meridia, Xenical, Phentermine, Celebrex, and Viagra raise risks of counterfeit medicine, improper dosage, and addiction, among other dangers. These unethical and unscrupulous practices encourage and support abuse. They make the Internet a wild west of medicine marketing.

Congress must establish minimum standards and rules. Federal law should define what is a valid prescription and adequate consumer notice of the physical location of the pharmacy, the name and credentials of the physician, and quality assurance and privacy of health record information. Congress should also require every Internet pharmacy to comply with all licensing requirements of each state where it sells drugs. Finally, it should provide for federal and state criminal and civil enforcement authority, including tough penalties and nationwide injunctive relief similar to the Federal Telemarketing Sales Act.

Internet pharmacies offer one potential solution to escalating drug costs -- through real savings for consumers. Indeed, rising prescription drug costs, particularly affecting our millions of uninsured and our elderly, have created a public health crisis. Between 1997 and 2001, consumer spending on prescription drugs rose nearly 20% annually. Approximately 75% of adults between the ages of 50 and 64 years use one or more prescription drugs.

Savings available through Internet pharmacies are documented in a survey that I conducted on pharmacy prescription drug prices. In the survey, which will be completed and released next week, pharmacies across the state and six Internet pharmacies certified by the National Association of Boards of Pharmacy under their Verified Internet Pharmacy Practice site (VIPPs) were requested to provide retail prices for 30 most commonly prescribed drugs. The survey found that consumers can save hundreds of dollars each year by price comparison shopping among pharmacies.

Importantly for today's discussion, the survey also found that Internet sites had the lowest price for 18 of the 30 prescription drugs. For example, the average Internet pharmacy price for

Paxil was $81.71 while the average non-Internet pharmacy price was $97.88, producing an annual savings of almost $200 for patients with typical dosages. Consumers should also be aware that the neighborhood pharmacy price for some drugs may be lower than the Internet. There may be other reasons -- such as ability to consult and confide in a resident pharmacist -- that consumers choose a local bricks and mortar establishment rather than an Internet pharmacy.

Internet pharmacies can save consumers money, but also pose a significant health and financial risks, if they are not properly licensed and regulated.

More than 400 Internet web sites offer prescription drugs. According to a 2000 Government Accounting Office report, there are typically three types of Internet pharmacies: (1) pharmacies that dispense prescription drugs only after receiving a prescription from the consumer's health care provider; (2) pharmacies that have a resident physician who provides a prescription based on consumer answers to a questionnaire; and (3) pharmacies that dispense prescription drugs without any prescription from a health care provider.

The first category of Internet pharmacies offers consumers a safe and effective alternative to a local pharmacy, often saving consumers hundreds of dollars. The second and third categories are simply disasters waiting to happen. Consumers play Russian Roulette when buying drugs without adequate professional diagnosis and review. They open their homes and health to prescription drugs that may be inappropriate, adulterated or even counterfeit.

In 2001, I filed 4 lawsuits against 7 pharmacies and 3 physicians located in other states that were illegally dispensing drugs to Connecticut consumers. These pharmacies and physicians violated Connecticut's unfair trade practices act by failing to register as a non-resident pharmacy, engaging in medical diagnosis without a license in Connecticut, advertising illegal services and requiring consumers to waive all liability claims against the pharmacy or physician.

These online outlaws sold popular and powerful drugs that are readily and commonly abused. In one instance, a pharmacy dispensed a very strong and potentially addictive diet pill to an investigator from my office who filled out a questionnaire stating that she was 5 foot 7 inches tall and weighed only 120 pounds.

State attorneys general have worked together against these rogue pharmacies. The Food and Drug Administration and the Federal Trade Commission have also brought lawsuits and taken administrative action. But the laws enforced by the states and the federal government are typically general licensure provisions and unfair trade practices acts. We need federal legislation that will provide a strong, clear, legal and direct tool for both federal and state actions.

First, Congress needs to require that all Internet websites provide information on the physical location of the pharmacy, the legal entity owning it as well as a contact person for consumer complaints, a list of employees, and any state licenses. This information is critical for consumers and will greatly facilitate accountability -- pinpointing responsible corporate officials if the pharmacy violates federal or state laws.

Second, Congress should require that all Internet pharmacies dispense pharmaceutical drugs only with a prescription that meets standards of the state where the consumer lives. For example, Connecticut General Statutes §20-614 requires that every prescription contain: (1) the written signature of a prescribing practitioner; (2) the address of the practitioner; (3) the date of the prescription; (4) the name, dosage form, strength and amount of the drug prescribed; (5) the

name and address of the patient; (6) directions for use; (7) any required cautionary statements; and (8) the number of refills. This requirement will ensure that pertinent facts are adequately documented for every filling of the prescription.

