DRUGSTORES ON THE NET: THE BENEFITS AND RISKS OF ON-LINE PHARMACIES

HEARING

BEFORE THE

SUBCOMMITTEE ON
OVERSIGHT AND INVESTIGATIONS

OF THE

COMMITTEE ON COMMERCE
HOUSE OF REPRESENTATIVES

ONE HUNDRED SIXTH CONGRESS

FIRST SESSION

JULY 30, 1999

Serial No. 106–51

Printed for the use of the Committee on Commerce

U.S. GOVERNMENT PRINTING OFFICE
58–498CC WASHINGTON : 1999

COMMITTEE ON COMMERCE

TOM BLILEY, Virginia, *Chairman*

W.J. "BILLY" TAUZIN, Louisiana
MICHAEL G. OXLEY, Ohio
MICHAEL BILIRAKIS, Florida
JOE BARTON, Texas
FRED UPTON, Michigan
CLIFF STEARNS, Florida
PAUL E. GILLMOR, Ohio
Vice Chairman
JAMES C. GREENWOOD, Pennsylvania
CHRISTOPHER COX, California
NATHAN DEAL, Georgia
STEVE LARGENT, Oklahoma
RICHARD BURR, North Carolina
BRIAN P. BILBRAY, California
ED WHITFIELD, Kentucky
GREG GANSKE, Iowa
CHARLIE NORWOOD, Georgia
TOM A. COBURN, Oklahoma
RICK LAZIO, New York
BARBARA CUBIN, Wyoming
JAMES E. ROGAN, California
JOHN SHIMKUS, Illinois
HEATHER WILSON, New Mexico
JOHN B. SHADEGG, Arizona
CHARLES W. "CHIP" PICKERING, Mississippi
VITO FOSSELLA, New York
ROY BLUNT, Missouri
ED BRYANT, Tennessee
ROBERT L. EHRLICH, Jr., Maryland

JOHN D. DINGELL, Michigan
HENRY A. WAXMAN, California
EDWARD J. MARKEY, Massachusetts
RALPH M. HALL, Texas
RICK BOUCHER, Virginia
EDOLPHUS TOWNS, New York
FRANK PALLONE, Jr., New Jersey
SHERROD BROWN, Ohio
BART GORDON, Tennessee
PETER DEUTSCH, Florida
BOBBY L. RUSH, Illinois
ANNA G. ESHOO, California
RON KLINK, Pennsylvania
BART STUPAK, Michigan
ELIOT L. ENGEL, New York
THOMAS C. SAWYER, Ohio
ALBERT R. WYNN, Maryland
GENE GREEN, Texas
KAREN McCARTHY, Missouri
TED STRICKLAND, Ohio
DIANA DeGETTE, Colorado
THOMAS M. BARRETT, Wisconsin
BILL LUTHER, Minnesota
LOIS CAPPS, California

JAMES E. DERDERIAN, *Chief of Staff*
JAMES D. BARNETTE, *General Counsel*
REID P.F. STUNTZ, *Minority Staff Director and Chief Counsel*

SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS

FRED UPTON, Michigan, *Chairman*

JOE BARTON, Texas
CHRISTOPHER COX, California
RICHARD BURR, North Carolina
Vice Chairman
BRIAN P. BILBRAY, California
ED WHITFIELD, Kentucky
GREG GANSKE, Iowa
ROY BLUNT, Missouri
ED BRYANT, Tennessee
TOM BLILEY, Virginia, (Ex Officio)

RON KLINK, Pennsylvania
HENRY A. WAXMAN, California
BART STUPAK, Michigan
GENE GREEN, Texas
KAREN McCARTHY, Missouri
TED STRICKLAND, Ohio
DIANA DeGETTE, Colorado
JOHN D. DINGELL, Michigan, (Ex Officio)

CONTENTS

Page

Testimony of:

Abromowitz, Herman I., Member, Board of Trustees, American Medical Association 251

Behrens, Christine, WWMT 16

Bernstein, Jodie, Director, Bureau of Consumer Protection, Federal Trade Commission 44

Catizone, Carmen A., Executive Director, National Association of Board Pharmacies 246

Culmo, Cynthia T., Director, Division of Drugs and Medical Devices, Texas Department of Health 260

Egan, Kathy, NBC10/WCAU Philadelphia 14

Fong, Ivan K., Deputy Associate Attorney General, Department of Justice 87

Michel, Bob 17

Neupert, Peter, President and CEO, Drugstore.com 269

Razzouk, William, Chief Executive Officer, PlanetRx.com 265

Stovall, Hon. Carla J., Attorney General, State of Kansas 18

Woodcock, Janet, Director, Center for Drug Evaluation and Research, Food and Drug Administration 93

Yui, Ellen 9

Material submitted for the record by:

Kocot, S. Lawrence, Senior Vice President, Government Affairs and General Counsel, National Association of Chain Drug Stores, prepared statement of 283

DRUGSTORES ON THE NET: THE BENEFITS AND RISKS OF ON-LINE PHARMACIES

FRIDAY, JULY 30, 1999

HOUSE OF REPRESENTATIVES,
COMMITTEE ON COMMERCE,
SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS,
Washington, DC.

The subcommittee met, pursuant to notice, at 9 a.m., in room 2123, Rayburn House Office Building, Hon. Fred Upton (chairman) presiding.

Members present: Representatives Upton, Bilbray, Whitfield, Blunt, Bryant, Bliley (ex officio), Klink, Stupak, Green, McCarthy, and DeGette.

Also present: Representative Brady.

Staff present: Lori Wall, majority counsel; Amy Davidge, legislative clerk; and Chris Knauer, minority professional staff.

Mr. UPTON. Good morning.

Before we begin this hearing this morning, I want to remind witnesses that are testifying here today that the committee expects to receive testimony 2 days prior to the hearing. The purpose of this rule is so that members and their staffs have time to adequately review the statement and are able to educate themselves on the testimony that they will be giving at the hearing as well as prepare questions.

I would note that, with the exception of one witness, every piece of testimony was late. In fact, the testimony from the FDA was not received until after 8 o'clock last night, and that is unacceptable.

This committee noticed the hearing more than 2 weeks prior to this date and provided ample time for invited witnesses to provide testimony. Ironically, those witnesses who were notified last were the first ones to have their testimony submitted to the committee, and in the future I would ask all of you to extend the courtesy of having your testimony at least 2 days prior to the hearing.

I would also note for the record that last night we had votes after midnight. There are a number of subcommittees that are already meeting this morning and so we expect members to straggle in over the next couple of hours. And I would note for the record that all members, by unanimous consent, will have their opening statement made as part of the record.

Today, this subcommittee is holding the first hearing in the history of the Congress on the issue of on-line pharmacies. Several years ago, no one would have even known what the term meant, sort of like Y2K. Today, technology allows us to order everything from daily prescription medication to contact eye solution to Q-Tips

from one Web site over the Internet, have it delivered to our door promptly and often at a lower price than the neighborhood drugstore. Clearly, electronic commerce is growing at a rapid pace across the country and across the world.

With this growth in electronic commerce, we also need a dose of caution. The Internet can often pose dangers to consumers who are not able to distinguish legitimate Web sites from those that may be violating the law. Many Web sites today allow consumers to order prescription medication, often without ever seeing a doctor face-to-face and sometimes even without a valid prescription. Among the concerns is the product quality of these drugs and whether patients may be at risk of serious and even fatal drug reactions due to lack of oversight from a physician.

Since this committee began its investigation of on-line pharmacies over 7 months ago, the number of Web sites selling pharmaceuticals has increased rapidly. Estimates are that there are some 400 Web sites on the Internet today selling instant prescriptions. Some of these sites operate for a short period of time at one Web site address before disappearing and showing up under another name, making it difficult for anyone to track them down. Others prey upon Y2K fears of consumers. These sites advertize that in order to make sure the consumer has enough medication at the turn of the century they should order their pharmaceuticals from a particular Web site, often at a higher price than the consumer would otherwise pay.

As part of our investigation, we have met with Federal regulators, State medical and pharmacy boards, health care associations and a host of other interested parties. Like these organizations, our first and foremost interest has been the public health care concern arising from unscrupulous Web sites selling products without a valid prescription or situations where the customary physician-patient relationship simply does not exist.

In my home district of Kalamazoo, Michigan, Channel 3 News was able to order Viagra for a cat, dog, a deceased individual and a man with a heart condition. I would note that the cat's name was Tom, and they even admitted that he had been neutered. The ease at which these transactions happened was more than alarming. These unscrupulous sites pose a threat to the health and safety of the American public and certainly undermine the public's confidence in legitimate on-line pharmacies.

Our hearing today is an attempt to discover the jurisdictional lines that exist dividing State responsibility with that of the Federal Government. As many here well know, the issue of licensing pharmacies and doctors lies within the States. Other issues, such as dispensing without a prescription at all, lie within the FDA. Clearly, in order for us to begin to solve some of the problems associated with on-line pharmacies, we must all work together. The Internet poses new challenges that did not exist certainly 10 years ago. Technology is outpacing our abilities to react in many instances.

This is not to say that we have had no success. Some States and even some Federal agencies have had limited success in enforcing the laws currently on the books. We need to make sure that these enforcement actions against unscrupulous sites continue.

Just as we need a dose of caution in dealing with the growth of on-line pharmacy, we also need a dose of caution in responding to abuses of it. We will hear today of the positive ways in which this technology is serving the needs and pocketbooks of consumers. We don't want to inadvertently strangle the further growth of this technology in an effort to prevent its abuse by some. It is a double-edged sword.

It is my understanding that an interagency working group has been established to look at how best to prevent the misuse of this technology most effectively. I think that is an appropriate first step. I would like to see this effort intensified and broadened to include the States and other parties which have responsibility under current law for the regulation of pharmacy and interstate commerce.

I will continue to be vigilant in looking at this issue and am committed to holding additional hearings. I would like to thank all of the witnesses who are here today, especially Christine Behrens from WWMT-News 3 in Kalamazoo; and I welcome the ranking member of the subcommittee, Mr. Klink from Pennsylvania.

Mr. KLINK. Thank you, Chairman Upton, for having this hearing and really thank you for your cooperation and the majority's cooperation in working so closely with us in the minority on what I think is probably one of the most important issues that we will take on this year. The ramifications are just unbelievable.

Without a doubt, the promise and the potential of the benefit of on-line pharmacies are very dramatic. The ability to prescribe a wide range of medications without the need to wait in long lines or to discuss one's ailments in public are significant. So, too, is some of the health information being dispensed by certain legitimate sites, but with these benefits come some significant risks. Presently, any U.S. Citizen can logon to the Internet and purchase almost any prescription drug and often without a prescription or providing only minimal information.

Mr. Chairman, the sale of potentially dangerous drugs and the potential volume of such activity is not trivial. At last glance, our subcommittee staff has identified nearly 200 sites. You can look at them. Many of these sites operate from abroad, and they sell everything from extremely addictive pain killers to steroids. The National Association of Boards of Pharmacy has identified perhaps as many as 400 sites, and such lists grow longer each day. We have identified another 30 or so sites each week that we have looked.

Many sites, both domestic and international, are able to sell to U.S. Consumers with no scrutiny at all. I am extremely troubled by the vacuum of regulatory oversight that now exists at both the State and Federal level, particularly given the endless laundry list of drugs that are now available.

Today we are going to hear from the many regulators, including officials from the Food and Drug Administration, the Federal Trade Commission, the Department of Justice and from several States. They will tell us what they are doing, and they will say that they are doing bold and magnificent things in overseeing the explosion of Internet pharmacies. They also will try to convince us that they have a framework in place to diligently address this matter.

But I want to tell you something. So far, I am not convinced that either the States or the Federal Government is even close to getting a handle on this problem. The States seem overwhelmed and indeed in need of resources, while the Federal Government is still trying to determine which agency or which department is in charge; and, meanwhile, these sites are proliferating.

Alarmingly, no Federal or State agency has so far been able to provide this subcommittee with the most basic of information regarding the bulk of the pharmacy sites now operating on-line. For example, we still don't know the physical location of most of these sites or even if they operate with a U.S. State-issued license. We also know very little about the persons behind such sites or whether they hold all the appropriate license for the State in which they are doing business.

There are other concerns. For example, are such practitioners in good standing with the State boards of pharmacy or medicine from which they hold credentials? How would we know? These are simple questions that should be answerable in a matter of minutes, and they can be for the average brick and mortar pharmacy located in your neighborhood. Yet because we are so awed by e-commerce we tolerate a system that discloses almost no information to the consumer or to the regulator.

Now, I appreciate the sensitivity of using the words rules and e-commerce both in the same sentence. But I will tell you, Mr. Chairman, I am concerned that a wild-west world is unfolding before us, where many consumers are accessing potentially dangerous drugs with little or no practical guidance. Yet because it is e-commerce there is a mentality it must be progress.

But is it progress if a 6- or 7-year-old child can purchase a prescription drug over the Internet and have it delivered to her door with no questions asked? Is it progress if people posing as cats or dead people are able to get drugs that they ordered, even though they disclosed that information on-line with their consultations? And is it progress if a person that discloses that they are taking a drug that would produce severe interactions with the other drugs that they are taking that they receive that drug anyway with no questions asked? That is not progress. That is greed, and it is sloppy public policy.

My constituents and, frankly, all of the citizens of this great Nation deserve the same level of protection with on-line sites that they have with their corner drugstore, nothing more, nothing less.

Mr. Chairman, under the present regulatory system, getting a drug to market is an extremely rigorous process. This subcommittee has dealt with it. It takes years of trials and review before a drug is approved. If approved, a host of State and Federal licensing requirements exist over the manufacturer and the doctors and the pharmacists that issue and fill the prescriptions. This system is designed to protect consumers from addiction, drug interactions and the use of unapproved or dangerous substances. Yet, in many cases with just a click of the mouse, we now have managed to turn this entire system upside down and inside out. What is it about e-commerce that permits us to tolerate a system with almost no rules when the stakes are so high? Indeed, the stakes are life and death.

Mr. Chairman, just what protection should a consumer have when purchasing potentially dangerous drugs from the Internet? Presently, there is nothing that requires a drug-dispensing Web site to disclose anything to the public. Buyers usually don't know if a site is licensed or if the site uses licensed doctors or pharmacists. In many cases, the buyers don't even know the physical address of the site or if it has ever been inspected. That is because, under the current laws, elevators, escalators and hair stylists are required to display more licensing information than Web sites that are selling potentially lethal drugs.

Let me conclude by saying that because so many sites appear to be operated in this unregulated gray zone and report to almost no one, the true quality and source of these drugs might be viewed with caution. Counterfeit and expired drugs can be repackaged and sold as new, and the public may never know they are at risk. And I, frankly, would like to know the sources of many of these drugs as well as their quality.

Further, I would be interested to hear from the makers of Xenical, Propecia and Viagra, just to name a few, but these are three of the drugs that are most prevalent on these sites. I want to know about how they think their products are getting into the market through e-commerce. How have they penetrated this stream of commerce? Are they legitimate and thus being diverted or are these counterfeit products? What do the manufacturers know?

Like the many Federal agencies that are being asked to explain their actions in this area, perhaps the drug makers should be invited, Mr. Chairman, to one of our next hearings. They may have some of their own accountability issues.

I thank you for your patience, and with that I yield back my time.

Mr. UPTON. Thank you.

The gentleman from Tennessee, Mr. Bryant.

Mr. BRYANT. Thank you, Mr. Chairman. I do appreciate your holding this hearing today and would especially like to welcome Mr. William Razzouk of PlanetRx.com. As you may know, Mr. Chairman, Memphis, Tennessee, is the distribution center of the Nation, and we are proud to welcome PlanetRx.com's pharmacy to our State of Tennessee.

Mr. Chairman, first, do no harm is sage advice for and from our medical community. The Internet offers a vast opportunity for consumers and businessmen alike. This new and seemingly limitless resource provides everyone who can click their index finger with access to a wealth of information, instant communication and the convenience for shopping for goods and services from the comfort of their own home. But for all the Internet does now I think it is safe to say that it is still in its infancy and, as such, it is very susceptible to the actions or perhaps even inactions of government, both State and Federal.

I feel very strongly that government, both Congress and this administration, must tread carefully, though, that we ensure not to hurt the delicate new business opportunities that are available on the Internet. At the same time, however, e-commerce can only continue to grow if consumers feel secure about shopping on the Inter-

net, and I think the two speakers that have given very excellent statements before me have indicated the potential for problems out there. Businesses such PlanetRx.com and Drugstore.com have invested significant resources in building a solid reputation with their customers, but this reputation can be tarnished by the unscrupulous Web sites offering consumers the chance to purchase medications without a prescription.

Mr. Chairman, this is an important hearing because I think it will help show us what the role of government should or perhaps should not be with respect to e-commerce, and I am looking forward to hearing from our distinguished witnesses, and I thank the Chair.

Mr. UPTON. Thank you.

The gentleman from California, Mr. Bilbray.

Mr. BILBRAY. Thank you, Mr. Chairman.

Mr. Chairman, I have reviewed some of the written testimony, but I would ask my colleagues to reserve our conclusions until we hear from the witnesses, are able to dialog with the witnesses and develop some kind of consensus.

There has been a reference of the fact that e-com is actually maybe turning into the wild west. Well, let me tell you, as a Californian, that is not necessarily a negative thing. I want to say, though, that there is going to be problems. I think that we have problems. I think we have problems not only with pharmaceutical drugs but I think we have problems with consumer products across the board, including the sale of alcohol over the e-com. But I think that we should approach this as saying that e-com is a great challenge, but it is a great opportunity.

You know, one of the major clashes that this country had with Great Britain before we broke away was the fact that Great Britain figured that it was easier not to allow any settlers to move into the wild west, that we should outlaw them and keep them east of the Alleghenies, and that would have been easier for government to restrict the individual's ability to move to the west and get into trouble. I think that we do have troubles in the wild west, and I think that we need to address them. But I hope that as we approach this that the issue with the challenge of Congress, the challenge of government and the challenge of the community at large is to work out the problems, maintain this great opportunity for individuals, for economic and social progress but at the same time avoid the potential for gross abuse of a new technology.

And so I look forward to finding those answers, a way to be able to tap into the good of the e-com and avoid the bad.

So, Mr. Chairman, I look forward to this testimony and yield back my time.

Mr. UPTON. Thank you.

[Additional statements submitted for the record follow:]

PREPARED STATEMENT OF HON. TOM BLILEY, CHAIRMAN, COMMITTEE ON COMMERCE

Today, this committee continues the work it began last year, examining various aspects of doing business on the Internet—known as e-commerce.

I have been a strong advocate and promoter of the consumer benefits of electronic commerce. This marketplace grows by leaps and bounds every month, revolutionizing the way America and the world conduct business.

As e-commerce continues its extraordinary growth, it can greatly improve the lives of ordinary Americans. This is especially true when it comes to the delivery of necessary prescription medication. Millions of Americans are dependent on prescription medication. On-line pharmacies have the potential to increase access and lower the cost of prescription drugs for millions of Americans.

In an age in which the words "time deficit" have entered the popular vocabulary, the ability to have necessary prescriptions delivered to the front door by overnight delivery, and at a real cost savings, is a tremendous convenience for time-pressed working families.

For the disabled and for the millions of senior citizens who have difficulty getting around, this new marketplace has the potential to drastically improve their access to medications, and thus their quality of life.

However, we must not be blind to the vast potential of the Internet to attract unscrupulous operators, who set up sites to sell their wares, without the best interest or safety of consumers in mind. Many web sites are offering prescription drugs prescribed by an unseen on-line doctor or without even a prescription. Many of these sites give no indication of their location or the individuals operating it, raising concerns about the legitimacy of the web site. Because of their slick packaging, many of these sites fool consumers into believing that they are legitimate providers, when in fact they are unlicensed to dispense drugs or do so in ways that violate state or federal laws.

I want to stamp out these bad actors. We need to encourage strong enforcement action by the States and the Federal government of the laws already on the books. Some states, such as Kansas, take action against on-line pharmacies and web doctors who have violated the laws of their respective states. Several other States are beginning to follow the lead of Kansas to shut down these sites. We applaud their efforts.

Additionally, I believe that the Federal and State governments must work together to address illegal or unscrupulous practices by on-line pharmacies. I suggest the establishment of a joint Federal-State task force to examine whether current laws and regulations are adequate to protect purchasers of drugs on the Internet—and if not to recommend changes to those laws.

At the same time, it is important that we do not over react by piling layers of new regulations on to an emerging marketplace—one that provides great benefits to consumers. I am excited about the promise this new marketplace brings to working families, the disabled, and senior citizens across the country. Let's continue our oversight of this new marketplace, to ensure that its promise is fulfilled in a way that also protects on-line purchasers. I would like to thank all of our witnesses for joining us here today.

PREPARED STATEMENT OF HON. BART STUPAK, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF MICHIGAN

Thank you Mr. Chairman. I applaud you for holding this very important hearing today.

With the explosion of internet commerce over the past several years, we have realized a significant change in the way business is conducted. It seems that every day there is a new internet business coming on-line or going public on the stock market. There are 10,000 new internet domain names being registered *each day*. Many of the new domains belong to well established businesses who are making the transition to E-commerce. Others are being assigned to speculative upstart businesses who hope to take advantage of this fantastic and relatively new medium of commerce. Still others are starting up questionable businesses with little regard for the health, safety, or welfare of the internet consumer. Mr. Chairman, it is those unscrupulous businesses that concern me greatly.

In preparation for this hearing I took the time to surf many of the websites which provide drugs over the internet. In very few instances was it clear that companies took reasonable and necessary safeguards when filling prescriptions over the internet. Sites such as Drugstore.com and PlanetRX.com appear to be among the sites that provide such safeguards. I applaud their efforts to supply safe, physician prescribed pharmaceuticals.

Unfortunately, there are countless other sites that are peddling drugs with very little, if any, verification of prescription or health needs. On many of the sites I found that there is no way to tell whether the site is operated by legitimate licensed pharmacists or if there is even a medical doctor who reviews the application for the drugs. I could not tell where the supplier, or website operator, was located. Are they located in the United States/Europe/Asia/the Middle East? Are they receiving their

drugs directly from the manufacturer or a licensed wholesaler? Are the drugs you're ordering truly of the purity and potency that you need or even actually the drug that you thought you ordered? If not, what is the consumer's recourse with no address, phone number or identification for follow-up questions, let alone follow-up monitoring based on drugs provided to you? These are just a few of the questions that I have and I am sure today's hearing will raise many more.

When I go to my local neighborhood pharmacy to have a prescription filled, I walk in and have a face-to-face conversation with the pharmacist. That pharmacist is required by the State of Michigan to abide by many regulations in order to operate his or her business. They must have completed the requisite education in order to dispense the prescription drugs, the pharmacy must be licensed, and they purchase the medications from licensed, reputable and accountable wholesalers and manufacturers. In order to receive my medication, I must present a prescription from my doctor. Before filling the prescription, the pharmacist will check to ensure that the medication I'm receiving will not cause a harmful or deadly reaction with other prescription drugs that I may be taking.

Why then, do we not have these same precautions for internet businesses acting as pharmacies? Why do these web sites not have to disclose where they are doing business from or give a number to call for questions let alone for an emergency, should there be a problem. Why do they not have to post who the doctor is who is reviewing the request that is being sent in? And why do these sites not have to list the states or countries that they are licensed in? I have had the opportunity to review some of the written testimony and it appears that the FTC and Ms. Culmo of the Texas Department of Health have expressed many similar concerns and I look forward to their testimony today.

Lastly, I am concerned about the issue of privacy for those who may choose to purchase prescription drugs over the internet. If a person decides to purchase prescription medication via an internet pharmacy, what provisions do we have in place that would prohibit the internet drugstore from selling information about you and your health records or financial transactions to other businesses? Will your medical history now become the newest item for sale on the internet so you can be spammed? If you order viagra from one of these unregulated businesses will this personal information suddenly be sold to other net businesses who want to peddle you products or services associated with the prescriptions.

Mr. Chairman, I look forward to hearing answers to the questions I've outlined here this morning. This is not merely an issue of E-commerce, it is a matter of public health and individual privacy.

Mr. UPTON. I have been alerted a number of members are on their way down, but I think in the meantime we will ask the witnesses for the first panel to take their place at the table. Ms. Ellen Yui; Ms. Kathy Egan from NBC10/WCAU in Philadelphia; Ms. Christine Behrens, WWMT and Channel 3, Kalamazoo; Mr. Bob Michel; and the Honorable Carla Stovall, Attorney General from the State of Kansas, if you would take a place at the table.

As you may know, this subcommittee has a long tradition of taking testimony under oath. There is a vote on, but I think I will swear you in at this point, and then I think we will take a break. And if members could come back promptly after this vote, we will continue with the testimony when I get back.

We have a long tradition of taking testimony under oath. Do any of you have objection to that? We also, under House rules, allow you to have counsel if you would like. Do any of you desire counsel?

If you would stand and raise your right hand.

[Witnesses sworn.]

Mr. UPTON. You are now under oath, and we will take a brief adjournment for us to go vote, and we will return with your testimony in about 10 minutes.

[Brief recess.]

Mr. UPTON. We will reconvene.

The good news is we are going to have only one more vote that will interrupt us today, in all likelihood, and that won't be for a couple of hours so we can get into this in earnest.

Okay. You have been sworn in. I was with Mr. Klink. He should be back within a minute or 2. So I think we can get started with your testimony.

We will start with Ms. Yui. Did I say that right?

Ms. YUI. Yes.

Mr. UPTON. Welcome to the subcommittee.

Let me just make a point for all witnesses. We would like, if you can, to limit your remarks to about 5 minutes. I have a little timer that is here that is pretty fancy. You will see these lights go on and off.

I guess it is not a pretty neat timer. It doesn't work. We will watch the clock, I guess. We need two light bulbs, but if you limit your remarks to 5 minutes, that will be perfect.

Your entire statement, obviously, will be made part of the record. Please go ahead.

TESTIMONY OF ELLEN YUI; BOB MICHEL; KATHY EGAN, NBC10/WCAU PHILADELPHIA; CHRISTINE BEHRENS, WWMT; AND HON. CARLA J. STOVALL, ATTORNEY GENERAL, STATE OF KANSAS

Ms. YUI. Mr. Chairman, thank you for inviting me here today to testify about the benefits of drugstore shopping on-line.

I am very familiar with the world of e-commerce because I spend a good part of my day in front of the computer, and it is that personal computer that has afforded me the opportunity to run a small business from my house, enabling me to continue my career as a communications consultant, earn money, and be near my two boys, all at the same time. My husband also runs his own business, which would not be possible without the Internet. We conduct our banking on-line and purchase personal computers, software, books, CDs, plane tickets, even great cheese from France, on-line.

With that in mind, I wish to talk to you today about three thoughts that come to mind when I think of on-line pharmacies: convenience; privacy, which has a double meaning here; and cost.

Time, or the lack of it, is the overriding theme of my life. I actively seek services and products that will save me time, make me more efficient, educate me and, of course, save money for those looming college tuitions.

Permit me to take a minute and describe for you my typical day as a working mom, and you will understand why.

When I wake up at 6 o'clock in the morning a clock watch—a stopwatch clicks on in my brain, and I start running from one juggling act to another. I try to get out of bed before my family to walk my two dogs. This is not always possible because my husband travels 3 to 4 days a week, basically making me a single mom much of the time. I get myself dressed, my kids dressed, feed everybody breakfast, get the kids off to school and then race back to my desk at home before the phone starts ringing. I work all day.

If I am lucky, I can squeeze in a personal errand, such as running to the supermarket, the dry cleaners, car wash, maybe volunteer at my children's school, but getting away from my desk seems

to be more and more problematic. At 5 o'clock, my wonderful child care provider goes home; and it's another dog walk, homework, dinner, baths, reading to the boys, sometimes a little more work or bills, and then I collapse. You could poll 1,000 working moms across this country, and I would venture to guess you would hear 1,000 similar renditions of that story.

Juggling all of this leaves me almost no time for shopping, any kind of shopping. I am almost embarrassed to admit how often I run out of basic supplies at home. So the opportunity to purchase cough syrup, ibuprofen, Band-Aids, tissues, vitamins, hair spray or my favorite nail polish, without long lines, crowded aisles, slow cashiers and parking hassles is a dream come true. For me it's a luxury that translates into 1 more hour of quality time with my kids. And dragging them to stores is not pleasant for the kids, for me or for anybody in that store.

But also important to me is the good health care information that is provided on these sites. I am very skeptical of any drug, prescribed or over-the-counter, and I am always a bit nervous about their possible side effects, particularly in my children's small bodies. I was thrilled to discover the wealth of information that I can access on-line.

In my family, we do require some regular medication; and on-line pharmacies can take my order and payment in minutes, deliver the prescription directly to my home and even send me a reminder e-mail that it's time to refill my prescription. Now, for me, that's a Godsend.

For years, I purchased prescription drugs from our local family pharmacy conveniently located in my doctor's building; and, frankly, he is who I want to do business with. I am a small business owner. I support small businesses. But, unfortunately, he's nearing retirement age, he's scaling back and he's not as convenient anymore. To my chagrin, the age of personal service at pharmacies has passed. Because of many negative experiences I've had with impersonal service and multiple incorrectly filled prescriptions at major chain pharmacies, I don't believe I am missing out on customer service by buying on-line.

In fact, today's drug counters don't offer an opportunity for a private discussion between a pharmacist and a consumer. You can picture what I mean. You're down on the floor, you're looking up at the pharmacist and often shouting questions, letting the whole world know that your kids have caught something at school, like whooping cough, head lice or something else you don't want to share with the world.

With some on-line pharmacies, I can even e-mail questions directly to a pharmacist in the privacy of my own home 24 hours a day, 7 days a week. Now, that's a service and a convenience I need in my life.

That's not to say I don't have quite a few reservations, and here's the flip side of the privacy issue. I'm always cautious about on-line purchases and sometimes worry that I might expose myself to financial fraud or that a company will sell my name and data about my buying purchase patterns to another firm. And of course, as a mother, I hope Congress can find a way to prevent children from buying inappropriate or illegal drugs over the Internet.

I am also making the assumption, perhaps naive, that I am just as protected on-line as I am protected at any major chain pharmacy. I know that protecting consumers is a daunting task for Congress, the FDA and other regulatory bodies.

Finally, cost. On-line pharmacies can offer products at reduced cost. As they become more accepted by consumers and health plans, their ability to offer products at competitive prices will increase, and that is good news for consumers, not to mention that more time for my family is priceless.

Thank you very much, and I'd be happy to answer any questions.

[The prepared statement of Ellen Yui follows:]

PREPARED STATEMENT OF ELLEN YUI

Mr. Chairman, thank you for inviting me here today to testify about the benefits of drugstore shopping online.

I am very familiar with the world of e-commerce because I spend a good part of every day in front of a computer. And, it is that personal computer that has afforded me the opportunity to run a small business from my house, enabling me to continue my career as a communications consultant, earn money, and be near my two boys, all at the same time. My husband also runs his own business, which would not be possible without the Internet. We conduct our banking on-line, and purchase personal computers, software, books, CDs, plane tickets, even great cheese from France, on-line.

With that in mind, I wish to talk to you today about three thoughts that come to mind when I think of on-line pharmacies: convenience; privacy—which has a double meaning here; and cost.

Time, or the lack of it, is the overriding theme of my life. I actively seek services and products that will save me time, make me more efficient, educate me, and of course save money for those looming college tuitions.

Permit me to take a minute and describe for you my "typical day as a working mom," and you'll understand why. When I wake up at 6:00 am, a stopwatch is clicked on in my brain, and I start running from one juggling act to another. I try to get out of bed before my family and walk my two dogs. This is not always possible, as my husband travels three to four days a week, basically making me a single mom much of the time. I get myself and my kids dressed, feed everybody breakfast, get the kids off to school, and then race back to my desk at home before the phone starts ringing. I work all day.

If I'm lucky, I can squeeze in a personal errand, such as running to the supermarket, the dry cleaners, car wash, maybe volunteer at my children's school, but getting away from my desk seems to be more and more problematic. At 5:00, my wonderful childcare provider goes home, and it's another dog walk, then homework, dinner, baths, reading to the boys, sometimes a little more work or bills, and then I collapse. You could poll 1,000 working moms across this country, and I would venture to guess you'd hear 1,000 very similar renditions of that story.

Juggling all of this leaves me almost no time for shopping, *any* kind of shopping. I am almost embarrassed to admit how often I run out of basic supplies at home. So, the opportunity to purchase cough syrup, ibuprofen, Band-Aids, tissues, vitamins, hairspray, or my favorite shade of nail polish—without long lines, crowded aisles, slow cashiers, and parking hassles—is a dream come true. For me, it's a luxury that translates into one more hour of quality time with my kids. And dragging them to stores is not pleasant for the kids, for me, or for anybody in that store.

But also important to me is the good healthcare information that is provided on these sites. I am very skeptical of any drug—prescribed or over-the-counter—and am always a bit nervous about their possible side effects, particularly in my children's small bodies. I was thrilled to discover the wealth of detailed information available about prescription drugs through on-line pharmacies.

In my family, we require some regular medication. On-line pharmacies will take my order and payment in minutes, deliver the prescription directly to my home, and even send me a reminder email that it's time to refill the prescription, now that's a Godsend.

For years, I purchased prescription drugs from our local family pharmacy, conveniently located in the same building as our doctors' offices. And as a small business owner, I go out of my way to support small businesses. Unfortunately, now that our pharmacist is nearing retirement age and cutting back his hours, he's not as con-

venient anymore. To my chagrin, the age of personal service at pharmacies has passed. Because of negative experiences I have had with impersonal service and multiple incorrectly filled prescriptions at major chain pharmacies, I do not believe I am missing out on customer service by buying on-line.

In fact, today's drug counters do not offer an opportunity for a private discussion between customers and the on-duty pharmacist. You can picture what I mean. You are down on the floor, looking up at the pharmacist and often shouting questions, letting the whole world know that your kids caught something from school, like whooping cough, or head lice, or something else that you don't really want to share.

With some on-line pharmacies, I can even email questions directly to a pharmacist in the privacy of my home 24-hours, 7 days a week. Now that's service, and a convenience I need in my life.

This is not to say I don't have reservations, and here's the flipside of the privacy issue. I am always cautious about on-line purchases and sometimes worry that I might expose myself to financial fraud, or that a company will sell my name and data on my buying habits to another firm. And of course, as a mother, I hope Congress can find a way to prevent children from buying inappropriate or illegal drugs over the Internet.

Finally, cost. On-line pharmacies can offer products at reduced cost. As they become more accepted by consumers and health plans, their ability to offer products at competitive prices will increase. And that is good news for consumer—not to mention that more time for my family is priceless.

Again, thank you for inviting me here today. Now I would love to answer any of your questions, so fire away.

Mr. UPTON. Maybe we should operate with the lights not on in the future. It worked pretty well.

Mr. Michel.

TESTIMONY OF BOB MICHEL

Mr. MICHEL. Good morning. My name is Bob Michel.

Mr. UPTON. If you could put the mike a little built closer, that would be terrific. It moves.

Mr. MICHEL. Will that work?

Mr. UPTON. Better. No, no, just keep moving it a little closer.

Mr. MICHEL. All right. Can you hear me now? Is it on or off? Can you hear me, sir?

Good morning. My name is Bob Michel. Chairman Upton and members of the Commerce Subcommittee on Oversight and Investigations, thank you for the opportunity to appear before you today to testify on the importance and value of reputable Internet drugstores to senior citizens.

On-line pharmacies provide senior citizens a source of low-cost, easily available pharmaceutical products literally at their fingertips.

I am 65 years old, semi-retired. I do management consulting work for a number of companies, and I am an active member of the Seniors Coalition, a 3 million member organization that supports legislation aimed at protecting the best interests of seniors in our country.

I come before you today representing myself as an advocate for all senior citizens. It's been widely reported that seniors are the fastest growing segment of Internet users today. A survey last year by the Nielsen Media Research and CommerceNet found that 7.6 million Internet users are 50 years or older, making up about 15 percent of the Internet-using population in the United States and Canada.

I have used the Internet for some time now, and I rely on the Internet for a number of e-commerce transactions. I understand

you're holding this hearing today to discuss the safety of on-line pharmacies. Of course, I support public safety on the Internet. If someone is circumventing the law by distributing drugs without a valid prescription, it is likely they're already breaking an existing State or Federal law. My advice is, shut them down if they are unlicensed or illegally dispensing drugs over the Internet.

However, I don't think you want to overcontrol or overregulate the on-line pharmacies who are performing a valuable, legitimate service to millions of Americans who can enjoy the convenience of turning on their computer and ordering medication that may otherwise be difficult to obtain.

I am a cancer survivor. I'm on blood pressure medication. My wife is diabetic and requires daily doses of insulin. If my wife needs to go to a doctor on one side of town and then make a trip to a pharmacy on the other, it can make for a long, stressful day.

Nowadays, my wife talks to her doctor regularly on the phone. He calls her prescription in to a local pharmacy. When we retire to the wilds, in the not-too-distant future, we intend to have her doctor and mine send our prescriptions to a legitimate, on-line pharmacy such as PlanetRx, Drugstore or Soma.com and receive the medication via mail.

On-line pharmacies offer tremendous opportunities to make life easier for seniors, many of whom are feeble or unable to navigate about very easily, by allowing them to get their prescriptions filled electronically and mailed directly to them. I think on-line pharmacies could especially be helpful to seniors who live in rural areas where getting to the local pharmacy in the middle of winter can be very taxing and at times hazardous.

Furthermore, my wife and I both love to travel, and when we do, we often carry a laptop. It would be great to be able to have our doctor write a prescription, fax it to our on-line pharmacy and then have the pharmacy deliver it to us anywhere in the world.

I am watching the legislation Congress is working on to give seniors more accessible, affordable prescription drug benefits. I hope that on-line pharmacies are factored into the mix when the final legislation is enacted.

Mr. Chairman and members of the subcommittee, I think you recognize that e-commerce is the new and exciting wave of the future. It should not be stymied by a well-intended but overzealous regulatory system. Please don't inhibit legitimate on-line pharmacies from effectively complementing or even competing with storefront pharmacies in this country.

Thank you for allowing me to express my views.

[The prepared statement of Bob Michel follows:]

PREPARED STATEMENT OF BOB MICHEL

Good morning. My name is Bob Michel.

Chairman Upton and members of Committee on Commerce Subcommittee on Oversight and Investigations, thank you for the opportunity to appear before you today to testify on the importance and value of safe Internet drugstores. Online pharmacies provide senior citizens low cost, easily available pharmaceutical products at their fingertips.

I am 65 years old and semi-retired. I do management consulting work for a number of companies. I am an active member of the Seniors Coalition, which is a 3 million-member organization that supports legislation aimed protecting the best interest of seniors in the United States.

I come before you today representing myself as an advocate for all senior citizens. It has been widely reported that senior citizens are the fastest growing element of Internet users. A survey last year by Nielsen Media Research and CommerceNet found that 7.6 million Internet users are 50 or older, making up about 15 percent of the Internet-using population in the United States and Canada.

I have used the Internet for five years now and I rely on the Internet for a number of e-commerce transactions.

I understand you are holding this hearing today to discuss the safety of online pharmacies. I support public safety on the Internet. My opinion is that if someone is breaking the law by distributing drugs without a prescription, it is likely they are already breaking an existing state and or federal law. My advice is to arrest them if they are illegally dispensing drugs over the Internet.

However I don't think you want to overcontrol or regulate the online pharmacies who are performing an valuable service to millions of Americans who can enjoy the convenience of turning on their computer and ordering medication that may otherwise take them all day to order.

I am a cancer survivor and I need to take blood pressure medication. My wife is diabetic and requires daily doses of insulin. If my wife needs to go to her doctor on one side of town and then make a trip to the pharmacy on the other side of town, it can make for a stressful day. Nowadays, my wife talks to her doctor regularly on the phone and he calls in her prescription to the pharmacy. It would be so much easier if she can have her doctor send in her prescription to a legitimate online pharmacy like PlanetRx.com or Drugstore.com. or Soma.com.

Online pharmacies are a terrific opportunity to make life easier for senior citizens by allowing them to get their prescriptions filled electronically. I would think online pharmacies could especially help senior citizens who live rural areas where getting to the local pharmacy in the middle of winter can be very taxing.

Furthermore, my wife and I both love to travel and when we do, we always carry a laptop computer. It would be great to be able to have our doctor write a prescription, fax it to our online pharmacy and then have the pharmacy deliver it to us anywhere in the world.

I am watching the legislation Congress is working on to give seniors more accessible prescription drug benefits. I hope that online pharmacies are figured into the mix when the final legislation is enacted providing low-cost prescription drugs to senior citizens.

Mr. Chairman, members of the Subcommittee on Oversight and Investigations, thank you allowing me to express my views that e-commerce is the new and exciting wave of the future and should not be stymied by a regulatory regime. Please don't try and stop legitimate online pharmacies from competing with other pharmacies in this country.

At this time, I am prepared to answer any questions you may have.

Mr. UPTON. Thank you.

Ms. Egan.

TESTIMONY OF KATHY EGAN

Ms. EGAN. Good morning. I'm Kathy Egan from NBC10 in Philadelphia. I want to thank you, Mr. Chairman and members of the subcommittee, for allowing me to appear today. We were asked to share what our investigation uncovered.

Most of us know the Internet has the potential for great things. It can educate, make life easier and be a great tool to exchange ideas. But our NBC10 investigation also revealed it can allow people access to dangerous prescription drugs without a prescription.

Our 2-month investigation shows the Internet has become the 1990's version of the wild, wild west. Anything goes. You can find a Web site that will sell you almost anything. Last year, the Internet economy generated an estimated $301 billion in U.S. Revenue, according to a University of Texas study. Many people today turn to the Internet like they used to turn to their mom and pop corner store as the place to buy things. One study estimates 56 percent of U.S. Companies will sell their products on-line by the year 2000. With consumers spending more on drugs per year than on books,

CDs and videos combined, it is easy to see why prescription drug Web sites are growing in popularity.

We had absolutely no problem finding Web site after Web site that would sell us a virtual candy store of prescription drugs like Viagra and Prozac. Worse yet, many of these sites required no prescription and very little prescreening, if any, to weed out people who don't need the drugs. In many cases, the most crucial information you need to give is your credit card number.

In researching and producing our story, it was difficult to discern who is actually regulating these Internet drug companies. We called the U.S. Food and Drug Administration, the Federal Trade Commission, U.S. Customs, the Pharmaceutical Manufacturers Association, other national pharmacy groups and the State boards of pharmacy in our tri-state area. Since we also purchased a controlled substance, we called the U.S. Drug Enforcement Agency. Virtually every agency we talked to said they were interested in the problem, but they referred us to another group or agency. What's more, one government official told us no agency is up to speed on this problem.

As you know, this is not an issue to be taken lightly. More and more people are gaining access to the Internet. One study says that seven new people get on the Internet every second. To give you an idea, that means that in the time it takes me to testify it means nearly 2,000 people have become Internet subscribers for the first time.

Once more, the group that's most Internet savvy is the younger generation, our children. They know how to surf the net, where the sites are and how to work the system.

To give you an example, recently in Philadelphia in a suburb there, teens from Conestoga High School were hospitalized after ingesting a drug ingredient purchased on the Internet. The drug DMX, dextro-meth-orphan, is the ingredient that stops the cough in cough syrup. This shows how children can get access to dangerous drugs and drug ingredients.

In our NBC10 report, we showed even a 7-year-old buying a prescription diet drug that wasn't yet approved in the United States, no questions asked. We are going to show you that in just a minute, but we also want to tell you what kinds of responses we got when we confronted some of the Internet drug companies. One company squarely put the burden on the consumer, saying people need to educate themselves on the medication they are taking. Another company just flat out denied they even sold prescription drugs to us, and we found this company didn't have a license to sell in the U.S.

In summary, some experts we've spoken to say Internet companies selling prescription drugs without prescriptions are light years ahead of the regulatory agencies, and they fear if something isn't done soon Americans may overdose, improperly use or suffer drug interactions that could injure or even kill them.

Again, thank you for letting me to testify today, and we'd like to show you an excerpt of our News 10 investigation.

[Video played.]

[The prepared statement of Kathy Egan follows:]

PREPARED STATEMENT OF KATHY EGAN, NBC/WCAU PHILADELPHIA

Thank you, Congressman Klink, and members of the subcommittee, for allowing me to appear today. We were asked to share what our NBC 10 investigation uncovered. Most of us know the Internet has the potential for great things. It can educate, make life easier, and be a great tool to exchange ideas. But our NBC10 investigation also revealed, it can allow people access to dangerous prescription drugs when they shouldn't be able to get them.

Our 2-month investigation shows the Internet has become the 1990's version of the wild, Wild West. Anything goes! You can find a website that will sell you almost anything. Last year, the Internet economy generated an estimated 301.4 Billion dollars in U.S. revenue according to a University of Texas study. Many people, today, turn to the Internet like they used to turn to their Mom and Pop corner store as the place to buy things. One study says an estimated 56 percent of U.S. companies will sell their products on-line by the year 2000. With consumers spending more on drugs per year than they do on books, CDs, and videos combined, it's easy to see why prescription drug websites are growing in popularity.

We had absolutely no problem, finding website after website, after website that would sell us a virtual candy store of powerful prescription drugs like Viagra and Prozac. Worse yet, many of these sites required very little prescreening, if any, to weed out people who don't need the drugs. In many cases, the most crucial information you need to give is your credit card number.

In researching and producing our story, it was difficult to discern WHO is actually regulating these internet drug companies. We called the U.S. Food and Drug Administration, the Federal Trade Commission, the Pharmaceutical Manufacturers Association, Other National Pharmacy groups, and the state boards of pharmacy in our tristate area. Since we also purchased a controlled substance, we called the U.S. Drug Enforcement Agency. Virtually every agency we talked said they were interested in the problem but referred us to another agency or group. What's more, one government official told us NO agency is up to speed on this problem.

As you know this isn't an issue to be taken lightly. More and more people are gaining access to the Internet. In fact, one published estimate says 7 new people get on the Internet every second. To give you an idea that means in the time it takes me to testify nearly 2,000 people have become Internet subscribers for the first time. What's more, the group that's most Internet savvy is the younger generation, our children. They know how to surf the net, where the sites are, and how to work the system.

To give you an example: Recently in a Philadelphia suburb, teens from Conestoga High School were hospitalized after ingesting a drug ingredient purchased on the Internet. The drug, dextromethorphan, is the ingredient that stops the cough in cough syrups. This shows how children can get access to dangerous drugs and drug ingredients.

In our NBC 10 report, we showed even a 7-year-old buying a prescription diet drug that wasn't approved yet in the United States. No questions asked. We'll show you that in a moment. But we also want to tell you what kind of responses we got when we confronted some of the internet drug companies. One company squarely put the burden on the consumer, saying people need to educate themselves on the medication they're taking. Another company just flat out denied they sold prescription drugs to us, and we found this company didn't have a license to sell in the U.S.

In summary, some experts we've spoken to say Internet companies selling prescription drugs are light years ahead of the regulatory agencies. And they fear if something isn't done soon, Americans may overdose, improperly use, or suffer drug interactions that could injure or even kill them.

Thank you again for the opportunity to speak to you today. Let's go ahead now and show you an excerpt of our NBC10 investigation.

Mr. UPTON. Thank you for that report.

Ms. Behrens.

TESTIMONY OF CHRISTINE BEHRENS

Ms. BEHRENS. Good morning.

My name is Christine Behrens. I am a reporter from WWMT-News 3, which is a Grand Rapids-Kalamazoo television station in Michigan.

In February of this year, we did a series of investigative reports on Internet pharmacies. The reports were entitled, Prescription for

Danger. We tested a number of Web sites that had been advertising prescriptions for the anti-impotence drug Viagra. Many of the advertisements said, "No prescription, no problem", and we found that it wasn't a problem, and I'd like to go ahead and show the tape.

[Video played.]

Ms. BEHRENS. Thank you.

Mr. UPTON. Just glad you spelled Fred with a PH.

[The prepared statement of Christine Behrens follows:]

PREPARED STATEMENT OF CHRISTINE BEHRENS, WWMT NEWS 3 REPORTER

In February of this year WWMT-News 3, a Grand Rapids-Kalamazoo, Michigan television station, did a series of investigative reports on Internet Pharmacies. The reports were titled "RX for Danger." We tested a number of web sites that had been advertising prescriptions for the anti-impotence drug Viagra.

The drug has become very popular since being introduced in the spring of 1998, perhaps one of the most popular drugs in America. But, it has also been linked to more than 120 deaths since it hit the market, most often occurring in men with heart disease. The drug carries warnings that it should not be used in conjunction with nitrate drugs, as combining the drugs could lower blood pressure to dangerous levels.

Some of the Internet pharmacies tout how easy it is to get the drug. One site (http:kwikmed.com) advertises, "No prescription, No problem?" Another site (www.medservices.com) says, "Viagra, from the privacy of your home or office. Next day delivery." We decided to find out if it really is easy to get an order filled.

All of the web sites we tested post warning signs for heart disease victims, and many on line pharmacies ask prescription buyers list a health history and medications taken as part of the application. The application, which most on-line pharmacies refer to as an "on-line consultation" costs up to $85. The News 3 probe found pharmacists or doctors who review these consultations seem to be paying little attention to what the applicant/prescription buyer types in the blanks.

In one case, we logged on to www.WorldExpressRx.com and filled out the "On line consultation," on behalf of a cat named Tom. Tom's owner, honestly filled out Tom's medical history. The questionnaire asked about past surgeries. The answer that was typed in was "Neutered, 12/15/88." We indicated his weight was 15 and his height 6. Tom's 10 pills of 100 mg. of Viagra were shipped after a charge of $167 was made to a family credit card. The lack of physician attention to the information listed suggests that no review was done at all.

In a second case, a prescription application was made on behalf of a News-3 employee's dog, under the name of "Phrederick L. Schnauzer." A similar reference was included in the application that the applicant had been neutered, but the web site did not question that. Instead, "Phrederick Schnauzer's" application was turned down because he lives in the United States. The British firm "CCNow cannot legally sell prescription drugs to customers who are in the U.S." stated a return e-mail to Phred's owner. The order was not processed and the credit card was not charged.

In a third case, to again test the potential for on-line pharmacy abuse, a prescription was made on behalf of my dead grandfather, Jess Sprague whose date-of-birth was clearly stated May 6, 1900. Jess Sprague died 24 years ago. The order was placed with the Pill Box Pharmacy, based in San Antonio, Texas. With no question of the applicant's stated age, which would have been 98 years old had he been alive in February of this year, grandpa's Viagra arrived within two weeks.

But perhaps the most alarming case involves a News-3 employee who truthfully filled out an application for a Viagra prescription including his detailed health history of heart trouble. Steve Kelso clearly listed his current prescription for a nitrate drug, one of those listed on the web site (www.WorldExpressRx.com) as a potential danger for a person using Viagra.

"I certainly thought that I would be denied Viagra, that given my condition, and given the medications I am on, it would seem totally contraindicated to prescribe me Viagra," said Kelso. But he got it within days after a charge was made to his credit card.

Doctors and pharmacists we interviewed told us they were worried about the lack of face-to-face consultants with these types of operations. They are raising questions about who is evaluating the "on-line consultations," and writing and approving prescriptions.

In addition, we also found that other popular prescription drugs are available from web sites; others the News-3 investigation discovered include the anti-histamine medication Claritin, and the hair growth pill Propecia, as well as several weight loss drugs.

SUMMARY:

In talking with state and federal agencies and lawmakers over who is responsible for regulating on-line prescription drug sales, we found there seems to be confusion. In fact, it doesn't seem to be against the law. And it is difficult to find out where many of these pharmacies originate.

I am not advocating for or against on-line pharmacies. But, our investigation revealed some alarming facts and raised a number of questions. Is anyone reviewing the "on-line consultations?" Did anyone bother to read Steve Kelso's application, or any of the other applications we submitted? We provided glaring clues when filling out "on-line consultations."

We presented situations that obviously would not have been approved if there was a face-to-face doctor/patient consultation.

Mr. UPTON. Ms. Stovall.

TESTIMONY OF HON. CARLA J. STOVALL

Ms. STOVALL. Thank you very much for the opportunity and the invitation to be here. What I would start off by saying is if the Internet is indeed perceived as the wild, wild west, then I think that Attorneys General offices, State regulatory agencies and Federal agencies are the Matt Dillon of the new frontier. Because we are armed with appropriate weapons to try to deal with this issue, just like we deal with other crimes that are committed in this country.

There are certainly benefits to pharmacies being available on-line, and we heard from the first two conferees, and I certainly agree with that. There are some great benefits. But, obviously, stopping the illegal activity that we heard a lot about is what's important. We wouldn't wink and nod if somebody wrote their own prescription out and took it into the local downtown pharmacy to get it filled. Patients cannot write their own prescriptions, and yet what we see going on in the Internet is very much that same thing. So just like we would stop it from going on in our local communities physically, we would also try to stop it over the Internet.

My office has engaged in some of the same sort of stings that you heard about from the first TV stations, so I won't belabor the way that it's so easy to have that happen. But, nonetheless, what we see happening is not physicians prescribing medications but simply orders for medication being filled, and there's a big difference in that.

As you know, some drugs carry tremendous side effects and health consequences that someone who is knowledgeable, with the regard of those contraindicating factors, ought to be involved with performing.

Viagra that we've heard a lot about from the TV stations is one of the most popular drugs apparently that's out there now, and yet between March and November, 1998, 130 men died while taking Viagra. Many of them had heart conditions that resulted in their death. That was cardiovascular incidents they call them. It's not been determined what part Viagra played in that, and I don't mean to suggest that, but, nonetheless, when 130 people die by taking that particular medication, it's something that would cause us concern. The number of men who died taking Viagra is not listed on

the Web sites that I have looked at that offer Viagra, nor is the fact that those 130 men that died ranged in age from 29 all the way up to 87. So those are what are our concerns.

We filed in the Kansas Attorney General's office under consumer protection saying it's deceptive and unconscionable for prescription drugs to be given out over the Internet without a physician licensed in my State, without a pharmacy licensed in my State being involved in the process. We are armed with appropriate weapons we think to combat these Internet activities, just as we already have done with other kinds of consumer protection scams over the Internet, with gambling over the Internet, with pornography on Web sites as well.

The State Attorneys General wouldn't want to see this area Federalized just because Internet companies do cross State boundaries. We think the growth of e-commerce, the good as well as the bad, that comes with that give Attorney General Offices, State regulatory agencies and Federal agencies the opportunity to work together in addition with the AMA, for example, as well as the National Association of Boards of Pharmacy. The pharmacy board has come out with, I'm sure you know, a kind of seal of approval that legitimate pharmacies could put on their Web sites. And while that's not certainly the full answer to the problem and I don't think the pharmacy association would tell you that it is, it's at least a step in the right direction.

What I will recommend to colleagues of mine is that we encourage State legislatures to require a certain amount of information be disclosed on any web sites that are giving prescription medication. What was so difficult for us when we sued was trying to locate who it was that we were doing business with. And very much as Congressman Klink talked about, it's the identity of those people and their whereabouts that present problems. So we would require and ask that legislatures require current and accurate addresses of the corporate offices, of any of their affiliate offices, the identities of the principals involved and their locations, as well as information about what State the pharmacy and/or the doctors involved are located in.

What we found is that there will be a Web site company with a particular incorporation status and then there will be the pharmacy company or the company that actually dispenses the drugs, and you've got many shelves to go through. So if all of that information was required to be on the Internet, we find that that would be most helpful.

If there is Federal legislation that this committee comes forward with, we would hope that it would be a floor and not try to be a ceiling to preempt States from doing anything but to be able to allow us to work in the areas that we traditionally have done with the licensing and regulating of the practice of medicine and pharmacology, and we would want to continue to do that.

There is one thing that we would like and that is, if we were able to have Federal authority, much like we have in the telemarketing area, which would allow, pursuant to the FTC rules, State Attorneys General to go to Federal court and get nationwide injunctive relief, that would be of use, I think, to the Federal Government as well as to all State governments. We can do that now, as I indi-

cated, with the telemarketing rules and would find that helpful. Then one Attorney General in one action in Federal court could get the company to cease and desist doing business across the country, and that would be the fastest way we think to adequately protect consumers and constituents.

I really thank you for the opportunity to be here and share what it is we have done in Kansas and what other States are doing as well. Missouri has filed similar suits, and I know other of my colleagues are getting ready to do that. So we have been involved, but I'm happy to answer questions that you might have.

Thank you.

[The prepared statement of Hon. Carla J. Stovall follows:]

PREPARED STATEMENT OF CARLA J. STOVALL, KANSAS ATTORNEY GENERAL

Chairman Upton, Ranking Member Klink, members of the Subcommittee, thank you for the invitation to testify today and for your leadership on the important issues the Subcommittee is considering. Let me also thank Chairman Bliley and Ranking Member Dingell of the full Committee for taking part in this hearing and for your attention and concern about the issues involved.

The Internet and the World Wide Web offer countless opportunities for Americans as we move into the 21st Century. In Kansas, we view the Internet as an important lifeline for rural America. We know that, through cyber technology, it will soon be possible to participate as fully in the global economy from Dodge City or Goodland as from New York or Los Angeles. Our state is soon to be the site of the largest distribution center for Amazon.com, and we are proud to be the home of Sprint, which is on the cutting edge of telecommunications technology. So we welcome the dawn of the Information Age and the burgeoning growth of "e-commerce".

But we also know that the Internet brings with it new opportunities for old-fashioned lawlessness and fraud, and for repackaged challenges to States' rights. Law enforcement authorities around the country, both state and federal, are struggling to combat pornography, pyramid schemes, gambling, and a host of other ancient evils that have cropped up anew online. Investigating and prosecuting online offenders in all these areas raise new challenges for law enforcement. But two principles should always guide us: (first) an illegal act does not become legal merely because it is committed through the Internet, and (second) a state does not become powerless merely because a threat to the health and welfare of its citizens invades online rather than in person, by mail, or in some other traditional manner.

Those are the principles that led the State of Kansas to challenge web site operators who are recklessly—and illegally—selling prescription-only drugs to Kansans via the Internet. And let me be very clear—our law enforcement actions are aimed at stopping the *illegal* Internet sale of drugs to Kansans, not at stopping online drug sales entirely. We have no quarrel with doctors who prescribe to Kansas patients who use the Internet, so long as those doctors are properly licensed by the State of Kansas and meet all substantive requirements for practicing in the State. And we have no objection to legitimate pharmacies that dispense prescription medications to Kansans using the Internet, so long as those pharmacies are properly registered with the State of Kansas and operate by the same standards as the drug store on Main Street standards designed to protect the health and welfare of our citizens.

We do object strenuously to those who believe they can sell potentially dangerous drugs to our citizens, without complying with state laws, merely because they set up a web page. As a Kansas Board of Pharmacy official said, the click of a mouse does not establish a physician-patient relationship.

We have filed six lawsuits, naming as Defendants eight companies, six doctors and four other individuals. All of them participated in the sale of prescription drags to Kansans. None of them required any in-person examination or consultation prior to prescribing and dispensing those drugs. Some of them sold "lifestyle" drugs, such as Viagra, to minors without any apparent hesitation. None of these Defendants is properly licensed or registered in the State of Kansas.

I have submitted with my testimony a summary of this pending litigation filed by the State of Kansas, and I would ask that this summary be included in the hearing record.

The theory of our cases is simple: By prescribing drugs to Kansans, certain Defendants practiced medicine in our state without the required legal authority. By

dispensing drugs to Kansans, certain Defendants practiced pharmacy in our state without the required legal authority. And by recklessly dispensing drugs without any doctor-patient relationship whatsoever, while failing to disclose to consumers material information such as health risks associated with use of some of these drugs, all of the defendants committed deceptive and unconscionable acts in violation of our Consumer Protection Act.

Will we win these cases? We certainly think so! There are tough problems, such as overcoming jurisdictional challenges and locating elusive Defendants using multiple shell corporations and mail drops. But we are confident our basic approach is sound, and we are confident the Courts will continue to apply Kansas law to protect Kansans within our State!

And make no mistake about it—this is very much about protecting the health and welfare of Kansas citizens. Many of these medications have potentially serious side effects. If used improperly, many of them can kill. We would not even consider repealing our State laws that establish standards for dispensing dangerous medications within the State, and there is no reason to accept a lesser standard when dangerous drugs are sold to our citizens online. In fact, this issue first came to our attention when physicians in our state expressed concern that patients under their care could receive prescription drugs without the treating physician's knowledge, increasing the risk of inadvertent drug interactions.

Kansas is in front on this issue, but we are not alone. I know my colleagues in other states are increasingly active in opposing illegal Internet drug sales. I believe a united, coordinated effort among states will serve us well in this matter.

We welcome Federal involvement as well, although the solution is not to "federalize" this problem. States historically have had a dominant role in regulating doctors and pharmacies for the protection of local citizens. We should strengthen, not diminish, that role.

To that end, I believe states should explore the possibility of establishing disclosure requirements for entities that sell prescription medications across state borders. One of the most difficult challenges in the Kansas prosecutions has been finding the companies and people responsible for selling into our State. We have had to sort through multiple shell corporations, addresses that turned out to be mail drops, overlapping addresses shared by different entities, and similar evasive tactics. I believe companies selling dangerous drugs across state lines should be required to maintain current, accurate, accessible information about their principals, their physical addresses, and their identities. We should not have to struggle to find them.

To the extent new federal legislation is considered, I hope you will keep in mind two important principles:

First, any federal requirements should be only a floor, not a ceiling. Do not preempt the States. Allow us to continue to set substantive requirements for the regulation of doctors and pharmacies that operate within our borders, and let us continue to have tougher requirements than the federal government as we see fit.

Second, any new federal enforcement scheme should retain states as key actors. I know there is discussion of a regime modeled on the FTC's Telemarketing Sales Rule that would allow state Attorneys General to take action in federal court to curb illegal online pharmacies and to obtain nationwide injunctive relief. I believe there is a certain appeal in this, and NAAG certainly has no objection.

Each of these ideas may help. But, ultimately, the answer to this problem will not be to reinvent the wheel. Each jurisdiction in this country, including the federal government, has requirements in place to ensure that dangerous drugs are dispensed safely. We do not need new standards. Rather, we need new cooperation among states, and with federal agencies, to ensure that our existing standards are followed and applied to Internet sales.

That is the effort we in Kansas are trying to lead. That is the effort that the National Association of Attorneys General supports. And that is the effort that, I hope, the Congress will help us to continue.

Thank you.

Mr. UPTON. Thank you very much.

We will try this timer again. No, I give up.

Okay, we are going to recognize members for 5 minutes for questioning, and I will give a little tap of the gavel when that occurs.

First of all, I very much appreciate all of your testimony. Clearly, as I think was given in many of the opening statements, it is a double-edged sword. There are many positives, as Mr. Michel—by

the way, I hope you retire to Michigan; it is a great State—but obviously many, many positives, but there are negatives as well.

Ms. Stovall, I know that there is an association of attorneys generals, and I don't know if this has been a topic at some of the meetings—national meetings that you have had. Has that been the case and what interaction have you had with other attorneys generals across the country?

Ms. STOVALL. We met just recently in June in Nashville and talked about this issue. It has been an issue that has been discussed within our organization even prior to that but not on quite as formal a basis. I can assure you there is great interest with attorneys general on this issue, and I think we will see additional action within days, I think more lawsuits will be filed by attorneys general.

Mr. UPTON. You indicated in Kansas that you have filed I think six complaints, is that right? Are you planning to do more?

Ms. STOVALL. We filed six actual lawsuits. We don't frankly at this point intend to do more because of limited resources. And it is really not any shortage of law enforcement ability that is our problem, it is the shortage of resources to shut these down. So that is our difficulty.

Mr. UPTON. Have any of those six cases culminated in a final decision? Are they all pending?

Ms. STOVALL. They are still all pending. We have had service on almost all of the defendants we have sued, but many of those companies we sued now have an indicator on their web site if you are from Kansas, don't call us, because they will now no longer sell to Kansas citizens. So that was the relief, frankly, we were after. So although we are a long way from final disposition, the immediate relief is granted.

Mr. UPTON. I know as we have looked over much of the information our staffs were able to complete, one of the big problems with the Internet is that you could live in Michigan, the on-line situation could be in Florida, as was indicated in Ms. Egan's testimony, with the particular suite or P.O. Box there, and often if you have—in some cases where they do have you sort of walk through a checklist of physicians to make sure that they are adequately reviewed, we found one case where actually the physician was licensed in Mexico and did not have a U.S. License.

As Ms. Egan's report indicated, as they tried to talk to who can be responsible for this, and they talked with the FDA, Customs, DOJ, State boards, DEA, pharmaceutical boards, and her testimony through the video was that no agency was up to speed. Have you witnessed that same problem? Are you getting cooperation from Federal agencies in terms of who ought to have the lead?

Ms. STOVALL. Certainly there has been cooperation, and State Attorneys General are not looking for the Federal agencies to take the lead at all. We appreciate the assistance that they have given us when requested on this and other issues.

But even right now, when we talk about the Internet, we talk about the physical drugstore on Main Street, there isn't any one agency now that is responsible for all the business that goes on there or at a doctor's office. So I don't know that we would be correct in assuming that there should only be one agency now that

regulates the prescriptions as well as the dispensing of them, just because it is on the Internet.

Mr. UPTON. For Ms. Behrens and Ms. Egan, what kind of reaction or follow up have you had since your program aired and have you had any further thoughts about investigating a variety of things and what are the positives you have seen as well?

Ms. BEHRENS. Well, the reaction we got from people at the local State and Federal level was similar to what she was saying here, that they are not really sure whose jurisdiction it is, but they are aware of the problem, and they are trying to get a handle on it.

As far as any follow-up, we—Tom the Cat received E-mails checking to see how he was doing with his Viagra and asking if he needed more.

As far as checking into any other drugs, we talked about Zenecal, and I know that some of the State officials in Michigan were concerned a lot more about the weight loss drugs because of the danger.

Ms. EGAN. I know the DEA told me they wanted to look into this problem. They were really concerned about it, but they felt like the Internet is just so far ahead of them at this point that they are trying to figure it out, that the laws are in place is what I was told, but they just need to be able to catch up with the people that are selling drugs on the Internet without a prescription.

I want to stress the "without a prescription" also. Because we didn't look at prescription drugs with a prescription.

Mr. UPTON. Thank you.

Mr. Klink.

Mr. KLINK. I just thought I would let the bells finish ringing, Mr. Chairman.

First of all, Mr. Chairman, this has been a very enlightening hearing. I want to thank you.

Before I start, I just wanted to identify the gentleman who has joined us up here, our dear colleague, the Honorable Robert Brady from Philadelphia. Bob is on the Small Business Committee. In fact, he has been working with us on this issue; and he asked if he could come in and observe the hearing today. I thank you for the courtesy of allowing him to serve.

I would ask unanimous consent if my friend, who has been working on some legislation on this matter with us, could have 30 seconds to welcome his constituent, Ms. Egan from Philadelphia.

Mr. UPTON. Without objection.

Mr. BRADY. Thank you, Mr. Chairman. Thank you ranking member, my dear friend from Pennsylvania.

I just wanted to welcome Ms. Kathy Egan to our congressional hearing. It is a unique situation where an elected official and a politician from the city of Philadelphia welcomes somebody from the news media. I don't want to miss that opportunity. But she is a unique lady, and I just wanted to thank her for publicizing this problem, doing all you are doing and thank you for your tireless efforts in dealing with this problem. I wanted you to know myself and anybody else I can convince—I don't think I need much convincing to assist you in any effort you can take to rectify this.

I thank you, and I welcome you here.

And I thank you, Mr. Chairman, and thank the committee for your indulgence.

Mr. KLINK. Mr. Chairman, I will tell you this. What I appreciate about Mr. Brady's efforts in this matter—he is on the Small Business Committee. About a month ago, this issue came up, and so they began to look at this themselves within the Small Business Committee. He told me the interest he had, but he automatically realized that we in the Commerce Committee could do so much more. I thought that was very enlightening.

Mr. UPTON. That is true. I suggest the Judiciary Committee be removed.

Mr. KLINK. So, at this point, I am happy that he has worked with us on this issue. It is nice when we can work across our jurisdictions together.

Ms. Egan, you know, you mentioned in your testimony that there was virtual candy stores. I remember that being in your report. Would it surprise you if some of the web sites out there apparently are willing to sell on-line drugs like Comprageisic and Codipront, both highly addictive painkillers, by answering a medical questionnaire and submitting credit card numbers? Does that at all surprise you?

Ms. EGAN. That doesn't surprise me, based on what we saw. All we had to put in on a number of these drugs was name, address and credit card. I put in I worked at NBC10 in Philadelphia, and we got the stuff Fed-Ex'd right to our door, and it was no problem. Left at our door, I might add, where anybody could pick it up. They didn't make sure someone was there to get it. It raises another concern. I have two little kids, and that raises a concern as far as that is concerned.

Mr. KLINK. Anybody could have picked it up?

Ms. EGAN. It was left right outside the door.

Mr. KLINK. I was looking at another news article here, and the reason I mentioned Codipront and Comprageisic, there was a news report from a month or so ago, U.S. News and World Report. It says, both of these drugs sent by Pharma Group contained codeine, a narcotic painkiller, and are on DEA's list of most addictive medication. "if you went to the post office to pick these up," a spokesperson said, "it is not inconceivable that the DEA could put you in jail." that is how serious it is. Yet things like this are dropped on people's door step every day.

I think it is important, and I know it is very difficult, and I apologize, but what we have done is blown up some charts of some of the pain relievers. I am going to read through some of the names, those I can pronounce. I don't know a lot of these things. I am not a pharmacist.

Too often, we dwell on things like Senecal, Viagra, and they are the most prevalent, but they are indeed not the only kinds of medications. So we are not picking on any manufacturer. We are not picking on any particular drug. But there are things like Fiorinal Codeina, Codeisan, Perduretas de C., Termalgin, Codipront, Darvon, and it goes on and on and on. So the list of drugs, and it really does read like a virtual candy store of narcotics, could cause a lot of problems.

So let me ask both Ms. Behrens and Ms. Egan, I imagine both of you talked to a number of State and Federal regulatory officials about the kind of drugs you were able to access when you were doing your reports. Could each of you elaborate a little further on what the response was by those agencies? I take it that you didn't feel those agencies really had their act together and that they were able to communicate to you and the news media, and you are the ones going to be telling the public what is going on, that they really had come to grips with how they could control these controlled substances.

Let me start with Ms. Behrens.

Ms. BEHRENS. That is exactly the response we got. We talked with someone from the Department of Consumer and Industry Health Services in Michigan, and they seemed to have the best grip on it. But they were focusing more, like you were saying, on the drugs that were narcotics, that they were concerned that people may be able to get narcotics. What we focused on was Viagra and didn't test any other drugs in our series. But when we talked with some State officials, that was the concern a little bit more than the narcotic drugs that might be available.

Mr. KLINK. I think the committee has found the same thing.

Ms. Egan?

Ms. EGAN. The agencies we talked to were definitely concerned, but they didn't seem to have anything in place to go after right then and there. They didn't seem to be up to speed on it, as I had said. The FDA gave us a news release from 1992 talking about mail order drugs when we brought this to their attention. So I just—we couldn't find anybody who said yes, this is who is in charge, this is what we are doing about it, this is what needs to be done. They said it was just such a new problem that nobody knows.

Mr. KLINK. Some have argued that the on-line pharmacy industry should be able to be self-regulating. Let me ask first Ms. Stovall and then each of the reporters your opinion of that. Have you seen evidence that they would be able to be self-regulating?

Ms. STOVALL. Absolutely not. We wouldn't want that any more than we would like regulation lifted on pharmacies that are on Main Street or physicians on Main Street. Regulation needs to happen in the way that we do now, but not just to regulate through the Internet.

Mr. KLINK. Reporters?

Ms. BEHRENS. Well, I interviewed someone from one of the on-line pharmacists and that was exactly his opinion, is that they can self-regulate.

When I said, but how are you prescribing to—why are you prescribing to a dead man? He said, that shouldn't have got by. I don't know how that got by.

I asked him, what would be your concern if a teenager ordered Viagra or any other drug over the Internet? And his response was, teenagers don't have credit cards. My response to him was, my grandfather didn't have a credit card either.

As far as an opinion on—obviously, from our report it simply—there are no regulations. But I am not here to give an opinion on whether there should be or shouldn't be.

Ms. EGAN. Likewise, I can't give an opinion either, but I feel that from what we found and the experts we talked to, that the biggest problem was without a prescription and that it was getting into the hands of children, and that the experts we talked to had a real problem with that, with the danger that is involved with so many kids able to get on the Internet. It is so easy for them to do this, and it was so easy for us to do this.

Mr. KLINK. Mr. Chairman, I see the red light, but I would point out, of the 200 sites we found and with the 400 sites that we are being told by the National Boards of Pharmacy are out there, there is no sign that any of these sites—that few of them, anyhow, have done any kind of self-regulation. So I think we need to look further into this.

I yield back my time.

Mr. UPTON. Thank you.

I would note that my dad used to be in charge of consumer affairs for Whirlpool and helped develop the first 800 number; and the first question on the checklist when something was wrong was, is it plugged in? And it is now plugged in.

I recognize Mr. Bryant.

Mr. BRYANT. Thank you, Mr. Chairman. I think we have an outstanding panel here, and I appreciate the contribution you have all made.

Ms. Stovall, good to see you again today on another matter.

I think it was mentioned maybe in the testimony of Ms. Yui or Mr. Michel, one, that we have to be careful and remember in going through all this very important debate that there is a difference between using an on-line pharmacy to fill a prescription legitimately and the misuse of the system through illegally using that system to dispense drugs, legal drugs, over the Internet. I think it is important that we remember that. Because I think, for the most part, the people involved in this are honest and legitimate. But, again, it is the minority out there that are doing bad things and that are making a lot of money. And certainly profit is why they are out there in any illegal trade, whether it is this type of trade or anything else.

Ms. Stovall, I think you suggest some good ideas, and I am particularly intrigued by the thought of some sort of seal of approval that would be on the site. Then I thought, well, of course, they could make one up and counterfeit that very quickly. But that would have to tie hand in hand with some type of State registration, with numbers and locations where people, real people, can be identified and found, and periodically these things could work together in some sort of network, I would think, that could give us a little better assurance.

Ms. STOVALL. I think that is exactly right, Congressman, and that is what we would advocate.

Right now, there can be a pharmacy in the neighboring State of Missouri, for example, that is licensed to do business in my State, and that can be lawful. But they do have to be licensed, have to be approved by the Kansas Board of Pharmacies. So pharmacies in other places that are selling over the Internet can indeed be lawfully engaging in business, but they have got to register, got to give

that information that you have talked about. So I think you are right. They can partner really well.

Mr. BRYANT. I think to the extent we are talking about drugs that are regulated when they are sold in pharmacies in States by the States, that as much as we can, without interfering with the flow of commerce, replicate that on the Internet for things like drugs—I am not talking about you have to get licenses for everything you sell over the Internet. But I think in an area as important as this, we have to do that.

You mentioned you feel like, as a State Attorney General, you are armed sufficiently right now, but you suggest perhaps some way to better assist you in working interstate, with other States. Would something in the nature of a uniform act maybe giving State attorneys generals the ability to work together across State lines—would a uniform act or something like that——

Ms. STOVALL. I don't know that we even need to go that far. I think, for the most part, attorneys general are pretty satisfied with their own commercial codes or their own consumer protection codes rather that they deal with now for non-Internet kinds of fraud. So those tools can apply.

What I referenced was the ability for us just to be able to go to Federal Court, and if I were to go to Federal Court in Kansas City and get an injunction against a company that was doing business in my State but in 30 other States, we would be able to enjoin them by that one action and stop them from distributing the drugs. So that would be more of a help in my view than a model code. It doesn't mean there isn't some benefit to it, but it is not anything we have thought would be necessary.

Mr. BRYANT. Let me close my portion of this by stating that, in keeping this distinction out there between people who are legitimately and honestly doing business, I want to, with unanimous consent, introduce into the record a news release and two additional pages accompanying that news release from Pfizer Company, who everyone knows is a maker of Viagra and many other fine products, and also who has a distribution center in my district, by the way, what efforts they are making to work with the Federal agencies, the State agencies, such as Kansas, the professional associations, the pharmaceutical associations, as well as using the courts and litigation lawsuits to enforce trademarks and things like this, to assist in this effort. I would like to make that a part of the record.

Again, I would commend all of the companies—all the legitimate companies out there who are working hard and together with other people working hard to solve this, what can be a very difficult problem. I yield back my time.

Mr. UPTON. Without objection, it will be made part of the record.

[The information referred to follows:]

Pfizer Inc
235 East 42nd Street
New York, NY 10017

www.pfizer.com

News

Andy McCormick
212-573-1226

PFIZER STATEMENT ON INTERNET PRESCRIBING

WASHINGTON, July 30, 1999 - Pfizer Inc today reiterated its support for strong efforts to ensure appropriate prescribing and dispensing of and access to prescription medications. The use of the Internet in prescribing and dispensing decisions about prescription medications - including Pfizer's Viagra -- has generated concerns within the health care community and among policymakers at the state and federal levels.

Since the launch of Viagra in April 1998, Pfizer has been adamantly opposed to the prescribing of this medication without an in-person physical exam by a physician. The company has taken a number of initiatives to bring this issue to the attention of relevant authorities, including:

- Requesting Federal Trade Commission enforcement actions against Internet prescribing sites
- Contacting all state Boards of Medicine and Boards of Pharmacy seeking support for national FTC action
- Working with state Boards of Medicine to address issues at the state level
- Initiating trademark infringement lawsuits and reporting fraudulent schemes to the appropriate enforcement authorities

"Pfizer continues to work with monitoring and enforcement agencies to maintain the integrity of the doctor-patient relationship," said Dr. Mike Magee, Pfizer senior medical advisor. "Appropriate diagnosing and prescribing is the only way to ensure the best medical outcome with any medicine."

###

Pfizer Inc
235 East 42nd Street
New York, NY 10017-5755

Pfizer Inc Initiatives on Internet Prescribing

April 1998

- Viagra® is introduced in the United States.
- **Trademark Infringement.** Pfizer begins legal enforcement actions against hundreds of entrepreneurs infringing Pfizer's Viagra® trademark by selling products ranging from T-shirts to alcoholic beverages.

June 1998

- **Internet Sales Without Prescriptions.** Pfizer is made aware of Internet sites selling Viagra® without requiring a doctor's prescription. Because Pfizer does not have a private right of action under pharmacy laws, the company passed its information on to state pharmacy boards and the National Association of Boards of Pharmacy.
- **Internet "Prescribing."** Pfizer was made aware of Internet sites issuing improper electronic "prescriptions" and began working with appropriate authorities from both a policy and legal enforcement standpoint. Because Pfizer does not have a private right of action under pharmacy laws, the company relayed its information to state pharmacy boards and the National Association of Boards of Pharmacy.

August 1998

Federal Government Action

- **Federal Trade Commission (FTC).** Pfizer begins working with the FTC and requests an FTC enforcement action against identified Internet "prescribing" sites. State medical and pharmacy licensing boards sent numerous letters to the FTC in support of such action.
- **Food & Drug Administration (FDA).** In January 1999, Pfizer meets with senior FDA officials, including Associate Commissioner Bill Hubbard, to discuss the issue and to encourage FDA to support FTC action.

State Government Action

- **State Boards of Medicine and State Boards of Pharmacy.** In August 1998 and January 1999, Pfizer contacts all state Boards of Medicine and Boards of Pharmacy seeking support for national action by the FTC. This resulted in numerous letters

from boards to the FTC. Pfizer also relayed information to individual boards regarding specific cases that may have required enforcement action.

- **National Association of Boards of Pharmacy (NABP) and Federation of State Medical Boards (Federation).** In June 1998, Pfizer begins working with the NABP and the Federation. Pfizer supports the NABP's Internet pharmacy standards program and has encouraged the Federation effort to develop an enforcement clearinghouse for actions by individual boards against physicians involved with Internet "prescribing."

- **Administrators in Medicine (AIM).** Pfizer has supported the AIM's involvement with the Federation in an enforcement clearinghouse. AIM is the professional association for executive directors of state medical boards.

- **State Attorneys General.** Pfizer has been in regular contact with state attorneys general concerning pending investigations and enforcement actions. The company has and will cooperate with their efforts.

Private Legal Action

- **Trademark Infringement.** Internet "prescribing" often involves substantial misuse of Pfizer trademarks and other Pfizer intellectual property. Pfizer has aggressively protected its intellectual property rights by sending cease and desist letters to over 300 Internet sites and bringing numerous trademark infringement lawsuits.

- **False Advertising.** Pfizer pursued numerous Internet sites (and other advertisers) who were using the Internet to make a variety of false and misleading representations about Pfizer products or about their own products in comparison to Pfizer's.

- **Consumer Fraud.** Pfizer has reported various fraudulent schemes (e.g. "bait and switch") to the FTC, FDA, Customs, Federal and State Attorneys General and other law enforcement agencies.

Pfizer Inc continues to work with the appropriate monitoring and enforcement agencies to stem inappropriate prescribing of and access to prescription medications.

Mr. UPTON. Mr. Stupak from Michigan.

Mr. STUPAK. Thank you, Mr. Chairman.

I apologize for being a few minutes late. I was at the Health and Environment Subcommittee. Senator Levin from Michigan, of course, testified there, so I had to be there. But I certainly enjoyed the tapes and the testimony of our witnesses.

I am sure Pfizer and others are trying to do what they can to stop this, but, Mr. Chairman, if I may, it reminds me a little bit like Yogi Berra says, it is deja vu all over again. Here we go. I love Yogi Berra, but I don't like what is going on on the Internet.

Go back, this subcommittee, a number of years ago, Mr. Chairman, and you were part of it, we spent years investigating the issues of drug counterfeiting and drug diversion; and those investigations ultimately led to the Prescription Drug Diversion Act under the leadership of John Dingell. And we had all these assurances it wasn't needed, yet we spent time investigating.

Our investigation back then revealed that—all manner of dangerous activities that directly threatened the lives and health of all Americans, and that is what we have going on here today.

All manner of prescription pills and tablets back then were removed from their required packaging and resold into a black market estimated to be about $500 million annually. Liquid prescription medicines were removed from their lawfully labeled packaging and sold in containers such as used pop bottles. In 10 separate incidents substances were sold to Americans as prescription drugs that were simply counterfeit. The packaging was duplicated perfectly, but the drugs were not, just like we saw in Ms. Egan's tape. Two million fake birth control pills were sold in this country from overseas. Approximately half of those birth control pills contained no active ingredient whatsoever.

In another case, thousand dose bottles of prescription pain reliever in packages and with labels indistinguishable from the real thing contained aspirin as the only active ingredient, endangering the lives of anyone with a fairly common allergy.

Mr. Chairman, I don't want to see us do this, repeat the same mistakes that were made in the past. We are seeing it all over again, just a new forum for counterfeiting, for black marketing, for hoodwinking the American people.

Mr. Chairman, we started this investigation in January. There were 26 web sites. There is close to 400 now. So from January, 26 to close to 400 right now.

Everyone has come here and told basically their story, and I agree there may be some legitimate web sites out there, but of the 400, I can't think of more than two that we have found. So there is 398 out there still selling and trying to pull it over. As long as you have your credit card, you get what you want.

So as we take a look at this, Mr. Chairman, I hope we don't make the same mistakes. I hope we go at this aggressively, and we really get at the crux of the problem.

I guess as we listen to all this—I know, Ms. Yui, you are a very caring person and want to do what is right for your children and all that. You talk about buying on the Internet and the benefit. I agree there are some benefits there. But how do you determine

whether you are getting safe drugs, legitimate drugs, for your children? How do you know that, if there are 400 sites there?

Ms. YUI. You don't know. I did say that I do rely quite a bit on the media. I do read quite a bit. And I would look for companies that have been covered by consumer reporters. I think it would be of great value to have some sort of Federal or State insignia or perhaps a society of doctors—a Federal society of doctors that would approve a site. I don't know if they would want to get into that liability issue.

But I think with any product you buy over the Internet there is that risk that you run. You may not be with a legitimate site. And you need to hold off as a consumer and wait to see which are the sites that survive, which are the sites again that are covered by the press and which you hear about.

Mr. STUPAK. Have any of these companies you purchased from ever contacted you to make sure you are who you say you are and you have a prescription for the medicine?

Ms. YUI. Unfortunately—and this is very new to me—my health care plan does not cover—does not allow me to purchase on-line and I would only do it for convenience. Until it is convenient for me, and I am also hoping through health care plans signing on to some of these sites or affiliating with some of these sites, that is my protection. If the health care plan says they are legitimate, they allow me, cover me, allow me to use my copay payment to pay on it, which is still rare, unfortunately, for consumers.

Mr. STUPAK. You have no way of knowing whether it is legit, what you are getting? They don't double-check with you?

Ms. YUI. I would assume that if my health care plan has accepted the company, that they hopefully have done that for me, just like they have done with the doctor.

Mr. STUPAK. Well, do you order it, or does your health care plan order the drugs for you?

Ms. YUI. That you order, but my doctors prescribed them. I would never order something that my doctor hasn't prescribed, just like I wouldn't at any——

Mr. STUPAK. How do you know what you are getting is what you ordered? How do you know what you are getting over the Internet is what you ordered, what your doctor prescribed? Do you have any way of knowing it is——

Ms. YUI. I guess I would have no more way of knowing than if a major chain pharmacy or any pharmacy has put the right pills in the bottle. I am trusting. That is true. I think any consumer you have to assume—and it would be, as I said, be of great value to know—have something that alerts a consumer that the FDA or State regulatory body and also maybe some professional groups have checked out this site, they are legitimate, and I think that is true of probably any consumer product that is sold on-line.

Mr. KLINK. Would the gentleman yield one moment?

The difference I think—Ms. Yui, you said you have no difference, no better way of knowing if it is a legitimate drug that you were prescribed than if you go to the corner pharmacy. The difference is the corner pharmacy has a license on the wall from the State, and they are inspected. These 400 sites on the web, there is no evi-

dence that they have been licensed. There is no evidence that they have been inspected. We don't know where the drugs come from.

So from the perspective of the corner pharmacy, we know who made the drugs. There has been a chain of custody and control of those medications. We don't know about that with the Internet pharmacy, because they are dropped off via the mail, UPS, Federal Express. We don't know where they came from. It is like they were dropped out of the sky. As Ms. Egan said, dropped on the porch. Anyone could grab them.