Third, Congress should require that all Internet pharmacies comply with state licensing requirements for pharmacies. Connecticut is one of 40 states that requires every non-resident pharmacy to register before it ships, mails or delivers prescription drugs into the state. Under Connecticut General Statutes §20-627, a non-resident pharmacy must (1) disclose annually the location, names and titles of all principal corporate officers and all pharmacists dispensing drugs to Connecticut residents; (2) provide a statement of compliance with the pharmacy licensing laws in the state in which it is located; (3) provide the most recent inspection report from the local pharmacy regulatory authority and (4) provide a toll-free telephone number for patients to contact a pharmacist who would have access to the patient's records. These basic provisions are critical to protecting public health.

Fourth, Congress should specify that any health care provider who acts as an agent for an Internet pharmacy and who writes a prescription for a resident of another state must comply with that state's medical licensing requirements.

Fifth, Congress should clarify that any violation of these provisions is enforceable in federal district court by either the Federal Trade Commission, the Food and Drug Administration or state attorneys general. A state attorney general would have jurisdiction over an Internet pharmacy or health care provider if such pharmacy dispenses prescription drugs to residents of that state or the health care provider writes a prescription for a resident of that state.

Sixth, Congress should enact tough criminal and civil fines for violations, including the imposition of nationwide injunctive relief, as authorized by the Federal Telemarketing Sales Act. Currently, injunctive relief sought by a state attorney general is applicable only to that state, thereby necessitating 50 separate lawsuits to stop one pharmacy on a nationwide basis.

Finally, since about half of the Internet pharmacies are based in foreign countries, Congress should prohibit the use of any financial instrument -- such as checks, money orders and electronic transfers -- to foreign Internet pharmacies that do not comply with the law. This prohibition is under consideration as an effective measure to cut the financial lifeblood of rogue, foreign based Internet gambling sites. It can be similarly effective against rogue Internet pharmacies.

The state attorneys general are willing to work with the FTC, the FDA and Congress in addressing this critical public health problem.

Chairman TOM DAVIS. We'll begin the questioning with Mr. Burton.

Mr. BURTON. I think everybody in the Congress and in the country wants to make sure that the kinds of pharmaceuticals that are being consumed by Americans are safe. We all want that. We don't want adulterated pharmaceuticals. But at the same time, we have millions of Americans who can't afford to pay the prices for some of these pharmaceuticals here in the United States, and yet they can afford the pharmaceuticals that are the same from Canada. We've already heard that there are no known cases of pharmaceuticals damaging Americans from Canada where a prescription has been filled up there.

So my feeling is—and I'd like to ask all of you this question—what would be wrong if we had some kind of a reciprocity agreement between States and between countries where they could check and make sure that these online pharmaceutical distributors comply with the laws of, say, Canada as well as the United States, or Iowa as well as Indiana? It seems to me that we ought to be bending over backward not only to make sure things are safe, but to make sure that our citizens are not discriminated against by pharmaceutical companies.

I mean, when you have a product that costs one-third more in the United States than it does in Canada and you know that the pharmaceutical company that is selling that product in Canada is making a very good profit up there, then you know they're making an absolute killing on that product down here in the United States. And you can't say that the Americans should bear the brunt of that.

I have friends of mine that were paying over $1,000 a month for very significant kinds of drugs because they had not only high blood pressure but diabetes and a whole host of things, and in Canada they are getting them for about a third or half of that. Now, why should they have to pay double what they would pay in Canada? And if you have an agreement, a reciprocity agreement between the countries that the two governments could agree on, it seems to me that would be a legitimate thing for Americans to expect.

Do any of you have a comment on that?

Mr. CATIZONE. I have a comment on that also. We have one documented incident of a patient in the United States being injured by a medication from Canada. Action is being filed in the State of Oregon. A patient being treated for breast cancer received the wrong medication and for 3 months was taking that medication, and unfortunately that patient is not doing well now. She has hired an attorney. The attorney has filed an action and also reported it to the State Board of Pharmacy in Oregon——

Mr. BURTON. OK.

Mr. CATIZONE [continuing]. As well as with authorities in British Columbia.

Mr. BURTON. So there is one case that you know of?

Mr. CATIZONE. Right. The position that we have taken, Representative——

Mr. BURTON. Well, let me just interrupt. I'm sorry. There is one case that you know of?

Mr. CATIZONE. Yes, sir.

Mr. BURTON. Are there any other cases that you know of?