Ms. YUI. That is what I said.

I certainly appreciate that regulating this is a daunting task for Congress, for regulatory bodies. I don't know how you can do that. I don't know how you regulate Internet commerce. It is full of problems. But I did order—for instance, I was on a health care plan once that I was able to order prescription drugs through the mail, and it was wonderfully convenient.

Mr. STUPAK. From your health care plan?

Ms. YUI. Yes.

Mr. STUPAK. Have you ever gone on the Internet and ordered?

Ms. YUI. I have not been able to. My health care plan doesn't allow me to, and I am not going to pay out of pocket for it.

Mr. STUPAK. I agree——

Ms. YUI. I have done research on the Internet, but, no, I haven't been able.

Mr. STUPAK. Some of these are great. Like this one here has a very nice-looking doctor here that really I would like to trust him, but you can't. There is not even a phone number on here to call this nice-looking doctor to see if you are getting what you want. How do you check it out?

Ms. YUI. I wouldn't do business with that site. You have to be smart as a consumer. I would also talk to my doctor. I think doctors play a great role in this. I think doctors need to be educated about what is out there. And doctors can say to you, you know, this is a good site; this isn't a good site. I think there needs to be consumer public education and education of professionals.

Mr. STUPAK. You have got to be smart. Our reporters were very smart. They put down "Cat," "Dog," "Dead Person" and "person who shouldn't receive it," but the person filling on the other side sent it anyway. Once they got their money, they didn't care how smart, how trusting, or what your health condition was. All they wanted was your money.

Ms. YUI. It is alarming. That is what I am saying. It is a big job. I don't know how do it. But there are definite benefits to this.

Mr. STUPAK. I agree.

Ms. YUI. And the benefit is what we also need to protect.

Mr. STUPAK. I agree, and that is the dilemma we are in.

Mr. Chairman, if I may, I know I said there are two legitimate sites that I have found. I understand there are probably more, but I can only think of two that I have found in cruising the net to get prepared for this hearing.

Thank you for your indulgence, Mr. Chairman.

Mr. UPTON. Thank you. That is why we have the best and the brightest on this committee.

Mr. Bilbray.

Mr. BILBRAY. Thank you, Mr. Chairman. I hope through the hard work of this committee we will be able to not only identify more legitimate sites but be able to develop more.

One of the points that was brought up basically, I guess, by Kathy about the issue about no prescriptions, you know, personally if a dead man is getting drugs, you know, that is not my concern. At least we know it is not going to hurt him. My concern, though, is that you are talking about people gaining access to prescription drugs without a prescription. I am going to be really interested to hear from the third panel about how we want to justify that you can't go to the street corner, you can't go to the grocery store, you can't go to a pharmacy and purchase prescription drugs without a prescription. Do you want to make a comment about that?

Ms. STOVALL. To do that now would be illegal, just like to do it over the Internet without a prescription is illegal. So it is illegal. Laws are broken all the time. We know that. That is why we have law enforcement. That is what I want us to continue to focus on.

Mr. BILBRAY. You hit on the issue about the fact it is not so much we don't have the laws on the book. It is like everything else that technology has done in the last two decades. It is so far ahead of government, we just haven't figured out how to catch up yet.

Ms. STOVALL. The bad guys are always ahead of the good guys. Law enforcement is always catching up and cleaning up after they have committed crimes, and this area is no different, unfortunately.

Mr. BILBRAY. I think we need to admit, too, that the bad guys are intermixed with a whole lot of good guys sometimes, and so we definitely don't want to just line everybody up. That is one of the concerns I have, is when we get into this prescription issue—and I would just, you know, say this to ask the questions—are we going to reach a place to where consumers need scanners to be able to transmit prescriptions, to be able to communicate that they do have the prescription? How else are we going to do this?

Ms. STOVALL. I think either faxing it—if the patient has their prescription and they fax it to this on-line pharmacy who then calls the doctor's office to verify or the doctor's office just originally contacts your on-line pharmacy of choice to verify, I think that is what has to happen to make sure we are dealing with physicians licensed in the State and pharmacies licensed in the State.

Mr. BILBRAY. In California, there has been enforcement of physicians selling over the Internet. In fact, I know of physicians who have had their licenses temporarily revoked because they basically violated the physician responsibility of oversight, I guess is what it was. This is a new field of physicians saying, how much of the oversight do I do? I think the outrage is when you get people actually asking for information, like you did in your reports, and then ignoring the information, not using that in considering it. That should be at least—what a ridiculous thing, of asking the consumer to go through the whole rigmarole and then not consider it and throw it out.

The question is, is that, when we go through this oversight, are States enforcing this segment universally to physicians who are using the Internet, or is it just a California-specific item you are hearing?

Ms. STOVALL. Absolutely not just specific in California. Many other States that have their healing arts board or their board that looks at physicians and regulates them have been involved in it.

Mr. BILBRAY. In monitoring the Internet.

Ms. STOVALL. I can't say monitoring the Internet as they look at all the sites. But when referrals are made or things come to their attention, most certainly administrative actions have been taken against physicians in more States than just California and my State of Kansas.

Mr. BILBRAY. California has so many public employees that we get them to do something every once in a while.

Ms. STOVALL. You have a lot of physicians, too, so there is a lot of opportunity there.

I would say, if I could, AMA has very much spoken out against the practice you have talked about, prescriptions—just on-line prescribing medications for people they don't know, haven't seen and have no connection with. So the physicians themselves also are trying to police them as well.

Mr. BILBRAY. You know, I want—when we talk about a lot of these items, Mr. Chairman, I think we need to be careful as we use brand names, the perception of danger or whatever. I mean, Minoxidal used to be a prescription drug. There was a whole lot of cold medicines that used to be prescription drugs. We shouldn't perceive that a prescription drug is automatically dangerous and threatening. It is just many of them are going through a period before they become over the counter. So I think, in all fairness to a lot of these name drugs and treatments, that we are going to see a lot of things that was discussed here that are going to be over the counter.

My big question is, when we get into this, and I am really speaking because other panels are coming up, this issue of how we do oversight, I really believe and I would ask law enforcement this, again and again and again, when we are talking about issues of child pornography being sold to young people, accession to the Internet and a lot of these other things, don't you agree that somewhere down the line we are going to have to develop user ID capabilities so we know that the person who is hitting that keyboard is actually the person who claims to be?

Ms. STOVALL. I won't go so far as to agree with that. But I would say that because of E-commerce and what is available, we do need to find, I think, some way to restrict age access to certain sites. Because we know young people buy alcohol, they buy prescription drugs, they get pornography, and that is a problem. I don't for a second pretend to have the technical capability to figure that out. You are right. We need to protect our young people.

Mr. BILBRAY. On our committee we are just working on the electronic signature stuff. That is all the technology we are looking at.

I yield back, Mr. Chairman.

Mr. UPTON. Ms. DeGette.

Ms. DEGETTE. Thank you, Mr. Chairman.

Mr. UPTON. You need to turn your microphone on.

Ms. DEGETTE. Just like Ms. Egan, I have a 9-year-old daughter who likes to order things on the Internet, and in fact she just or-

dered the third Harry Potter book from England because you can't yet get it in the United States.

I look at all of these scores of web sites that people can get drugs from, and it seems to me the problem is not really are you getting drugs from a P.O. Box in Florida. We can take care of that. The problem is, like this one, "Viagra, no prescription needed for Viagra in Europe." It says here a doctor's prescription is recommended but not required to order Viagra, because, it says, if you do not have a prescription, we can refer you to one or more doctors who issue them on-line. That must be the dog and cat doctors who do it.

Then here is another one, Pharma Group, issuing all kinds of things from Europe—antibiotics, antidepressants, including Prozac, on and on and on.

So my question is to Ms. Stovall. What you are saying is we have the laws on the books and the States attorneys general can enforce them. What is the mechanism you see for the States to be able to enforce these laws against foreign companies, which I think is probably our biggest problem?

Ms. STOVALL. Again, not just State AG's but the regulatory agencies in States as well as the Federal agencies, too. It is just like when we deal with any other issues over the Internet or otherwise when the companies are not located within the continental United States. Getting them is difficult. There isn't any question when they are foreign companies about that. But what other kinds of laws can be initiated to help us, I don't know, because it is illegal now for them to do those things.

Ms. DEGETTE. That goes to my next question. You say that you are enforcing your fraud laws, and that is good, and there may be some fraud involved. But if, for example, this Viagra company, if they actually claim to have doctors taking the medical history and issuing a prescription, then I don't quite understand how a fraud law would be broken in that case?

Ms. STOVALL. It is deceptive and unconscionable. It is deceptive because they say they have a physician who is going to provide you a prescription.

Ms. DEGETTE. What if they do?

Ms. STOVALL. They are not doing it pursuant to medical standards, which is that you have an examination and you know the actual history of the patient.

Ms. DEGETTE. Let me ask you this. Of the three cases you say you have pending right now——

Ms. STOVALL. Six.

Ms. DEGETTE. Of the six cases you have pending, how many of those are involving overseas operations?

Ms. STOVALL. None of them that I am aware of.

Ms. DEGETTE. That is going to be, I would think, an attorney general's problem, how do you find that person and bring them into your local jurisdiction—especially—well, it is worse with the Internet, because there is no place from which they sell these drugs. They are selling them over cyberspace. That is a law enforcement issue.

Ms. STOVALL. Mail order fraud is that way. Child pornography is that way. It is difficult when they are overseas, no question.

Ms. DEGETTE. Let me follow up a little bit with our reporters, because a lot of the big issues we have got here seem to involve big-name-brand drugs—Viagra, other kinds of drugs like that. Let's start with Ms. Behrens. Pfizer makes Viagra. My question would be, assuming the cat and the dog and the dead person and everyone else are getting real Viagra, what is the responsibility of the pharmaceutical companies to work with these mail order places to restrict improper use of their product?

Ms. BEHRENS. I interviewed someone from Pfizer, and the response I got was they are aware of the problem and concerned about the problem, but the answer I got wasn't really an answer. They were saying that they don't directly distribute to the pharmacies that are selling these. They distribute to someone in the middle, a warehouser, and then that is where the pharmacies are getting the Viagra.

Ms. DEGETTE. Let me follow up with Ms. Egan. Do you think that the drug manufacturer should keep a closer control over where their products are going?

Ms. EGAN. I don't feel like I can really answer that. I talked to some people from Merck and some of the other drug companies. Likewise, like Christine said, they were very concerned, and they want to get a handle on this, too, is what they had told us. They are launching investigations as well. But I don't feel like I can answer that question.

Ms. DEGETTE. Mr. Chairman, it might be useful at a future hearing to bring some of the drug manufacturers in and see if they can work collectively with us to try to resolve this really increasing problem.

Mr. UPTON. Good idea. Thank you.

Mr. Whitfield.

Mr. WHITFIELD. Thank you, Mr. Chairman.

Ms. Stovall, I am assuming—I didn't hear your testimony, but I would assume two legal theories that you pursue are that, one, there is not a pharmacist licensed in the State of Kansas that would distribute—that would prescribe these medicines on the Internet; and, two, that the physician—I mean, that would not fill the prescriptions. Two, the physician is not licensed to practice medicine in Kansas. So those would be the two legal theories that you would pursue?

Ms. STOVALL. That is exactly right, Congressman. That is why we allege it is a violation, deceptive and unconscionable behavior for physicians and pharmacies not licensed in my State to give medication to patients.

Mr. WHITFIELD. I assume the second big problem would be finding out who you are going to serve your papers on for legal suits. I did notice, just looking at part of your testimony, there has been one doctor that you have not been able to find, but you have been able to obtain temporary injunctions or restraining orders or something to prevent them from selling, is that right?

Ms. STOVALL. They have stopped selling into the State of Kansas, and we have enjoined them from doing that. Many of their web sites now say, if you are a Kansas patient, don't call us.

Mr. WHITFIELD. I was reading an article not too long ago that there was a web site that came out of Bogota, Colombia, that was

selling home abortion and female self-sterilization kits. The way the FDA determined they didn't have authority over this company was because it was out of Bogota, Colombia, but the Internet provider had a service contract that whoever sold over this web site had to meet all U.S. Laws, and in doing that they were able to stop them from selling by going to the provider.

Have you all worked in that way?

Ms. STOVALL. We haven't had to go that way. We maintain we have got jurisdiction over any company that advertises in our State on the Internet, and that is the sufficient nexus with my State to get legal jurisdiction. So we haven't had to go as far as that. But we could, if needed.

Mr. WHITFIELD. Ms. DeGette was talking about if it was a company doing business in Bogota, Colombia, how would you obtain process over them?

Ms. STOVALL. It would be very difficult to do it. But, nonetheless, it would be illegal for them to have a market the State of Kansas. So any time it is a foreign jurisdiction that presents problems. There is no question about that.

Mr. WHITFIELD. I think you did indicate one thing that would be quite helpful, if there was at least some sort of Federal requirement of an address and principal parties involved so that you would always know who they are and where they could be located, at least theoretically.

Ms. STOVALL. Theoretically, and where they are licensed, what States they are licensed to practice medicine or pharmacology in, and whether it is a series of State or Federal requirements. Either way, we find that would be helpful.

Mr. WHITFIELD. Right now I guess there is no requirement like that. Is that true?

Ms. STOVALL. I am not aware of any State that has that requirement. Again, States are trying to catch up with the Internet, so we would introduce it in our next legislative session. I think we will see lots of changes in laws because of the Internet.

Mr. WHITFIELD. But it seems like this contract that the Internet service providers can require that all U.S. Laws must be met to distribute a particular product would be one pretty effective way to go after this, it would seem.

Ms. STOVALL. But assuming that company in Colombia signed that contract and then violated it by selling a product that is not lawful in Kansas, you still have the difficulty of going to get them.

Mr. WHITFIELD. But in this case the FDA informed the service provider that it was violating the law by aiding the distribution of an unapproved drug and that they could be held liable.

Ms. STOVALL. Right. I understand where you are headed. We have had good success with Internet providers that have gambling web sites as well, that when we have contacted them and said this is illegal in Kansas, they stopped the service.

Mr. WHITFIELD. Right. Well, it is quite an interesting dilemma, and a lot of public policy issues are there.

I see my time has expired, Mr. Chairman.

Mr. UPTON. Thank you.

Mr. Green.

Mr. GREEN. Thank you, Mr. Chairman. I apologize for being late, but I have a committee meeting upstairs. I would like to ask unanimous consent to place my statement into the record.

Mr. UPTON. Without objection.

[The prepared statement of Hon. Gene Green follows:]

PREPARED STATEMENT OF HON. GENE GREEN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TEXAS

Mr. Chairman, I would like to start by thanking you for holding this important hearing.

While the growth over the past several years in e-commerce has been a positive experience for both consumers and retailers alike, in the past, this Committee has tried to look at ways to balance the right of open access to the Internet with responsible safeguards to protect consumers from online predators.

To ensure this continued growth and prosperity, we need to provide appropriate safeguards to protect consumers from online scams. An emerging area of concern is the growth of on-line pharmacies who operate without regard for standard practices of medicine.

Recent reports of a Viagra prescription being filled for a cat and broader concerns that legitimate prescriptions are being filled inappropriately, underscore the fundamental need for action.

At the same time that this Congress is attempting to reduce the cost of prescription drugs for seniors, we have a responsibility to ensure that the cheaper alternatives are safe and effective.

In my home state of Texas, seniors frequently travel to Mexico to purchase prescription drugs at below-market prices. Unfortunately, the drugs they purchase in Mexico are unregulated and therefore, potentially harmful.

On-line pharmacies present not only this problem, but the additional fact that it is nearly impossible to regulate the Internet.

While I do not support regulation of e-commerce as a matter of practice, there are steps that can be taken to improve the system before the drugs are sent to the consumers.

First, we should make sure pharmaceutical wholesalers are only selling their products to legitimate and credible pharmacies.

This means you can't send thousands of pills to someone .just because they are willing to pay for them.

Second, the FDA or FTC should help consumers navigate the maze of online pharmacies by highlighting both the good and bad players in the industry.

While we can and should pass safeguards to guide online pharmacies, we have to recognize that enforcement of these guidelines will be nearly impossible.

However, by educating the public and highlighting unethical behavior, we can hopefully reduce the number of individuals who are victims of online scams.

Mr. GREEN. I think the first panel we have—and, one, I want to welcome you. My home is in Houston, and particularly in Texas what we see is my senior citizens drive from Houston to the border to buy their prescriptions. They will come back across, and they have a limit of the 30-day supply or something like that. I know from the testimony of Mr. Michael, for seniors, it is much cheaper on-line.

The frustration we have as policymakers, whether it be in Austin or Kansas or Texas, in trying to regulate it yet still allow for the opportunities that economies of scale benefit. The frustration, I guess, we have because they are violating State law or maybe Federal law on postal regulations, to use the U.S. Mail.

On Monday, we are going to debate a bill on alcohol sales. You know, people are buying wine over the Internet, and yet each State has different laws and—although we all have the same drinking age, I guess, now. But how do you check someone's drinking age over the Internet anymore than you can do—my first question, I guess, Ms. Stovall, do you know of any other States that are being as aggressive as Kansas is in dealing with this?

Ms. STOVALL. I would certainly like to say we are the lead, but that is from my own desire to brag. But my neighboring State of Missouri has filed suit against a company. Texas is doing a lot with their administrative agencies as well. There are other State AG offices very close to filing and many administrative agencies that already have pursued administrative actions.

Mr. GREEN. Okay. Anybody on the panel, is there a way we can balance it? Because, again, people in the northern part of our country go to Canada to buy their prescriptions, and obviously in the western or southern part, you go to Mexico. Is there any way we can balance it and still have the savings sometimes that our seniors literally have to take advantage of to be able to benefit from their own prescriptions?

Ms. STOVALL. I think we just enforce the laws that are on the books. There are legitimate pharmacies now that prescribe over the Internet and do so within the full parameters of lawful activity, and we just need to be able to have the resources to enforce the law against those that don't. Then we do get the benefits of good service when it is a licensed pharmacy. Then you know it is a legitimate drug that has been approved by the FDA being dispensed, so the questions raised earlier would be resolved, and then that is how I think you get those benefits.

Mr. GREEN. So you are not suggesting we need any new Federal laws to deal with this, just the resources to apply current law, both State and maybe Federal?

Ms. STOVALL. The only Federal help I think that would be of assistance is if there is the ability of a State AG to file in Federal court and get nationwide injunctive relief, like we have with telemarketing. That would be the only thing at this point I see that might be particularly helpful.

Mr. GREEN. Any response from any other witnesses?

Ms. EGAN. I think one of the problems we saw was you order from one company, it seems to get shipped from another company, and then there is like another company. It is not one company. It comes from Germany, Japan, Hong Kong, you name it. So it is like a shell game.

Mr. GREEN. And you are——

Ms. EGAN. It makes it hard to get a handle on who it is you are actually seeking.

Mr. GREEN. Much less the location. Of course, if they are within the United States, you have that ability. It is tougher when you go to Colombia, Germany, Japan, wherever else.

What responsibilities do you feel like the major manufacturers—because in the testimony in the news media, you know, again, a lot of our pharmaceuticals that are in the United States are the ones we are actually buying from overseas. Do you think there is a responsibility of the drug manufacturers with regard to the pharmaceuticals? Anyone?

Ms. STOVALL. I think from a practical standpoint those major manufacturers know it is in their own best interests to try to control the flow of their product. As Congressman Bryant indicated, Pfizer has stepped forward to our office and said we want to help and be involved in this process. I think from a liability standpoint that is what they need to do to protect themselves.

Mr. GREEN. Thank you, Mr. Chairman. I thank this panel.

Mr. UPTON. Thank you.

I would like to say a number of members have a couple of additional questions, so we will proceed along that line. And, hopefully, not all members will have questions; and those questions will, in fact, remain at just a couple.

I have—I guess as I have listened to the testimony and to try to sum things up, this is a very perplexing problem. You have a drug manufacturer that might be headquartered in one State. Their actual manufacturing site may be in another State. You have got an individual in whatever State using the Internet, which is national. You have got a physician who may or may not be licensed in this country but perhaps from another State, and you are using an interstate carrier, whether it be the Postal Service or Federal Express or UPS.

Whereas the system has worked for decades and decades under State regulation and authority, as physicians—and physicians are licensed differently in different States with different regulations and different information that is allowed to be dispensed to the patient, you have got a question of, which laws are you enforcing? Are you enforcing the State of Kansas laws or the State of Michigan laws or the State of Pennsylvania laws? And you have got a number of probably unscrupulous characters, as was illustrated in Mr. Stupak's exhibit, of some over 300 Internet providers that may not be licensed or regulated at all.

So, Ms. Stovall, when you say you don't really want Federal legislation because the Kansas legislation—and all of a sudden, if you are from Kansas and they have now got that little disclaimer, if you are from Kansas, don't bother to register, reminds me of some of those sweepstakes winners. If you are from, I don't remember what State it was, but don't bother to apply. That doesn't always work.

If you want to go to Federal Court, that is one of your comments here, you would like the access to Federal courts. Again, it is sort of difficult to go to Federal Court perhaps without a Federal law versus a State law that might be on the books. So it really is a very perplexing problem.

You know, as we sort of struggle with clear abuses, you know, as we talk to the pharmaceutical manufacturers, they distribute to other wholesalers, and it is sort of a hands-off operation. That is how the system works. And, obviously, they are in the business of doing billions of tablets or whatever of a variety of different things, as Mr. Klink illustrated. You would have to have almost a pretty radical approach to the way they currently distribute their medication, which is, I think, most observers would say we have a better system in this country than just about anyplace else in the world.

So the system, that system, isn't necessarily broken, but with the advent of the Internet, yes, we do have problems, whether it is Phred the dog or Tom the cat or someone who died 20-some years ago, let alone any other wild-eyed example that I think we can come up with.

So I would just appreciate maybe further input from you. I will be talking to my State Attorney General to see what her thoughts are as she interacts with her colleagues, including you, in terms of

what we can do to particularly help the States enforce their laws in a more reasonable and careful manner.

I yield to Mr. Klink.

Mr. KLINK. Thank you, Mr. Chairman.

I just wanted to read into the record, this is the FDA Week from this week, July 23: An unapproved HIV test kit highlights problem with Internet promotion. Highlighting the recent difficulties FDA is having in regulating methodical products promotioned on the Internet, FDA recently issued a warning to consumers about unapproved HIV testing kits being sold on-line. This test was found to indicate false negative results, FDA said. In other words, blood samples from known HIV patients came back as negative. FDA sources say this is not an unprecedented case and may highlight the problems that FDA is facing with the new medium.

It goes on to say, one of the ways that FDA gets involved in these cases, whether it is Internet sale of pharmaceuticals or these test kits, is you have to get a complaint from somebody that feels that they have been ripped off. It is like it is okay to sell heroin on the street corner or crack cocaine. We will only send out the drug officers after one of the customers complains.

Think about it. That is literally what is happening. The FDA, the Federal Trade Commission, seem ill-equipped to deal with this. They are going to testify a little later on and tell us they have these task forces. My question is, what have these task forces accomplished?

We want to work with the States. I am willing to bend over backwards to preserve States rights, but there has to be some universal method of dealing with this problem. We haven't gotten it.

This is a great panel. You all have been great witnesses. We haven't gotten there yet. I am really thankful for this beginning hearing.

The question that we have is, General Stovall, I will start with you, it appears that if we—at a very minimum, we had some regulations that said, all right, tell us where you are located, where your offices are, on the web site, they have to be there. Where is your web site located? Where you operate from? Where is your warehouse? Who are your doctors? Who are the principals? Who licenses you? By what authority are you selling these medications? And if you are not doing that, then there should be authority, either the States and the Federal Government working together, to shut those web sites down. That seems to me to be a start. I am asking your opinion.

Ms. STOVALL. Absolutely. That was in my testimony as well. I agree with you wholeheartedly, that either all the States or the Federal Government need to make those requirements for disclosure.

Mr. KLINK. Well, we began, as Chairman Upton said, 7 or 8 months ago looking at this issue. For the last couple of months, we have been drafting a bill to do exactly that.

We would like to work with you, General, and with other State officials; and we have sent staff, majority and minority staff, across the country. We have been stymied by the fact that it appears that the States are overwhelmed by this.

One State official told us, and this is not negative toward the States, we don't have time to sit and play on the Internet all day. That is the way they viewed it. I understand that.

But it is a serious problem, and that is what it would require. It would require somebody actually sitting there on the Internet. And we are finding, as I said in my opening statement, I think, 30, 40 different sites every week. So it is very difficult to do that.

Does that begin to get us then—let me ask Ms. Egan and Ms. Behrens—get us where we need to be, if at least those sites are then held accountable for who operates them, who they are licensed by, where they are located? In other words, some disclosure of who is responsible, that we could begin to determine the chain of control of these controlled substances? We are then doing it by law.

Ms. EGAN. I think it certainly gives consumers a better idea of what they are dealing with, and they could call a board of pharmacy and run that by them if they had a license and number and name. Even if somebody put in a fake one, they could check it. If they wanted to be that diligent, a consumer could do that.

Mr. KLINK. You know, I am sure some of you have heard about this, there is the VIPPS program, which is voluntary. The Board of Pharmacy is not a law enforcement agency. The question I would have is, how often would they go out and inspect, and if they inspect and found out something was wrong, then what do you do?

Somebody on the majority side mentioned the fact that you could counterfeit the VIPS' Good Housekeeping Seal of Approval. We all recognize that. So the question here is whether or not there is a role to be played between those of us in the Federal Government—and, again, somebody else mentioned a floor, not a ceiling. We can't have some States taking action and some not, a patchwork of one set of regulations in one State, one set in another, when these things are not only, as the Chairman said, sold across State linings but are international as well. How can we have the States—and I would ask General Stovall, how would you be prepared from the State of Kansas to send your people out to other nations and go to New Zealand, Singapore, China——

Ms. STOVALL. We have a lot of volunteers.

Mr. KLINK. When you get there, what authority do you have to take action?

Ms. STOVALL. We don't. That is the difficulty, and what I mentioned earlier. For companies doing business on foreign soil, it is very difficult for us. There isn't any question about that.

Mr. KLINK. Well, we are looking forward to drafting our bill, and we would like to work with you before we do to make sure that, again, we want State input, make sure that we are working together with the States on this issue, but we think that there is a role hand in hand for the State and Federal Governments to work together.

Ms. STOVALL. The National Association of Attorneys General would be delighted to work with the committee on that.

Mr. KLINK. Thank you, Mr. Chairman.

Mr. UPTON. Do other members have pressing questions that would otherwise prevent us—thank you very much, members and panel, appreciate your very good testimony. We look forward to working with all of you, and we may have additional questions that

we may forward on, particularly for those members that are at other subcommittees, and if you would respond to that, that would be terrific.

You are now formally excused. Thank you.

Our second panel consists of Dr. Janet Woodcock, the Director for the Center for Drug Evaluation and Research at the Food and Drug Administration; Ms. Jodie Berstein, Director of the Bureau of Consumer Protection in the Federal Trade Commission; and Mr. Ivan Fong, Deputy Associate Attorney General, Department of Justice.

If you could take seats at the table, and before you sit down, you might have heard me tell the first panel that we have a long tradition of taking testimony under oath. Do any of you have objection to that?

Hearing none, under House rules, you are allowed to have counsel if you desire. If you would raise your right hand.

[Witnesses sworn.]

Mr. UPTON. You are now under oath. Your testimony is made part of the record in its entirety, and we would like to ask you, if you can, to summarize your testimony in 5 minutes or less.

Mr. UPTON. Ms. Bernstein, we will start with you.

TESTIMONY OF JODIE BERNSTEIN, DIRECTOR, BUREAU OF CONSUMER PROTECTION, FEDERAL TRADE COMMISSION; IVAN K. FONG, DEPUTY ASSOCIATE ATTORNEY GENERAL, DEPARTMENT OF JUSTICE; AND JANET WOODCOCK, DIRECTOR, CENTER FOR DRUG EVALUATION AND RESEARCH, FOOD AND DRUG ADMINISTRATION

Ms. BERNSTEIN. Thank you, Mr. Chairman, members of the subcommittee. I am pleased to be here to present the testimony of the Federal Trade Commission and to work with the committee on these important issues. The Commission's been monitoring the marketing of health care products and services on the Internet and pursuing law enforcement in this area for some time. The agency's conducted enforcement and consumer education initiatives to combat——

Mr. UPTON. If you could put the mike just a little closer, there is a little noise coming from the hallway. That would be great.

Ms. BERNSTEIN. [continuing] to combat on-line health fraud and is leading the effort to protect consumer privacy on-line. We are monitoring on-line pharmacy Web sites as well, conducting investigations, and making referrals to other State and Federal authorities as appropriate.

Prescription drugs available through on-line pharmacies offer consumers convenience and value. You have heard that a lot this morning, and we would reiterate that. Many on-line pharmacies appear to operate the same way as mail order pharmacies do; that is, in keeping with standards of State licensing authorities. Nevertheless, our review of the current practices of some on-line pharmacies and physicians that provide on-line prescription services indicate the potential for consumer injury is significant.

For example, just imagine the possibilities, and you've heard some this morning, for harm when prescriptions are issued without an adequate review of a consumer's medical history or when unap-

proved drugs are sold to consumers over the Internet by overseas pharmacies.

I know you have heard some of the anecdotes already, but we have one that I thought I would share with you as well. Our staff engaged in two mock on-line consultations in order to obtain the prescription drug Viagra. They were people, not dogs or cats, but nonetheless are illustrative. Although a number of factors were described in the medical history by our folks, and those medical histories should have raised serious concerns about the appropriateness of using a prescription for Viagra, such symptoms as bypass surgery, obesity, family history of heart disease and no information about other medications, a prescription was issued without question. Our staff were able to purchase Viagra on-line. Fortunately, through careful investigation we were able to identify both the doctor and the pharmacy involved in the sale and refer them to the relevant State and medical pharmacy boards.

The rapid growth in on-line sales of prescription drugs and the increase in the practice of on-line prescribing occurring across State, even international, borders present significant technological logistical challenges to the traditional regulatory framework. State medical and pharmacy boards have expressed concerns that their existing enforcement tools are not adequate to police the on-line marketplace. In many cases it can be difficult without extensive investigations to identify the name, location, State of licensure or registration for the physicians, pharmacies and Web site operators involved in the practices.

Our review of the 90 sites that Representative Dingell and Representative Klink sent us found—and we do have a visual—that there are very few that are providing adequate identifying information, sometimes no more than a mail drop. As you can see from the Pill Box that we've put in our graphic, this is what our review of those sites found. We have tried to summarize it for you.

Seventy percent of the sites were registered to a U.S. Address, although it was not easy to ascertain that. Forty percent provided a physical address on the site. Eighty percent offered an on-line consultation as a way to obtain a prescription, and most required a consultation. Twenty percent sold prescription drugs without a prescription, and only four sites appeared to require the patient to provide a prescription from the patient's own physician before they'd sell the drug.

Although medical information is the most sensitive kind of personal information, and these are some findings we made on the issue of privacy, none of the sites posted an adequate privacy statement describing what information's collected, how it would be used and whether it'll be disclosed to third parties. Sixty percent of the sites simply said that the information would be treated confidentially without saying how it would be used, and 40 percent of the sites provided no notice, not a word, about how they would handle the information from the consumers.

As to the identity of the prescribing physician or dispensing pharmacy, virtually none of the on-line pharmacy sites provided that information. Even when these parties can be located, it's difficult and expensive for any State medical or pharmacy board to pursue law enforcement against an out-of-State physician or phar-

macy, as you just heard from General Stovall, and we agree with that, with her analysis.

The Commission can protect consumers that use on-line pharmacies by bringing cases against specific deceptive practices, and we can and we have assisted other Federal and State authorities in their investigatory work, but the FTC's authority is limited and may not fully address the important consumer protection issues relating to the appropriate standards for prescribing and dispensing drugs traditionally regulated by the States. Based on our experience, we have recommended, and we do recommend and you've already heard much about it, that help for the State authorities in their investigations is necessary.

We would hope the subcommittee, and it already has stated that it probably will, consider legislative measures to mandate the posting of identifying information about physicians, pharmacies and Web site operators. Very specific information is required, and I won't go through that because I believe, Congressman Klink, you just identified the appropriate information.

We also would like to recommend that the subcommittee consider whether other measures are necessary, and again, General Stovall mentioned the FTC's experience in the telemarketing area. When telemarketing proliferated without a Federal statute, the same kinds of interstate problems arose; that is, the States were able to enforce within their own borders, but found the difficulties of stopping at the border to be a severe impediment. The Congress adopted the Telemarketing Sales Act which set a Federal standard and for the first time authorized the States to pursue those claims in Federal court.

We have worked very closely with the States, and in effect, we have 51 cops on the beat instead of one. It has been a very valuable experience from a federalism point of view, and we think the same kind of response could be helpful here. Thank you for giving us the opportunity to present our testimony this morning.

[The prepared statement of Jodie Bernstein follows:]

PREPARED STATEMENT OF JODIE BERNSTEIN, DIRECTOR, BUREAU OF CONSUMER PROTECTION,

Mr. Chairman and members of the Subcommittee, I am Jodie Bernstein, Director of the Bureau of Consumer Protection of the Federal Trade Commission ("FTC" or "Commission"). I am pleased to have this opportunity to review with you the Commission's consumer protection activities relating to the practices of online pharmacies.[1]

I. INTRODUCTION

The Commission is well aware of the rapid growth of the marketing of health care products and services via the Internet and has been actively monitoring and pursuing law enforcement in this area for some time. The agency, for instance, has conducted enforcement and consumer education initiatives to combat health fraud on the Internet; has been a leader in protecting consumer privacy in the online medium; and is now monitoring online pharmacy websites, conducting investigations, and making referrals to other federal and state authorities as appropriate. This morning I will discuss our authority in this area, how the FTC's role relates to that of other federal and state authorities, and describe some of our enforcement efforts and other activities to protect the online consumer from the deceptive marketing of

[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.

health care products generally, and prescription drugs specifically. I would also like to identify what the Commission believes are the most significant challenges facing federal and state authorities with enforcement authority over online pharmacies and suggest possible solutions.

The Internet offers significant consumer benefits in the form of greater and easier access to detailed health information, as well as more convenient, and often cheaper, access to health care products and services. In 1998, 22.3 million adults in this country sought health and medical information online, nearly 70% before visiting a doctor's office.[2] The number is predicted to increase to 30 million by the year 2001.[3] More and more often, consumers are turning to the Internet not just for health information but to purchase health care products. Unfortunately, the online medium also provides an easy opportunity for irresponsible marketers to prey on sick or vulnerable consumers with potentially serious consequences to consumers' health and pocketbooks.

Like other health care promotions on the Internet, the availability of prescription drugs via online pharmacies offers potential benefits to consumers, including convenience and value. Many online pharmacies appear to operate in essentially the same manner as mail order pharmacies and in keeping with standards of state licensing authorities. Nevertheless, our review of the current practices of some online pharmacies and of some physicians that provide online prescription services indicates the potential for serious consumer injury. 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. The Commission has limited anecdotal evidence of specific occasions where consumers have, in fact, received a prescription drug via the Internet that would be clearly inappropriate or even dangerous because of the age, health, or other drug use of the consumer.[4]

As the Subcommittee is aware, the rapid growth in online sales of prescription drugs and the increase in the practice of online prescribing, both of which are occurring across state and even international borders, present significant technological and logistical challenges to the traditional regulatory framework. State medical boards and state pharmacy boards have both expressed concerns that their existing enforcement tools are not adequate to police the online medium.[5] 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. Our review of almost 100 sites provided by Subcommittee staff found that very few provided adequate identifying information. 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 against an out-of-state physician or pharmacy prescribing or dispensing prescription drugs inappropriately via the Internet.

The Commission can play a role in protecting consumers who use online pharmacies by bringing cases against specific deceptive practices. The agency can also assist other federal and state authorities in their investigatory work. The FTC's authority, however, is limited and may not fully address the important consumer protection issues raised here. To a large extent, the practices that present the greatest concerns involve issues relating to the appropriate standards for prescribing and dispensing drugs, both of which have been traditionally regulated by the states. The Commission suggests that the Subcommittee consider whether additional legislative

---

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

[3] *Id.*

[4] We have received very few complaints about online pharmacies. In one complaint filed with the FTC, however, a parent reported that her minor son had obtained Viagra® over the Internet. Part of the parent's concern was the fact that her son had bipolar disorder, neurocardiac syncope, and was taking blood pressure medication at the time, clearly increasing the potential for injury from using this drug.

[5] *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.").

measures are necessary to address the unique characteristics of this medium and ensure greater protections for consumers. Specifically, requirements for clear and prominent disclosure of identifying information for the online prescribing physician, the online pharmacy and the website owner, if different, as well as the states where prescriptions will be dispensed, would greatly assist state law enforcement efforts. We also recommend that additional consideration be given to assisting states with extraterritorial jurisdiction issues.

II. SCOPE OF COMMISSION AUTHORITY

The Commission's authority derives from the agency's mandate to prevent deceptive or unfair acts or practices in commerce, pursuant to Section 5 of the Federal Trade Commission Act ("FTC Act").[6] The marketing of prescription drugs online would be deceptive in violation of FTC law if it involved a 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.[7] For example, the Commission would have authority to take action if an online pharmacy or website operator made false or misleading claims about the safety or efficacy of the drug it was offering.[8] Another example of a deceptive practice within the Commission's jurisdiction would be the misrepresentation by an online pharmacy of its privacy practices, for instance, false statements about how the site collects and uses medical information about the consumer.[9]

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.[10] Although some parties have suggested that certain online prescribing practices by physicians may be so inadequate as to be unfair, these practices raise difficult issues involving physician practices that the Commission has traditionally refrained from regulating.

III. INTERACTION WITH FEDERAL AND STATE REGULATORY AUTHORITIES

As we have noted, many aspects of the online prescribing and dispensing of prescription drugs do not fall clearly within the agency's traditional scope of authority or expertise and have been the primary responsibility of other federal and state agencies.

The other principal federal agency with authority in this area is the Food and Drug Administration ("FDA"). The FDA has primary jurisdiction to regulate labeling and advertising claims made by the manufacturer, distributor or packer of prescription drugs.[11] In addition, the FDA has the authority to take action against the dispensing of a prescription drug without a valid prescription.[12] Because the FTC and the FDA have such closely related and overlapping authority over a number of products, including prescription drugs, the two agencies coordinate closely pursuant to a longstanding liaison agreement.[13] In fact, the Commission recently referred to the

---

[6] 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. Under Section 4 of the FTC Act the agency has jurisdiction over marketers based outside the U.S. border selling in the U.S. market that violate Sections 5 and 12. 15 U.S.C. § 44.

[7] *See* Deception Policy Statement, appended to *Cliffdale Associates, Inc.,* 103 F.T.C. 110, 174 (1984).

[8] In fact, the Commission has challenged such claims in both the online context and in other media. *See, e.g., American College for Advancement in Medicine,* Dkt. No. C-3882 (June 22, 1999) (settlement resolving allegations respondent made unsubstantiated claims for effectiveness of therapy using prescription drug for treating heart disease); *FTC v. Pacific Medical Clinics,* 1992-1 Trade Cas. (CCH) ¶69,777 (S.D. Cal. April 8, 1992)(defendants misrepresented effectiveness of prescription drug for treating obesity).

[9] The Commission has been very active in the protection of consumer privacy particularly in the online context, as discussed below. The agency has also specifically challenged misrepresentations about the use of a consumer's medical information, although not in the online context. *See, e.g., Equifax, Inc.,* 96 F.T.C. 844 (1980), *rev'd on other grounds,* 678 F.2d 1047 (11th Cir. 1982)(deceptive to represent, inaccurately, that medical information would be released only to specified insurance companies).

[10] *See* Unfairness Policy Statement, appended to *International Harvester Co.,* 104 F.T.C 949, 1070 (1984); 15 U.S.C. § 45 (n).

[11] *See* 21 U.S.C. §§ 351 *et seq.*

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

[13] 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 labeling and advertising of prescription drugs if those claims are made by a manufacturer, packer, or distributor. *See* Working Agreement Between FTC and Food and

FDA's Office of Criminal Investigation two matters involving U.S. websites that were offering prescription drugs without requiring prescriptions.

Many of the concerns expressed about online pharmacies relate to the practice of physicians engaging in online medical consultations with consumers and issuing prescriptions without any pre-existing doctor-patient relationship. The question of when and under what circumstances, if at all, it is safe and appropriate to prescribe medications without actually seeing a patient is difficult and raises issues that fall beyond this agency's traditional expertise.

The Commission has long refrained from challenging practices that fall within the doctor-patient relationship, including communications between doctors and patients about course of treatment decisions.[14] The FTC does not have the authority to revoke an individual physician's license or to enforce state licensing requirements. The agency believes that judgments about the practice of medicine are better left to the individual state medical boards, which establish standards of practice and oversee the licensing of individual physicians. It is our understanding that many states currently prohibit the issuing of prescriptions based solely on a consumer's answers to an online questionnaire.[15]

Similarly, the licensing and regulation of pharmacies, like the licensing of physicians, has traditionally taken place at the state level by state pharmacy boards. The Commission does not have authority to revoke a pharmacy's license or to enforce regulations relating to licensing of pharmacies. Again, issues about what constitute appropriate practices by an online pharmacy are better left to the state authorities with the relevant expertise.

While the Commission believes that state authorities should continue to have responsibility for enforcement of licensing requirements for physicians and pharmacies, the FTC has and will continue to provide assistance to those authorities in individual investigations.

IV. SPECIFIC COMMISSION ACTIVITIES RELATING TO ONLINE PHARMACIES

The Commission believes its role with regard to online pharmacies is limited under the current legal framework and that the primary responsibility should remain with the states and FDA. Within the scope of our authority, we have taken a number of actions in this area: monitoring websites; conducting investigations; and making referrals to other federal and state authorities. In addition, we coordinate many of our activities through an interagency working group.

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. On April 26, 1999, an interagency working group, comprised of the FTC, FDA, the Department of Justice (DOJ), the Drug Enforcement Agency (DEA), and other federal and state agencies, met to consider the regulation of online pharmacies and other issues relating to the sale of drugs over the Internet. One of the group's tasks is to explore enforcement issues and potential jurisdictional gaps. One follow-up meeting has been held and an additional meeting is scheduled for September 1999. The FTC will continue to participate in the meetings of this group and to consult informally with appropriate authorities as specific issues arise.

Another important function of the Commission is that of monitoring the practices of online pharmacy sites and using our Internet expertise to assist other state and federal authorities in their enforcement efforts. The FTC has the technical capacity to monitor and investigate Internet marketing and is continuing to upgrade our cur-

---

Drug Administration, 3 Trade Reg. Rep. (CCH) ¶9,859.01 (1971). 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.

[14] In contrast, the Commission does 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. *Dr. Scott M. Ross,* 115 F.T.C. 54 (1992) (consent agreement resolving misrepresentations of safety, recovery period, discomfort of liposuction).

[15] *See, e.g.,* attached letters from Alabama State Board of Medical Examiners, dated March 11, 1999; State of Colorado, Department of Regulatory Agencies, dated March 23, 1999; State of Connecticut, Department of Consumer Protection, dated December 17, 1998; Government of the District of Columbia, Department of Health, Office of Professional Licensing, dated March 5, 1999; Kansas Board of Healing Arts, dated January 5, 1999; Louisiana State Board of Medical Examiners, dated January 29, 1999; State of Nevada, Office of the Attorney General, dated March 25, 1999; New Mexico Board of Pharmacy, dated January 19, 1999; State of Oklahoma, Board of Licensure & Supervision, dated February 19, 1999; State of Tennessee, Department of Health, Health Related Boards, dated March 10, 1999; State of Wisconsin, Department of Registration & Licensing, dated February 12, 1999.

rent technology. For example, our computer equipment permits staff to locate and preserve websites for evidentiary purposes.

The Commission's monitoring activities have led to a few preliminary investigations. In one situation, staff completed two mock online consultations in order to obtain the prescription drug Viagra®. For one of these consultations, staff described a number of factors in the "patient's" medical history that should have raised serious concerns about the appropriateness of issuing a prescription for Viagra®, such as bypass surgery, obesity, family history of heart disease and the absence of any information about other medications. In both cases, staff was issued a prescription without question and was able to purchase the Viagra® online. This investigation led to referrals to the relevant state medical and pharmacy boards. To the extent possible, Commission staff have also assisted state authorities in identifying and locating specific online pharmacies and physicians.

The Commission has also played a role in other closely related areas involving the marketing of health care products on the Internet and the protection of consumer privacy online. For example, the Commission recently announced "Operation Cure.All," a comprehensive consumer education and enforcement initiative to combat health fraud on the Internet. The project was the outcome of two "surf days"[16] in which the FTC and other government and private partner organizations identified nearly 800 websites making questionable claims that a product or treatment could cure or treat diseases like cancer, arthritis, AIDS, multiple sclerosis, diabetes and heart disease. As part of this project, the Commission announced four cases against companies marketing non-prescription health products on the Internet and is currently pursuing additional cases.[17] The Commission has also filed other cases against Internet marketers of health care products in recent years, including a dietary supplement program purported to cure Attention Deficit Disorder and another dietary supplement referred to as "Vitamin O" for the treatment of several diseases including cancer and pulmonary disease.[18]

Finally, the Commission has been active in the protection of consumer privacy online, an area that has great relevance to the subject of online pharmacies given that highly sensitive medical information is often collected as part of the online consultation. The Commission, for instance, has engaged in extensive monitoring of the privacy practices of websites, has conducted workshops on the issue, prepared reports to Congress on the self-regulatory efforts of industry on this topic, assisted in the development of legislation to protect children's online privacy, and issued proposed rules to implement that legislation.[19] The Commission has also brought enforcement actions against websites engaged in deceptive practices relating to the collection and use of personal consumer information.[20] Online pharmacies that make false or misleading representations about how they collect and use personal information would be subject to similar FTC challenge.

V. 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

---

[16] The FTC has developed a unique concept known as a "surf day." Together with other law enforcement partners, FTC staff use common search engines to surf the Internet for a specified period of time and send business education messages via e-mail to websites making potentially deceptive claims.

[17] *See Arthritis Pain Care Center (APCC) et al.,* File No. 982 3182 (June 24, 1999)(consent subject to final approval challenging arthritis claims for CMO dietary supplement); *Body Systems Technology, Inc.,* File No. 982 3177 (June 24, 1999)(consent subject to final approval challenging claims for treatment/cure of several diseases including cancer and AIDS for shark cartilage capsules and Cat's Claw herbal supplement); *Pain Stops Here! Inc., et al.,* File No. 982 3175 (June 24, 1999) (consent subject to final approval challenging claims for magnetic therapy to treat cancer, liver disease, arthritis and other conditions); and *Magnetic Therapeutic Technologies, Inc. et al.,* File No. 982 3150 (June 24, 1999)(consent subject to final approval challenging claims for magnetic therapy devices to treat various diseases and conditions including cancer and high blood pressure). Operation Cure.All also included a consumer education campaign that provided links on our website, www.ftc.gov, to sources of reliable health information, gave tips to consumers on how to avoid "virtual health fraud" and set up "teaser" sites to alert Inter

[18] *New Vision International,* FTC Dkt. No. C-3856 (March 3, 1999); *FTC v. Rose Creek Health Products, Inc.,* CS-99-0063-EFS (E.D. Wash.) (case pending).

[19] *See, e.g.,* "Self-Regulation and Privacy Online," Prepared Statement of the Federal Trade Commission before the Subcommittee on Telecommunications, Trade, and Consumer Protection of the U.S. House Committee on Commerce (July 13, 1999); *Federal Trade Commission, Self-Regulation and Privacy Online: A Report to Congress* (July 1999).

[20] *See, e.g., GeoCities,* C-3849 (Feb. 12, 1999)(consent order challenging misrepresentations about the website's use of personal information collected from children and adults).

and risk of consumer injury are those involving the professional conduct of individual physicians or issues relating to the licensing of pharmacies and safeguards on the dispensing of prescription drugs that have traditionally been regulated by state authorities. Those state authorities appear to have laws that are substantively adequate to stop irresponsible prescribing and dispensing of drugs via the Internet. The real challenge lies in dealing with the logistical difficulties of identifying responsible parties and enforcing laws across state boundaries. State authorities and other groups are attempting to address the most troubling practices through issuance of guidelines, certification programs and other non-legislative approaches,[21] but those efforts, while valuable, still do not provide the tools necessary for effective and meaningful enforcement.

Based on the Commission's experience in this area, we recommend that the Subcommittee consider legislative measures that would assist state authorities in their investigations by mandating that certain identifying information about physicians, pharmacies and website operators be posted. Specifically, we suggest that each website offering prescription drugs for sale be required to disclose the following information clearly and prominently:

1) the name, business address, and phone number of the pharmacy that will dispense the prescription and the state or states where such pharmacy is licensed or registered to do business;
2) the name, address, and phone number of each physician providing the online prescribing services and the state or states where such physician is licensed or authorized to practice medicine, if such service is offered;
3) the name, business address, phone number, and principal officers or owners of the online business offering prescription drugs, if different from the pharmacy or physician; and
4) the state or states from which the website will accept orders for prescription drugs.

Finally, the Commission recommends that consideration should be given to determining what other measures are necessary to assist state pharmacy and medical boards with enforcement of state laws against extraterritorial prescribing practices, including possibly granting states the authority to bring actions in federal district court.

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

[21] Specifically, it is our understanding that the National Association of Boards of Pharmacy is currently developing a certification program for online pharmacies, the "Verification of Internet Pharmacy Practice Sites (VIPPS)." In addition, the Federation of State Medical Boards is currently addressing the issue of online prescribing by physicians and considering a recommendation that prescribing, electronically or otherwise, without an adequate patient evaluation be considered unprofessional conduct under state medical practice. Finally, we understand that the AMA has adopted a resolution on this issue and is developing principles regarding online prescribing services.

ALABAMA STATE BOARD OF MEDICAL EXAMINERS
OFFICE OF THE GENERAL COUNSEL
848 WASHINGTON AVE
MONTGOMERY, AL 36104
MAILING ADDRESS
P.O. BOX 946
MONTGOMERY, AL 36101-0946

PATRICIA E. SHANER
GENERAL COUNSEL
TEL (334) 242-4116
FAX (334) 242-4155

WENDELL R. MORGAN
ASSOCIATE GENERAL COUNSEL
TEL (334) 242-4739
FAX (334) 269-5200

March 11, 1999

Bureau of Consumer Protection,
Advertising Practices
Federal Trade Commission
Sixth Street and Pennsylvania Avenue, NW
Washington D.C. 20580

RE: Internet Advertising of Viagra

Dear Sir or Madam:

This letter is written at the direction of the Alabama State Board of Medical Examiners to request that the Federal Trade Commission undertake an investigation of advertising which appears in the print media and on the Internet related to the interstate sale and distribution of the drug Viagra. It is the opinion of the Alabama State Board of Medical Examiners that advertisements soliciting interstate sale of Viagra are detrimental to the health and safety of the citizens of this state and is contrary to state and federal law.

As I am sure you are aware, Viagra is a legend drug regulated under the authority of the Food and Drug Administration which requires that it may be only dispensed upon the written order of a licensed practitioner. Alabama law, Section 34-24-501, et. seq., Code of Alabama 1975 prohibits the practice of medicine across state lines by a physician located in another state unless that physician has secured either a special purpose license or a full and unrestricted license to practice medicine in this state.

The Board has asked that I call to your attention to two advertisements in the February 16, 1999 edition of USA Today, both of which advertise the availability of Viagra over Internet sites. Copies of those advertisements as well as copies of the information on those Internet web sites are enclosed.

Due to the potential for serious side effects associated with the use of Viagra, the Board of Medical Examiners is of the opinion that it should only be prescribed within the

context of a legitimate physician-patient relationship by a practitioner licensed to practice medicine in that jurisdiction. The Board further believes that advertising of the type provided with in this letter is false and misleading because it fails to disclose to potential consumers the state and federal restrictions on the legal prescribing and distribution of this drug. Because of the limited authority of state agencies, it is incumbent upon the Federal Trade Commission to use its authority to regulate the advertisements placed in national publications and over the Internet. Please advise the Board of Medical Examiners of the actions your agency proposes to take in response to this request.

Thank you.

Yours sincerely,

Wendell R. Morgan
Associate General Counsel

WRM:skf

Enclosures

cc: Office of Consumer Protection,
Alabama Attorney General

Larry D. Dixon, Executive Director
Alabama State Board of Medical Examiners

Citation Search Result Rank 8 of 20 Database
AL ST s 34-24-501 AL-ST-ANN
Ala.Code 1975 § 34-24-501

TEXT

CODE OF ALABAMA
TITLE 34. PROFESSIONS AND BUSINESSES.
CHAPTER 24. PHYSICIANS AND OTHER PRACTITIONERS OF HEALING ARTS.
ARTICLE 10. LICENSING THE PRACTICE OF MEDICINE AND OSTEOPATHY ACROSS STATE LINES.
COPYRIGHT © 1998 BY STATE OF ALABAMA
Current through End of 1998 Reg. Sess.

§ 34-24-501. Definitions.

(a) The practice of medicine or osteopathy across state lines means the practice of medicine or osteopathy as defined in Section 34-24-50(1), as it applies to:

(1) The rendering of a written or otherwise documented medical opinion concerning the diagnosis or treatment of a patient located within this state by a physician located outside this state as a result of transmission of individual patient data by electronic or other means from within this state to such physician or his or her agent; or

(2) The rendering of treatment to a patient located within this state by a physician located outside this state as a result of transmission of individual patient data by electronic or other means from this state to such physician or his or her agent.

(3) This definition is not intended to include an informal consultation between a licensed physician located in this state and a physician located outside this state provided that the consultation is conducted without compensation to or the expectation of compensation to either physician and does not result in the formal rendering of a written or otherwise documented medical opinion concerning the diagnosis or treatment of a patient by the physician located outside the state.

(b) Board means the State Board of Medical Examiners created under Section 34-24-53.

(c) Commission means the Medical Licensure Commission created under Section 34-24-310.

CREDIT

(Acts 1997, No. 97-166, § 2.)

<General Materials (GM) - References, Annotations, or Tables>

HISTORICAL NOTES -- HISTORY

Effective date:

The act which added this section became effective July 1, 1997.

Ala. Code 1975 § 34-24-501
AL ST § 34-24-501
END OF DOCUMENT

Citation Search Result Rank 2 of 20 Database
AL ST s 34-24-502 AL-ST-ANN
Ala.Code 1975 § 34-24-502

TEXT

CODE OF ALABAMA
TITLE 34. PROFESSIONS AND BUSINESSES.
CHAPTER 24. PHYSICIANS AND OTHER PRACTITIONERS OF HEALING ARTS.
ARTICLE 10. LICENSING THE PRACTICE OF MEDICINE AND OSTEOPATHY ACROSS STATE LINES.
COPYRIGHT © 1998 BY STATE OF ALABAMA
Current through End of 1998 Reg. Sess.

§ 34-24-502. Licensure.

(a) License requirement. No person shall engage in the practice of medicine or osteopathy across state lines in this state, hold himself or herself out as qualified to do the same, or use any title, word, or abbreviation to indicate to or induce others to believe that he or she is licensed to practice medicine or osteopathy across state lines in this state unless he or she has been issued a special purpose license to practice medicine or osteopathy across state lines in accordance with the provisions of this article; provided however, that no person who holds a full, unrestricted and current license issued under Sections 34-24-310 to 34-24-343, inclusive, shall be required to obtain a special purpose license to practice medicine or osteopathy across state lines.
(b) Issuance of license. The Medical Licensure Commission shall issue a special purpose license to practice medicine or osteopathy across state lines upon presentation by an applicant of a certificate of qualification issued by the State Board of Medical Examiners in accordance with this section. The authority of the commission to issue, revoke, or suspend the special purpose license to practice medicine or osteopathy across state lines shall be the same as the general authority granted to the commission under Sections 34-24-310 to 34-24-406, inclusive. The State Board of Medical Examiners shall issue a certificate of qualification to the Medical Licensure Commission certifying an applicant for a special purpose license to practice medicine or osteopathy across state lines who has met the following requirements:
(1) The applicant holds a full and unrestricted license to practice medicine or osteopathy in any and all states of the United States or in territories in which such individual is licensed; and
(2) The applicant has not had any previous disciplinary action or other action taken against the applicant by any state or licensing jurisdiction.
(3) In the event of previous disciplinary or other action against the applicant, the board may issue a certificate of qualification if it finds that the previous disciplinary or other action does not indicate that the physician is a potential threat to the public. An individual shall submit an application for a certificate of qualification for a special purpose license to practice medicine or osteopathy across state lines on a form provided by

Copr. © West 1999 No Claim to Orig. U.S. Govt. Works

TEXT

the board and shall remit an application fee in an amount established by the board in its regulations.

(c) A special purpose license issued by the commission to practice medicine or osteopathy across state lines limits the licensee solely to the practice of medicine or osteopathy across state lines as defined herein. The special purpose license in this state is valid for a period of three years, shall expire on a renewal date established by the commission in its regulations in the third calendar year after its issuance, and may be renewed upon receipt of a renewal fee as established by the commission in its regulations. Failure to renew a license according to the renewal schedule established by the commission shall result in the automatic revocation of the special purpose license to practice medicine or osteopathy across state lines; provided, however, that an applicant may re-apply following automatic revocation for failure to renew.

CREDIT

(Acts 1997, No. 97-166, § 3.)

<General Materials (GM) - References, Annotations, or Tables>

HISTORICAL NOTES -- HISTORY

HISTORY

Effective date:

The act which added this section became effective July 1, 1997.

Ala. Code 1975 § 34-24-502

AL ST § 34-24-502

END OF DOCUMENT

Copr. © West 1999 No Claim to Orig. U.S. Govt. Works

Citation Search Result Rank 5 of 20 Database
AL ST s 34-24-503 AL-ST-ANN
Ala.Code 1975 § 34-24-503

TEXT

CODE OF ALABAMA
TITLE 34. PROFESSIONS AND BUSINESSES.
CHAPTER 24. PHYSICIANS AND OTHER PRACTITIONERS OF HEALING ARTS.
ARTICLE 10. LICENSING THE PRACTICE OF MEDICINE AND OSTEOPATHY ACROSS STATE LINES.
COPYRIGHT © 1998 BY STATE OF ALABAMA
Current through End of 1998 Reg. Sess.

§ 34-24-503. Effect of license.

(a) The issuance by the commission of a special purpose license to practice medicine or osteopathy across state lines subjects the licensee to the jurisdiction of the board and the commission in all matters set forth in Sections 34-24-50 to 34-24-83, inclusive, and Sections 34-24-310 to 34-24-406, inclusive, and the implementing rules and regulations of the commission and the board, including all matters related to discipline. It shall be the affirmative duty of every licensee to report to the Board of Medical Examiners in writing within 15 days of the initiation of any disciplinary action against the license to practice medicine or osteopathy of the licensee by any state or territory in which the licensee is licensed. In addition, the licensee agrees, by acceptance of such license, to produce patient medical records or materials as requested by the board or the commission or to appear before the board or the commission or any of its committees following receipt of a written notice issued by the board or commission. Such notice may be issued by the board or the commission pursuant to the authority granted under Sections 34-24-52, 34-24-56, and Sections 34-24-310 to 34-24-406 inclusive.

(b) The Medical Licensure Commission is hereby authorized to temporarily suspend a special purpose license to practice medicine or osteopathy across state lines without a hearing on either of the following grounds:

(1) The failure of the licensee to appear or produce records or materials as requested by the board or the commission; or

(2) The initiation of a disciplinary action against the licensee by any state or territorial licensing jurisdiction in which the licensee holds a license to practice medicine or osteopathy.

(c) Notwithstanding any other provision of law including the Alabama Administrative Procedure Act to the contrary, the temporary suspension provided herein shall remain in effect until either the licensee has complied with the request of the board or commission or the disciplinary action pending against the licensee has been terminated in favor of the licensee and the temporary suspension is terminated by a written order of the Medical Licensure Commission. In addition to the foregoing, a special purpose license to

Copr. © West 1999 No Claim to Orig. U.S. Govt. Works

TEXT
practice medicine or osteopathy across state lines is subject to each of the grounds for disciplinary action as provided in Section 34-24-360, in accordance with procedures set out in Section 34-24-361, and the Alabama Administrative Procedure Act.
CREDIT

(Acts 1997, No. 97-166, § 4.)

<General Materials (GM) - References, Annotations, or Tables>

HISTORICAL NOTES -- HISTORY

HISTORY

Effective date:

The act which added this section became effective July 1, 1997.

Ala. Code 1975 § 34-24-503
AL ST § 34-24-503
END OF DOCUMENT

Copr. © West 1999 No Claim to Orig. U.S. Govt. Works

Citation
AL ST s 34-24-506
Ala.Code 1975 § 34-24-506

Search Result

Rank 7 of 20

Database
AL-ST-ANN

TEXT

CODE OF ALABAMA
TITLE 34. PROFESSIONS AND BUSINESSES.
CHAPTER 24. PHYSICIANS AND OTHER PRACTITIONERS OF HEALING ARTS.
ARTICLE 10. LICENSING THE PRACTICE OF MEDICINE AND OSTEOPATHY ACROSS STATE LINES.
COPYRIGHT © 1998 BY STATE OF ALABAMA
Current through End of 1998 Reg. Sess.

§ 34-24-506. Sanctions.

(a) Any person who violates the provisions of this article is subject to criminal prosecution for the unlicensed practice of medicine or osteopathy under the provisions of Section 34-24-51, or injunctive or other action authorized in this state to prohibit or penalize continued practice without a license under the provisions of Section 34-24-52.
(b) Nothing in this article shall be interpreted to limit or restrict the commission's authority to discipline any physician licensed to practice in this state who violates the provisions of Sections 34-24-310 to 34-24-406, inclusive, while engaging in the practice of medicine within this or any other state.
CREDIT

(Acts 1997, No. 97-166, § 7.)

<General Materials (GM) - References, Annotations, or Tables>

HISTORICAL NOTES -- HISTORY

HISTORY

Effective date:

The act which added this section became effective July 1, 1997.

Ala. Code 1975 § 34-24-506
AL ST § 34-24-506
END OF DOCUMENT

Copr. © West 1999 No Claim to Orig. U.S. Govt. Works

VIAPRO

Viagra™ Accept no substitutes!

VIAGRA FACTS
REFILLS
NITRATE LIST
ORDER VIAGRA
NEWS LETTER
STORE

Viagra ® has just recently been approved for sexually dysfunctional or impotent men. Approximately 10 to 20 million men in the U.S. are sexually dysfunctional (previously referred to as impotence). The traditional medical treatment for these men varies from suppository methods to penile implant. The new medication Viagra ® by Pfizer is a revolutionary treatment that will help about 70% of men suffering from sexual dysfuntion. Viapro provides a simple, secure and confidential way for you to be evaluated for Viagra ® use and purchase your Viagra ® prescription online. Viapro offers secure online consultation with its resident physicians for men who are suffering from erectile dysfunction. If the physician approves the use of Viagra ®, the patient can order and refill Viagra through Viapro. Both your physician consultation and your Viagra ® prescription order and transaction are encrypted on our secure website for complete confidentiality. Please review facts about Viagra ® on our Viagra Facts page.

NOTE: We do not service the state of Arizona.

Order now and recieve
(click here)
a free pill splitter!

Looking for fun on the web?
SEND FREE VIRTUAL POSTCARDS NOW! → Pick card category Click Here!

Online Consultation and Prescription for Viagra ®

Express Rx
VIAGRA PRESCRIPTIONS ONLINE

HOME
ORDER VIAGRA
VIAGRA REVIEW
REFILL VIAGRA
CONTACT US

You are at
STEP 1

Waiver of Liability

I hereby release ExpressRX Services and all of its employees and contractors including physicians from any and all liability whatsoever associated or connected with my Viagra® Consultation and/or use of Viagra®. I hereby state that I am an adult and that I am aware of the potential side effects associated with Viagra ®. I hereby agree to answer truthfully all of the medical questions on my questionnaire.

I understand that no doctor, nurse, or administrative personnel can guarantee that Viagra ® , even if prescribed, will provide the results I seek. Further, I understand that even if prescribed, I may suffer adverse effects from Viagra ®. I hereby release ExpressRX Services and all of its employees and contractors including physicians from any and all liability whatsoever associated with any adverse effects I may suffer from my use of Viagra ®.

I am participating in this program at my own choice, at my own expense and my own liability and assume all responsibility for my use of Viagra ®. I fully understand that it is my responsibility to have an annual physical examination, including any suggested laboratory tests, to ensure that I have no disease(s) which might make Viagra® inappropriate for my condition. I further agree that I have consulted with my physician and/or pharmacist and hereby warrant that I am not taking any medications or combination of medications that are on the published list of medications which would make Viagra® contraindicated. I further agree to immediately notify any doctor whose present care I am under that I have chosen to take Viagra® so that they may advise to continue or discontinue use.

We are unable to accept returns or issue refunds for any orders due to the fact that this is a prescription medication.

Customer is responsible for all customs, tariffs, and taxes, if applicable to their country.

I DISAGREE I AGREE

HOME | ORDER VIAGRA | VIAGRA REVIEW | REFILL VIAGRA | CONTACT US | E-MAIL

ExpressRX is a DBA of ExpressMed Services Corp.

All trademarks and registered trademarks are of their respective companies.
© Copyright 1998 DomaNet Inc., all rights reserved ©

Online Consultation and Prescription for Viagra ®

You are at

STEP 2

Personal and Payment Info

Please provide the following information as completely and accurately as possible. All information must be provided to process your consultation. The following information is transmitted to us using a SSL secure connection.

Directions

- Please fill out all fields completely.
- **You will not be charged the $75.00 Consultation fee if you are not approved.**

Name:		
Address:		
City:		
State:		
Zip Code:		
Country:		
Phone:		
Email:		

If I am approved for Viagra ®, I would like my prescription to be charged to my credit card and dispensed by ExpressRX Services. This initial prescription is good for a total of 120 Viagra ® tablets. You may order as many as you wish at this time and the balance in the future with no further consultation fee. For patients who select the 100mg dose, ExpressRX Services is offering a FREE pill splitter.

Splitting the 100mg dose can result in a cost of only $4.95 per dose!!

I Request the following pill prescription

50 mg	100 mg
Select Quantity Desired	Select Quantity Desired BEST VAL

Send my prescription as follows

◉ Within the U.S.A, Federal Express (overnight) $18.00
○ Outside the U.S.A., Federal Express (2-4 days) $47.00

Attention: International Orders. By asking us to ship to another country, you are assuming all liability for any customs, duties, or tariffs. Should customs seize the shipment, we cannot refund your cost. If it is returned to us, you will be charged for shipping both ways. ☒ **I Agree**

Credit Card Information

Notes:	Name of Credit Card Holder:
• All amounts are in **US currency**. • If the address and zip code you listed above are the same as the address and zip code that your credit card statement is sent to, then don't enter anything for billing address and zip code. • For expiration dates in the year 2000 and above enter 00 for 2000, 01 for 2001, etc.	Enter Credit Card Number: Billing Address: Billing Zip Code: Expiration (MM/YY):

By submitting this consultation form

	Agree
I certify that I am 18 years of age or older.	☐
I am permitted by law to receive these products in my region/country/locale .	☐
I understand the side-effects of this drug.	☐
I do not have a current prescription for Viagra® from another physician.	☐
I certify that I am allowed by law to use the credit card I have selected below.	☐
I understand that my credit card will be billed for this consultation and that if I choose to have Viagra ® dispensed from ExpressRX Services, this too will be billed to my account if my consultation is approved.	☐
I certify that I will answer all the questions truthfully.	☐

Medical History

STEP 3

Your Medical History informs us of any possible medical contraindications you may have to taking Viagra®. This information would be required before any physician could treat you for any illness or condition.

What is your height (in inches)? ☐ Sex? ◉ male ○ female

What is your current weight (in lbs)? 0 What is your month and year of birth? ☐ (MM/YY)

Are you taking any of the following?

Nitroglycerin	Nitrek (transdermal)	Nitro-Bid®
Nitrodisc	Nitro-Dur®	Nitrogard ™
Nitroglyn	Nitrlingual Spray®	Nitrol® Ointment (Apoll-Kit)®
Nitrong	Nitro-Par	Nitrostar®
Nitro-Time	Transderm-Nitro®	Isosorbide Mononitrate
Imdur®	Ismo®	Monoket®
Isosorbide Dinitrate	Dilarate®-SR	Isordil®
Sorbitrate®	Erythatyl Tetranitrate	Pentaerythritol Tetranitrate
Sodium Nitroprusside	Deponit® Transdermal	

Do you have any of the following medical problems?

Coronary Artery Disease	Congestive Heart Failure	Valvular Heart Disease
Anatomic Deformation of the Penis	Peyronie's Disease	Multiple Myeloma
Obesity	Hypertension	Diabetes Mellitus
Prostate Cancer	Enlarged Prostate	Low Testosterone
Thyroid Disease	Atherosclerosis	Liver Disease
Kidney Disease	Stroke	Depression
Anxiety	Schizophrenia	Spinal Cord Injury
Endocrine Disorders	Sickle Cell Anemia	Leukemia

Have you had a complete physical exam with blood tests within the last year?	yes no
Do you consume more than 2 servings a day of alcohol?	yes no
Do you smoke cigars or cigarettes?	yes no

List current medications and any medical problems.

Are you unable to achieve and sustain an erection that is adequate for penetration until orgasm? yes no

Have you ever been evaluated for erectile dysfunction? yes no

I feel that I am incapable of having normal satisfying sex without prescription medication. true false

Where did you hear about us?

Newspaper Ad

Please Specify Which Newspaper

Please only click the Complete Consultation Button **ONCE**.
It may take a moment to check your information.

Complete Consultation

If you have any questions, please call
ExpressRX Services,
1-800-435-2668

HOME | PRODUCT REVIEW | REFILL VIAGRA | CONTACT US

ExpressRX is a DBA of ExpressMed Services Corp.

All trademarks and registered trademarks are of their respective companies.
© Copyright 1998 DomaNet Inc., all rights reserved ©

Turmoil in Little Saigon

Conflict over poster stirs up Vietnamese community

By Carol Morello
USA TODAY

WESTMINSTER, Calif. — Ghosts from the Vietnam War hang over a strip of Orange County called Little Saigon, where a businessman's quest to put up a Ho Chi Minh poster has provoked pain and anger among refugees.

A court ruled last week that Truong Van Tran has the First Amendment right to hang the poster and a Vietnamese flag at his video store. But police said Monday that they could not protect him if he waded through a crowd of 500 emotional protesters who blocked traffic and his door in defiance of a court order. Many of them went as they sang the anthem of the former South Vietnam, evoking memories of relatives who had died in the war and brutal years spent in re-education camps.

Last week, Tran collapsed when protesters crowded in on him and wiped spit off his face as he tried to reach his store.

After trying again Monday, Tran decided not to press the issue until another day, as 200 [illegible]

Tran: His views have softened

hard-line stance after he first fled Vietnam at age 17 to avoid being conscripted into the army. But he said his views softened after he took meditation courses and grew to believe that only forgiveness could heal wounds still raw from the protracted civil war.

For years before the United States re-established diplomatic relations with Vietnam in 1995, Tran tried to find a public forum to argue that the regime will gradually change if Americans visit and trade with Vietnam and if student exchanges expose Vietnamese to capitalism and freedom.

But no Vietnamese news [illegible]

Vocal: Andy Nguyen's sign compares Ho Chi Minh to Adolf Hitler

[illegible] when he heard his name being mentioned on radio talk shows. He was labeled a communist, and some callers said if he wasn't executed they thought his landlord was [illegible]

Protestors: [illegible] demonstrated [illegible] Saturday outside Truong Van Tran's video store

[illegible] constitution. He [illegible] cheap imitation [illegible] defiant letter [illegible] Vietnamese refugee [illegible] newspapers, in which he called a provocative reference to Uncle Ho.

Since then, [illegible] protesters have [illegible] outside his store [illegible] around the clock. They have plastered the window of his building with pictures of Ho Chi Minh, [illegible] with pictures of Ho Chi Minh [illegible] and flags and [illegible] with a slash across his face and a red X painted onto his forehead.

If he believes in the Communists, he should go back to Vietnam," said Lan Pham, 51, a civil engineer who fled Vietnam in 1975. "He came here as a political refugee, and now he's a traitor."

Ban Binh Bui, head of the Federation of Overseas Free Vietnamese Communities, said Tran has provoked the demonstrators' wrath. He compared it to hanging a picture of Hitler in a Jewish community, or of Pol Pot among Cambodian refugees.

"I respect his right to put up the flag in his home, where I cannot see it," he said. But don't stick a knife into my wound. He has First Amendment rights. But if you cross a line, you're going to have problems."

VIAGRA
Accept No Substitutes
1-800-314-2820
www.viapro.com

Delta Air Lines

Comedian Cleese: Laughter is best creative medicine

Relaxing, banishing anxiety help get new ideas flowing

British comedian John Cleese, 59, is renowned for his work with Monty Python's Flying Circus and his feature film role in A Fish Called Wanda, but he also is experienced at promoting creative thinking on the job. As co-founder of Video Arts, a business-training company, he has merged humor with advice for managers and employees. USA TODAY reporter Stephanie Armour spoke with Cleese about bringing levity — and ingenuity — into the workplace.

Love to laugh: Cleese says anxiety often inhibits creativity.

Q: Can creativity be learned?

A: Everyone can learn to be a lot more creative. You have to create space. Shut the door to your office, and if you can't do that, go to a park and sit on a bench. Then you have to be able to deal with the anxiety that comes out when you can't think of anything. And if you work with other people particularly, you have to have a kind of moratorium (stating) that anything anyone says is not to be criticized. People have to let their defenses down before they become creative.

Q: Do you see a lot of differences between the workaholic tendencies in the USA and Britain?

A: That kind of rather narrow, grinding spot is much stronger in England than it used to be, and I think it's a shame. But if you're going to take part in a great competitive world, how do you do so without losing some of the better aspects of life? I think the answer is to become super efficient. I always wanted to say, "Let's get efficient, guys, then we can go home early."

Q: How can employees find time to think creatively with such efficiency pressures?

A: It is the hardest thing in the world. Just because I know how to do it, because I have done it, doesn't mean I can do it very easily. If I'm anxious — and I think anxiety is the great enemy of creativity — it's very hard to get into a more meditative, mellow, thoughtful state of mind. It's a kind of anxiety like the expectant father. He marches up and down, ever anxious, anxious, anxious. We tend to kind of mask the effect with activity. I think that's probably the single greatest characteristic of the age we live in: anxious anxiety.

Q: When you're trying to be creative or funny and you have that anxiety, how do you break through that?

A: I literally go somewhere else, where I can't hear the phone ringing and my secretary protects me from the world for a period of time. But it's very, very hard for me to do anything and managing. If I get up in the morning to write, no problem. If I get up in the morning to do all the everyday stuff, no problem. But switching from one to the other feels sometimes almost physically painful. I sometimes wonder if it's switching backward and forward between the two halves of the brain very fast. Switching between the "flare" brain and the rose brain it's very hard to do. I think the benefit of laughter is it relaxes us in such that it allows us to switch more easily. Slowing yourself down is much harder.

Q: What about the fear that an idea will fail?

A: When you're creative you have to leave that out. You get interested in it (creating) for its own sake. When you start working with others, you get very interested in what you have to do to make the story work. You're not thinking, "If I don't succeed, the film will fail." That idea tends to come back to you at the end of the session. In the room, you're focused on the problem. Your mind is very free to play.

Office circus: Comedian John Cleese [illegible] modeling humor and creativity [illegible]

Q: Was the "Monty Python" group naturally funny, or was it work?

A: I always thought it was the result of a lot of hard work. The only way to understand Monty Python was that it was six writers who happened to perform the [illegible]. And the reason you [illegible] because we used to [illegible]

[illegible] about it. [illegible] was very [illegible] part. It [illegible] was [illegible] We were [illegible]

Q: Do you learn anything from that experience that would help manager's boost creativity?

A: I noticed when I first started to write with other people that you have to get to trust the person before you can just say the first thing that comes into your head. If you want to create with a group, you've got to feel that more about "we prepared to say the first thing that comes into your head, and, of course, not criticize."

Anything may spark anything else. Sometimes the best ideas come out of misunderstandings. You never know what's going to spark something.

If you start wagging your finger at people and saying, "You're wasting your time" or "You're not trying," it's not what it's about. It's about letting it all hang out.

Something's fishy: Cleese made a splash in 'A Fish Called Wanda.'

Q: What about employees who have no sense of humor? Is there hope for them?

A: I'm told there's an operation.

Q: Do people with a sense of humor have an edge in the workplace?

A: I think they have, but you can overstate it. There are two reasons why some people are humor-impaired. The first is anxiety.

The other thing is there are certain parts of America, like I'm sure there are parts of Germany and Switzerland, where that slightly detached view of life that comes from hard-nut humor has not been experienced. There are a lot of good sides to that hardness. There's a directness and an honesty. You can deal with people who have that kind of hardness, but you can't joke with them and that can be a shame.

When you're laughing, you're more relaxed. I find he's more comfortable, so we can have a free exchange. It's just about [illegible] there's something about that.

Q: What if you're a creative person and you're working in an intolerant environment? Is there hope for that employee?

A: Well, yes, provided the [illegible] don't think you can change it from the bottom up. If you get in an organization that is fundamentally tight-lipped and anxious [illegible] the bottom is going to [illegible] change that.

They can use humor to release their frustrations [illegible] and that's why in organizations [illegible] that humor gets a bad [illegible] The top people think it's [illegible] If sensible constructive criticism is allowed [illegible] want to be [illegible] structure. The only way people express their frustration [illegible] the bottom [illegible] the [illegible] with humor.

[illegible] people should have humor in the organization, it [illegible] fun. Do [illegible] all the [illegible] with [illegible] become [illegible] only [illegible] things can be expressed.

Q: What else about the contemporary workplace do you feel is important?

A: I'm concerned about aspects of life and I think it is linked to the rather manic pace of life. [illegible] I don't [illegible] believe that [illegible] primitive human value to [illegible] have decently looked people in the eyes. I grew up in England at the [illegible] used to quote that Chinese [illegible] The love of money is the root of all evil. And people look at [illegible] easily, and they weren't right.

Q: How can the profit quest be changed?

A: Maybe [illegible] think about it. I [illegible] and music. I [illegible] book [illegible] pick up the last five [illegible] years. They [illegible]

$4.95 50 mg dose VIAGRA® Next Day Delivery!
Doctor's Online 1-800-435-2668 "Allows a week"

Now available
ALPHA•TICKER
Your personal Investment Tic[illegible]
Free Download
www.alpha-ticker.com

STATE OF COLORADO

..ATE BOARD OF PHARMACY
W. KENT MOUNT, Program Administrator
1560 Broadway, Suite 1310
Denver, Colorado 80202-5146
Telephone (303) 894-7750 FAX (303) 894-7764
V/TDD (303) 894-7880

Department of Regulatory Agencies
M. Michael Cooke
Executive Director
Division of Registrations
Bruce M. Douglas, Director

Bill Owens
Governor

March 23, 1999

Richard L. Cleland, Esq.
Federal Trade Commission
6th Street & Pennsylvania Avenue, Room H-482
Washington, DC 20580

RE: Internet/Toll Free Telephone Prescribing

Dear Mr. Cleland:

On behalf of the Colorado State Board of Pharmacy, I am writing to urge the Federal Trade Commission (FTC) to take swift action to stop the indiscriminate prescribing and interstate dispensing/distribution of Viagra (sildenafil citrate, a legend drug manufactured by Pfizer), and other such products, over the Internet or by way of toll free telephone numbers.

The Colorado Board of Pharmacy has been alarmed by this growing practice. The Board was alerted to it by a *San Francisco Chronicle* reporter, Carl Hall, who, in June of 1998, was able to purchase a number of Viagra tablets as well as some other compounded female "sex stimulant" cream through Performance Drugs, Inc., via a local Denver-based pharmacy through an Internet website. Allegedly, Performance Drugs, Inc. was founded by a Colorado-licensed physician, whose name appeared on the drug packaging received by Mr. Hall. To get the pills and cream, Mr. Hall was apparently only required to fill out a short "medical history" online through the website.

The subject physician was subsequently disciplined by the Colorado Board of Medical Examiners (BME), for his role in allowing the public to obtain prescription drugs including Viagra, without a physical examination and without follow-up care by a physician. The BME found that the physician's prescribing practices for these potentially dangerous drugs constituted unprofessional conduct under the Colorado Medical Practice Act.

The Pharmacy Board's concern is that an Internet exchange, no matter how extensive, does not qualify as an initial medical examination. There is no legitimate patient-physician relationship established in these instances.

I further understand that complaints have been filed against several companies, which are possible targets of FTC enforcement actions. Given the potential significant risk for patients, I believe the FTC should promptly act to [illegible] when legend drugs, such as Viagra, are not legally prescribed, such as in the scenario described above.

In the meantime, as you may know, the National Association of Boards of Pharmacy (NABP) has recently approved the development of Verified Internet Pharmacy Practice Sites (VIPPS). The Colorado Board of Pharmacy applauds this effort and understands that the goal of the VIPPS program is to provide the public a means to assure themselves that the Internet pharmacy they select is a bona fide, fully-licensed facility exercising the best safe pharmacy practices the profession has to offer.

Please let me know if there is a question.

Sincerely,

FOR THE BOARD OF PHARMACY

W. Kent Mount
Program Administrator

Xc: Susan Miller, BME
Glenn Detweiler/Karen Oster, NABP
George W. Evans, Esq.
file

CONNECTICUT MEDICAL EXAMINING BOARD
DEPARTMENT OF PUBLIC HEALTH
410 CAPITOL AVENUE MS#13ADJ
P.O. BOX 340308
HARTFORD, CT 06134-0308

March 19, 1999

Richard L. Cleland, Esq.
Federal Trade Commission
6th Street & Pennsylvania Avenue
Room H-482
Washington, DC 20580

Dear Attorney Cleland:

I am writing to you in my capacity as chair of the Connecticut Medical Examining Board to express the view of the Board regarding the request by Pfizer, Inc. that the Federal Trade Commission investigate and take action regarding the prescription and dispensing of Viagra by companies over the Internet. The Board is the state agency charged with the regulatory responsibility for oversight of licensed physicians and physicians assistants in the State of Connecticut.[1] The Board believes that action at the federal level by the Commission is appropriate in addressing Internet prescription practices due to the difficulties for state licensing agencies like the Board to act against out-of-state physicians engaged in such conduct.

As discussed in filings by Pfizer with the FTC, such prescription practices raise issues regarding the propriety and adequacy of the prescribing physician's evaluation of the Internet patient.[2] Assuming that the physicians have acted in a manner that subjects them to disciplinary action by a state licensing board, the difficulties of exercising jurisdiction over an out-of-state physician who does not have a Connecticut license in these circumstances are substantial. First, there is the question of whether the physician is actually practicing medicine in this state or his

1. Another Connecticut agency, the Department of Consumer Protection regulates the dispensing of medications by pharmacists. Improper prescribing of medication by physicians and physicians assistants is within the Board's jurisdiction.

2. Pfizer also argues other practices require FTC involvement. In addition, the incentives for physicians in such arrangements must also be examined to see if they are compensated based on the number of prescriptions issued leading to the possibility that prescriptions are not based upon the clinical needs of the patient.

home state. The issues of telemedicine are complicated and even after several years of debate, many questions remain unresolved. In Connecticut, state law requires licensure for physicians who diagnose or treat Connecticut patients via telemedicine on *a regular, ongoing or contractual basis*. It is debatable whether physicians prescribing medications over the Internet as described by Pfizer meet these requirements. If they do, the Board has authority to issue a cease and desist order against physicians for practicing medicine without a license in the state. See Conn. Gen. Stat. § 19a-11. The Board may also seek to enforce its order by seeking an injunction in state court. Id.[1] However, the ability of the state to serve and secure jurisdiction over the out-of state physicians as a practical matter may not exist. Assuming that the home state of the physician working for the Internet dispensary can be identified, the remaining recourse is for the Board to file a complaint with the licensing agency for the state where the physician practices. However, the physician's home state agency may not enforce Connecticut's requirement of licensure, although it could look at whether the conduct of the physician constitutes a violation of their medical practice act (e.g. negligent or incompetent practice of medicine). Furthermore, in order to prosecute the physician, the home state may need to secure testimony from the patient who may be difficult to secure as a witness.

All of these various actions require substantial resources and authority for investigation of interstate conduct. Such resources and authority are typically less prevalent in state agencies than in the federal government. As this discussion demonstrates, the particular circumstances of the Internet prescribing of medication should be reviewed by the Commission. For these reasons, the Board strongly supports the review by the Commission of Internet prescription of medications.

Very truly yours,

Dennis O'Neill, M.D.
Chair, Connecticut Medical Examining Board

cc: G. Evans, Esq.

There is no express provision for seeking injunctive relief in federal court.

STATE OF CONNECTICUT

DEPARTMENT OF CONSUMER PROTECTION

DRUG CONTROL DIVISION

December 17, 1998

Richard L. Cleland, Esquire
Federal Trade Commission
6th & Pennsylvania Avenue
Room H482
Washington, DC 20580

Dear Attorney Cleland:

I am writing concerning a recent submission made to the Commission by Pfizer, requesting that action be taken to stop, under certain circumstances, the prescribing and interstate distribution of the prescription legend drug Viagra. I am referring specifically to the request of Hugh Latimer made on behalf of Pfizer dated September 21, 1998. That document outlines the prescribing and subsequent dispensing of Viagra via the Internet by Worldwide Medicine, The Pillbox Pharmacy and Orca International, on the basis of a medical history and self-assessment completed by the patient. This distribution scenario is one that our Agency has actively investigated, with limited success, for the past year. A growing number of firms have become involved in the distribution of prescription legend drugs in this manner, which I consider to be a direct threat to the health of the public in Connecticut and other States.

I am writing to strongly support Pfizer's request for intervention by the Federal Trade Commission. I have been involved in the regulation of the practices of medicine and pharmacy in Connecticut for the past twenty-five years. In that context, I state without hesitation that the newly emerging practice of Internet prescribing and subsequent distribution of legend drugs without a bonafide physician-patient relationship, represents one of the most potentially dangerous health related situations our citizens have faced. I do not feel it necessary to restate Pfizer's position concerning the complete lack of requisite medical and pharmaceutical controls when patients are expected to diagnose their own medical problems and then

165 Capitol Avenue, Hartford, Connecticut 06106-1630
Fax: (860) 566-7630 ● TDD: (860) 566-1547
An Affirmative Action / Equal Opportunity Employer

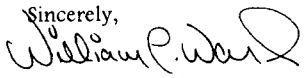
ingest potent drugs that have been dispensed pursuant to invalid prescriptions. This is clearly established and stated in Pfizer's submission to you. I do however feel that it is imperative to convey to you that we, at the State level, can be of limited effectiveness at best in dealing with this interstate problem.