Mr. CATIZONE. We've just begun tracking that information.

Mr. BURTON. But you only know of the one right now?

Mr. CATIZONE. Yes, sir.

Mr. BURTON. How many cases in the United States where doctors have prescribed medicine and people were injured from the medication that they received here in the States?

Mr. CATIZONE. Estimates run anywhere from 1 to 10 percent of all patients treated have some——

Mr. BURTON. That's 1 to 10 percent of all patients?

Mr. CATIZONE. Yes.

Mr. BURTON. So you're telling me there is one patient in Oregon that was damaged by a pharmaceutical product coming out of Canada, but you say 1 to 10 percent of the people are damaged here in the United States?

Mr. CATIZONE. Yes, sir.

Mr. BURTON. So it is really not a big difference. In fact, unless you find something else, the percentage is probably lower coming in from Canada, unless you find other things.

Mr. CATIZONE. We've just begun looking at it. Until we——

Mr. BURTON. I understand, but yes, see the point I'm trying to make——

Mr. CATIZONE. And the point we'd like to make is our position has been very clear. We believe either the laws should be enforced that currently exist or, as you have suggested, there should be mutual recognition of products approved by Health Canada and the FDA——

Mr. BURTON. Well, I don't have any problem with that.

Mr. CATIZONE [continuing]. As well as licensing of those pharmacies by U.S. State boards of pharmacy.

Mr. BURTON. I don't have any problem with that. What I do have a problem with are the pharmaceutical companies making all of this money on the backs of American citizens when they are selling the same product up there and making a profit out of it. I don't believe in price controls. I believe in the free enterprise system. But at the same time I don't believe Americans should be raped by pharmaceutical companies when they are selling the same product in other parts of the world for a heck of a lot less money and we have the highest-priced pharmaceuticals in the world, so they are levying all of the profit or the biggest part of the profit on the backs of the American citizens, and it is just not right. We should not be discriminated against. And I am for the free enterprise system.

Thank you, Mr. Chairman.

Mr. BLUMENTHAL. If I may add——

Chairman TOM DAVIS. Sure. Please.

Mr. BLUMENTHAL [continuing]. Just a sentence or two, I, on behalf of myself as the Attorney General of Connecticut, not speaking for all of my colleagues across the country, would very strongly welcome a more-transparent and free market internationally that gives our consumers the benefit of lower prices in an international or global market, which now is not the case, so long as quality, contamination, adulteration, dosage—all of those standard measures of

acceptability—were the subject of the United States oversight, which I think is the purpose of your suggesting some kind of reciprocity agreement.

Mr. BURTON. That's right. And I appreciate your saying that, General. Thank you.

Chairman TOM DAVIS. Thank you, Mr. Burton.

Mr. Towns.

Mr. TOWNS. Thank you very much, Mr. Chairman.

You know, Dr. Thompson, you mentioned legislation is needed in a certain area, and I really didn't get that. Somehow I lost that part. Where do we need legislation?

Dr. THOMPSON. Actually, we have offered to work with this committee to help define the doctor/patient relationship, which has been in the past a source of confusion and has led—has caused a decrease at times in Federal action because of the confusion about the doctor/patient relationship. We would welcome an opportunity to help narrowly define that for the purposes of Internet practice.

Mr. TOWNS. Right. But I thought you made some suggestions. I thought you gave some specific suggestions that you felt were areas in which we need legislation. I'll come back to you.

Dr. THOMPSON. Actually, there were three things. One is that we would highly recommend that there be national disclosure of the Internet sites and the physicians who are prescribing the medications.

Second, we would strongly encourage some Federal legislation to allow for injunctions against these Internet pharmacies beyond the State jurisdictions. The States, as you know, are restricted, and you heard testimony earlier about the restrictions from going after pharmacies and businesses in other States. Perhaps Mr. Blumenthal would care to expand on that. But certainly we would like injunctive relief that would help us go after pharmacies and businesses across State lines.

Mr. TOWNS. Thank you. Also, after you comment on that, Mr. Blumenthal, at the same time I want to know your views on uniformity in terms of the possibility for some guidelines that would just cover all States.

Mr. BLUMENTHAL. I think the need for uniformity is a very real concern, and if I might suggest to the committee, there is an excellent model, which is the Federal Telemarketing Sales Act, as described earlier by Mr. Beales of the FTC. The Federal agency there has the option to enforce a case. If the State chooses to do so independently, it can go to Federal court, but at least the FTC has the ability to enforce a national standard in every case because it has what he aptly termed a "right of first refusal." And so the kind of framework that I am suggesting—and I think it has been suggested widely—is that there be the authority on the part of States to enforce a standard that the FTC in a sense would supervise and assure uniformity, but make it potentially nationwide in every case through the Federal courts and give the States the option to enforce their cases in Federal court, which would give much more teeth to the present system.