Boards of Medicine and Pharmacy throughout the country are aware of the problem about which I am writing, and have cooperated fully with one another in attempting to deal with this situation as best they can. However, the ability of these distributors to change business names and holdings and move and operate between states makes appropriate enforcement actions virtually impossible at the State level.

It is my contention that legend drugs, such as Viagra, prescribed on the basis of a patient's self-assessment, without any direct contact with the prescribing practitioner are not legally prescribed. I am not aware of a single Medical Board in the country that has not represented this position. Further, since these prescriptions are not valid, pharmacies filling them are dispensing these drugs illegally and pharmacists knowingly involved in this practice are in violation of their State Pharmacy Practice Acts. I am fully aware that this represents a difficult regulatory situation, since utilization of the Internet has developed at such a rapid pace. It is imperative however, that action be vigorously pursued at the Federal level in addressing this problem and many like it which will follow. Regardless of some limited success, these matters simply cannot be resolved effectively at the State level.

I am writing in full support of Pfizer's request for action by the F.T.C. and am prepared to do whatever is necessary to assist you in this effort. I look forward to hearing from you regarding this matter.

Sincerely,



William P. Ward, Director

WPW/jps

CC: Arnold I. Friede, Senior Corporate Counsel, Pfizer, Inc.

GOVERNMENT OF THE DISTRICT OF COLUMBIA
DEPARTMENT OF HEALTH
OFFICE OF PROFESSIONAL LICENSING
614 H STREET, N.W., ROOM 108
WASHINGTON, D.C. 20001

March 5, 1999

Richard L. Cleland, Esq.
Federal Trade Commission
6th Street and Pennsylvania Avenue, NW
Washington, D.C.20580

Re: Internet Prescribing

Dear Mr. Cleland:

The D.C. Board of Medicine has voted to endorse the enclosed letter from the Kansas Board of Healing Arts, regarding internet prescribing. It is the Board's position that prescriptions written without a complete history and physical do not meet the accepted standard of care and are potentially hazardous to public health and safety.

Sincerely,

James R. Granger, Jr.
Executive Director

Enclosure

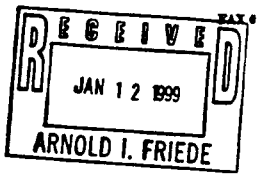
c: Arnold I. Freide
Senior Corporate Counsel
Pfizer, Inc.
Via fax: (212) 573-1445

Mark W. Stafford
General Counsel
Kansas Board of Healing Arts
Via fax: (785) 296-0852

KANSAS BOARD OF HEALING ARTS

BILL GRAVES
Governor

235 S. Topeka Blvd.
Topeka, KS 66603-3068
(785) 296-7413
FAX # (785) 296-0852
(785) 368-7102



January 5, 1999

Richard L Cleland Esq
Federal Trade Commission
6th and Pennsylvania Avenue
Washington DC 20580

Dear Mr. Cleland:

The legal staff at Pfizer, Inc. have kindly suggested I contact you regarding concerns of the Kansas Board of Healing Arts relating to Internet prescribing of Viagra. I understand that the Commission has been asked to take enforcement action against this unfair trade practice. The Board strongly supports this request.

Enclosed are two petitions the Board has filed in the state district court. While these actions are important steps toward protecting the public health, we believe that a much broader approach would be more effective. Most state boards simply lack the resources to seek injunctions against the many organizations selling Viagra over the Internet.

Others have already shared with you the dangers the drug poses for certain people. These dangers are avoidable with appropriate physician supervision. Such supervision does not occur when the drugs are sold over the Internet. Direct Internet sales to purchasers absent physician supervision erodes the decision to require a practitioner's prescription for the drug. If a consumer is allowed to order the drug on demand without completion of a valid history and physical, the drug is, in reality, being sold as an over-the-counter drug rather than as a prescription-only drug.

LAWRENCE T. SHEARER, JR.
Executive Director

MEMBERS OF THE BOARD
RONALD J. SHELLER, D.C., PRESIDENT
Topeka
RONALD D. SLETZ, M.D., VICE-PRESIDENT
Overland Park

WILLIAM BRYANT, Chairman
JAMES D. EDWARDS, D.C., Topeka
RICHARD D. ELLIS, M.D., Lawrence
GERRY L. FRAYSER, D.C., Hutchinson
JOHN P. GRAVES, D.C., Lawrence
JOHN D. JONES, M.D., Lawrence
LANCE MALKEWICH, D.C., Topeka

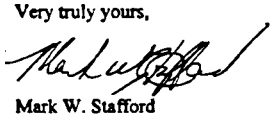
LAUREL H. RICHARD, Emporia Lawrence
CHRISTOPHER P. RODGERS, M.D., Hutchinson
HAROLD J. SAUER, D.P.M., Independence
EMILY TAYLOR, Lawrence
DON K. TRUONG, D.C., Wichita
TERRY D. WARREN, M.D., Fredonia

Additionally, the medical purpose for prescribing the drug is highly questionable. Consumers can purchase the drug through the Internet without a proper diagnosis of erectile dysfunction. This dysfunction and its underlying cause cannot be determined merely by a purchaser's completion of an order form and a review of the order form by a remote physician.

In conclusion, the Board will continue its effort to protect the citizens of Kansas from the illegal and incompetent practice of medicine by those who sell Viagra over the Internet. Sadly, this effort is not enough to effectively address a national problem. We urge the Commission to initiate enforcement action rather than to rely upon piecemeal attempts at enforcement by a few states.

If you have questions, or if we may assist in this or in other matters, please feel free to contact us.

Very truly yours,



Mark W. Stafford
General Counsel

MWS:mat

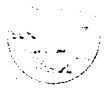
Enclosure

cc: Arnold Friede
Senior Corporate Council
Pfizer, Inc.
Legal Division
235 E. 42nd Street
New York, NY 10017-5755

KANSAS BOARD OF HEALING ARTS

77

BILL GRAVES
Governor



235 S. Topeka Blvd.
Topeka, KS 66603-3068
(785) 296-7413
X # (785) 296-0852
(785) 368-7102

January 5, 1999

Richard L Cleland Esq
Federal Trade Commission
6th and Pennsylvania Avenue
Washington DC 20580

Dear Mr. Cleland:

The legal staff at Pfizer, Inc. have kindly suggested I contact you regarding concerns of the Kansas Board of Healing Arts relating to Internet prescribing of Viagra. I understand that the Commission has been asked to take enforcement action against this unfair trade practice. The Board strongly supports this request.

Enclosed are two petitions the Board has filed in the state district court. While these actions are important steps toward protecting the public health, we believe that a much broader approach would be more effective. Most state boards simply lack the resources to seek injunctions against the many organizations selling Viagra over the Internet.

Others have already shared with you the dangers the drug poses for certain people. These dangers are avoidable with appropriate physician supervision. Such supervision does not occur when the drugs are sold over the Internet. Direct Internet sales to purchasers absent physician supervision erodes the decision to require a practitioner's prescription for the drug. If a consumer is allowed to order the drug on demand without completion of a valid history and physical, the drug is, in reality, being sold as an over-the-counter drug rather than as a prescription-only drug.

LAWRENCE T. BUENING, JR
EXECUTIVE DIRECTOR

MEMBERS OF THE BOARD
RONALD J. ZOELLER, D.C., PRESIDENT
TOPEKA
DONALD S. BLETZ, M.D., VICE-PRESIDENT
OVERLAND PARK

WILLIAM BRYANT, WASHINGTON
JAMES D. EDWARDS, D.C., EMPORIA
HOWARD D. ELLIS, M.D., LEAWOOD
ROBERT L. FRAYSER, D.O., HOISINGTON
JOHN P. GRAVINO, D.O., LAWRENCE
JANA D. JONES, M.D., LANSING
LANCE MALMSTROM, D.C., TOPEKA

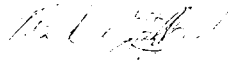
LAUREL H. RICKARD, MEDICINE LODGE
CHRISTOPHER P. RODGERS, M.D., HUTCHINSON
HAROLD J. SAUDER, D.P.M., INDEPENDENCE
EMILY TAYLOR, LAWRENCE
HAI K. TRUONG, D.O., WICHITA
ROGER D. WARREN, M.D., HANOVER

Additionally, the medical purpose for prescribing the drug is highly questionable. Consumers can purchase the drug through the Internet without a proper diagnosis of erectile dysfunction. This dysfunction and its underlying cause cannot be determined merely by a purchaser's completion of an order form and a review of the order form by a remote physician.

In conclusion, the Board will continue its effort to protect the citizens of Kansas from the illegal and incompetent practice of medicine by those who sell Viagra over the Internet. Sadly, this effort is not enough to effectively address a national problem. We urge the Commission to initiate enforcement action rather than to rely upon piecemeal attempts at enforcement by a few states.

If you have questions, or if we may assist in this or in other matters, please feel free to contact us.

Very truly yours,



Mark W. Stafford
General Counsel

MWS:mat

Enclosure

cc: Arnold Friede
Senior Corporate Council
Pfizer, Inc.
Legal Division
235 E. 42nd Street
New York, NY 10017-5755

State of Wisconsin \ DEPARTMENT OF REGULATION & LICENSING

Tommy G. Thompson
Governor

Marlene A. Cummings
Secretary

1400 E. WASHINGTON AVENUE
P.O. BOX 8935
MADISON, WISCONSIN 53708-8935
E-Mail: dor@mail.state.wi.us
(608) 266-2112
FAX# (608) 267-0644
TTY# (608) 267-2416
TRS# 1-800-947-3529

February 12, 1999

Richard L. Cleland, Esq.
Federal Trade Commission
6th and Pennsylvania Avenue
Washington, DC 20580

Dear Mr. Cleland:

I write concerning the prescribing of prescription drugs such as Viagra® based solely upon interstate electronic contact between a prescriber and patient, such as through the Internet.

Enclosed is an order entered by the Wisconsin Medical Examining Board regarding a physician in this state: the Board clearly hold this kind of prescribing without examining the patient to be unprofessional conduct. I also am investigating two organizations, both located outside Wisconsin, who are soliciting orders for Viagra®; the content of their web sites is enclosed together with their locations. You have received a letter from Mark W. Stafford, General Counsel, Kansas Board of Healing Arts, regarding two different organizations such as these.

I echo Mr. Stafford's comments concerning the inability of most states to seek injunctions against such organizations. Certainly, Wisconsin does not have the ability to police this kind of activity all around the country. This is a national problem, and calls for a national enforcement effort by a national authority with the resources and tools to be effective on a national scale.

Sincerely yours,

Arthur Thexton
Prosecuting Attorney
608-266-9814
FAX 266-2264
athexton@mail.state.wi.us

cc: Arnold Friede, Esq., Senior Corporate Counsel, Pfizer, Inc.--Legal Division, 235 E. 42nd St., New York, NY 10017-5755
i:\thomasdm.ltf

LOUISIANA STATE BOARD OF MEDICAL EXAMINERS

January 29, 1999

Personal and Confidential

Richard L. Cleland, Esq.
Federal Trade Commission
6th & Pennsylvania Avenue
Room H482
Washington, DC 20580

Re: Internet Sites Offering
or Dispensing Viagra

Dear Mr. Cleland:

The Louisiana State Board of Medical Examiners (the "Board") wishes to express its support for the Complaint lodged with the Federal Trade Commission ("FTC") by Pfizer, Inc. and its request that the FTC exercise its jurisdictional authority to seek injunction of unfair practices by operators of Internet sites offering or dispensing Viagra in the absence of a physical examination by a physician.[1]

As you are undoubtedly aware, the order of or prescription for medication involves determinations which are of course essentially diagnostic and treatment decisions which can have critical implications for the patient. The practice described in Pfizer's submission, *i.e.*—the "prescription" or "dispensation" of medication, which is contraindicated in certain circumstances based upon patient self-assessment without any physician examination or contact—represents conduct which is likely to cause harm, and in some instances death, to unwitting and inappropriately diagnosed patients throughout this country. It is the Board's view that it is neither ethical nor legal for a physician to prescribe medication, treatment or a plan of care generally if the physician has not examined the patient and established a diagnostic basis for therapy. Thus, in Louisiana, dispensing medication in the absence of physical examination represents conduct which is inconsistent with the prevailing and usually accepted standards of care and may be indicative of professional or medical incompetency.

Moreover, it has long been the Board's formally-stated position that any diagnosis, prescription, recommendation or administration of treatment, so as to effect the diagnosis or treatment for or with respect to an individual who is a resident of or located in Louisiana, constitutes the "practice of medicine" in this state, as defined by the Louisiana Medical Practice Act.[2] As matter of law, to be valid, effective and lawful, a prescription or order

---

[1] Corr., Hugh Latimer, Esq., to FTC (Sept. 21, 1998).

[2] LA. REV. STAT. ANN. §§ 37:1261-1292 (West 1988 & Supp. 1995). In pertinent part, as defined by the Act, the "practice of medicine" means

> the holding out of one's self to the public as being engaged in the business of, or the actual engagement in, the diagnosing, treating curing, or

for medication must be issued or given by an authorized practitioner (*i.e.*, a Louisiana licensed physician) with respect to an individually identified patient, based on the practitioner's examination and diagnosis of the patient. Thus, when medication is dispensed upon the prescription or order of a physician licensed in another state—but not Louisiana—to a patient located in Louisiana, such activity constitutes the unauthorized practice of medicine and subjects those involved to criminal incarceration, civil injunction, fines and penalties.[2]

Unfortunately, the practice which is the subject of Pfizer's Complaint is one with which we have had some experience, *albeit* little success, resolving satisfactorily. Over the past year, the Board has investigated the advertisements of several firms offering to dispense Viagra "without a physician's examination." 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. Similar to our experiences, we are aware that other state boards also enjoyed meager success in investigating and curbing entrepreneurs involved in such practices. The jurisdictional, geographical and resource limitations of state medical boards and governments, stifle our ability to address the situation at the state level and, in the absence of FTC intervention, will undoubtedly guarantee that such conduct will continue unabated in the future.

In closing, we fully endorse, encourage and support Pfizer's request for FTC intervention and wish you every success in your efforts. Please advise us of the resolution of this matter and in the interim, if we may be of any assistance, please feel free to contact us.

Very truly yours,

LOUISIANA STATE BOARD OF
MEDICAL EXAMINERS

By: Delmar Rorison

Delmar Rorison
Executive Director

DR/am
cc: George W. Evans
Asst. Gen. Counsel, Pfizer, Inc.

---

relieving of any bodily or mental disease, condition, infirmity, deformity, defect, ailment, or injury in any human being...whether by the use of any drug, instrument or force...or any other agency or means; or the examining...of any person or material from any person for such purpose....

La. Rev. Stat. § 37:1262(1).

[2] SEE—LA. REV. STAT. ANN. §§ 37:1271, 1286 AND 1290.

ANGUS S. KING, JR.

STATE OF MAINE
BOARD OF OSTEOPATHIC LICENSURE
142 STATE HOUSE STATION
AUGUSTA, MAINE

March 10, 1999

Richard L. Cleland, Esquire
Federal Trade Commission
6th & Pennsylvania Avenues
Washington DC 20580

Dear Mr. Cleland:

The legal staff of Pfizer, Inc., the makers of Viagra has apprised our Board of Internet sales of their drug. As an individual state licensing Board, we have inadequate power to stop such unlicensed prescribing and respectfully ask your help in protecting the people of the State of Maine from the dangers of direct purchase of what is a prescription drug.

Thank you.

Sincerely,

Joseph R. D. deKay, D.O.
Chairman of the Board

PHONE: (207) 287-2480

FAX: (207) 287-2485

Division of Registration
Leverett Saltonstall Building, Government Center
100 Cambridge Street, Boston, MA 02202

February 18, 1999

Richard L. Cleland, Esquire
Federal Trade Commission
6th Street & Pennsylvania Avenue
Washington, DC 20580

Dear Attorney Cleland:

In response to a request by Pfizer, Inc. for a Board opinion on the indiscriminate "prescribing" and "dispensing" of Viagra (sildenafil citrate) over the internet or by toll free telephone numbers, please be informed that the Massachusetts Board of Registration In Pharmacy ("Board") discussed the issue formally on Tuesday, February 09, 1999, at which time they requested that I write to you stating the formal position of the Board in these matters.

As a condition of reimbursement to state and pharmacies participating in the Medical Assistance Program ("Medicaid") the federal Omnibus Budget Reconciliation Act of 1990 (OBRA 90, 42 U.S.C 1396r-8) required each state to create a statute that requires pharmacists to provide certain services to patients receiving prescriptions under the Medicaid program. The result in Massachusetts ,was the promulgation of M.G.L. c. 94C, §2 21(A) and 247 CMR § 9.07, which require minimum services to be provided to ***every patient for each new*** *prescription dispensed, including prospective drug review and obtaining patient profile/history. These mandates are consistent with other boards of pharmacy throughout the country and have created a responsible and safe standard of pharmaceutical care.*

The Board believes that any *legitimate* pharmacist attempting to comply with state and federal counseling mandates, and monitoring their patient's drug therapy would be placed at an extreme disadvantage by practices which do not require, or monitor such standards are being met. It is highly unlikely that the patient would disclose to their consulting pharmacy that they were obtaining Viagra, or any other drug through the internet, and this may, place the patient at serious and imminent risk, depending upon their medication history. Until such time as these alleged illegal practices are regulated, there continues to be a threat to safety of all consumers, and should therefore be halted at once, pending a formal investigation and subsequent promulgating of laws which ensure that adequate and safe medical practices are being followed, practices which require patient physical assessment by a practitioner acting in the usual course of professional practice, and complete medication history disclosure.

Federal Regulations at 21 CFR § 1306.04(a) states in part that " *a prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. An order purporting to be a prescription issued not in the* ***usual course of professional treatment*** *is not a prescription------.* The Board believes that this may be an additional factor for the Federal Trade Commission to consider in halting these practices until an official outcomes investigation is completed.

The Board mirrors William Ward, Director of Connecticut Drug Control's letter to the Commission dated December 17, 1998, which supports Pfizer's efforts for immediate national action.

Sincerely,

Charles R. Young, R.Ph., CFE, Executive Director
Board of Registration In Pharmacy

STATE OF NEVADA

OFFICE OF THE ATTORNEY GENERAL

1325 Airmotive Way, Suite 340
Reno, Nevada 89502
Telephone (775) 688-1818
Fax (775) 688-1822
WEBSITE: http://www.state.nv.us/ag/
E-Mail aginfo@govmail.state.nv.us

FRANKIE SUE DEL PAPA
Attorney General

THOMAS M. PATTON
First Assistant Attorney General

March 25, 1999

Richard L. Cleland
Federal Trade Commission
6th Street & Pennsylvania Avenue
Room H-482
Washington, D.C. 20580

Dear Mr. Cleland:

I am the Senior Deputy Attorney General who represents the Nevada State Board of Pharmacy. As such, I reviewed the materials provided to me by George W. Evans regarding Pfizer, Inc.'s petition to the FTC regarding certain prescribing practices for Viagra over the internet. On January 15, 1999, I presented this letter to the Nevada State Board of Pharmacy. The Pharmacy Board voted unanimously to support the national action undertaken by Pfizer and the FTC to attempt to stop the present internet prescribing practices of Viagra. I am writing this letter to you at the Pharmacy Board's direction.

The Nevada State Board of Medical Examiners has publicly interpreted its laws to mean that it is malpractice for a physician to prescribe medication such as Viagra for a new patient without first conducting such physical examination as may be necessary to determine whether the patient has a condition for which a given medication is appropriate. The present method of prescriptive practice over the internet being conducted by physicians on numerous websites selling Viagra does ***not*** satisfy the Board of Medical Examiners' interpretation.

The Pharmacy Board likewise has determined that the internet pharmacy practices of at least one pharmacy in Nevada regarding its dispensing of Viagra prescriptions does not comply with Nevada law. The pharmacy has since ceased its internet dispensing of Viagra. The Pharmacy Board strongly believes that personal consultation between a pharmacist and a patient is in the best interests of the patient and the public. In an era where the practice of pharmacy is evolving to allow a pharmacist to spend more time speaking with his or her patients, the anonymous prescription transaction being perpetuated by irresponsible internet pharmacies and Viagra purveyors is a giant step backward and greatly and unnecessarily endangers the public.

The Pharmacy Board will be reviewing and potentially passing on regulations at its meeting on April 29, 1999 that will be Nevada's attempt to regulate internet prescriptions in Nevada. If you are interested in Nevada's regulation, let me know and I will send you a copy of the present draft of the regulation.

It is the Nevada Pharmacy Board's hope that through efforts such as the proposed FTC action and Nevada's own regulations improper and irresponsible use of the internet to make a quick and dangerous profit on unlawful prescriptive practices will stop. The internet is being used correctly, lawfully, and responsibly by some pharmacies, and it is certain that the use of the internet will only increase. The Pharmacy Board is encouraged that other agencies are as interested in curtailing the improper use of the internet as it is, and so it endorses and supports Pfizer's and the FTC's action.

If you have any questions or would like any further information, please contact me.

Sincerely,

FRANKIE SUE DEL PAPA
Attorney General

By: _____
LOUIS LING
Senior Deputy Attorney General
Boards & Commissions
(775) 688-1956

LL/avh
c: Keith W. Macdonald
George W. Evans

State Of

New Mexico

New Mexico Board of Pharmacy

1650 University Blvd., NE - Suite 400B
Albuquerque, NM 87102
Phone: (505) 841-9102 Fax: (505) 841-9113
Instate Toll Free: 1-800-565-9102
E-Mail: nmbop@nm-us.campus.mci.net
Website: www.state.nm.us/pharmacy

January 19, 1999

Richard L. Cleland, Esquire
Federal trade Commission
6th Street & Pennsylvania Avenue
Room H-482
Washington, DC 20580

Dear Attorney Cleland:

I am writing concerning a recent submission made to the Commission by Pfizer, asking for the support of the Federal trade Commission to aid in the indiscriminate prescribing and dispensing of Viagra ® over the internet through the use of toll free numbers.

The New Mexico Board of Pharmacy strongly supports Pfizer's request for intervention by the Federal Trade Commission. It is not legal, in New Mexico, for a practitioner to practice medicine in New Mexico without being licensed in New Mexico. Prescribing of medications in New Mexico requires that a practitioner patient relationship be established before medications are prescribed. This involves a physical examination, which is not possible over the internet. If these prescriptions are issued illegally, then pharmacies that are filling these prescriptions are doing so illegally. If there are other medications similarly being prescribed, then this is also illegal.

The New Mexico Board of Pharmacy supports Pfizer's request for immediate action in this matter and will do whatever is possible to assist you.

Sincerely,

Jerry Montoya
Chief Drug Inspector/Acting Director

JM/jrs

Mr. UPTON. Thank you.
Mr. Fong.

TESTIMONY OF IVAN K. FONG

Mr. FONG. Good morning, Mr. Chairman, members of the subcommittee. Thank you for inviting the Department of Justice to testify today on this important topic. I will summarize the written testimony that you have received.

We are not at this time advocating any particular legislative action, but would hope to inform you about our efforts to respond to the many complex legal and policy issues raised by this new development.

The growth in Internet prescription drug sales undoubtedly has the potential, as you've heard this morning, to provide significant societal benefits. Individuals who might otherwise have difficulty going to a pharmacy to obtain needed medications—shut-ins, the elderly, those in rural communities, for example—will surely benefit from the convenience of being able to order and obtain their prescription drugs on-line. On-line sales are also likely to foster price competition for prescription drugs among licensed sellers.

Recognizing these benefits is consistent with the administration's general policy concerning the Internet and electronic commerce. That policy includes support for industry self-regulation where possible, technology-neutral laws and regulations, and an appreciation of the Internet as an important medium, both domestically and internationally, for commerce and free speech.

In the area of on-line sale of prescription drugs, this means that any enforcement initiatives that we undertake should be carefully designed to deter unlawful pharmacy practices to accomplish important public health goals without stifling the growth of the Internet generally or chilling its use as a communication medium, including its use for lawful commercial purposes.

In the context of law enforcement, we believe this means that the government should treat physical activity and cyberactivity in the same way; that is, if an activity is prohibited in the physical world but not on the Internet, then the Internet becomes a safe haven for that criminal activity. Similarly, conduct that is not a Federal crime in the physical world should not be subjected to Federal criminal sanction simply because it is committed in cyberspace.

In short, as a matter of policy, the same laws and regulations that currently apply to the corner pharmacy ought to apply to on-line pharmacies. The Internet, of course, has the strong potential to magnify the problem of unscrupulous activity or unlawful conduct in an unprecedented way. From a strictly legal standpoint, however, we believe that sales over the Internet ought not be treated any differently from, for instance, sales from your neighborhood pharmacy or sales that involve the use of the telephone.

The Department of Justice is affirmatively responding in several ways to the recent growth of on-line pharmacies. We have begun to analyze the legal bases for possible enforcement actions. We're continuing to investigate and prosecute conduct that has long been illegal, but is only recently reappearing on the Internet, and we are working with other Federal agencies, States and relevant profes-

sional associations to develop coordinated public education as well as civil and criminal enforcement efforts.

As you have heard this morning, there are a number of different kinds of on-line pharmacies. Some of them require a prescription from a licensed physician. Others offer an on-line diagnosis and will use the medical questionnaire that we have seen, and a third category allows consumers to purchase prescription drugs without a prescription at all.

These kinds of pharmacies raise different questions, and they are different in the following respects. Some consumers are able to purchase drugs from physicians without the traditional protections afforded by the doctor-patient relationship, such as an office visit that allows for a physical examination or critical interactive questions or follow-ups. A second area of concern are situations in which consumers purchase drugs that are mislabeled or counterfeit. Finally, there are concerns that certain Web sites are nothing more than scams, collecting credit cards and cash, but providing no product.

In our legal analysis, I want to highlight something that was mentioned this morning, which is that to the extent there is any question about the illegal nature of the obtaining of a prescription drug without a prescription, it's useful for me to quote directly from existing law. This is part of the FDA statute: "The act of dispensing a drug contrary to the provisions of this paragraph," which requires a written prescription from a practitioner licensed by law to administer such drug, "shall be deemed to be an act which results in the drug being mislabeled while held for sale." And as you know, introduction or distribution of misbranded drugs into interstate commerce is a Federal offense.

We believe that the Department of Justice is and stands ready to prosecute these cases. We work very closely with our investigative agencies, and we look forward to answering your questions, and thank you for this opportunity to testify on this topic.

[The prepared statement of Ivan K. Fong follows:]

PREPARED STATEMENT OF IVAN FONG, DEPUTY ASSOCIATE ATTORNEY GENERAL, DEPARTMENT OF JUSTICE.

Mr. Chairman and Members of the Subcommittee: Good morning. My name is Ivan Fong. I am a Deputy Associate Attorney General at the Department of Justice. The Office of the Associate Attorney General is responsible for the management and oversight of, among other areas, the Department's civil litigating components, which include the Antitrust, Civil, Civil Rights, Environment and Natural Resources, and Tax Divisions. My particular responsibilities include civil litigation and technology policy issues, which include Internet and electronic commerce issues, as well as the enforcement of certain consumer statutes. This morning, at your invitation, I will address the Department's views regarding the sale of prescription drugs over the Internet. We are not at this time advocating any particular legislative action with respect to the sale of these drugs over the Internet. Rather, we hope to inform you about our efforts to respond to the many complex legal and policy issues raised by this new development.

A. ADDRESSING UNLAWFUL CONDUCT THAT INVOLVES THE USE OF THE INTERNET

Before I outline what the Department is doing in the area of Internet prescription drug sales, it is important to underscore, by way of background, a simple, and by now almost trite, point: The Internet has revolutionized and will continue to revolutionize the way in which we communicate, transact business, and indeed interact with one another.

The growth in Internet prescription drug sales, for example, undoubtedly has the potential to provide significant societal benefits. Individuals who might otherwise have difficulty going to a pharmacy to obtain needed medications—such as shut-ins, the elderly, and those in rural communities—will surely benefit from the convenience of being able to order and obtain their prescription drugs online. Online sales are also likely to foster price competition for prescription drugs among licensed sellers.

Recognizing these benefits is consistent with the Administration's general policy concerning the Internet and electronic commerce. That policy includes support for industry self-regulation where possible, technology-neutral laws and regulations, and an appreciation of the Internet as an important medium both domestically and internationally for commerce. In the area of online sale of prescription drugs, this means that any enforcement initiatives that we undertake should be carefully designed to deter criminal and illegal pharmacy practices on the Internet to accomplish important public health goals without stifling the growth of the Internet generally or chilling its use as a communication medium, including its use for lawful commercial purposes.

In the context of law enforcement, we think the Administration's overall policy can be translated into the following general principles.

- First, the government should treat physical activity and cyberactivity in the same way. If an activity is prohibited in the physical world, but not on the Internet, then the Internet becomes a safe haven for that criminal activity. Similarly, conduct that is not a federal crime in the physical world should not be subject to federal criminal sanction simply because it is committed in cyberspace.
- Second, laws and policies relating to enforcement must account for technological change, but should endeavor to be technology-neutral. Laws and policies tied to particular technologies may quickly become obsolete and require further change or may unintentionally provide an advantage to one type of technology over another.
- Third, the Internet is different from prior modes of communication in that it is a multi-faceted communications medium that allows not only point-to-point transmission between two parties (like the telephone), but also the widespread dissemination of information to a vast audience (like a newspaper).

These general principles form the starting point for our analysis of the legal and policy issues relating to the sale of prescription drugs over the Internet. They suggest that, as a matter of policy, the same laws and regulations that currently apply to the corner pharmacy ought to apply to online pharmacies. The Internet, of course, magnifies the problem of unscrupulous activity or unlawful conduct in an unprecedented way. For example, searching Internet sites for the prescription drug "Viagra" and the word "buy" results in an overwhelming number of sites where Viagra can be purchased on line. Nevertheless, from a legal standpoint, we believe that sales over the Internet ought not be treated differently from, for instance, sales from your local pharmacy or sales that involve the use of the telephone.

B. THE ROLE OF THE DEPARTMENT OF JUSTICE IN INTERNET PRESCRIPTION DRUG SALES

The Department of Justice is affirmatively responding in several ways to the recent growth in online pharmacies and prescription medical device distributors. We have begun to analyze the legal bases for possible enforcement against illegal practices of online pharmacies. We are continuing to investigate and prosecute conduct that has long been illegal, but that is only recently reappearing on the Internet. And we are working with other federal agencies, states, and relevant professional associations to develop coordinated public education as well as civil and criminal enforcement efforts.

At the outset, it is important to note that we are only beginning to appreciate the complex and highly diverse operations involved in sales and distribution of pharmaceutical products over the Internet. We have learned, for example, that online pharmacies can generally be classified into three basic categories:

- The more traditional online pharmacies require consumers to obtain a prescription from a licensed physician before ordering the drug. A valid prescription is then submitted to the pharmacy before the drug is dispensed.
- A second category of online pharmacies offers services to "diagnose" a patient online, "prescribe" the medication, and distribute it without a physician ever physically seeing the patient. These pharmacies typically use an online medical questionnaire, which asks for the patient's health profile, current medication, and medical history. Based on this questionnaire, a doctor who may be affiliated with the website "diagnoses" the patient's ills and prescribes medication, which the website's pharmacy then distributes.

- A third category of online pharmacies allows consumers to purchase prescription drugs without any pretense of a prescription.

Cutting across these categories are different concerns that may be raised by online pharmacies. One area of concern arises from situations in which consumers are able to purchase drugs from physicians without the traditional protections built into the doctor-patient relationship, such as an office visit that allows for a physical examination and for the doctor to ask the patient critical questions designed to limit the harm caused by drug allergies and interactions. A second area of concern are situations in which consumers purchase drugs that are mislabeled or counterfeit. Finally, there are concerns that certain websites are nothing more than scams, collecting credit cards and cash, but providing no products. Each of these situations raises different legal issues and policy concerns and implicates the jurisdiction of different governments and agencies.

1. Overview of Legal Issues

The Department of Justice—through its Civil and Criminal Divisions, local United States Attorney's Offices, the Federal Bureau of Investigation, and other components—enforces numerous consumer protection statutes for which the primary regulatory authorities are administrative agencies such as the Food and Drug Administration (FDA), the Drug Enforcement Administration (DEA), and the Federal Trade Commission (FTC).

(a) Enforcement under the Food, Drug and Cosmetic Act—The federal Food, Drug and Cosmetic Act (FDCA) generally prohibits the manufacture and distribution of misbranded and adulterated drugs, thus requiring drugs to be labeled accurately and handled in ways that prevent them from becom ing contaminated or misused. In 1951, to protect the public from abuses arising from the sale of potent prescription drugs, and to relieve retail pharmacists from burdensome and unnecessary restrictions on the dispensing of over-the-counter drugs, Congress established the system that currently governs the sale of prescription drugs. *See,* 21 U.S.C. § 353(b)(1). Under that system, Congress relied on two health professionals—the patient's physician and a pharmacist—to protect patients from the knowing or accidental misuse of medicines that are toxic or that have the potential for causing harm.

Accordingly, drugs that are considered prescription drugs under the FDCA may be distributed only with a valid prescription under the professional supervision of a physician. *See,* 21 U.S.C. § 353. A prescription drug is considered "misbranded" if it is not dispensed pursuant to a valid prescription in accordance with 21 U.S.C. § 353(b). Introduction or distribution of misbranded drugs into interstate commerce violates the FDCA. *See,* 21 U.S.C. § 331(a). An online pharmacy that provides prescription drugs without a prescription—the third category of online pharmacies noted above—would therefore be in violation of this requirement.

Legal action to curtail such conduct—including the drugs distributed without a valid prescription—may be brought criminally or civilly. For a felony conviction, the government must establish that the defendant acted with an intent to defraud or mislead either the consumer or the government, or that the defendant is a repeat offender. Civil cases and misdemeanor prosecutions do not require proof of an intent to defraud or mislead.

For online pharmacies that offer online diagnosis, prescription, and distribution of medication—the second category of online pharmacies noted above—the issue is whether the online interaction results in a valid "prescription" under 21 U.S.C. § 353(b). If not, then the online pharmacy may be found to be distributing "misbranded" medication in violation of the FDCA.

In analogous situations, the Department has successfully prosecuted doctors and veterinarians for dispensing drugs without a valid prescription. For example, in several recent cases, we found that certain doctors were prescribing and distributing anabolic steroids to athletes and entertainers. The evidence showed that they distributed steroids not to treat medical conditions, but for purely cosmetic purposes, and that they did not examine the patients before dispensing the steroids. In those cases, we successfully argued that under section 353(b), one may distribute prescription drugs only if (1) there is a *bona fide* doctor-patient relationship, and (2) the distribution is pursuant to a course of individualized treatment for a legitimate medical purpose.

Whether a particular online pharmacy, such as one that provides an online questionnaire for the consumer to complete before the drug is dispensed, can satisfy these standards will depend on the specific facts involved and evidence presented. It may also depend on whether the resulting "prescription" is a valid prescription under relevant state law. The states of Kansas, Maryland, and Washington, for example, have taken legal action against doctors, websites, and pharamacies that dispense prescription drugs over the Internet in violation of state law.

(b) Other Enforcement Theories—Apart from enforcement under the FDCA, the Department can also rely on other legal authorities. For instance, the Controlled Substances Act prohibits the dispensing of a controlled substance without a valid prescription. *See,* 21 U.S.C. §§ 822, 829, and 841. A regulation issued by DEA defines "prescription" in a way that may exclude "prescriptions" for controlled substances that are obtained through an online questionnaire. As an example of a prosecution in this area under the Controlled Substances Act, a grand jury in Maryland recently returned a 34-count indictment against a physician for dispensing several controlled substances, including phentermine and fenfluramine, without a legitimate medical purpose.

Another potential avenue for enforcement involves the Federal Trade Commission Act (FTC Act), 15 U.S.C. § 45 *et seq.,* under which we could proceed with a civil enforcement action in conjunction with the FTC. The FTC Act protects consumers from unfair or deceptive acts or practices. Many online pharmacies operate by making important representations to consumers. For example, the FTC has found websites that advertise that a physician reviews each application to purchase prescription medications. To the extent these representations are false or deceptive, or if a website operator sells prescription drugs and represents that the drugs are safe and effective without disclosing their possible adverse effects, then such operators may be engaging in unfair or deceptive trade practices.

Indeed, some online pharmacies may suggest that completion and analysis of an online medical questionnaire is the equivalent of a visit to a doctor's office. Yet it seems clear that in almost all circumstances, filling out an online questionnaire is not the same as seeing a doctor. In fact, some prescription drugs, such as Viagra, have package insert labeling that specifies that a physical examination is required for proper prescribing of a product and physician follow-up. Because some of these websites appear to provide deceptive information, these sites may violate the FTC Act, and thereby subject the website operator to a civil enforcement action.

The Department could also pursue similar theories under the federal mail and wire fraud statutes whenever an online or other pharmacy defrauds consumers in any way. Whether such a suit would be criminal or civil, under 18 U.S.C. § 1345 or 21 U.S.C. § 332, would depend on the precise facts of the case and the evidence of fraudulent intent. Schemes involving the sale of drugs or health products over the Internet may violate other related federal criminal laws. Some websites offer to bill private or public health care programs or insurers for a "doctor's" advice or for the price of the drug or product itself. If any false representations are made to the insurer to obtain payment, violations of a number of federal criminal laws may occur, and the civil fraud laws may also be implicated.

(c) Prescription Drugs Sales from Foreign Sources—The FDA has found that a fair percentage of online drug distribution is conducted by firms operating outside of the United States. These firms may be in countries where quality standards or manufacturing practices do not approach what the FDA requires for the approval of prescription drugs in the United States. Any effort to prohibit these firms from selling prescription drugs in the United States would be complicated, especially if the activity in question is legal in the country where it is originating.

In addressing the online sale of prescription drugs, the United States must continue to enlist the cooperation of foreign governments in enforcing the laws of the United States relating to such sales. Although international awareness and cooperation on fighting crime has grown, we must continue to resolve philosophical differences between countries on combating the sale of illegal goods online and also to develop practical ways to enforce our laws. For example, our concern with prescription drugs from foreign countries is not necessarily with the Internet aspect of the sale, but with the illegal introduction of those drugs into the United States. Law enforcement agencies in the United States will have to obtain the cooperation of their counterparts in foreign countries with online prescription firms to prevent the shipping of such drugs into the United States. Such cooperation is particularly important because interdiction of relatively small quantities of prescription drugs sent through traditional mailing channels is not feasible. Overall, the Department supports the efforts being made to develop a comprehensive and global response to crimes facilitated by the Internet.

2. The Department's Experience in Related Areas

The Department has successfully prosecuted doctors and pharmacists for prescribing drugs without a valid prescription. In the 1950's, for example, the Department prosecuted doctors and pharmacists who sold amphetamine and Benzedrine to undercover agents without any prior examination or diagnosis. In the 1980's and early 1990's, before steroids became a controlled substance, several doctors received significant sentences for supplying high-profile athletes and entertainers with pre-

scription steroids for illegitimate cosmetic reasons. The DEA has investigated and we have prosecuted many physicians for dispensing controlled substances without a legitimate medical purpose.

As I mentioned, online prescribing of approved drugs can present difficult legal issues. Nevertheless, we believe that the recent surge in online prescribing is ultimately a new version of an old problem. In the 1950's, individuals purchased drugs without valid prescriptions from doctors working out of truck stops. In the 1980's, doctors sold steroids out the back door of their offices. Today, it is the Internet, and not a truck stop or the back door, that can serve as an unscrupulous doctor's means to peddle drugs without prescriptions. When investigators bring those cases to our attention, we stand ready and able to prosecute them.

The Department has already begun to investigate doctors and websites that dispense drugs based exclusively upon an online diagnosis, which usually consists of a medical questionnaire that the patient either fills out online or prints off her computer and mails or faxes to the website. For example, as I mentioned above, a grand jury in Maryland recently returned a 34-count indictment against a physician for dispensing controlled substances without a legitimate medical purpose. I should note that this doctor has since turned in his medical license to the state of Maryland. The Department is actively working with state officials, both from attorneys general offices and state medical boards, to identify other doctors and pharmacists who unlawfully prescribe drugs online.

The Department has also taken an active role in prosecuting website operators who illegally sell FDA-regulated products, such as unapproved drugs and devices, over the Internet. For example, in February 1999, a seller of bogus HIV self-test kits was sentenced to 63 months for mail fraud, wire fraud, and money laundering. We are also prosecuting cases against the operators of websites that sell the components necessary to make gamma hydroxy butyrate, commonly known as GHB, a dangerous unapproved drug often used in sexual assaults to incapacitate victims. Although I cannot discuss the details of these cases, I can say that the Department's efforts regarding GHB have made obtaining this drug over the Internet more difficult than it once was.

3. Coordination of Enforcement Efforts

One of the most significant challenges we face in this area is coordination of enforcement policies and initiatives among a variety of federal, state, and other entities. We rely heavily, for example, on the hard work and dedication of federal and state investigating agencies in all of our cases. Our investigative agencies, with training and resources, will be able to develop cases that we can prosecute against online pharmacies and doctors affiliated with such pharmacies, should they dispense prescription drugs in ways that violate federal law.

We have also engaged in and will continue to engage in substantial efforts to coordinate our work with that of FDA and other federal agencies. We will work closely with FDA as it begins to implement its action plan to address Internet drug sales. We are also endeavoring to coordinate with the FTC, the FDA, and the National Association of Attorneys General on issues such as the fraudulent or misleading marketing of prescription drugs over the Internet.

Of equal importance is the need to train criminal investigators to deal with the special problems that Internet investigations pose. We have found that many websites that we are investigating disappear as quickly as they appear. If the site has not been "mirrored" or otherwise retained, an opportunity to take enforcement action disappears. It is vital that agents know how to conduct Internet investigations from their inception.

In sum, the Department has taken and will continue to take an active role in coordinating with other federal agencies to respond to the potential risks to public health and safety that may accompany the growth of Internet sales of prescription drugs. We are participating with FDA and other agencies to explore what recourse is available to enforce existing laws that govern Internet prescription drug sales, particularly against foreign drug firms selling to U.S. consumers. As I have noted, foreign-based online pharmacies and their online sale of pharmaceutical drugs present particularly difficult and complex enforcement issues. We recently met with representatives from the FTC, FDA, FBI, the Customs Service, the Postal Service, and the National Association of Attorneys General to discuss this issue. With the other agencies, we will be evaluating existing laws and determining whether to recommend changes to address the problems we have identified.

Thank you for the opportunity to present the views of the Department on this important topic. I would be pleased to answer any questions you might have.

Mr. UPTON. Thank you.

Dr. Woodcock.

TESTIMONY OF JANET WOODCOCK

Ms. WOODCOCK. Thank you for this opportunity to discuss the benefits and risks of pharmaceutical sales over the Internet. I was very happy to rearrange my schedule to accommodate this important hearing because this is a very significant issue for our agency.

Now, at FDA, we regard the Internet as an important new tool that opens up vast opportunities for our citizens to share information, to communicate and engage in new forms of commerce, as other witnesses have already alluded to. It's rapidly becoming an essential mechanism that more and more Americans use for their personal and professional needs.

The Internet also plays a prominent role in FDA activities. Our scientists use it to support regulatory research and to exchange data with scientists worldwide. We rely heavily on our Web site and other Internet tools to communicate drug information to consumers and health professionals and to inform industry and other FDA constituencies about our policies and procedures.

And we applaud the fact that the Internet has facilitated drug dispensing by reputable pharmacies. As in other sectors, ethical Internet pharmacies can offer advantages to consumers such as speed and ease of ordering, wide product selection, on-line pharmacists' consultation, reliable drug information and economic benefits of competition. But as a public health agency, we must be and we are concerned about emerging on-line practices that pose health risks to the public.

Mr. Chairman, members of the committee, as you know, Congress has established a system of drug regulation that has served this country well. As part of this system, FDA protects consumers and patients by reviewing new medicines for safety and effectiveness and by monitoring their performance once marketed. The States also play a key role by licensing and oversight of the health care professionals, mainly medical doctors and pharmacists who are authorized to prescribe and dispense FDA-approved drugs.

This traditional system that relies on professional accountability and responsibility to protect the public is being challenged by the Internet. There have always been unscrupulous people who have tried to circumvent the system by selling unapproved drugs, by selling drugs without a prescription, by offering expired or illegally diverted drugs or marketing products with fraudulent health claims. Any of these illegal practices may expose consumers to risk, such as life-threatening adverse drug effects, dangerous drug interactions or contaminated drugs. The power of the Internet to reach millions of unsuspecting consumers across all borders increases both the opportunity for these unscrupulous people and the magnitude of the public risk from their actions.

In addition to the potential for expansion of illegal drug sales, we are also concerned about drug prescribing via the Internet based solely on the buyer's answers to a simple questionnaire outside of the context of a traditional physician-patient relationship. According to the AMA, the American Medical Association, a health care practitioner who offers a prescription for an unseen and

unexamined patient based solely on an on-line questionnaire has generally not met an appropriate standard of medical care.

Over the past several years, FDA has countered illegal on-line drug sales by taking successful enforcement actions. We have not been idle in this regard. Today we are announcing a multifaceted program that is designed to intensify our efforts. We've committed to the following action plan, which is fully described in my submitted testimony. We will expand the agency's surveillance and enforcement activities on the Internet. We will enter into agreements with State regulatory and law enforcement officials to work cooperatively to enforce Federal and State laws against unlawful sellers and prescribers.

We have signed principles of understanding with the National Association of Boards of Pharmacy and the Federation of State and Medical Boards. These principles have been endorsed by the American Medical Association and the APA.

We will work with Congress and Federal agencies to address illegal Internet marketing by foreign sites, and we will expand our public health outreach activities to alert consumers to the risk, because, as we know from other areas, we must work on the demand side as well as the supply side of this problem.

Over the coming year we will resource these initiatives by focusing on illegal Internet drug marketing, tapping resources that are currently focused on these illegal activities in a non-Internet context.

We believe these initiatives are consistent with the administration's framework for global electronic commerce announced in July 1997, and the President's memorandum on successes and further work on electronic commerce issued last November.

In conclusion, I want to give notice to those who are illegally selling drugs on the Internet that we are taking action. Misuse of the Internet for illegal sale of potentially dangerous drugs must stop.

This concludes my oral testimony, and I will be glad to answer your questions.

[The prepared statement of Janet Woodcock follows:]

PREPARED STATEMENT OF JANET WOODCOCK, DIRECTOR, CENTER FOR DRUG EVALUATION AND RESEARCH, FOOD AND DRUG ADMINISTRATION

INTRODUCTION

Mr. Chairman and Members of the Committee, I am Dr. Janet Woodcock, Director, Center for Drug Evaluation and Research (CDER), Food and Drug Administration (FDA or Agency). I am pleased to have this opportunity to participate in this discussion of the benefits and risks of pharmaceutical sales over the Internet. The sale of consumer products over the Internet has grown rapidly, including the sale of drugs. While the growth in online drug sales by reputable pharmacies is a trend that can benefit consumers, online drug sales also present risks to unsuspecting purchasers and some unique challenges to regulators, law enforcement and policymakers. FDA is concerned about the public health implications of Internet drug sales, and we are responding to these concerns as part of our overall goal of developing and implementing risk-based strategies to protect public health and safety.

It is important to recognize that other products regulated by the Agency, such as medical devices, biological products, and foods, including dietary supplements, also are sold online, and when sold unlawfully, may pose risks to the public health. This testimony, however, will focus on the advantages and risks of online pharmaceutical sales, outline the authority and enforcement activities of FDA in this area, and discuss new initiatives that FDA is taking to better respond to the regulatory challenges. FDA believes these initiatives are consistent with the Administration's July 1, 1997 Framework for Global Electronic Commerce (*Framework*) and the Presi-

dent's November 30, 1998 Memorandum on Successes and Further Work on Electronic Commerce.

The *Framework* suggested a set of principles to guide the government's approach as we face the new and ever changing challenges posed by the Internet. Five principles were articulated that apply to the policy questions raised by Internet prescription drug sales.

These are:

1) The private sector should lead.
2) Governments should avoid undue restrictions on electronic commerce.
3) Where governmental involvement is needed, its aim should be to support and enforce a predictable, minimalist, consistent and simple legal environment for commerce.
4) Governments should recognize the unique qualities of the Internet.
5) Electronic Commerce over the Internet should be facilitated on a global basis.

In the context of prescription drug sales over the Internet, government should encourage private sector leadership in achieving a safe marketplace. The private sector has an important role to play in promoting consumer education and in providing seals of approval and other verification for legitimate sales. Government should refrain from imposing any unnecessary regulations, but should protect consumer health and safety through effective enforcement of existing law on illegal drug sales. If new regulations are needed these should be designed to support a predictable, minimalist, consistent and simple legal environment for commerce. Rapid technological developments will change the nature of the challenges we face today and we must remain flexible in developing solutions. Finally, the global nature of electronic commerce poses particular problems in the area of Internet drug sales and we should strive for consistent principles across State, national, and international borders that lead to safe and predictable results regardless of the jurisdiction in which a particular buyer or seller resides.

As I will describe in more detail later in my testimony, FDA has developed and begun implementing an action plan to address the problems associated with online drug sales. The steps FDA is taking under its action plan include:

- The expansion of enforcement efforts against illegal online sales. FDA has established priorities for taking enforcement actions involving online sales, expanded its capability to monitor violative Internet sites through advanced technology search tools, and established a process to triage and monitor ongoing cases. Using existing resources, through this process, FDA expects to establish a higher profile enforcement presence regarding unlawful online sales.
- FDA is working with other Federal agencies and State agencies to better coordinate enforcement efforts. FDA worked closely with the Federal Trade Commission (FTC) in developing the cases announced as part of Operation Cure-All and has been working with the Department of Justice (DOJ) and others regarding online sales issues.
- FDA has initiated a series of meetings with State regulatory bodies and other organizations to discuss better ways to regulate online sales.
- FDA will expand public outreach efforts to warn consumers about the dangerous practices involving online purchases.

As described below, the Agency will seek to enforce existing statutory and regulatory provisions when illegal online drug sellers engage in unlawful conduct without imposing burdensome restrictions on legitimate sellers. Therefore, the Agency's efforts should help foster consumer confidence in electronic commerce through effective consumer protection online without imposing undue restrictions on legitimate electronic commerce.

BENEFITS OF ONLINE DRUG SALES

The growth and development of the Internet in recent years has opened up vast new opportunities for the exchange of information and for the enhancement of commerce. Electronic mail and chat groups have facilitated communications dramatically. Information gathering that once took hours or days of research, whether for a highly technical scientific paper or an elementary student's homework assignment, can now be accomplished in minutes.

The Internet is rapidly transforming the way we live, work, and shop in all sectors of the economy. In the health sector, telemedicine allows people in remote areas to access the expertise of doctors in urban hospitals. The Internet permits increasing numbers of individuals to obtain medical information helping them to better understand health issues and treatment options. In fact, more than 22 million Americans used the Internet last year to find medical information. According to *Investor's Business Daily,* 43 percent of web surfers access health care data online each year.

Health concerns are the sixth most common reason that people use the Internet, and according to the market research firm, Cyber Dialogue Inc., this number is growing by 70 percent a year.

Legitimate prescription drug sales on the Internet can provide tremendous benefits to consumers. These benefits could include: lower prices through increased competition among licensed sellers; greater availability of drugs to shut-in people for whom going to the pharmacy can be difficult; increased availability to people who may live a great distance from the pharmacy; the ease of comparative shopping among many sites to find the best prices and products; and, greater convenience and variety of products for all customers who prefer online ordering of prescription drugs.

Perhaps the chief attractions to purchasing consumer goods online are the speed and ease of choosing and ordering products. Many reputable online pharmacies allow patients to consult with a pharmacist from the privacy of their home. Moreover, online pharmacies are able to provide customers with written product information and references to other sources of information much 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 is possible.

While online sales will be important for some customers, the more traditional pharmacies can offer benefits and services often not available through the Internet. Such pharmacies are an essential component in the delivery of effective health care.

We are not aware if composite sales figures for online pharmacies have been compiled. But the increasing recognition of the Internet as a legitimate and important vehicle for drug sales is evidenced by the recent activity of major drugstore companies and Internet retailers in financing, supporting and sponsoring online pharmaceutical outlets. Earlier this year, for example, CVS Corporation acquired the online pharmaceutical retailer Soma.com, and announced last month that the online retail sites of the two companies will merge. Also last month, Rite-Aid Corporation announced a partnership with Drugstore.com to combine the benefits of online ordering with access to traditional retail locations and insurance reimbursement services. We expect this expansion of the online drug sales industry to continue over the next few years.

As beneficial as this new technology is, however, there are some concerns. The Internet also creates a new marketplace for sales that are already illegal in the nonwired world (and wired world), such as unapproved new drugs (including counterfeit drugs), prescription drugs marketed without a valid prescription, and products marketed with fraudulent health claims. The unique qualities of the Internet, including its broad reach and ability for anonymity, pose new challenges for the enforcement of existing laws. The global nature of the Internet creates particular 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 will need to work closely with foreign governments to share information on the drug approval process and develop mechanisms to cooperate on law enforcement with respect to certain prosecutions.

The challenge for government is to promote policies that will allow legitimate electronic commerce to flourish by creating a marketplace where consumers can have confidence in the quality of the medical prescription and of the medicine delivered. A safer marketplace can be fostered through effective enforcement of existing laws and by taking steps to encourage programs that provide certification, or seals of approval, to legitimate doctors and pharmacists operating in the virtual world.

CONCERNS ABOUT ONLINE SALES

As you know, the establishment of FDA as it exists today grew out of a time early in the century when consumers were victimized by dishonest purveyors of fraudulent potions and compounds that were ineffective, dangerous, or both. A system of drug regulation was established in this country that has served us well. Under this system, FDA reviews new drugs to ensure their safety and effectiveness. In addition, certain types of drugs must be prescribed and dispensed by health care professionals licensed and overseen by the State in which they practice. But even with this system in place, there are those who still try to sell unapproved or unsafe drug products, and the Internet provides them with new opportunities for reaching unsuspecting and vulnerable consumers and undermining established safeguards. It is fair to say that the speed and ease of ordering products on the Internet that attract consumers likewise entices some unscrupulous sellers to use the Internet as their new medium of choice. Unlike some other forms of electronic commerce, the unauthorized sale of prescription and unapproved drugs poses a potential threat to

the health and safety of consumers. Moreover, consumers who are desperate for a cure to a serious medical problem are particularly vulnerable. Thus, they may be more susceptible to the hype surrounding an unapproved product or more likely to fall prey to the sale of an adulterated product.

Internet drug sales raise public health issues similar to those raised by sales, in other contexts, of unapproved new drugs (including counterfeit drugs); the sale of prescription drugs without a valid prescription; the sale of expired or illegally diverted pharmaceuticals; and the marketing of products based on fraudulent health claims.

Congress and State legislatures have enacted laws to protect patients from harm resulting from the use of unsafe drugs, counterfeit drugs, and the improper practice of medicine and pharmacy. Under these laws, to receive a prescription drug for the first time, generally a patient must be physically examined by a licensed health care practitioner who determines the appropriate treatment and issues a prescription for an FDA-approved drug. The patient then has the prescription filled by a registered pharmacist working in a licensed pharmacy that meets State practice standards. However, the Internet makes it easy for individuals to bypass these safeguards when selling drugs to patients. A web site can be easily created to look like a legitimate pharmacy when in fact both the seller and product are illegitimate.

Patients who buy prescription drugs from an illegitimate site are at risk of suffering life-threatening adverse events. For example, one type of dangerous product commonly sold on the Internet is a kit for preparing gamma hydroxy butyrate (GHB). This unapproved drug, which is sold for bodybuilding and recreational use and is used also in sexual assaults to incapacitate the victims, is a clear threat to public health when sold in this manner. Other risks include potential side effects from inappropriately prescribed medications, dangerous drug interactions and contaminated drugs, as well as the possible ill effects of impure or unknown ingredients found in drugs manufactured under substandard conditions. Further risk to patients is posed by their inability to know what they are really getting when they buy these drugs. Although some patients may be purchasing the real thing, some may be buying counterfeit copies that contain inert ingredients, outdated legitimate drugs that have been diverted to illegitimate resellers, or dangerous sub-potent or super-potent versions that were improperly manufactured.

Besides magnifying existing problems by reaching millions of consumers worldwide, online drug sales create unique issues for regulatory and law enforcement bodies. Internet technology can obscure the source of the product as well as the persons responsible for making and shipping the product. The participants in a transaction can be widely dispersed geographically and they may well never meet. For example, a consumer in one State, using an Internet site emanating from a computer in a second State, may order a drug actually dispensed from a third State, under a prescription from a doctor in a fourth State. Thus, issues cross traditional regulatory boundaries as well as Federal and State jurisdictional lines. If one or more participants in the transaction are located outside of the United States, the task of regulating the activity is further complicated. Similarly, the fact that sellers can easily change the location and appearance of their Internet sites makes enforcement all the more difficult.

The Agency is particularly concerned about the apparent absence of a doctor-patient relationship in some Internet transactions. FDA believes 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 familiar with the patient's current health status and past medical history. In situations where the customary physician-patient relationship does not exist, the patient is essentially practicing self-diagnosis. Consequently, the risk of negative outcomes such as harmful drug interactions, allergic reactions, contraindications, or improper dosing is greatly magnified. We also are concerned about the proliferation of sites that substitute a simple questionnaire for a face-to-face examination and patient supervision by a health care practitioner. Another concern in such situations is that the legal protections for privacy of medical records, which the Administration strongly supports, may not be available. According to the American Medical Association, a health care practitioner who offers a prescription for a patient they have never seen before and based solely on an online questionnaire has generally not met the appropriate medical standard of care.

The sale of drugs to U.S. residents via foreign web sites is another area of concern to the Agency. Some medications sold on the Internet may be legal in foreign countries but not approved for use in the United States, and some products may include addictive and dangerous substances. Products not approved for sale in the United States generally do not conform to the good manufacturing practices and quality assurance procedures required by U.S. laws and regulations. Generally, the prescrip-

tion drug available from a foreign pharmacy is either a product for which there is no U.S. approved counterpart or a foreign version of an FDA-approved drug. It is illegal for a foreign pharmacy to ship such drugs into the U.S. Additional requirements, enforced by the Drug Enforcement Administration, are imposed on the importation of controlled substances. Foreign sales pose a difficult challenge for U.S. law enforcement because the seller is not within U.S. jurisdiction.

FDA AUTHORITY AND ENFORCEMENT ACTIVITY

The types of unlawful conduct involving online drug sales that FDA has identified are similar to unlawful activities that occur in other sales contexts. Under the Federal Food, Drug, and Cosmetic (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 must establish the same elements of a case, bring 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 already has investigated and referred cases for criminal prosecution and civil enforcement actions against some online sellers of drugs and other FDA-regulated products, particularly sellers of drugs not approved by the Agency. FDA intends to significantly expand its enforcement activities regarding online sales. The Office of Regulatory Affairs (ORA) and the Office of Compliance in the Center for Drug Evaluation and Research (CDER) are the primary organizations within FDA with responsibility for regulating online drug sales. These offices review web sites that consumers, industry, health professionals or government personnel report as appearing violative. Since June 1998, the Agency has taken numerous compliance actions based on violative labeling claims. In at least 27 of these cases, the violative claims had an Internet component. To date, the Agency has identified over 60 cases related to suspected illegal Internet sales, with the first Internet prosecution having been undertaken in 1994. Actions included sending warning letters to firms illegally selling unapproved new drugs online and issuing Import Alerts to online sellers of illegal foreign pharmaceuticals. FDA has also contacted web site managers and asked for their voluntary cooperation in removing violative sites. Warning letters to online pharmacies based in foreign countries are shared with the government of that country. Additionally, CDER's Division of Drug Marketing, Advertising, and Communications has taken steps against online drug promotion that violates the FD&C Act by making unsubstantiated claims or misrepresentations of drugs, or by a lack of fair balance in describing risks and benefits.

The Office of Criminal Investigations (OCI) is the entity within FDA responsible for conducting and coordinating investigations of suspected criminal violations of the FD&C Act, the Federal Anti-Tampering Act (FATA), and other statutes including applicable U.S. Criminal Code violations. OCI maintains liaison and cooperative investigative efforts with other Federal, State, Local, and international law enforcement agencies.

In November 1998, a defendant in California began serving a five year Federal prison term after being convicted of selling online unapproved HIV home test kits which used fabricated test results. For the first time in FDA history, the individual was convicted on wire fraud charges stemming from the use of the Internet to sell an illegal medical product. Previous wire fraud charges involving illegal medical products were based only on telephone and facsimile use.

In another case, in November 1998, a police department in Illinois advised OCI it had discovered an unconscious male individual in a hotel parking lot. The subject was taken to a local hospital and treated for a drug overdose. Police contacted family members and determined that the individual had been taking GHB. Police found suspected GHB in the subject's possession and found additional suspected GHB in his hotel room. Police requested OCI assistance with lab work and a technical computer search as they suspected the subject had obtained GHB kits and preparation instructions from the Internet. OCI identified the subject's source of supply, which was on an Internet site located in Canada. The investigation by OCI and the police department established that the subject had purchased a quantity sufficient to warrant a GHB felony distribution charge under Illinois law. The individual was found guilty of possession of a controlled substance in Illinois and sentenced to two years state probation.

In a third case, OCI was advised by a State Board of Pharmacy that an Internet site was offering prescription drugs to U.S. customers from foreign manufacturers, by acting as an authorized "buyers club" using the "personal importation policy" of FDA. OCI notified the U.S. Customs Service (USCS) at a particular U.S. international mail facility to watch for suspicious shipments bound for the operator of this Internet site. As a result, USCS intercepted what appeared to be steroid shipments to the web site's address. Search warrants were obtained and over a period of approximately four weeks, nine incoming shipments of steroids were searched and control delivered by USCS and OCI agents. Deliveries coordinated with surveillance of the suspect revealed a sophisticated operation centered out of an apartment building. OCI and USCS arrested the suspect and simultaneously served a search warrant at the business location. The primary suspect was sentenced in Federal court.

As a last example, in July of 1996, OCI headquarters was contacted by a women's health care provider to advise that several clients had directed her to an Internet site promoting an abortion kit. She believed the site contained several unfounded statements. The FDA Division of Urology and Reproductive Drug Products reviewed the Internet site and determined that the drugs in the kits presented a serious health risk to women when used without a doctor's supervision because of a possibility of heavy vaginal bleeding and death. Using computer technology and the help of computer security companies, OCI traced the site to Easy Life Labs in Colombia, South America. OCI placed an anonymous order for the kit. The company responded and FDA laboratory analysis showed the drugs to be those warned against by the Agency's experts. The company's web site temporarily went off line, but in March of 1997, the original health care provider called back to say the company was operating again using a different name. One of the drugs provided was unapproved for use in the U.S. OCI contacted the foreign drug company's U.S. Internet service provider (ISP) and told them that one of their subscribers was using its service to promote and sell this unapproved drug. Additionally, the ISP was informed of FDA's public health concerns about the proposed use of the unapproved drug and that this was in criminal violation of the FD&C Act. The service provider voluntarily removed the violative ads.

Although FDA has taken action against unapproved drugs sold over the Internet and will continue to do so in the future, as you know, FDA does not generally regulate the practice of pharmacy or the practice of medicine—the States traditionally have regulated both the prescribing and dispensing of drugs. Several States, however, have found it difficult to identify and locate violators and to bring effective enforcement actions because the seller and the purchaser of a drug may reside in different States and because it is often difficult to identify the persons responsible for a web site. As a result, FDA and State agencies need to work cooperatively to enforce the FD&C Act and State laws in this area.

FDA has initiated contacts with other agencies and States to address these issues. For example, on February 8 of this year, the Agency hosted a meeting with representatives of health professional organizations that looked at the prescribing and dispensing of drugs on the Internet. FDA, the Federation of State Medical Boards of the United States, the National Association of Boards of Pharmacy (NABP), the American Medical Association and the Association of Food and Drug Officials gave presentations. Discussions centered on the roles that each organization plays in regulating prescribing and dispensing on the Internet and how the various roles could better compliment each other. At that meeting, the NABP announced a new program to verify the legitimacy of Internet sites dispensing prescription drugs. The program, known as the Verification of Internet Pharmacy Practice Sites, or VIPPS, will provide a NABP "seal of approval" to sites meeting the organization's standards. Over time, this seal of approval may assure consumers that the designated sites are offering FDA approved pharmaceuticals.

FDA believes that by working with the States, we can regulate the domestic sale of both approved and unapproved drugs (except for controlled substances where the Drug Enforcement Administration generally takes the lead for the Federal government), as well as the sale of prescription drugs without a valid prescription. When a sale involves health fraud, multiple Federal agencies have authority to take action, including the Department of Justice, the Federal Bureau of Investigation, the Federal Trade Commission, the Postal Service, the Office of the Inspector General in the Department of Health and Human Services and FDA. The States also have similar authority. FDA has worked with many of these agencies in bringing cases involving health fraud and will continue to do so.

The most difficult problem to address is the online sale of drugs to U.S. residents by sellers in foreign countries. FDA, and the other Federal agencies and State bodies, possess limited jurisdiction over sellers in foreign countries and must work with

foreign governments to bring action against such individuals. FDA, the Customs Service, the Postal Service, and the Drug Enforcement Administration have greater authority to stop drugs imported illegally into the United States when the product reaches the U.S. border. These agencies have been successful in stopping some products from entering the country. The difficulty of finding these products at the border makes this a very challenging task. The sale of drugs to U.S. residents by foreign sellers poses the greatest challenge for the Federal government.

FDA'S INTERNET DRUG SALES ACTION PLAN

FDA has drafted an action plan outlining expanded activities the Agency will take to address the unlawful sale of drugs over the Internet. This plan is based on internal deliberations, meetings with Federal and State regulatory and law enforcement bodies, as well as organizations representing consumers, health care practitioners, and the pharmaceutical and pharmacy industries. FDA has identified five major areas of focus pertaining to the regulation of online drug sales, which are to:

- customize and expand the Agency's regulatory and criminal enforcement efforts;
- identify when and with which Federal agencies FDA should partner in joint activities;
- partner with State bodies to address domestic Internet sales;
- engage in public outreach; and,
- provide input to Congress regarding legislation.

1) Customize Enforcement Efforts

FDA's role in regulating online drug sales should be consistent with its traditional regulatory role. We also believe that, given the Agency's current limited resources, our existing approaches to enforcement should be adapted to focus more effectively on the problems posed by online drug sales. An effective Internet enforcement process requires establishing priorities, identifying and monitoring potentially violative web sites and making appropriate referrals for criminal prosecution and/or refer/pursue civil enforcement. The Internet action plan calls for FDA to enhance its enforcement efforts by undertaking the following actions.

Establish Priorities—FDA will initially focus its online drug sales-related enforcement activities to the following areas, particularly where there is a significant public health risk:[1]

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

Increase Data Acquisition—FDA will expand its capability to monitor the Internet and identify violative sites by acquiring an advanced search tool and upgrading its data capabilities. This will allow the Agency to determine the kind and extent of unlawful conduct on the Internet and provide a measurement by which the Agency can judge whether its enforcement efforts have had an impact on illegal Internet behavior.

Coordinate Triage—The Agency has established a three-member case assessment team with representatives from the Office of Enforcement and OCI within the Office of Regulatory Affairs (ORA) and from CDER. This team will evaluate violative sites; and make appropriate referrals for criminal prosecution and/or refer/pursue civil enforcement; and, ensure that criminal and civil enforcement actions are efficiently coordinated. Any Agency employee who identifies a potential violation on the Internet will refer the information to the team. This process should ensure that decisions are made in a timely way with 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 completion.

Increase Enforcement Presence—FDA believes that to effectively curb unlawful conduct involving online drug sales, more cases must be pursued. To do this, the Agency will draw from existing activities to increase its current enforcement efforts because we believe that illegal online drug sales pose a significant public health risk. The Agency will begin this effort with a modest reallocation of current fiscal year funds.

---

[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.

2) Identify Federal Agency Partners

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 may be instances when working with another agency or State could result in a more effective enforcement action. In fact, FDA worked closely with FTC in developing the Operation Cure-All cases and also has been working with DOJ and State regulatory bodies.

To ascertain whether and when FDA should coordinate efforts with one or more governmental bodies, above and beyond the relationships that exist today, the Agency has researched the roles that the various Federal and State bodies should play regarding online drug sales. FDA also has met with several of those agencies, as described above, to identify opportunities for partnering in enforcement actions.

FDA believes that an important area where cooperation among Federal agencies can be quite beneficial is the sale of drugs to U.S. residents by foreign sellers. The Customs Service, the Postal Service, FDA, and the Drug Enforcement Administration all play important roles in taking action against the illegal importation of drugs. However, the Federal government's limited ability to bring enforcement actions against sellers in other countries, as well as the feasibility of stopping drugs from entering the United States, pose difficult challenges for law enforcement. Generally, a determination of when and with whom FDA would engage in joint enforcement should be based on the kinds and severity of violative conduct identified through continuous Internet monitoring. Although FDA is expanding its Internet monitoring capabilities, the Agency also is developing partnering arrangements with other agencies. In addition, FDA will participate in any Administration-led working groups that address online drug sales.

3) Partner with State Bodies and Other Organizations

FDA has met with and 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. These organizations 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, and,
- the Pharmaceutical Research and Manufacturers Association.

FDA believes that illegal selling and prescribing of approved prescription drugs over the Internet can be effectively addressed through cooperative efforts by FDA and the States. FDA is drafting partnering agreements with several State bodies to coordinate Federal and State activities aimed at illegitimate sellers and prescribers of prescription drugs.

4) Engage in Public Outreach

Every drug sale involves at least a purchaser and a seller. Although different purchasers buy drugs on the Internet for different reasons, all may be targets of unscrupulous business practices, such as the selling of unsafe, expired, or counterfeit drugs. Public outreach offers one mechanism by which the Agency can help protect consumers from dangerous or inappropriate drugs. Using the following media, FDA will expand its public outreach to explain what compliance and enforcement actions we already have taken and to inform the public about dangerous practices involving Internet purchases:

- Talk papers
- Articles in FDA Consumer Magazine
- Information on FDA's web site to inform consumers about what to avoid if purchasing drugs online, for example, buying prescription drugs without a prescription
- Work with the media.

The Agency also chairs the public education subgroup of the Interagency Internet Sales Working Group. The subgroup met last week to begin addressing whether and

in what coordinated outreach activities the Federal agencies could engage. Some agencies have already issued educational materials. The subgroup will seek to build on existing activities and avoid pursuing duplicative efforts.

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

5) Provide Input to Congress Regarding Legislation

Congress did not enact the current laws governing drug sales with the Internet in mind. Additional fact-finding will be needed to determine whether and to what extent existing regulatory and law enforcement frameworks do not adequately address Internet-related conduct. FDA believes that any decision to pursue new legislation should be made only after a careful and thorough analysis of the issues based on sufficient information, including discussions with relevant non-governmental bodies. FDA has met with and continues to meet with Federal and State governmental bodies and non-governmental organizations to obtain their perspectives on how online drug sales should be regulated. Where appropriate, the Agency will provide input to Congress regarding whether and what legislation is needed in this area.

CONCLUSION

Mr. Chairman, online shopping for pharmaceutical products clearly provides certain benefits for consumers. But it also has a number of risks. Additionally, the nature of this technology presents law enforcement and policy makers with unique challenges. FDA is grappling with the challenges posed by online drug sales, and with our need to carefully balance consumer access to information and products with protecting the public health. We believe we can adapt our compliance and enforcement techniques to the new electronic marketplace, and we will continue to assess what changes in our procedures or the law might be appropriate. We look forward to working with Congress on this important issue.

I would be happy to answer any questions you may have.

Mr. UPTON. Well, thank you very much.

You know, as we began to get evidence for this hearing and began to schedule it, and Mr. Klink and I talked a number of times over the last number of months in terms of the problems, and you were here for the first panel, and whether it be our own local media in our own districts or really across the Nation, it seems like this is just the tip of the iceberg. I mean, if any dog or cat can get this, or folks that have been dead for decades, with pretty relative ease, 9-, 10-year-olds as well, we have a problem. We have a big problem.

As we listen to our own Attorney General speak, and again, for Kansas, they are looking after six—only six cases that they have identified, but just because of those six cases, all of the sudden many of the Internet pharmaceutical groups have, in fact, said Kansas is the State that we don't want to mess with, let us look at the other 49.

Mr. Fong, you indicated at the end of your testimony that the act of dispensing drugs illegally and improperly is, in fact, a Federal offense and that you stand ready to prosecute those in violation. How many—I mean, knowing some of the evidence that we have seen today, how many cases are you actively pursuing at this time?

Mr. FONG. We have, as I indicated in my testimony, been working with our investigative agencies. We work in partnership. We are at the tail end of the process in many ways, and we are only a piece of the puzzle, but we are in the process of working on investigations, and I can't tell you today that we have complaints that we've filed in this area, but we have filed numerous actions in analogous situations involving precisely the fact pattern that you mentioned, as I indicate in my written testimony, cases against in-

dividuals selling unapproved drugs as well as drugs without a prescription, steroids for example.

Mr. UPTON. So there are cases pending?

Mr. FONG. Some of these cases are more than pending. Some individuals have been sentenced.

Mr. KLINK. Will the gentleman yield to me for a moment?

Mr. UPTON. Sure.

Mr. KLINK. Could you tell us how many cases there have been, not necessarily now, but could you present the subcommittee with verification as to how many cases there are and what the adjudication has been of those cases?

Mr. FONG. I can certainly ask and get back to you.

Mr. KLINK. Thank you.

[The following was received for the record:]

From September 1985 to May 1999, there were 236 convictions of distributing drugs without prescriptions: 151 steroid cases; 59 animal drug; and 26 GHB.

Mr. UPTON. Ms. Bernstein, there was—when you get your picture in the Wall Street Journal, that's always sort of an extra little mark, prominence. In a story today by John Simons, it indicates that Ms. Bernstein is watching, but she walks a fine line within the Clinton administration, which has a hands-off stance toward Internet regulation. The administration would prefer that the industry police itself. Yet in your testimony you indicated that you do think you would support the mandating of—the posting of information, similar, I would presume, to some of the thoughts Mr. Klink raised with the earlier panel.

Who is speaking for the administration on this, as we have heard from Dr. Woodcock and Mr. Fong, and is this statement on the mark in terms of what the Journal reported today?

Ms. BERNSTEIN. Mr. Chairman, I guess John Simons wasn't sworn as I was this morning, but I think the Journal statement is correct.

Mr. UPTON. He may be over here. I don't know what he looks like so——

Ms. BERNSTEIN. I think that statement was—was correct. The Commission voted to support legislation that required the disclosure of that identifying information. I do not believe the administration has objected to the Commission's position on that. Does that respond to your question?

Mr. UPTON. Well, the comment in the story says that the administration would prefer that the industry police itself. So that would seem to the casual reader that they would oppose legislation that you commented on.

Ms. BERNSTEIN. Let me expand further if I may, Mr. Chairman. The administration has favored a self-regulatory approach on the Internet in connection with privacy particularly; that is, generalized privacy protection, not on this issue where existing laws have already been violated, and do raise public health concerns. The Federal Trade Commission has supported that nonregulatory position in connection with privacy as well. So I view them as different issues, if you will, and I believe the Commission and the administration do as well.

Mr. UPTON. My time has expired. I yield to Mr. Klink.

Mr. KLINK. Mr. Chairman, before I begin my questioning, might I take care of a bit of housekeeping with you? I would ask unanimous consent that at this point in the record that the majority and minority counsels work together to insert into the record at this point in the hearing all of the correspondence between our subcommittee and committee with the agencies represented on this panel and their responses.

Mr. UPTON. Without objection.

Mr. KLINK. Thank you, Mr. Chairman.

[The information referred to follows:]

ONE HUNDRED SIXTH CONGRESS

TOM BLILEY, VIRGINIA, CHAIRMAN

W.J. "BILLY" TAUZIN, LOUISIANA
MICHAEL G. OXLEY, OHIO
MICHAEL BILIRAKIS, FLORIDA
JOE BARTON, TEXAS
FRED UPTON, MICHIGAN
CLIFF STEARNS, FLORIDA
PAUL E. GILLMOR, OHIO
JAMES C. GREENWOOD, PENNSYLVANIA
CHRISTOPHER COX, CALIFORNIA
NATHAN DEAL, GEORGIA
STEVE LARGENT, OKLAHOMA
RICHARD BURR, NORTH CAROLINA
BRIAN P. BILBRAY, CALIFORNIA
ED WHITFIELD, KENTUCKY
GREG GANSKE, IOWA
CHARLIE NORWOOD, GEORGIA
TOM COBURN, OKLAHOMA
RICK LAZIO, NEW YORK
BARBARA CUBIN, WYOMING
JAMES E. ROGAN, CALIFORNIA
JOHN SHIMKUS, ILLINOIS
HEATHER WILSON, NEW MEXICO
JOHN B. SHADEGG, ARIZONA
CHARLES W. "CHIP" PICKERING, MISSISSIPPI
VITO FOSSELLA, NEW YORK
ROY BLUNT, MISSOURI
ED BRYANT, TENNESSEE
ROBERT L. EHRLICH, JR., MARYLAND

JOHN D. DINGELL, MICHIGAN
HENRY A. WAXMAN, CALIFORNIA
EDWARD J. MARKEY, MASSACHUSETTS
RALPH M. HALL, TEXAS
RICK BOUCHER, VIRGINIA
EDOLPHUS TOWNS, NEW YORK
FRANK PALLONE, JR., NEW JERSEY
SHERROD BROWN, OHIO
BART GORDON, TENNESSEE
PETER DEUTSCH, FLORIDA
BOBBY L. RUSH, ILLINOIS
ANNA G. ESHOO, CALIFORNIA
RON KLINK, PENNSYLVANIA
BART STUPAK, MICHIGAN
ELIOT L. ENGEL, NEW YORK
THOMAS C. SAWYER, OHIO
ALBERT R. WYNN, MARYLAND
GENE GREEN, TEXAS
KAREN McCARTHY, MISSOURI
TED STRICKLAND, OHIO
DIANA DeGETTE, COLORADO
THOMAS M. BARRETT, WISCONSIN
BILL LUTHER, MINNESOTA
LOIS CAPPS, CALIFORNIA

JAMES E. DERDERIAN, CHIEF OF STAFF

U.S. House of Representatives
Committee on Commerce
Room 2125, Rayburn House Office Building
Washington, DC 20515–6115

March 2, 1999

The Honorable David M. Walker
Comptroller General of the United States
U.S. General Accounting Office
441 G Street, N.W.
Washington, D.C. 20548

Dear Mr. Walker:

During the past several years, Internet use has evolved dramatically from a tool used mainly by research centers and universities to a powerful means of moving commerce available to millions of households. American consumers now use the Internet to purchase everything from airline tickets to investments to almost any item traditionally sold in a store.

One group of goods increasingly sold this way are pharmaceuticals. Companies reportedly selling pharmaceuticals online include "Thepillbox.com," "Drugstore.com," "Soma.com," and "PlanetRX.com." Ranging from both over-the-counter health aids to actual prescription drugs, many of these online pharmacy websites (also called "cybermedicine") now allow consumers using a home computer to purchase a range of pharmaceutical products once only available through a face-to-face visit with a doctor and a pharmacist. According to some press accounts, some Internet websites may even allow for a "virtual" doctor visit: medical information is submitted to a web-based drugstore, an online doctor reviews it and, based on that information decides whether to send a prescription directly to a customer's residence. This suggests that some web-based companies may be processing and delivering prescriptions for patients they have never seen, a medical practice some view as highly unethical and prone to serious problems.

A host of serious regulatory concerns are indeed raised by online pharmacies. For example, as patients are often required to submit highly sensitive and personal medical data to the online prescription company before their prescriptions are filled (or processed), it is unclear how effective each online company's methods are for safeguarding such information. Unlike losing a credit card number to an unscrupulous actor, misdirected or stolen personal medical information could have very serious long-term consequences for the consumer.

Others have suggested that online pharmacies could contribute to the problem of drug interactions, as the traditional face-to-face doctor-patient relationship is replaced by an online computer transaction. Although it appears that some online pharmacies require customers to fill out forms listing what other medications they are taking, or what other medical conditions they have, it is not clear that all firms require this, or how such a check of this information will ultimately be conducted. Finally, it remains murky how online pharmacies will process (if at all) controlled substances, and not be susceptible to abuse by hackers or other criminal elements. For example, if, as reported, some Internet pharmacies provide prescription drugs without requiring a patient to actually visit a doctor or pharmacist, certain controlled substances could be seriously susceptible to abuse.

In sum, we are concerned that the rapidly exploding trend of online pharmacies may be outpacing formal state and federal controls, and thus raising a host of serious issues. Given our concerns, we are requesting that the General Accounting Office (GAO) conduct a formal review of this area to determine the following:

(1) How pervasive is the online pharmaceutical industry? Please determine roughly how many online operations now exist, trends for this industry, and the dollar value in sales presently being conducted by online pharmacies.

(2) Please determine the differences between online pharmacies that presently operate over the Internet. For example, some reports suggest that most online pharmacies only fill prescriptions. Other reports, however, have suggested that some actually provide for a doctor consultation (for example, a quick questionnaire is submitted over the Internet, the doctor reviews it, and then the prescription can be approved and sent directly to the patient without a doctor ever seeing the patient). How prevalent is this latter operation? Do any trends appear in comparing one form of online pharmacy operation with another?

(3) Please determine how these firms are or are not being regulated by state and federal agencies. First, who are the primary regulators of online pharmacies at both the federal and state level? What are each of their responsibilities relative to online pharmacies? Are there serious jurisdictional gaps? If so, what are they, and what are their implications for the consumer? Second, what are existing regulators presently doing to oversee existing online pharmacies? What concerns have been reported? What issues do regulators see these firms as posing? As an example, can medical information be sold by one online pharmacy company to another? Third, do existing laws and regulations adequately apply to online pharmacy operations? If not, what are the discrepancies, and what changes, if any, may need to be made?

(4) How do these firms deal with issues such as medical records privacy/protection, the selling of controlled substances, or drug interactions? How serious are these issues and what

shortcomings, if any, do online pharmacies have with regards to these issues? Also, how do online pharmacies prevent unqualified persons from receiving prescriptions? Are online pharmacies more susceptible to fraud or deception? If so, please explain how?

(5) What quality issues pertain to the methods used to ship these online pharmaceutical products? Do their actual sources need to be considered by state and federal regulators? If so, what are they and what are their implications for the consumer? Does the existing regulatory structure make it more difficult to guarantee quality, safety, and effectiveness? If not, why?

Thank you for your cooperation and attention to our request. If you have any additional questions about this matter, please have your staff contact Mr. Christopher Knauer of the Minority staff at (202) 226-3400. We look forward to working with you on this and other important pharmaceutical integrity and consumer protection issues.

Sincerely,

JOHN D. DINGELL
RANKING MEMBER
COMMITTEE ON COMMERCE

RON KLINK
RANKING MEMBER
SUBCOMMITTEE ON OVERSIGHT
AND INVESTIGATIONS

HENRY A. WAXMAN
MEMBER
COMMITTEE ON COMMERCE

SHERROD BROWN
RANKING MEMBER
SUBCOMMITTEE ON HEALTH
AND ENVIRONMENT

Committee on Commerce Correspondence

See Also
Oversight
Online Pharmacies
Telecommunications
E-Commerce

Online Pharmacies

March 18, 1999

The Honorable David M. Walker
Comptroller General
United States General Accounting Office
441 G Street, NW
Washington, DC 20548

Dear Mr. Walker:

On February 17, 1999, the Commerce Committee adopted its Oversight Plan for the 106th Congress. Included in this plan is a notice of the Committee's intent to continue its ongoing investigation into the growing practice of online pharmacies selling their goods over the Internet.

"During the 105th Congress, the Committee followed the development of a number of on-line health care resources. In particular, a growing number of companies are now preparing to distribute prescription pharmaceuticals on-line, and some are moving into the realm of providing health care advice and diagnosis without physically meeting the patient. The Committee will hold hearings on the growth of on-line health care, and evaluate a variety of new consumer protection issues which have arisen in relation to this new field. The Committee will work to ensure that consumers are able to select the best health care options available and to protect themselves against unscrupulous or unqualified providers."

In the course of this ongoing review, the Committee has identified various potential benefits that online distribution of pharmaceuticals may provide for patients. For example, in addition to the potential for lower costs that is commonly associated with Internet commerce, online pharmacies also have the capability to offer patients greater access to medical information about their treatment and round-the-clock access to trained medical professionals from the comfort and privacy of their own homes. In addition, online pharmacies may provide a means of reducing the number of unnecessary deaths caused by the failure of patients undergoing long-term drug regimens to renew their prescriptions in a timely fashion.

The Committee has also identified many areas of potential fraud and abuse that have been exploited by unscrupulous rogue Internet operators which pose a threat to the health and safety of the American public and threaten to undermine the public's confidence in legitimate online pharmacies. For example, the Committee is concerned about the practice of prescribing medications over the Internet without a physical consultation between doctor and patient. Several Internet sites offer to prescribe medications to patients based solely on their answers to simple questionnaires raising concerns about the adequacy of the medical care these sites deliver. In addition, the Committee has identified evidence suggesting that "cowboy operators" are procuring medications in Mexico and selling them over the Internet without any formal pharmaceutical knowledge.

To assist the committee in its work, I am requesting that the GAO undertake a formal review of a number of issues we are examining in our review of

online pharmacies.

1. The National Association of Boards of Pharmacy, a coalition of state pharmaceutical boards, has just launched their new Verified Internet Pharmacy Practice Sites (VIPPS) program, in order to review the licensure of online pharmacies with the aim of issuing a report on their legal status. This system is designed to review online pharmacies to ensure that they are obeying the various state and federal regulations for the industry. Please review their proposal and report on its adequacy as a self-regulatory device for the online pharmacy industry. In the course of your review, please compare the VIPPS system to other models of self-regulation.