I can't emphasize how important that would be as a deterrent to these kinds of rogue pharmacies, because right now they feel that they can simply move from one State to another, that they can

choose States where, for one reason or another, enforcement authorities may not be as vigorous as they would be in other States. They can avoid State court jurisdiction. They can throw up procedural hurdles and technicalities. I think many of those obstacles would be removed by this kind of Federal system with Federal jurisdiction modeled on the Federal Telemarketing Sales Act.

Mr. TOWNS. Right, because I'm not even sure what a valid prescription is. What is a valid prescription? I'm not sure, you know. Do you want to comment on that? That's the reason why I think we need some Federal involvement here.

Dr. THOMPSON. Well, the State medical boards have been very clear about the writing of a prescription, and in all circumstances have enforced the notion that there should be an adequate doctor/patient relationship, and this is not satisfied by a survey over the Internet. It is only satisfied by a face-to-face encounter with a physician, including a history and a physical examination and some permanent documentation of that encounter we know as a medical record. Those are at least the minimal standards that the state Boards would require for a doctor/patient relationship to be established prior to the writing of a prescription.

Mr. TOWNS. Thank you. My time has expired, Mr. Chairman.

Chairman TOM DAVIS. Thank you very much.

General Blumenthal, let me ask you, Mr. Catizone has already testified that the VIPPS program already requires disclosure from its participating Web sites. It is an established program. It has seen some very positive results. What about States enacting legislation to make this certification process mandatory? Is that helpful? Is it possible? Is it probable?

Mr. BLUMENTHAL. I think again, Mr. Chairman—and that question is really a very important and key one—the States could do so. Connecticut, as a matter of fact, has, at one point or another, proposed to do so, but I think we need the help of the Federal Government in enforcement.

Chairman TOM DAVIS. Absolutely.

Mr. BLUMENTHAL. And the VIPPS program is excellent. It works well. It is done in good faith by the NABP and I think is an excellent model. We can expand on it and perhaps enact it into law, but doing it State by State may not be the answer, simply because of the enforcement difficulties I mentioned earlier.

Chairman TOM DAVIS. I mean, the problem is you could shut down a Web site and find the people. They can come up under some other auspices somewhere else. And the fact is, because of the price differential, consumers will take the chance and many times just do it. It's almost impossible to police. I'm not even sure the Federal Government could police it, but we would obviously have more jurisdiction. Is that a fair comment?

Mr. BLUMENTHAL. I think that is a very accurate and fair comment, Mr. Chairman.

Chairman TOM DAVIS. Yes. Connecticut consumer protection laws, in addition to medical and pharmacy laws, have served as a vehicle for you to go after the Web sites. When does the illegal dispensing of drugs become the issue for the Federal level? When do we cross that threshold and it becomes a Federal issue as opposed to a State issue?

Mr. BLUMENTHAL. Well, I think there is overlapping jurisdiction. As you've heard from the earlier panel, a violation of Federal law could involve the same kinds of unfair or deceptive advertising practices that we have prosecuted at the State level. It's the reason that we have sued a number of the Internet Web site pharmacies, as well as doctors. We sued physicians who participated in those kinds of illegal practices.

I think the Federal jurisdiction relates to the quality and purity of drugs. We don't have the authority over, for example, contamination, counterfeiting, mis-dosage, misbranding of drugs in the same way that the Federal Government and specifically the FDA does.

Of course, there are different issues of enforcement. We don't have the same kind of powers to enforce Federal law now in this area or to go into Federal court.

Chairman TOM DAVIS. OK.

Mr. Catizone, let me ask you, the VIPPS seal that you place on—the VIPPS Seal of Approval that consumers ought to be able to stand by, have people been stealing this seal illegitimately and putting it on a Web site? Has this been a problem?

Mr. CATIZONE. No. The security systems we have in place with our software people have prevented that from happening. If we have detected any site where they have tried to copy it, it is immediately known to us and we immediately take action against that site also.

Chairman TOM DAVIS. OK. All right. Thank you.

Dr. Thompson, what type of actions can you take against a physician who is illegally prescribing to consumers over the Internet without first establishing a valid patient/physician relationship?

Dr. THOMPSON. The disciplinary actions can include anything from a hand slap to a revocation of a license. In fact, at least four physicians have had their licenses revoked as a result of prescribing over the Internet without establishing a physician/doctor relationship. It includes anything from fines to suspensions to, as I mentioned, revocation.