2. Online pharmacy laws rely heavily upon established mail-order pharmacy laws in the various states. Please evaluate the adequacy of existing state mail-order laws for pharmaceutical products. In the course of your evaluation, please determine whether there are any states that have not enacted mail-order pharmacy laws, and also determine which states have redrafted their mail-order pharmacy laws to include the new Internet pharmacies.

3. In February 1997, the GAO undertook a review of Pharmacy Benefit Managers (PBMs) in the report "Pharmacy Benefit Managers: FEHBP Plans Satisfied with Savings and Services, But Retail Pharmacies Have Concerns" (GAO/HEHS 97-47). Earlier in 1996, the GAO testified on "Prescription Drug Pricing: Implications for Retail Pharmacies" (Testimony,09/19/96, GAO/T-HEHS-96-216). These reports detailed a variety of problems which traditional retail pharmacies are having with PBMs, concerns which are shared by some of the online pharmacies. Please provide the Committee with an updated review of the effect that PBMs have on pharmaceutical prices, and assess the extent to which online pharmacies will also be affected by these practices.

4. Many of the questionable practices that are being undertaken by Internet operators are located outside the United States. PharmacyInternational.com, a Thailand-based company, has received considerable attention in the drug abuse community as an easy source of prescription medication. What procedures are being established within the federal law enforcement community to monitor these international sites? For example, are Postal Inspectors and Customs agents provided information as to suspect sites so as to properly monitor their imports?

5. Since 1983, the FDA, using their "enforcement discretion," has refrained from preventing individuals traveling to a foreign country and returning with doctor-prescribed, non FDA-approved drugs, provided that the individual has procured no more than a three-month supply. This is the so-called "personal use" exemption. Several online pharmacies are reportedly taking advantage of this exemption, advertising that it is "legal" to ship mail-order non-FDA approved pharmaceuticals so long as they are for personal use. Is this sort of activity valid under the FDA's personal use exemption? Has the FDA undertaken any enforcement action against online pharmacies trying to use the "personal use" exemption?

6. It appears that there is a growing trade in the online sale of Schedule II pharmaceuticals, such as Morphine and Demerol, occurring in Usenet groups, chat rooms, and within adult-oriented web sites. Please evaluate federal law enforcement efforts to police the growing online narcotics trade.

7. Several rogue Internet sites have reportedly been engaged in the sale of repackaged "adulterated" medications. Some examples of adulterated medications include prescription medications that have passed their expiration dates or damaged medications that were salvaged from warehouse fires. Please review the existing state and federal regulations regarding adulterated drugs and determine whether adequate efforts have been made to prevent the sale of adulterated medications over the Internet.

8. Please examine the treatment that state privacy laws accord to patients rights with regard to online pharmacies. Are online pharmacies treated the same as local pharmacies when it comes to privacy laws? Are there any states that would allow an online pharmacy to sell the medical information they obtain from their service?

9. Rules for the transmission of doctors' prescriptions vary from state to state. Some allow faxes, some allow telephone orders, and some are moving toward electronic mail or other forms of Internet transmission. Please review the laws for prescription transmission in various states and evaluate how online pharmacies are dealing with the differences in state law.

Should you have any questions regarding this request, please contact Andrew Leyden or Duncan Wood of the Committee staff at (202) 226-2424. Thank you for your cooperation with this matter.

Sincerely,

Tom Bliley
Chairman

Attachment

cc: The Honorable John D. Dingell, Ranking Member
The Honorable Fred Upton, Chairman
Subcommittee on Oversight and Investigations
The Honorable Ron Klink, Ranking Member
Subcommittee on Oversight and Investigations

The House Committee on Commerce
2125 Rayburn House Office Building
Washington, DC 20515
(202) 225-2927
Commerce@mail.house.gov

ONE HUNDRED SIXTH CONGRESS

TOM BILILEY, VIRGINIA, CHAIRMAN

W.J. "BILLY" TAUZIN, LOUISIANA
MICHAEL G. OXLEY, OHIO
MICHAEL BILIRAKIS, FLORIDA
[illegible]ARTON, TEXAS
[illegible]UPTON, MICHIGAN
[illegible] STEARNS, FLORIDA
PAUL E. GILLMOR, OHIO
JAMES C. GREENWOOD, PENNSYLVANIA
CHRISTOPHER COX, CALIFORNIA
NATHAN DEAL, GEORGIA
STEVE LARGENT, OKLAHOMA
RICHARD BURR, NORTH CAROLINA
BRIAN P. BILBRAY, CALIFORNIA
ED WHITFIELD, KENTUCKY
GREG GANSKE, IOWA
CHARLIE NORWOOD, GEORGIA
TOM COBURN, OKLAHOMA
NICK LAZIO, NEW YORK
BARBARA CUBIN, WYOMING
JAMES E. ROGAN, CALIFORNIA
JOHN SHIMKUS, ILLINOIS
HEATHER WILSON, NEW MEXICO
JOHN B. SHADEGG, ARIZONA
CHARLES W. "CHIP" PICKERING, MISSISSIPPI
VITO FOSSELLA, NEW YORK
ROY BLUNT, MISSOURI
ED BRYANT, TENNESSEE
ROBERT L. EHRLICH, JR., MARYLAND

JOHN D. DINGELL, MICHIGAN
HENRY A. WAXMAN, CALIFORNIA
EDWARD J. MARKEY, MASSACHUSETTS
RALPH M. HALL, TEXAS
RICK BOUCHER, VIRGINIA
EDOLPHUS TOWNS, NEW YORK
FRANK PALLONE, JR., NEW JERSEY
SHERROD BROWN, OHIO
BART GORDON, TENNESSEE
PETER DEUTSCH, FLORIDA
BOBBY L. RUSH, ILLINOIS
ANNA G. ESHOO, CALIFORNIA
RON KLINK, PENNSYLVANIA
BART STUPAK, MICHIGAN
ELIOT L. ENGEL, NEW YORK
THOMAS C. SAWYER, OHIO
ALBERT R. WYNN, MARYLAND
GENE GREEN, TEXAS
KAREN McCARTHY, MISSOURI
TED STRICKLAND, OHIO
DIANA DEGETTE, COLORADO
THOMAS M. BARRETT, WISCONSIN
BILL LUTHER, MINNESOTA
LOIS CAPPS, CALIFORNIA

JAMES E. DERDERIAN, CHIEF OF STAFF

U.S. House of Representatives
Committee on Commerce
Room 2125, Rayburn House Office Building
Washington, DC 20515–6115

March 25, 1999

The Honorable Jane E. Henney, M.D.
Commissioner
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

Dear Commissioner Henney:

During the past several years, Internet use has evolved dramatically for the purchase of a range of products from airline tickets to investments to almost any item traditionally sold in a store. One group of goods increasingly sold this way includes pharmaceuticals. Ranging from both over-the-counter health aids to actual prescription drugs, many Internet websites now allow consumers using a home computer to purchase pharmaceuticals once only available through a face-to-face visit with a doctor and a pharmacist.

The regulation of pharmacies has traditionally been a state function. States have generally focused on ensuring that pharmacies observe specific guidelines to safely dispense medications to the public, and that they are licensed and operated by qualified and trained staff. State regulators also ensure that any pharmacy under its jurisdiction properly stores and safeguards the pharmaceuticals it sells. The Food and Drug Administration's (FDA) role in regulating pharmaceutical sales is focused generally on ensuring that any drugs sold in the U.S. are FDA approved, properly manufactured, and thus safe and effective. FDA also ensures that all claims and instructions by the drug maker for the product are accurate and not misleading. With the exception of some mail-order operations, because most pharmacies have operated within a local environment (*e.g.*, the corner drug store), this federal-state partnership, for the most part, has been effective in safeguarding public health.

The recent explosion of online sites that both advertise and sell prescription drugs across state and even international lines, may be undermining this regulatory structure. It is not clear who bears the ultimate responsibility for regulating Internet pharmacies, nor is it clear what actions are being taken to ensure that the public is being protected in this new consumer environment. Although some believe that it is mostly the states that are responsible for shouldering most of this burden, the cross-border nature of most Internet sites, coupled with the sheer volume of their activities, may make this an impossible undertaking. The states alone may not have the necessary resources, expertise, or jurisdiction to do this job.

Without a doubt, a host of serious regulatory concerns are posed by Internet pharmacies. For example, as patients are often required to submit personal medical data to an online pharmacy before their prescriptions are processed, highly personal information could be released (accidentally or deliberately) by an online pharmacy without the customer's permission. Some online pharmacies could contribute to the problem of drug interactions, as the traditional face-to-face doctor-patient relationship or pharmacist-patient relationship is replaced by an online computer transaction. Finally, it remains murky how online pharmacies will process (if at all) controlled substances, and not be susceptible to abuse by hackers or other criminal elements. If, as reported, some Internet pharmacies provide prescription drugs without requiring a patient to actually visit a doctor or pharmacist, certain controlled substances could be seriously susceptible to abuse.

Because of our concerns in this area, we would like you to address the following:

(1) What agency or department (at either the state or federal level) does FDA believe is the primary regulator of Internet pharmacies? For this question, please also identify and describe the roles of the other state/federal agencies that may make up this structure.

(2) What specific activities or functions does FDA believe it is responsible for with regard to regulating Internet pharmacies? Please describe both the precise activities now conducted by FDA, and the number of full-time equivalents (FTEs) dedicated to all identified efforts. Does FDA believe it has enough resources to conduct the activities it presently feels are under its jurisdiction in this regard? If, not, what additional resources does FDA require?

(3) Does FDA believe that existing laws and regulations, or the present state/federal regulatory structure, adequately regulate online pharmacy operations? If not, what are the discrepancies, and what changes, if any, does FDA believe must be made?

(4) Please describe FDA's knowledge regarding the differences between existing online pharmacies. For example, some reports suggest that most online pharmacies only fill prescriptions. Other reports, however, have suggested that some actually provide for a doctor consultation (for example, a quick questionnaire is submitted over the Internet, it is reviewed, and then the prescription is then approved and sent directly to the patient without a doctor ever seeing the patient). How prevalent is this latter operation? Do any trends appear in comparing one form of online pharmacy with another?

(5) What is FDA's understanding of how these firms deal with issues such as medical records privacy/protection, the selling of controlled substances, or drug interactions? How serious are these issues and what shortcomings, if any, do online pharmacies have with regard to these issues? Does FDA have any knowledge of how online pharmacies prevent unqualified persons from receiving

prescriptions? Are online pharmacies more susceptible to fraud or deception? If so, please explain how?

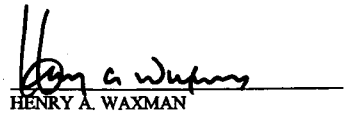
(6) Finally, what quality issues does FDA believe relate to the methods used to ship online pharmaceutical products, and does FDA believe it has jurisdiction in this area?

Thank you for your cooperation and attention to our request. If you have any additional questions about this matter, please have your staff contact Mr. Christopher Knauer of the Minority staff at (202) 226-3400. We look forward to working with you on this and other important pharmaceutical integrity and consumer protection issues.

Sincerely,

JOHN D. DINGELL
RANKING MEMBER
COMMITTEE ON COMMERCE

RON KLINK
RANKING MEMBER
SUBCOMMITTEE ON OVERSIGHT
AND INVESTIGATIONS



HENRY A. WAXMAN
MEMBER
COMMITTEE ON COMMERCE

SHERROD BROWN
RANKING MEMBER
SUBCOMMITTEE ON HEALTH
AND ENVIRONMENT

cc: The Honorable Tom Bliley, Chairman
Committee on Commerce

The Honorable Michael Bilirakis, Chairman
Subcommittee on Health and Environment

The Honorable Fred Upton, Chairman
Subcommittee on Oversight and Investigations

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

APR - 8 1999

The Honorable Thomas Bliley
Chairman
Committee on Commerce
House of Representatives
Washington, D.C. 20515

Dear Mr. Chairman:

This letter is to follow up on our meeting of January 20, 1999 at which we discussed your concern about the promotion and sale of prescription drug products over the Internet. I want to reiterate that I share your public health concern arising from the rapid growth in the sale and promotion of prescription drug products on the Internet. Subsequent to our meeting, Food and Drug Administration (FDA or the Agency) staff met with Commerce Committee staff on March 12, 1999 to further explore these issues.

Our primary concern about Internet sales is based on the long-standing principle that the selection of specific drug products or treatment regimens for a particular patient should be made with the advice of a licensed physician familiar with the patient's current health status and past medical history. FDA is greatly concerned about situations where the customary physician-patient relationship or a pharmacy intermediary does not exist. In these situations, the prescriber must largely rely on the patient to practice self-diagnosis, which multiplies the risk of negative outcomes such as harmful drug interactions, allergic reactions, contraindications, or improper dosing.

Under the Federal Food, Drug, and Cosmetic Act, FDA can take action against illegal promotion of a prescription drug; the importation, sale, or distribution of an adulterated or misbranded prescription drug; and the importation, sale or distribution of an unapproved new drug. The States, however, have traditionally regulated the prescribing and dispensing of drugs as well as the prescriber-patient relationship. Additionally, FDA possesses limited authority over international sales and limited resources to control interstate and international sales. Clearly, oversight of the variety of public health related activities that can occur on the Internet requires the attention not only of FDA and other

Federal agencies, but also State licensing and regulatory boards, the pharmaceutical industry and medical professional organizations.

The Agency is in the process of developing Guidance for Industry to provide clarification on use of the Internet for promoting drug products. Also, I have established a working group within FDA to explore avenues open to the Agency to address Internet sales and to foster collaboration with other Federal agencies.

FDA has already worked with the Federal Trade Commission (FTC) to review Web sites that dispense prescription drugs. We are ready to expand our cooperation with other agencies as needed, and will be meeting with a number of them this month to discuss further cooperative efforts. Participants will include the FTC, Drug Enforcement Administration, Federal Bureau of Investigation, Customs Bureau, Postal Service and State officials.

FDA is continuing to talk with representatives of pharmaceutical companies, the American Medical Association, the Federation of State Medical Boards and the National Association of Boards of Pharmacy to raise awareness of this issue. Finally, we are working to alert the public to the problem via press interviews, speeches, and FDA-authored articles such as those in the "FDA Consumer" magazine.

Again, I very much appreciate your interest in this important issue and look forward to working with you and others in the Congress to respond to the public health concerns raised by the growing Internet commerce in prescription drug products.

Sincerely,

Jane E. Henney, M.D.
Commissioner of Food and Drugs

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

MAY - 7 1999

The Honorable John D. Dingell
Ranking Minority Member
Committee on Commerce
House of Representatives
Washington, D.C. 20515

Dear Mr. Dingell:

Thank you for your letter of March 25, 1999, co-signed by Representatives Waxman, Klink and Brown, on the subject of pharmaceutical sales over the Internet. We appreciate and welcome your interest in this rapidly emerging issue, as the Food and Drug Administration (FDA or the Agency), other Federal agencies and State entities work to define and respond to the issues presented by this phenomenon. Each question in your March 25 letter is restated below (in bold type), followed by FDA's response.

(1)What agency or department (at either the state or federal level) does FDA believe is the primary regulator of Internet pharmacies? For this question, please also identify and describe the roles of the other state/federal agencies that may make up this structure.

We are not aware that any government agency is the "primary regulator" of Internet pharmacies. FDA does not generally regulate pharmacies. FDA regulates products and certain activities related to those products, particularly when carried out by or on behalf of a manufacturer, packer, or distributor. Under the Federal Food, Drug, and Cosmetic (FD&C) Act, FDA can take action against illegal promotion (labeling and advertising) of a prescription drug; illegal labeling of an over-the-counter drug; the importation, sale, or distribution of an adulterated or misbranded drug; the importation, sale, or distribution of an unapproved new drug; and the sale or dispensing of a prescription drug without a valid prescription. The States, however, have traditionally regulated the dispensing of drugs. Internet sites that carry out any of the above illegal acts are subject to regulatory action by FDA or the appropriate State agency.

Other aspects of Internet drug sales are subject to enforcement activities by other Federal agencies. The Federal Trade Commission (FTC) has responsibility for the advertising of non-prescription drugs, while the Drug Enforcement Administration (DEA) regulates controlled substances. The Department of Justice enforces civil consumer protection statutes and criminal provisions. Finally, the U.S. Postal Service and the U.S. Customs Service enforce statutes and regulations governing the importation and domestic mailing of drugs.

In an effort to enhance interagency cooperation, FDA facilitated a meeting with a number of federal agencies and representatives of state regulatory bodies on April 26, 1999. Meeting participants discussed their roles in regulating Internet sales of drugs in an effort to advance interagency cooperation and bring clarity to issues relating to jurisdiction. Participants included the FTC, DEA, Federal Bureau of Investigation, Customs Bureau, Postal Service and State pharmacy regulators.

(2) What specific activities or functions does FDA believe it is responsible for with regard to regulating Internet pharmacies? Please describe both the precise activities now conducted by FDA, and the number of full-time equivalents (FTEs) dedicated to all identified efforts. Does FDA believe it has enough resources to conduct the activities it presently feels are under its jurisdiction in this regard? If, not, what additional resources does FDA require?

As noted in the above response, FDA does not generally regulate pharmacies. FDA regulates products and certain activities related to those products, particularly when carried out by or on behalf of a manufacturer, packer, or distributor. The States, however, have traditionally regulated the dispensing of drugs.

The Office of Compliance in FDA's Center for Drug Evaluation and Research (CDER) reviews Web sites that consumers, industry or health professionals report as appearing to be violative. CDER has taken a number of actions, such as sending Warning Letters to firms using the Internet to illegally promote the sale of unapproved new drugs and issuing Import Alerts on illegal foreign products sold on-line. FDA has also contacted Web site managers and asked for their voluntary cooperation in removing offensive sites. Warning Letters to offshore

pharmacies are shared with the firm's home government, from whom we request cooperation. Additionally, CDER's Division of Drug Marketing, Advertising and Communications has taken steps against Internet promotion that violates the FD&C Act, for example, by making unsubstantiated claims for drugs or misrepresentations, or by a lack of fair balance in describing risks versus benefits.

FDA possesses limited authority over international sales and limited resources to control domestic and international sales. Clearly, oversight of the variety of public health related activities that can occur on the Internet requires the attention not only of FDA and other Federal agencies, but also State licensing and regulatory boards, the pharmaceutical industry and medical professional organizations.

The Agency is in the process of developing draft guidance for industry to provide clarification on use of the Internet for promoting regulated products.

FDA does not have any employees that are dedicated full-time to monitoring Internet sites that sell drugs or undertaking regulatory activities involving such sites. Assignments to regulatory personnel are made as information becomes available indicating that violations of the FD&C Act or FDA regulations may have occurred. Similarly, while some individuals with policy-making duties are currently spending substantial amounts of time on Internet drug sales issues, these also are not full-time assignments.

FDA has established an internal working group to explore other areas relating to Internet sales where the Agency's regulatory authority may be needed to protect the public health. Once this working group has made further progress and reported on its work, FDA then will be able to recommend to you what additional resources, if any, may be needed from Congress to address this area. We would also note that the assignment of personnel to Internet related issues may change as a result of the working group's efforts.

(3) Does FDA believe that existing laws and regulations, or the present state/federal regulatory structure adequately regulate online pharmacy operations? If not, what are the discrepancies, and what changes, if any, does FDA believe must be made?

As noted above, FDA's internal working group is currently exploring avenues available to the Agency under our existing authority to address Internet sales as well as additional authorities that may be needed. Once the working group makes recommendations on this matter, FDA will be able to indicate what legislative changes may be needed to provide additional authorities. We expect to gain additional perspective on this issue as we review the results of the April 26, 1999 meeting with Federal and State agencies.

Because pharmacies are generally regulated at the State level, the question of whether existing laws and regulations are sufficient to protect the public health from risks associated with Internet pharmacies should also be addressed to those State organizations responsible for the regulation of pharmacies.

(4) Please describe FDA's knowledge regarding the differences between existing online pharmacies. For example, some reports suggest that most online pharmacies only fill prescriptions. Other reports, however, have suggested that some actually provide for a doctor consultation (for example, a quick questionnaire is submitted over the Internet, it is reviewed, and then the prescription is then approved and sent directly to the patient without a doctor ever seeing the patient). How prevalent is this latter operation? Do any trends appear in comparing one form of online pharmacy with another?

As FDA has more closely examined Internet sales of drugs over the past few months, we are struck by the diversity of Internet sites and the multi-faceted nature of the issues that are presented. Not only are questions raised about the authenticity of some pharmaceutical products sold on-line at certain Internet sites, but the legitimacy of some prescribing activity is also at issue. Because these are electronic transactions, the participants may be widely dispersed geographically and may well never meet. A consumer in one state, for instance, using a Web site emanating from a

computer in another state, may order a drug dispensed from a third state, using a prescription from a doctor in a fourth state.

This geographic diffusion and other unique characteristics of the Internet present regulators with novel challenges. In the example above, if one or more participants in the transaction are located outside of the United States, the task of regulating this activity is further complicated. Similarly, the fact that Web site operators may easily move the location of their sites makes enforcement all the more difficult.

Additionally, as regulators consider new enforcement strategies, a careful line must be drawn between unsafe or illegal practices over the Internet and legitimate communication and commerce which is increasingly utilizing this new medium. Examples of valid prescribing and dispensing activities using the Internet are 1) the use by patients of Web sites sponsored by well-established pharmacies to order refills of existing prescriptions, and 2) the use by physicians of electronic means to transmit prescriptions to pharmacies for patients they have properly evaluated.

FDA's primary concern about Internet sales is based on the long-standing principle that the selection of specific drug products or treatment regimens for a particular patient should be made with the advice of a licensed physician familiar with the patient's current health status and past medical history. FDA is greatly concerned about situations where the customary physician-patient relationship does not exist. In these situations, the prescriber must largely rely on the patient to practice self-diagnosis, which multiplies the risk of negative outcomes such as harmful drug interactions, allergic reactions, contraindications, or improper dosing. We do not, however, know how prevalent this type of operation is or if there are identifiable trends as to the prevalence of one type of online pharmacy versus another. We are not aware of any reliable estimates of the number of Internet sites that sell drugs, as new sites appear on the Internet every day, just as others disappear.

(5) What is FDA's understanding of how these firms deal with issues such as medical records, privacy/protection, the selling of controlled substances, or drug interactions? How serious are these issues and what shortcomings, if any, do

online pharmacies have with regard to these issues? Does FDA have any knowledge of how online pharmacies prevent unqualified persons from receiving prescriptions? Are online pharmacies more susceptible to fraud or deception? If so, please explain how?

FDA is not in a position to say whether on-line pharmacies have shortcomings in these areas. Issues pertaining to medical records and privacy protection are generally regulated by the States. In addition, the regulation of controlled substances is handled by the DEA.

While pharmacies are not required to report instances of adverse events or drug interactions, they are encouraged to submit such reports to FDA's MEDWATCH system. FDA maintains a link to MEDWATCH on our Internet site at www.fda.gov/medwatch. We take the issue of drug interactions and adverse reactions very seriously, however, we are not aware that these problems are more prevalent at pharmacies utilizing the Internet.

As to the question of how online pharmacies prevent unqualified persons from receiving prescriptions, FDA recognizes that various on-line pharmacies have different policies and procedures relating to this issue. Clearly, many on-line pharmacies do require valid prescriptions, but FDA is very concerned that some pharmacies do not. At this time, we have no information suggesting that on-line pharmacies are more susceptible to fraud or deception than other pharmacies. Susceptibility to fraud is increased at any pharmacy that takes orders without the customer physically present at the establishment or which dispenses medications through the mail rather than in person.

(6) Finally, what quality issues does FDA believe relate to the methods used to ship online pharmaceutical products, and does FDA believe it has jurisdiction in this area?

Standards enforced by FDA apply to all drugs sold in commerce in the United States, regardless of whether the order is placed in person, online or by the mail. Products that fail to meet quality standards would be adulterated or misbranded under the FD&C Act and subject to regulatory action by FDA.

Page 7 - The Honorable John D. Dingell

We very much appreciate having your thoughts and knowing of your concerns regarding the sale of drugs over the Internet. We hope this information is useful to you and we look forward to working with you and your colleagues to address this important public health issue. A similar letter is being sent to your cosigners.

Sincerely,

Melinda K. Plaisier
Interim Associate Commissioner
for Legislative Affairs

cc: The Honorable Tom Bliley
Chairman
Committee on Commerce

The Honorable Michael Bilirakis
Chairman
Subcommittee on Health and Environment
Committee on Commerce

The Honorable Fred Upton
Chairman
Subcommittee on Oversight and Investigations
Committee on Commerce

ONE HUNDRED SIXTH CONGRESS

TOM BILILEY, VIRGINIA, CHAIRMAN

W.J. "BILLY" TAUZIN, LOUISIANA
MICHAEL G. OXLEY, OHIO
[illegible]EL BILIRAKIS, FLORIDA
[illegible]PTON, TEXAS
[illegible]PTON, MICHIGAN
CLIFF STEARNS, FLORIDA
PAUL E. GILLMOR, OHIO
JAMES C. GREENWOOD, PENNSYLVANIA
CHRISTOPHER COX, CALIFORNIA
NATHAN DEAL, GEORGIA
STEVE LARGENT, OKLAHOMA
RICHARD BURR, NORTH CAROLINA
BRIAN P. BILBRAY, CALIFORNIA
ED WHITFIELD, KENTUCKY
GREG GANSKE, IOWA
CHARLIE NORWOOD, GEORGIA
TOM A. COBURN, OKLAHOMA
RICK LAZIO, NEW YORK
BARBARA CUBIN, WYOMING
JAMES E. ROGAN, CALIFORNIA
JOHN SHIMKUS, ILLINOIS
HEATHER WILSON, NEW MEXICO
JOHN B. SHADEGG, ARIZONA
CHARLES W. "CHIP" PICKERING, MISSISSIPPI
VITO FOSSELLA, NEW YORK
ROY BLUNT, MISSOURI
ED BRYANT, TENNESSEE
ROBERT L. EHRLICH, JR., MARYLAND

JOHN D. DINGELL, MICHIGAN
HENRY A. WAXMAN, CALIFORNIA
EDWARD J. MARKEY, MASSACHUSETTS
RALPH M. HALL, TEXAS
RICK BOUCHER, VIRGINIA
EDOLPHUS TOWNS, NEW YORK
FRANK PALLONE, JR., NEW JERSEY
SHERROD BROWN, OHIO
BART GORDON, TENNESSEE
PETER DEUTSCH, FLORIDA
BOBBY L. RUSH, ILLINOIS
ANNA G. ESHOO, CALIFORNIA
RON KLINK, PENNSYLVANIA
BART STUPAK, MICHIGAN
ELIOT L. ENGEL, NEW YORK
THOMAS C. SAWYER, OHIO
ALBERT R. WYNN, MARYLAND
GENE GREEN, TEXAS
KAREN McCARTHY, MISSOURI
TED STRICKLAND, OHIO
DIANA DeGETTE, COLORADO
THOMAS M. BARRETT, WISCONSIN
BILL LUTHER, MINNESOTA
LOIS CAPPS, CALIFORNIA

JAMES E. DERDERIAN, CHIEF OF STAFF

U.S. House of Representatives
Committee on Commerce
Room 2125, Rayburn House Office Building
Washington, DC 20515–6115

June 14, 1999

The Honorable Jane E. Henney, M.D.
Commissioner
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

Dear Commissioner Henney:

As you know, the Committee on Commerce has been investigating a number of issues pertaining to the sale of pharmaceutical products over the Internet. Committee staff have met with officials from the Department of Justice (DOJ), the Federal Trade Commission (FTC), and the Food and Drug Administration (FDA) in an attempt to determine who is responsible for overseeing and regulating this area of commerce. These discussions have produced, at best, only vague responses. Presently, it remains unclear which federal agencies or departments are in charge, or what the responsibilities are for each agency. Thus far, the federal effort (as comprised by DOJ, FTC, and FDA) appears uncoordinated and disorganized.

Recently, Committee staff learned that the FDA had formed an internal working group on this matter. Staff also learned that an interagency group had also been formed to explore the jurisdiction(s) and activities of all identified federal agencies and departments on this matter. That group has already met at least once, and it is our understanding that more meetings are planned.

In light of these new developments and the ongoing confusion about who is regulating the sale and distribution of Internet pharmaceuticals, Committee staff had requested that FDA provide a telephone briefing on this matter. Committee staff was told that FDA was declining this request, but that some information might be available at an undetermined future date.

In light of the overall seriousness of this matter and the growing volume of Internet sites advertising and selling prescription drugs to the public, such delay is unacceptable. It is the Committee's responsibility to conduct due and diligent oversight into these matters, and it is FDA's duty to keep the Committee fully apprised. Accordingly, we are requesting, pursuant to Rules X and XI of the United States House of Representatives, that you provide the Committee with the following information by June 28, 1999:

(1) Please provide all records relating to FDA's regulation of pharmaceutical products sold over the Internet between the dates of May 12, 1999 (our last major FDA meeting on this matter), and the present.

(2) Please provide a full description of any role FDA has played in any interagency working group(s) regarding the sale and distribution of prescription drugs on the Internet since the May 12th meeting and the present. Please also provide the names of the members of the interagency working group(s) and their respective titles and telephone numbers.

(3) Please provide a full description of FDA's new internal working group on this matter. Please also provide the names of the members of the internal working group, their position titles, and their respective telephone numbers.

(4) As part of this response, please provide to the Committee the following information regarding the enclosed copies of Internet sites that appear to be selling pharmaceuticals over the Internet:

(a) The physical location of the site, and in what States it sells its products;

(b) A brief description of the pharmaceutical products sold through the site;

(c) The source of all such pharmaceutical products sold through the site;

(d) Whether the site is licensed in the U.S., and if so by what state(s). If not licensed in the U.S., please determine whether the site is licensed by a foreign regulatory authority, or if at all;

(e) Whether the FDA has ever reviewed the site for any advertising or usage claims made regarding any pharmaceutical product sold;

(f) The accuracy of any such claims made by the site that fall under FDA's jurisdiction.

(5) Finally, if you believe that any single State has already reviewed these numerous Internet sites for the above content, please list the State, and the name of the regulatory authority that conducted the review.

(6) Since 1983, the FDA, using its "enforcement discretion," has permitted individuals to return to the country with non-FDA approved drugs provided that the individual has procured no more than a three-month supply. This is the so-called "personal use" exemption. Several online pharmacies are reportedly taking advantage of this exemption, advertising that it is "legal" to ship mail-order non-FDA approved pharmaceuticals so long as they are for personal use. Is this sort of activity valid under the FDA's personal use exemption? Has the FDA undertaken any enforcement action against online

pharmacies trying to use the "personal use" exemption? If so, please provide all records relating to such action.

Please provide a response by June 25, 1999. If you have any questions on this matter, please contact Mr. Christopher Knauer at (202) 226-3400 or Ms. Lori Wall at (202) 226-2424 of our respective staffs.

Sincerely,

TOM BLILEY
CHAIRMAN
COMMITTEE ON COMMERCE

JOHN D. DINGELL
RANKING MEMBER
COMMITTEE ON COMMERCE

FRED UPTON
CHAIRMAN
SUBCOMMITTEE ON
OVERSIGHT AND INVESTIGATIONS

RON KLINK
RANKING MEMBER
SUBCOMMITTEE ON
OVERSIGHT AND INVESTIGATIONS

Enclosures

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

JUL 1 1999

The Honorable John D. Dingell
Ranking Minority Member
Committee on Commerce
House of Representatives
Washington, D.C. 20515-6115

Dear Mr. Dingell:

Thank you for your continued interest in the issue of the sale of pharmaceutical products over the Internet. This letter is in partial response to your letter of June 14, 1999, in which you and your colleagues posed a number of questions about activities of the Food and Drug Administration (FDA or the Agency) related to the sale of pharmaceutical products over the Internet.

I share your concern about the potentially serious public health implications posed by the growing number of Internet sites selling pharmaceutical products. I understand the view that Federal agencies, including FDA, may not as yet have devised a comprehensive strategy to deal with Internet drug sales. I want to assure you, however, that FDA is closely attuned to this issue. We are taking regulatory action (including criminal cases) where appropriate, and we are looking at what new steps or policies may be needed. First and foremost, FDA is concerned about the public health implications of Internet drug sales, and we are evaluating our efforts in this area as part of our overall goal of developing and implementing risk-based strategies to protect public health and safety.

FDA is working internally to determine more precisely what our role should be regarding the regulation of online drug sales and how we can best meet that role in light of our present resources and the current state of the law. Clearly, the present regulatory system established by the Food, Drug, and Cosmetic Act, as amended over the years by Congress, did not contemplate the challenges presented by the Internet.

FDA is also working with other agencies to determine what we collectively can do, given multiple agencies with existing authorities, to regulate the various aspects of Internet activity. Because the authority over Internet drug sales is widely dispersed throughout government (State and Federal), the identification and resolution of the numerous enforcement issues is complex and will take time to complete. As part of this process, FDA constructed the enclosed matrix describing the traditional enforcement authority of those Federal agencies involved in online drug sales. Although not comprehensive, the chart serves as a starting point for addressing whether and where cooperative efforts by two or more Federal agencies, as well as the States, should be undertaken.

On April 26 of this year, FDA hosted a meeting of eight Federal agencies and some State regulators to discuss the full range of issues pertaining to Internet drug sales. Subsequently, a decision was made to establish smaller working groups to facilitate a more detailed examination of various aspects of the problem. The working group on legal and regulatory issues held their first meeting on June 3, hosted by the Department of Justice, and is scheduled to meet again in mid-July. A second working group, addressing public education and information issues, is scheduled to meet in late July, hosted by FDA. In addition, we will be participating in other interagency working groups that will be convened by the White House.

FDA staff provided a briefing in May 1999, to Commerce Committee staff regarding our statutory authority, enforcement activities and regulatory issues. We will be happy to provide additional briefings to staff when the work on these matters proceeds further.

Please be assured that we welcome the participation of the Committee and want to work with you. In regard to the specific questions you have raised, we are gathering information necessary to respond and will provide specific responses in a subsequent letter. In the interim, if you have further questions or concerns, please let us know. A similar letter has been sent to your co-signers.

Sincerely,

Jane E. Henney, M.D.
Commissioner of Food and Drugs

Enclosure

Sale of Drugs on the Internet

The following chart artificially divides online drug sales into individual events in an effort to conceptually organize online drug sale-related activities. In practice, however, many civil and criminal investigations of schemes to violate federal laws do not classify violations according to the categories of this matrix. Instead, such investigations scrutinize the entire scheme and the actions and mental state of its participants in order to ascertain which federal laws were violated and whether a prosecution is viable. From the enforcement standpoint, the important issue is whether there are adequate remedies and jurisdiction to comprehensively and effectively address a public health and crime problem. In addition, multiple agencies may jointly engage in both investigative and enforcement efforts.

This chart is not intended to be comprehensive or complete nor does it express the official views of the listed agencies. Categories left blank for a particular agency do not necessarily indicate that that agency does not have authority or has not established a program pertaining to a certain Internet activity.

Entity	Statutes	Responsibility Over Sales (General)	Responsibility Over Promotion	Responsibility Over Prescribing	Responsibility Over Dispensing Practices	Internet-Related Programs	Other Internet-Related Activities
Customs Service	Title 19 USC 1497 (Failure to Declare); Title 19 USC 1595A(C) (gives Customs authority to enforce the laws and regulations of other government regulatory agencies); 19 USC 545 (General Smuggling)	Seize illegal products or illegally imported products at the U.S. Border and interior ports of entry (i.e., airports, commercial facilities, mail facilities); products will be seized if illegal in nature or illegally dispensed/imported via U.S. borders	None	None	Same as Responsibility Over Sales	The Customs Cybersmuggling Center (C3), whose mission is to bring together U.S. Customs Service resources in support of the Service's investigative, intelligence, computer forensic and interdiction programs to identify those persons, organizations and related businesses involved in cybersmuggling activities, as well as their methods and means of operation	C3 is also responsible for the investigation of violations related to international child pornography, child exploitation and child sex tourism; drug trafficking; the violation of Intellectual Property Rights statutes; the trafficking of weapons of mass destruction, their delivery systems and spare parts; and, international money laundering
DOD (TRICARE, Defense Criminal Investigative Services)	Chapter 55, Title 10 USC.; 32 CFR 199; Health Insurance Portability and Accountability Act; False Claims Act	Investigative action with referrals to DCIS/FBI for enforcement of civil and criminal penalties	Financial inducement to use "specific medication" will result in investigative action	Physicians must prescribe only medications that are approved by the FDA for human consumption and meet all state and federal regulations for prescribing medications	Pharmacists and pharmacies must meet state and federal regulations that pertain to them	None	None

ity	Statutes	Responsibility Over Sales (General)	Responsibility Over Promotion	Responsibility Over Prescribing	Responsibility Over Dispensing Practices	Internet-Related Programs	Other Internet-Related Activities
DHHS (OIG)	Mail Fraud; Wire Fraud; False Claims; Civil False Claims; kickbacks, money laundering, health care fraud offenses; Civil Monetary Penalties Act, when the conduct involves Medicare, Medicaid or other HHS funded health care	Enforcement actions against fraud when the conduct involves Medicare, Medicaid or other HHS funded health care		Enforcement actions against fraud when the conduct involves Medicare, Medicaid or other HHS funded health care	Enforcement actions against fraud when the conduct involves Medicare, Medicaid or other HHS funded health care		
DOJ (Fraud Section, Criminal Division; Office of Consumer Litigation; U.S. Attorneys Offices)	Mail Fraud; Wire Fraud; Interstate Transportation of Funds Taken by Fraud; False Claims; Civil False Claims; Money Laundering; Health Care Fraud Offenses; Food Drug & Cosmetic Act	Bring criminal or civil charges for fraud (e.g., misrepresentations about a product or about the legal or regulatory requirements of providers) and violations of the Food Drug & Cosmetic Act		Bring criminal or civil charges for fraud, e.g., fraudulent prescribing and billing practices	Bring criminal or civil charges for fraud, e.g., fraudulent billing practices		
DEA	Controlled Substances Act	Enforcement actions (civil and criminal) against illegal sales, distribution, importation, exportation of controlled substances		Enforcement actions (civil and criminal) against illegal prescribing of controlled substances without a valid medical reason	Enforcement actions (civil and criminal) against illegal dispensing of controlled substances without a valid medical reason	Internet Working Group	
FBI		Enforcement actions (civil and criminal) against fraud (e.g., misrepresentations about a product or about the legal or regulatory requirements of providers)		Enforcement actions (civil and criminal) against fraud, e.g., fraudulent prescribing and billing practices	Enforcement actions (civil and criminal) against fraud, e.g., fraudulent billing practices	Internet Fraud Complaint Center	

ity	Statutes	Responsibility Over Sales (General)	Responsibility Over Promotion	Responsibility Over Prescribing	Responsibility Over Dispensing Practices	Internet-Related Programs	Other Internet-Related Activities
FDA (CDER, CDRH, CBER, CVM, CFSAN, ORA)	Food Drug & Cosmetic Act	Enforcement actions (civil and criminal) and import alerts against unapproved drugs, adulterated (contaminated or otherwise unsafe) drugs, and misbranded drugs (e.g., misleading promotion, dispensing without a valid prescription) sold in, distributed in, or imported into the U.S.; enforcement actions (civil or criminal) against the reimportation, other than by the manufacturer, of American Goods Returned; enforcement actions (civil or criminal) against the sale, purchase, or trade or the offer to sell, purchase, or trade a prescription drug sample, a prescription drug purchased by a health care entity or a coupon for a prescription drug	Enforcement actions (civil and criminal) against illegal labeling of all drugs (and all other medical products and foods) and illegal advertising of prescription drugs (and restricted medical devices)	FDA does not traditionally regulate the practice of medicine	Enforcement actions (civil and criminal) against dispensing without a valid prescription (interpreted as dispensing without any prescription)	Internet Working Group; participate in FTC Internet "Surf Days"	Enforcement actions (civil and criminal) and import alerts against unapproved medical products, adulterated (contaminated or otherwise unsafe) medical products and foods, and misbranded medical products and foods sold in, distributed in, or imported into the U.S.
FTC	Federal Trade Commission Act		General jurisdiction over any deceptive or misleading statement in any medium over any drug product in or affecting commerce. As a matter of enforcement policy, and in accordance with the FTC's MOU liaison agreement with FDA, FDA has primary jurisdiction for prescription drug advertising and labeling.	Jurisdiction over deceptive or misleading statements in advertising and promotion. As a matter of enforcement policy, FTC does not take action over statements involving the practice of medicine.		Internet Advertising Program; Internet "Surf Days;" Rapid Response Team; Consumer Information System (online consumer complaints) and Consumer Sentinel, a complaint database; teaser pages; workshops on Internet and e-commerce issues and other consumer and business education	Online Privacy Initiative, including a Congressionally-mandated rulemaking
Postal Service (Postal Inspection Service; OIG)		Enforcement efforts against fraud, e.g., fraudulent billing practices		Enforcement efforts against fraud, e.g., fraudulent billing practices	Enforcement efforts against fraud, e.g., fraudulent billing practices		
States	Individual State's laws	Most states, to varying degrees, have the same or similar enforcement authority as FDA, although some have greater authority, e.g., immediate detention authority, cease and desist authority	Most states, to varying degrees, have the same or similar enforcement authority as FDA, although some have greater authority	Traditionally regulate practice of medicine. Enforcement actions against prescribing without a valid license and prescriber misconduct	Traditionally regulate practice of pharmacy. Enforcement actions against dispensing without a valid license, pharmacist misconduct, and quality standards violations by pharmacies		

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

JUL - 9 1999

The Honorable Thomas J. Bliley
Chairman, Committee on Commerce
House of Representatives
Washington, D.C. 20515-6115

Dear Mr. Chairman:

Thank you for your continued interest in issues relating to the sale of pharmaceutical products over the Internet. This letter is in further response to your letter of June 14, 1999. In a July 1, 1999 letter to you and your co-signers, Dr. Jane E. Henney, Commissioner of Food and Drugs, provided information about the Food and Drug Administration's (FDA or the Agency) activities related to the sale of pharmaceutical products over the Internet, and offered a briefing for your staff.

On July 1, a briefing was provided to Lori Wall and Chris Knauer of the Committee staff. During the briefing, we discussed the specific questions posed in your June 14 letter and we are providing responses to questions 1, 2, 3 and 6 pursuant to that conversation. Responses to the remaining questions will follow under separate cover. We also offered to provide a briefing to you and/or other Members of the Committee at your convenience.

Your question or request is restated, followed by our response.

1. **Please provide all records relating to FDA's regulation of pharmaceutical products sold over the Internet between the dates of May 12, 1999 (our last meeting on this matter), and the present.**

As per our discussion with Ms. Wall and Mr. Knauer, we are enclosing background documents that reflect the Agency's actions during this period. Should additional responsive documents be identified, they will be forwarded to the Committee.

2. Please provide a full description of any role FDA has played in any interagency working group(s) regarding the sale and distribution of prescription drugs on the Internet since the May 12th meeting and the present. Please also provide the names of the members of the interagency working group(s) and their respective titles and telephone numbers.

As Dr. Henney discussed in her letter of July 1, on June 3, FDA, along with other Federal agencies and a representative from the National Association of Attorneys General, participated in a meeting of the legal issues subgroup of the Interagency Internet Sales Working Group. The purpose of the subgroup, convened by the Department of Justice, is for the Federal agencies to discuss legal and regulatory issues pertaining to online drug sales. At the meeting, the agencies reviewed several hypothetical scenarios in an effort to identify unlawful conduct and to determine which Federal and/or State bodies had authority to bring action against the violators.