Chairman TOM DAVIS. It is not all black and white, though, is it?

Dr. THOMPSON. No.

Chairman TOM DAVIS. Because even some of these illegitimate sites are selling legitimate goods. We don't know that they are. We can't prove that they are, but in many cases they appear to be. It is giving consumers something they probably may not be able to afford otherwise, but it is an unfair competitive advantage and there are, as I think we've heard from the last panel, risks involved that really have not been articulated or measured appropriately—something maybe we need to do a better job of before we move on.

I appreciate your being here. I appreciate your testimony adding to this. Mr. Waxman has a bill. I think he might have picked up a couple cosponsors on our side today as a result of this.

Mr. TOWNS. Are we concluding?

Chairman TOM DAVIS. I'm going to let you ask more questions, Mr. Towns, if you want to.

Mr. TOWNS. Thank you. I appreciate that.

Chairman TOM DAVIS. I'm just thanking and just saying I appreciate for you really adding to our body of knowledge on this. It's

something a lot of Members aren't aware of. As you see, it gets wrapped up in the whole prescription drug controversy, legislation we're trying to pass this year but all the contradictions that occur in a marketplace that is cluttered sometimes with too much regulation and sometimes too little regulation.

Mr. Towns, did you have any additional questions?

Mr. TOWNS. I do, Mr. Chairman. I just wanted to ask Dr. Catizone a couple of questions. I understand that the National Association of Boards of Pharmacy certifies Internet pharmacy which meets certain criteria as verified. Internet pharmacy practice sites are called VIPPS. Can you tell us about this program, including how stringent the safety standards are and how many Internet pharmacies you've certified to this date up to date?

Mr. CATIZONE. The VIPPS program has very robust and stringent criterion for approval and for certification. As Mr. Blumenthal mentioned, we adhere to all of the various State laws as part of that certification program, so a pharmacy that operates in Illinois that wants to distribute medications in Connecticut must follow all the laws for those patients in Connecticut when dispensing those medications. We review the licensure. We do an onsite inspection. We check all of their State board inspection reports. We check all the disciplinary actions against the pharmacy or pharmacist and then post that information on the Web site for the patients to observe.

We have certified to date 13 sites representing 8,000 to 10,000 pharmacies in the United States.

Mr. TOWNS. I guess the next question would be how do you determine that an Internet pharmacy site provides the information consumers need? I mean, how do you tell, you know?

Mr. CATIZONE. There are a couple of different things we do. As part of our onsite inspection we look at all of their software programs for detecting adverse drug reactions, interactions, contraindications. We also check all of their procedures on how they adhere to the various State laws, and then independently, using covert Web names, we go then and search those sites and ask for information back from those Web sites, time how long it takes for the information to come, test their 1–800 numbers, and test their reaction to patient problems with medications the site may have sent to them, document that, review all that, and then set standards for those sites to meet.

Mr. TOWNS. OK. If you find that they're actually violating VIPPS program guidelines, you know, what do you do in a case like that?

Mr. CATIZONE. If they are violating our guidelines they are probably violating State laws, so we'll do one of two things. One, we'll notify the States in which they are operating that the you're probably violating their laws. Second, we'll move to withdraw their certification immediately from that site.

Mr. TOWNS. All right. Thank you very much.

Thank you, Mr. Chairman, for allowing me to ask additional questions.

Chairman TOM DAVIS. Thank you very much.

Again, I want to thank the panel. Is there anything else anyone wants to add?

Mr. BLUMENTHAL. Mr. Chairman, I might just respond to a point that you made which I don't think has been made by anyone else on the panel relating to the dangers of some of these Web sites going beyond adulteration or inappropriate or mis-dosed drugs. There are also very significant dangers of addiction and abuse of drugs as a result of these Web sites. The kinds of availability of, for example, very powerful pain killers, hydrocodones, opiates that are, in effect, given out not only affordably but abusively through a number of these Web sites is a major problem, and so I think addiction is a major part of the problem.

Chairman TOM DAVIS. Once you really take the physician out of the equation, a lot of bad things can happen on this.

Mr. BLUMENTHAL. Exactly. Thank you.

Chairman TOM DAVIS. Well, thank you very much. I want to again thank you for your testimony today. It was an outstanding panel. I'd like to thank the committee staff that worked on this hearing and thank Mr. Waxman for calling this issue to the committee's attention.

The hearing is now adjourned.

[Whereupon, at 12:30 p.m., the committee was adjourned, to reconvene at the call of the Chair.]

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