At the next meeting, currently slated for July, the participants will continue discussing what opportunities might exist for joint enforcement efforts and will address methods for improved monitoring of Internet web sites, possible roles for Internet service providers, data collection, and sales from abroad. This second meeting was to be scheduled six weeks after the first in order to provide time to gather information and arrange speakers for the second meeting.

The following individuals represented FDA at that meeting:

Jeffrey Shuren, Medical Officer, Office of Policy, Planning and Legislation, 301-827-0353

Jane Axelrad, Associate Director for Policy, Center for Drug Evaluation and Research, 301-594-5400

Melissa Moncavage, Public Health Advisor, Center for Drug Evaluation and Research, 301-827-2828

Roma Egli, Consumer Safety Officer, Center for Drug Evaluation and Research, 301-827-7367

Deborah Wolf, Regulatory Counsel, Center for Devices and Radiological Health, 301-594-1148

Susan Corrales, Consumer Safety Officer, Center for Biologics Research and Review, 301-827-6212

Judith Gushee, Consumer Safety Officer, Center for Veterinary Medicine, 301-827-0150

Donald Vasbinder, Consumer Safety Officer, Office of Regulatory Affairs, 301-827-0414

Raymond Mars, Consumer Safety Officer, Office of Regulatory Affairs, 301-827-5636

Marvin Blumberg, Consumer Safety Officer, Office of Regulatory Affairs, 301-443-6553

Kathleen Martin-Weis, Criminal Investigator, Office of Regulatory Affairs, 301-294-4030

Seth Ray, Associate Chief Counsel for Drugs, Office of Chief Counsel, 301-827-1148

Leigh Hayes, Assistant Chief Counsel for Drugs, Office of Chief Counsel, 301-827-1141

3. Please provide a full description of FDA's new internal working group on this matter. Please also provide the names of the members of the internal working group, their position titles, and their respective telephone numbers.

As we discussed with your staff on July 1, FDA has formed an internal Internet working group to examine the role the Agency could and should play in regulating drug sales. This is not a "formal" group, but more of an ad hoc group, intended to provide cross-cutting expertise. The working group will provide recommendations to the Commissioner outlining: 1) enforcement efforts the Agency can undertake with its current resources or could undertake with additional resources, given existing authority, 2) the Agency's enforcement focus, and, 3) whether legislation should be considered so as to more effectively regulate Internet drug sales.

The members of the working group are as follows:

Jeffrey Shuren, Medical Officer, Office of Policy, Planning and Legislation, 301-827-0353

John Taylor, Senior Advisor for Regulatory Policy, Office of Regulatory Affairs, 301-827-3320

Jane Axelrad, Associate Director for Policy, Center for Drug Evaluation and Research, 301-594-5400

Donald Vasbinder, Consumer Safety Officer, Office of Regulatory Affairs, 301-827-0414

Kathleen Martin-Weis, Criminal Investigator, Office of Regulatory Affairs, 301-294-4030

Seth Ray, Associate Chief Counsel for Drugs, Office of the Chief Counsel, 301-827-1148

Phil Broadbent, Legislative Analyst, Office of Policy, Planning and Legislation, 301-443-3793

6. **Since 1983, the FDA, using its "enforcement discretion," has permitted individuals to return to the country with non-FDA approved drugs provided that the individual has procured no more than a three-month supply. This is the so-called "personal use" exemption. Several online pharmacies are reportedly taking advantage of this exemption, advertising that it is "legal" to ship mail-order non-FDA approved pharmaceuticals so long as they are for personal use. Is this sort of activity valid under the FDA's personal use exemption? Has the FDA undertaken any enforcement action against online pharmacies trying to use the "personal use" exemption? If so, please provide all records relating to such action.**

FDA's guidance on "Coverage of Personal Importations," (copy attached) in general provides that Agency personnel may use their discretion to allow entry of shipments of violative FDA-regulated products when the quantity and purpose are clearly for personal use, and the product does not present an unreasonable risk to the user. According to the guidance, FDA personnel are not advised to exercise their discretion when

there is known commercialization or promotion to persons residing in the U.S. by those involved in the distribution of the product at issue. In addition, the guidance makes clear that although FDA may use discretion to allow admission of certain violative products, this should not be interpreted as a license to individuals to bring in such shipments.

Please be assured that we will provide additional information to the Committee as soon as it becomes available. In the interim, should you have further questions, or wish to schedule a Member briefing, please let us know. A similar letter has been sent to your co-signors.

Sincerely,

Melinda K. Plaisier

Melinda K. Plaisier
Interim Associate Commissioner
for Legislative Affairs

Enclosures

Interagency Meeting
Online Sales of Medical Treatments and Products - Enforcement Issues

Meeting Date: April 26, 1999

Time: 9:00 - 4:00

Location: Conference Room, Advisors and Consultants Staff, Center for Drug Evaluation and Research (CDER), Food and Drug Administration (FDA)

Attendees: See list at end

Meeting Facilitator: Melissa Moncavage, CDER, FDA

Presentations

1. *Carmen Catizone, Executive Director/Secretary*
   National Association of Boards of Pharmacy

Issues: We need to identify what additional state and federal regulations we need to regulate online pharmacies. States have no way to control pharmacies and physicians outside US jurisdiction. The Criteria NABP have developed are an interim step to address domestic pharmacies. Federal and state agencies need to cooperate to address online sales issues. State Medical Boards also need to participate in this process and need to dictate that some medical practices are illegal. The board is writing a report that is due in a year.

Draft Criteria: NABP developed draft criteria for online pharmacies titled Verified Internet Pharmacy Practice Sites (VIPPS). The comment period is open to the public for 30 days. The criteria are posted at http://www.nabp.net. NABP will discuss the criteria at the annual meeting in May. An application and inspection process for participation in the program is under development and expected to be ready by the end of 1999.

Research. NABP attempted to survey sites that sell Viagra and Propecia. These sites were difficult to characterize, however, because they changed names and had a system of referrals between sites.

NABP also surveyed 200 online pharmacies:
- 43% are "mom & pop," unlicensed operations
- 41% of those are contracting for pharmacy services
- 8% have separate ownership of site and pharmacy
- 8% are highly capitalized chains.
- Almost all Internet pharmacy sites distribute OTC drugs, Schedule II drugs, herbals, medical information
- 50% dispense devices
- One writes prescriptions

Pharmacies are set up and providing consults and charging consultation fees. Third party payers are being billed for Internet purchases. Medicaid and Medicare are being billed. Consumers who are now more comfortable with Internet pharmacies may be more likely to use off-shore pharmacies also.

Additional concerns include authenticity and confidentiality of Internet prescribing.

2. *Cynthia T. Culmo, Director, Drugs and Medical Devices Division, Texas Department of Health*
   Association of Food and Drug Officials (AFDO)

Background: AFDO consists of state, local, and federal food, drug, cosmetic, device, and consumer product regulatory officials, along with industry associate members. The association's main objective is to promote uniformity of laws affecting consumer commodities and to ensure uniform enforcement of those laws.

Issues: The Internet, with standardized and uniform regulations, could serve as a method to extend healthcare and health education nationally and internationally. However, the federal and state food and drug laws, drug and device laws, and consumer protection laws addressing deceptive advertising law and sales practices were not written to control Internet sales and delivery. Federal and state resources to carry out enforcement actions are limited and interagency cooperation in this regulatory arena is of particular importance. Interagency cooperation already exists in some areas in the form of partnerships, contracts, and memorandums and these should be used as models for future efforts. International standards and regulations should also be addressed in a manner consistent with international harmonization.

Recommendations: AFDO recommends four subgroups be established to address Internet sales issues:

- Cross jurisdictional responsibilities
- Priority
- Federal/state cooperation
- Education

AFDO members have expressed a willingness to participate in working groups. In their view, some of the on-line sales practices present a significant threat to the public health, and they necessitate serious and immediate consideration for close regulatory oversight. AFDO also recognizes that education must be a component of the oversight.

Handout: Written copy of comments

3. *Karen Morrissette, Deputy Chief, Fraud Section, Criminal Division, Department of Justice*

Priorities: Health care fraud is a priority issue for DOJ, including the US Attorneys. Misrepresentations, either explicit or implicit, about a product or about the legal or

regulatory requirements of providers are the basis for civil or criminal fraud. The goal of the parties in these cases is to obtain money from consumers.

Recommendations: On-line sales, fact patterns have to be examined. What licensing or other requirements are applicable? A legislative working group should examine what additional authorities are needed.

The first steps in evaluating on-line sales issues are to educate prosecutors, the field, and ourselves.

4. *Jonathan Rusch, Senior Litigation Counsel, Fraud Section, Criminal Division, Department of Justice*

Complaints: About 1,000 complaints/month are received through the Internet Fraud Watch Data. There are both aggregate data and specific reports on topics such as medical devices and drug products such as Viagra.

Possible Violations of Federal Law:
- General statutes: mail fraud, wire fraud (interstate and international faxes or phone calls, or by using the Internet to transmit), interstate transportation of funds taken by fraud, false claims, civil false claims act, and money laundering
- Specific Statutes: Food Drug and Cosmetic Act and Health Care Fraud Offenses

DOJ Resources:
- US Attorneys
- Criminal Division – Fraud Section and Narcotic and Dangerous Drugs Section
- Civil Division - Office of Consumer Litigation (FDA is involved with these activities) and Civil Fraud Section.

Existing Working Groups: DOJ cooperates with other agencies by participating in the following working groups:
- Telemarketing and Internet Fraud
- Health Care Fraud
- Securities and Commodities Fraud Working Group with and Internet Securities Fraud Subgroup in process

Other Activities: Activities for medical products are similar to other types of products. Specific coordination for strategic and operational activities include:
- Training for prosecutors and agents;
- Interagency coordination on cases and matters including proactive and reactive law enforcement activities and undercover operations;
- Data collection on scope and extent of problem
- Support for analytical and investigative resources
- Advice and support on prosecutions
- Public education and prevention of crime – very important

Internet Fraud Watch: DOJ has a contract with this private organization that receives 1,000 reports/month. The organization tracks consumer fraud. The web site is www.nfic.org.

Handout: Outline of presentation

5. *John Owens, Trial Attorney, Civil Division, Office of Consumer Litigation (OCL), Department of Justice (DOJ)*

Current Activities: DOJ, OCL, enforces criminally and civilly the Food, Drug and Cosmetic Act. The office is now addressing issues related to Internet sale of unapproved drugs. This includes the sale of aloe vera to terminally ill cancer patients and the sale of the party and date rape drug, gamma hydroxy butyrate (GHB), or kits with its components, gamma butyrolactone (GBL), an industrial solvent, and lye. Currently the drug is not a controlled substance under federal law, so DOJ relies for its enforcement efforts on the Food, Drug, and Cosmetic Act. There are several states that have made GHB a Schedule 1 drug and there is a bill proposed in Congress to make it a federal Schedule 1.

Cooperation with Other Agencies: DOJ conducts its enforcement activities with the assistance of the FDA's Office of Criminal Investigations. OCL must make a threshold determination that a product is a drug and relies on the Food, Drug and Cosmetic Act's definition of a drug to establish that basis. In order to charge a felony, DOJ must determine that the drug was misbranded or adulterated according to the Food, Drug and Cosmetic Act, and that the defendant violated the law with "intent to defraud or mislead" either consumers or state or federal governments. DOJ works with state and federal prosecutors to determine at what level and under whose jurisdiction to bring a case.

DOJ has identified areas of potential cooperation with the U.S. Customs Service regulations, the U.S. Postal Service, and the Department of Transportation. There is overlap is cases like the GHB case because Internet shippers do not disclose on Customs Service forms that they are shipping GBL or lye. It is dangerous to ship lye on an airplane because it can cause an explosion and the Federal Hazardous Substances Act is relevant in this context.

Potential Activities: OCL would like to address issues such as the Internet sale of prescription drugs such as Viagra and obesity drugs and the Internet sale from other countries into the U.S. of products not approved in the U.S. Many of the foreign Internet sites acknowledge that the products are not approved by the FDA.

Handouts: "Office of Consumer Litigation Monograph" and presentation outline

6. *Matteo Valles, Supervisory Special Agent, Health Care Fraud Unit*
   Economic Crimes Unit
   Federal Bureau of Investigations (FBI)

FBI has a Healthcare Fraud Unit that looks at fraudulent billing practices and drug diversion. There is also an Economic Crimes Unit that has a joint venture with the

National White Collar Crimes Center. The Center has a national repository for complaints. The Center may look at the Internet and build a record on individuals that have participated in Internet crimes.

7. *Wayne Michaels, Staff Coordinator, International Drug Unit, Drug Enforcement Administration (DEA)*

DEA perceives a growing problem with controlled substances, as well as precursor chemicals, being sold over the Internet.

DEA Working Group: Mr. Michaels now chairs an Internet working group in the Office of Diversion. The group is addressing investigation policy, legal policy, and training. Guidance will include the use of "intellectual software" i.e. Web Crawler, to assist in obtaining and following investigative leads. DEA has invited IBM to meet with DEA to discuss intellectual software.

Distribution System: Legal controlled substances are distributed domestically in a "closed system." This system includes a licensed physician seeing and legitimately prescribing a drug for a patient, the patient then taking the prescription to a pharmacy where it dispensed legitimately. The drugs originate from legal sources, and travel through established channels with documentation at every step.

Foreign Pharmacies: It is illegal for an individual to order a controlled substance from a foreign pharmacy for delivery in the U.S. The International Narcotics Control Board monitors the import/export of controlled substances between countries.

Important Issues to Address: Inter-agency coordination and collective action are important as well as the proper authority to address the issue of the online practice of medicine and online prescribing of potentially dangerous drugs.

Public Information: DEA has a web site with information about drugs that travelers may bring into the country.

8. *Dan Johnson, Program Integrity Assistant, Tricare Management Activity, Department of Defense*

Introduction: Tricare Management Activity, formally known as CHAMPUS, is a healthcare entitlement program offered to the Uniformed Services through the Department of Defense. Tricare's vision statement is to design and build a quality health care system for military families. The website for Tricare's policy manual is http://www.tricare.osd.mil and their mail order pharmacy website is http://www.dscp.dla.mil/medical/pharm/nmop.htm

Fraud Activities: Tricare has an MOU with the Inspector General, DOD Defense Criminal Investigation Service. When investigating and developing fraud cases, Tricare prioritizes the cases based on high dollar fraud cases and patient harm cases. The three most common pharmacy frauds are:

- Generic/brand substitution - the pharmacy bills the healthcare provider for the brand name drug but fills the prescription with the generic drug;

- Prescription splitting - the pharmacy only fills a portion of the prescription and the patient does not pick up the remainder of the prescription, but the pharmacy bills the health care provider for the entire prescription; and
- The pharmacy charges the health care providers for prescriptions that are not picked up by the patient.

Handout: Tricare "Fraud and Abuse Bulletin"

9. Delbert Richburg, Special Agent, US Customs – Cybersmuggling

Congress recently funded Cybersmuggling, a new center to address customs Internet issues. Cybersmuggling develops policy and conducts investigations. Current emphasis is in child pornography and money laundering. Additional investigations address medical products on the Internet, including controlled substances. For example, Cybersmuggling recently seized controlled substances bought and sent into the US from a company with a web site called Vitality Health Products.

Cybersmuggling would like to work with other agencies on cases and to participate in Internet sales task forces.

10. Gerald Vajgert, Postal Inspector, US Postal Inspection Service

The Postal Inspection Service is holding an Internet symposium in late June for fraud inspectors.

Types of Fraud: The most common types of fraud on the Internet are not new:
- Billing fraud
- Prescription fraud
- Medical product fraud

Postal Service and Private Carriers are held to different laws. The postal service must have probable cause to open a suspect package. Private carriers abide by the sealed container laws; which are enacted sate by state.

11. Richard Cleland, Division of Advertising Practices
Federal Trade Commission (FTC)

Jurisdiction: The Federal Trade Communication Act (FTC Act) provides FTC with broad jurisdictional authority over commercial practices, with few exceptions. Section 5 of the FTC Act prohibits unfair and deceptive acts or practices. Sections 12 and 15 prohibit advertising that is false in any material respect.

Under a 1954 FTC/FDA liaison agreement, FDA retains primary responsibility over all medical product and food labeling and prescription drug advertisements. FTC, has primary responsibility over the advertising of foods and all other medical products.

Advertising Principles: The following basic advertising principles apply regardless of the communication medium:

- Tell the truth (do not mislead consumers);
- Tell all the truth (do not omit critical information that consumers need to use or to decide whether to purchase products); and
- Make sure it is the truth (consistent with the advertising substantiation doctrine, there must be a reasonable basis for the claims).

For medical products, generally a reasonable basis for a claim requires competent and reliable scientific evidence such tests, analyses or other evidence accepted by experts in that field. FTC will take into account the standards of other agencies, such as FDA, to determine the appropriate standard for testing and substantiation.

Approach to Internet Fraud: FTC employs aggressive, coordinated law enforcement, public/private partnership, and consumer and business education to combat fraud on the Internet.

Law Enforcement: To date, FTC has filed over 75 actions for violations on the Internet.

Consumer Education: FTC's web site, www.ftc.gov, receives 250,000 hits each month with an average stay time of 4.5 minutes. The agency's www.consumer.gov site provides consumers with links to other sites. FTC also sponsors teaser sites that resemble typical web sites selling a product (e.g., www.ari.net/nordicalite for weight loss and www.ari.net/virilityplus for impotence). If a consumer "purchases" a product from one of the sites, he or she is informed that had the purchase been real, they would have been subject to a scam operation. FTC also provides consumers with two mechanisms to furnish the agency with feedback or complaints, health/claims@ftc.gov and through www.ftc.gov.

Business Education: FTC provides outreach to Internet businesses through the published guidance, *Advertising and Marketing on the Internet: Rules of the Road*, and surf days. The agency has held over two dozen such events since 1997.

Internet Health Claims Surf Days: During its 1998 surf day, FTC and the other participating bodies identified 500 violative web sites. Subsequently, FTC sent e-mails to each of the companies with violative sites. FTC will release the results of its evaluation of the surf day in the near future.

Other Activities: FTC's self-evaluation of its role in regulating on-line prescription and dispensing practices concluded that little opportunity exists for the agency's involvement because it is unclear that there is a deceptive practice. In February 1999, FTC organized a dedicated Internet group to address Internet-related activities. The agency will hold a pubic workshop on May 14 regarding the interpretation of its rules and guides for electronic media. On June 8-9, FTC will hold a second public workshop to address the types of consumer protection necessary for global commerce.

12. Norman Drezin, Deputy Director
Division of Drug Marketing, Advertising, and Communications
Food and Drug Administration

FDA's authority: FDA regulates human and animal drugs, biological products, medical devices, radiological products, and foods. Certain products have unrestricted distribution, such as over-the counter drugs, some devices, and dietary supplements. Other products have restricted distribution, including prescription drugs and biological products, blood products, in-vitro diagnostic test, and some devices. Some products require FDA approval prior to marketing, such as drugs, certain devices, and biological products. To assure the product is used safely and effectively, the product must have adequate directions for use before marketing approval. Additionally, the patient-prescriber relationship and the patient-pharmacist relationship help to ensure patient safety and proper use of the product. However, even with these precautions and gatekeepers, products have to be removed from the market because of danger to pubic health.

Potential for Consumer Harm: If a consumer purchases medical products on the Internet without a gatekeeper, can the consumer use the product safely? There is significant potential for consumer harm for several reasons:

- Self-diagnosis without a medical history or exam;
- Allergic reactions to products
- Drug-drug interactions,
- Drug effect on other medications, and
- Harmful dosing.

Concerns: FDA has the following concerns about Internet promotion and sale:

- Approved products without a valid patient-prescriber relationship, without a valid prescription, and for off-label uses;
- Treatments or cures for serious illnesses or diseases, of unapproved products, and nutritional supplements with medical claims;
- Prescription drugs;
- Biologics;
- Diagnostic test kits for drugs of abuse, HIV, TB, high risk diseases, communicable diseases, and pregnancy;
- Devises such as hearing aids, contact lenses and ultrasound;
- Unapproved drugs and devices for the treatment of various conditions; and
- Nutritional products for medical treatments.

Cases: Recent FDA cases include the Lei-Home Access HIV Test. A California businessman promoted and sold an unapproved HIV home collection system on the Internet and through several pharmacies. He was sentenced to 63 months incarceration.

Possible Working Groups:

- Federal-State issues
- Health fraud
- Import-export issues

- Innovative legal and regulatory strategies
- Consumer education programs.

Handout: Presentation overheads

13. Marvin Blumberg, Special Assistant for Import Regulation Operations and Policy
Division of Import Operations Policy
Food and Drug Administration

Import/Export Concerns: Many products offered for sale on the Internet do not meet US requirements yet may be legal in the country of origin and vice versa. Over 400 Internet sites promote FDA regulated products, including nutritional supplements (properly labeled or with medical claims), unapproved pharmaceuticals and treatments, foreign versions of US approved drugs (chemical versions), health fraud, medical devices and other FDA regulated products. Sales are difficult to monitor and control because they are sold mainly as mail order and are small, non-commercial shipments to individuals. It is difficult to identify specific products on entry. FDA needs to cooperate with Customs, DEA, and USDA.

Internet sales are only part of the import problem. US citizens travel to other countries and bring unapproved products into the country.

Personal Import Policy: Agency has authority to refuse admission of products brought into the US. Under the FDA personal importation policy, however, FDA may exercise enforcement discretion to allow importation. This policy has been in effect since 1954. Recently information about the scope of this policy has been exaggerated. FDA takes into account risks to the consumer and resources when it considers using enforcement discretion. US Customs is responsible for examination of person belongings, baggage, and international mail upon entry.

Discussion

Suggestions for possible groups included the following:
- Federal/State issues
- Overall legal and regulatory issues
- Foreign and domestic issues
- Training at all levels
- Public education and research
- Information sharing
- Approved/unapproved products
- Along product lines

Legal/regulatory could encompass the federal/state and foreign/domestic topic. Breakout groups by product would not be necessary. Public education and information sharing could be separate groups.

Internet prescribing is a difficult topic to address. Agencies have different views about what a valid prescription is and what a valid doctor-patient relationship is. There may be gaps in the legal and regulatory framework.

Organizations not present at the meeting that should be involved in further discussion include the American Medical Association and the American Federation of State Medical Boards.

The group agreed there was a need to have another general meeting to discuss online sales issues.

Decisions Reached

DOJ will facilitate a group to examine legal/regulatory issues. DOJ will also facilitate the next general interagency meeting in September.

Toni Stifano, CBER, FDA, will organize a group to address public education of online sales opportunities for public education.

Melissa Moncavage, CDER, FDA, will provide information about attendees, contacts, and current related working groups to all meeting participants. She will have draft minutes to the participants by the week of May 3. Attendees will send cases to her to compile a list to share with the group.

Online Sales of Medical Treatments and Products – Enforcement Issues 11
Interagency Meeting April 26, 1999

Attendees and Phone Numbers:

Association of Food and Drug Organizations	
Cynthia T. Culmo, R.Ph., Chair, Drugs, Devices, and Cosmetics Committee, Association of Food and Drug Organizations	512-719-0237
Attorneys General	
Douglas Yauger, Director, Bureau of Consumer Protection	717-787-9707
Customs Service	
Delbert Richburg, Special Agent	703-293-8005
Janus Thom, Special Agent	703-293-8005
Defense Criminal Investigation Service	
Jean Doyle, Program Director, Financial Crimes/Health Fraud	703-604-8608
Department of Health and Human Services	
Elise Stein, Program Specialist, Office of Evaluations & Inspections, Office of the Inspector General	202-619-2686
Department of Justice	
Karen A. Morrissette, Deputy Chief, Fraud Section, Criminal Division	202-514-0640
John Owens, Trial Attorney, Office of Consumer Litigation	202-307-1862
Jonathan J. Rusch, Sr. Litigation Counsel, Fraud Section, Criminal Division	202-514-0631
Steve Shandy, Program Analyst, Fraud Section, Criminal Division	202-514-9577
Drug Enforcement Administration	
Denise Curry, Liaison Unit Chief, Liaison and Policy Section	202-307-7292
Wayne Michaels, Staff Coordinator, International Drug Unit	202-307-4264
Federal Bureau of Investigations	
Peggy Campane, Special Agent, Washington Field Office	703-762-3261
Rick D. Germroth, Special Agent, Washington Field Office	703-762-3258
Matteo Valles, Supervisory Special Agent	202-324-5025
Federal Trade Commission	
Karen Bokat, Senior Litigator, Bureau of Competition	202-326-2912

Richard Cleland, Division of Advertising Practices	202-326-3088
Anne Maher, Assistant Director Division of Advertising Practices	202-326-2987
Toby Milgrom Levin, Team Leader Internet Advertising Program	202-326-3156

Food and Drug Administration

Center for Biologics Evaluation and Research

Susan Corrales, Consumer Safety Officer Division of Case Management	301-827-3212
Toni Stifano, Associate Director for Regulatory Policy Office of Compliance & Biologic Quality	301-827-6096

Center for Devices & Radiological Health

Charma Konnor, Director Division of Bioresearch Monitoring	301-594-4717
Andrea Latish, Consumer Safety Officer Division of Enforcement 2	301-594-4611
Byron Tart, Director Promotion and Advertising Policy Staff	301-594-4639
Deborah Wolf, Regulatory Counsel Promotion and Advertising Policy Staff	301-594-4639

Center for Drugs Evaluation and Research

Jane Axelrad, Associate Director for Policy	301-594-5400
Norman Drezin, Deputy Director, Division of Drug Marketing, Advertising, & Communications	301-827-2831
Roma Egli, Division of Non-Traditional Drug Compliance	301-827-7367
John Loh, Team Leader, Compliance Evaluation Branch Division of Prescription Drug Compliance & Surveillance	301-594-0101
Kathy Miracco, Deputy Director Division of Prescription Drug Compliance & Surveillance	301-827-7316
Melissa Moncavage, Public Health Advisor Division of Drug Marketing, Advertising & Communications	301-827-3886
Margaret M. O'Rourke, Senior Regulatory Expert Division of Prescription Drug Compliance & Surveillance	301-827-7296
Bradford W. Williams, Director Division of Labeling & Non-Prescription Drug Compliance	301-827-7364

Center for Food Safety Applied Nutrition

Lynn Larsen, Director, Division of Programs & Enforcement Policy, Office of Special Nutritionals	202-205-4727

Center for Veterinary Medicine

Judy Gushee, Consumer Safety Officer Office of Compliance	301-827-0150
Mukund Parkhie, Veterinary Medical Officer Division of Epidemiology and Surveillance	301-827-0164

Office of the Commissioner	
Philip E. Broadbent, Office of Legislative Affairs	301-827-0103
Jeffrey Shuren, Medical Officer, Office of Policy	301-827-3360
Office of the Chief Council	
Laura Epstein, Attorney	301-827-1173
Leigh Hayes, Attorney	301-827-1981
Doug Snyder, Attorney	301-827-1148
Office of Regulatory Affairs	
Charles Ahn, Consumer Safety Officer Investigator	301-827-5637
Marvin Blumberg, Special Assistant for Import Regulatory Operations and Policy Issues, Division of Import Operations and Policy	301-443-6553
Patrick Durkin, Criminal Investigator Office of Criminal Investigations	301-294-4044
Elizabeth E. Hiner, Division of Federal-State Relations	301-827-2903
Kathleen Martin-Weis, Office of Criminal Investigations	301-294-4043
Joseph L. McCallion, Division of Import Operations & Policy	301-594-1218
Anne Hope Scott, National Health Fraud Coordinator Division of Federal State Relations	301-827-2911
National Association of Boards of Pharmacy	
Carmen Catizone, Executive Director/Secretary	847-698-6227
Postal Inspection Service	
Gerald Vajgert, Postal Inspector	202-268-7730
Carlos Rivera, Special Agent Office of the Inspector General	703-248-2360
Tricare Management Activity, Department of Defense	
Dan Johnson, Program Integrity Assistant	303-676-3551
Marva R. Moss, Health Care Fraud Specialist Program Integrity Branch	303-676-3588

Draft – Internal Circulation Only

OPTIONS FOR FDA INTERNET SALES-RELATED ACTIVITIES

THRESHOLD ISSUES

1. Describe appropriate FDA role regarding online sales

2. Identify FDA's enforcement priorities regarding online sales

   For example:
   1. Unsafe products
   2. Unapproved products
   3. Violative promotion claims
   4. Selling prescription drugs w/o prescription

3. Determine whether FDA will devote more resources to regulating Internet sales-related activities and to enforcement

OPTIONS

Monitoring and Case Identification

Limited Resource Requirements

1. Create a complaint receipt process
2. Investigate newer search technologies and techniques

Additional Resource Requirements

1. Establish a clearinghouse for and database of complaints received, provide personnel for complaint data analysis
2. Implement newer search technologies and techniques
3. Determine the extent of the problem
4. Devote more resources to the investigation of potential cases

FDA Enforcement

Limited Resource Requirements

1. Streamline processes for internal communication and coordination of enforcement and investigative activities, identify most effective enforcement tools for particular types of cases (e.g., civil, criminal, regulatory, publicity)
2. Issue the Internet promotion draft guidance document
3. Streamline processes for communication and coordination with other federal agencies and the States
4. Train appropriate personnel on procedures and priorities for enforcement
5. Work with Customs and Postal Service to explore options for personal entries and mail entries

Additional Resource Requirements

1. Increase enforcement actions
2. Make imported illegal products and illegally imported products an enforcement priority for FDA inspectors

Draft – Internal Circulation Only

Coordinated Federal and State Enforcement

Civil Enforcement and Regulatory Actions
1. Ensure adequate communication, cooperation, and coordination with FTC and the States (NAAG)

Criminal Prosecutions
1. Create interagency working group to develop a federal criminal enforcement strategy or
2. Create joint task forces when appropriate

Online Prescribing

Limited Resource Requirements
1. Discuss possible solutions with the National Association of State Attorneys General, the American Medical Association, and the Federation of State Medical Boards

Online Dispensing (Pharmacies)

Limited Resource Requirements
1. Discuss possible solutions with the National Association of State Attorneys General and the National Association of Boards of Pharmacy

Public Education

Limited Resource Requirements
1. Interagency public education working group to draft action plan

Additional Resource Requirements
1. Implement some or all of the interagency working group's recommendations

Legislation
1. Determine whether new legislation is needed in this area and, if so, communicate this to Congress.

Draft – Internal Circulation Only

OPTIONS FOR FDA INTERNET SALES-RELATED ACTIVITIES

Areas	Limited Resources	Additional Resources	Recommendations for Other Federal Bodies
Monitoring	1. Create complaint receipt process 2. Investigate newer search technologies and techniques	1. Establish a clearinghouse for and database of complaints received 2. Implement newer search technologies and techniques 3. Determine the extent of the problem 4. Devote more resources to the investigation of potential cases	1. Expand FBI's Internet Fraud Complaint Center
FDA Enforcement	1. Streamline internal processes 2. Train personnel 3. Streamline processes for communications and coordination with other federal agencies and the States 4. Issue the Internet promotion draft guidance document 5. Work with Customs and Postal Service	1. Increase enforcement actions 2. Make imports an enforcement priority for FDA inspectors	
Coordinated Federal and States Enforcement	*Civil Enforcement and Regulatory Actions* 1. Ensure adequate communication, cooperation, and coordination with FTC and the States	*Criminal Prosecutions* 1. Create joint task forces where appropriate	*Criminal Prosecutions* 1. Create interagency working group to develop a federal criminal enforcement strategy
Online Prescribing	1. Discuss possible solutions with the National Association of State Attorneys General, the American Medical Association, and the Federation of State Medical Boards		

Draft – Internal Circulation Only

Areas	Limited Resources	Additional Resources	Recommendations for Other Federal Bodies
Online Pharmacies	1. Discuss possible solutions with the National Association of State Attorneys General and the National Association of Boards of Pharmacy		
Public Education	1. Interagency public education working group to draft action plan	1. Implement some or all of the interagency working group's recommendations	1. Federal agencies to implement some or all of the interagency working group's recommendations
Legislation			1. Determine whether new legislation is needed in this area and, if so, communicate this to Congress
Internet Policy			1. Establish an interagency working group to address consumer protection issues for Internet sales

DEPARTMENT OF HEALTH & HUMAN SERVICES

June 14, 1999

Food and Drug Administration
Rockville MD 20857

TO: The Deputy Secretary
Through: COS_____
ES _____

FROM: The Commissioner of Food and Drugs

SUBJECT: Sale of Drugs on the Internet—FOLLOW-UP BRIEFING
Tuesday, June 15, 1999, 4:00 p.m., Deputy Secretary's Conference Room

FDA Attendees: Jane Henney, William Hubbard, Margaret Porter, Melinda Plaisier, Jeffrey Shuren, John Taylor, Jane Axelrad, Melissa Moncavage, Bradford Williams, Seth Ray, Terry Vermillion, Ron Varsaci

PURPOSE

To discuss the course of action FDA should undertake regarding online drug sales.

BACKGROUND

At our May 25 meeting on Internet sales, I raised with you the need for FDA to determine what its role should be regarding online drug sales, as well as the importance of addressing drug sales in the context of a broader Internet policy directed at consumer protection. As part of this process, you asked that FDA develop a matrix outlining the enforcement authority of the various agencies that are involved in the sale of drugs on the Internet.

DISCUSSION

Since that meeting, FDA has drafted the matrix (see attachment) and identified actions it will undertake. These activities include exploring methods to systematically monitor the Internet, prioritizing enforcement cases, continuing to participate in interagency working groups concerning online sales, and engaging industry, health professional boards, the States, and other groups on the problem. FDA also plans to issue the Internet promotion draft guidance and develop 2001 budget requests for additional funding to expand enforcement and public education-related activities.

I look forward to meeting with you to elaborate on FDA's course of action.

Jane E. Henney, M.D.

Attachment

SUMMARY OF ONLINE DRUG SALES MATRIX

Entity	Sales (General)	Promotion	Prescribing	Dispensing	Related Programs
Customs Service	Seize illegal products or illegally imported products at the U.S. border			Same as sales	Cybersmuggling Center
DOD	Limited to providers of care and other services to DOD employees		Same as sales	Same as sales	
DHHS (OIG)	Fraud involving Medicare or other HHS funded care		Same as sales	Same as sales	
DOJ	Fraud and violations of the FFDCA		Fraud	Fraud and dispensing prescription drug w/o prescription	
DEA	Illegal sales, distribution, importation, and exportation of controlled substances		Illegal prescribing of controlled substances without a valid medical reason	Illegal dispensing of controlled substances without a valid medical reason	Internet Working Group
FBI	Fraud		Fraud	Fraud	
FDA	Sale, importation, and distribution of unapproved, adulterated, and/or misbranded products and selling prescription drug w/o prescription	Illegal labeling of products and illegal advertising of prescription drugs	Does not traditionally regulate practice of medicine	Dispensing prescription drug w/o prescription	Internet Working Group
FTC		Deceptive or misleading statements	Deceptive or misleading statements		Rapid Response Team
Postal Service	Fraud		Fraud	Fraud	
States	Similar to FDA	Similar to FDA	Traditionally regulate practice of medicine	Traditionally regulate practice of pharmacy	

INTERNET-RELATED ENFORCEMENT ACTIONS

CDER

FIRM[1]	PRODUCT[2]	CLAIMS[3]	VIOLATIONS[4]	TYPE[5]	RESOURCES[6]	STATUS[7]	FOLLOWUP[8]
Holistic Alternatives; St. Louisville Ohio	Laetrile	Cures Cancer	505(a); 502(a); 502(f)(1) of FD&C Act	Injunct.		Complaint rec'd 9/1/98: Sent to OCC for Filing 9/4/98	

[1]Name of firm subject to enforcement action and its location.

[2]Product or products that were found to be in violation.

[3]Claims made for the product (e.g., cures cancer, lowers cholesterol).

[4]Specific violations of law or regulations found (e.g., 505(a), 502(a)) For a list of types of actions see attached.

[5]Type of enforcement action taken (e.g., injunction (inj); warning letter (wl); criminal prosecution (pros); civil penalty (cp); seizure (seize)). If possible, put like enforcement actions in consecutive rows (e.g., criminal prosecutions, injunctions, warning letters, seizures).

[6]Resources involved in bringing the case by organization (e.g., Phil. Dist; HQ Compliance, OCI, OCC, DOJ) and an estimate of the number of FTE and/or contract dollars used to bring the case. For example, if money was spent establishing or accessing a data base, state how much.

[7]Describe the status of the action. Include date begun, current status (e.g., under investigation by field; in Office of Compliance for review; in OCC for review; at DOJ). If action is completed, list date completed. If we can, we might want to list the common steps and the time it took for each of them.

[8]What further follow-up action needs to be taken (e.g., check site periodically).

OFFICE OF THE COMMISSIONER MEETING
EXECUTIVE SUMMARY

Date: June 11, 1999
Time: 11:30 - 12:30 p.m.
Location: Rm. 14-68, PKLN

Subject: Online Sales of FDA-Regulated Products

Attendees: Jane Henney, Michael Friedman, Bonnie Malkin, Sharon Smith Holston, Bill Hubbard, Jeff Shuren, Jane Axelrad, Melissa Moncavage, Brad Williams, Byron Tart, Jerome Donlon, Margaret Porter, Kathy Martin-Weis, Seth Ray, Melinda Plaisier, and Ron Varsaci

Meeting Purpose: To brief the Commissioner and discuss options the Agency could take pertaining to online drug sales in preparation for the June 15 briefing for the Deputy Secretary.

Background: The Deputy Secretary has asked FDA to present him with an outline of a recommended course of action the Agency could take regarding online sales and a timeline for its completion. This briefing will be used to update the Commissioner on what has taken place since the May 25 meeting with the Deputy Secretary and to discuss possible actions the Agency could undertake in the area of sales of FDA-regulated products on the Internet.

Attachments:

Tab A – Options for FDA Internet Sales-Related Activities
Tab B – Summary of Online Drug Sales Matrix
Tab C – Internet-Related Enforcement Actions

Executive Secretariat Contact: Ron Varsaci, 827-4446

SUMMARY OF ONLINE DRUG SALES MATRIX

Entity	Sales (General)	Promotion	Prescribing	Dispensing	Related Programs
Customs Service	Seize illegal products or illegally imported products at the U.S. border			Same as sales	Cybersmuggling Center
DOD	Limited to providers of care and other services to DOD employees		Same as sales	Same as sales	
DHHS (OIG)	Fraud involving Medicare or other HHS funded care		Same as sales	Same as sales	
DOJ	Fraud and violations of the FFDCA		Fraud	Fraud and dispensing prescription drug w/o prescription	
DEA	Illegal sales, distribution, importation, and exportation of controlled substances		Illegal prescribing of controlled substances without a valid medical reason	Illegal dispensing of controlled substances without a valid medical reason	Internet Working Group
FBI	Fraud		Fraud	Fraud	
FDA	Sale, importation, and distribution of unapproved, adulterated, and/or misbranded products and selling prescription drug w/o prescription	Illegal labeling of products and illegal advertising of prescription drugs	Does not traditionally regulate practice of medicine	Dispensing prescription drug w/o prescription	Internet Working Group
FTC		Deceptive or misleading statements	Deceptive or misleading statements		Rapid Response Team
Postal Service	Fraud		Fraud	Fraud	
States	Similar to FDA	Similar to FDA	Traditionally regulate practice of medicine	Traditionally regulate practice of pharmacy	

Sale of Drugs on the Internet

The following chart artificially divides online drug sales into individual events in an effort to conceptually organize online drug sale-related activities. In practice, however, many civil and criminal investigations of schemes to violate federal laws do not classify violations according to the categories of this matrix. Instead, such investigations scrutinize the entire scheme and the actions and mental state of its participants in order to ascertain which federal laws were violated and whether a prosecution is viable. From the enforcement standpoint, the important issue is whether there are adequate remedies and jurisdiction to comprehensively and effectively address a public health and crime problem. In addition, multiple agencies may jointly engage in both investigative and enforcement efforts.

This chart is not intended to be comprehensive or complete nor does it express the official views of the listed agencies. Categories left blank for a particular agency do not necessarily indicate that that agency does not have authority or has not established a program pertaining to a certain Internet activity.

Entity	Statutes	Responsibility Over Sales (General)	Responsibility Over Promotion	Responsibility Over Prescribing	Responsibility Over Dispensing Practices	Internet-Related Programs	Other Internet-Related Activities
Customs Service	Title 19 USC 1497 (Failure to Declare); Title 19 USC 1595A(C) (gives Customs authority to enforce the laws and regulations of other government regulatory agencies); 19 USC 545 (General Smuggling)	Seize illegal products or illegally imported products at the U.S. Border and interior ports of entry (i.e., airports, commercial facilities, mail facilities); products will be seized if illegal in nature or illegally dispensed/imported via U.S. borders	None	None	Same as Responsibility Over Sales	The Customs Cybersmuggling Center (C3), whose mission is to bring together U.S. Customs Service resources in support of the Service's investigative, intelligence, computer forensic and interdiction programs to identify those persons, organizations and related businesses involved in cybersmuggling activities, as well as their methods and means of operation	C3 is also responsible for the investigation of violations related to international child pornography, child exploitation and child sex tourism; drug trafficking; the violation of Intellectual Property Rights statutes; the trafficking of weapons of mass destruction, their delivery systems and spare parts; and, international money laundering
DOD (TRICARE, Defense Criminal Investigative Services)	Chapter 55, Title 10 USC.; 32 CFR 199; Health Insurance Portability and Accountability Act; False Claims Act	Investigative action with referrals to DCIS/FBI for enforcement of civil and criminal penalties	Financial inducement to use "specific medication" will result in investigative action	Physicians must prescribe only medications that are approved by the FDA for human consumption and meet all state and federal regulations for prescribing medications	Pharmacists and pharmacies must meet state and federal regulations that pertain to them	None	None

Entity	Statutes	Responsibility Over Sales (General)	Responsibility Over Promotion	Responsibility Over Prescribing	Responsibility Over Dispensing Practices	Internet-Related Programs	Other Internet-Related Activities
DHHS (OIG)	Mail Fraud; Wire Fraud; False Claims; Civil False Claims; kickbacks, money laundering, health care fraud offenses; Civil Monetary Penalties Act, when the conduct involves Medicare, Medicaid or other HHS funded health care	Enforcement actions against fraud when the conduct involves Medicare, Medicaid or other HHS funded health care		Enforcement actions against fraud when the conduct involves Medicare, Medicaid or other HHS funded health care	Enforcement actions against fraud when the conduct involves Medicare, Medicaid or other HHS funded health care		
DOJ (Fraud Section, Criminal Division; Office of Consumer Litigation; U.S. Attorneys Offices)	Mail Fraud; Wire Fraud; Interstate Transportation of Funds Taken by Fraud; False Claims; Civil False Claims; Money Laundering; Health Care Fraud Offenses; Food Drug & Cosmetic Act	Bring criminal or civil charges for fraud (e.g., misrepresentations about a product or about the legal or regulatory requirements of providers) and violations of the Food Drug & Cosmetic Act		Bring criminal or civil charges for fraud, e.g., fraudulent prescribing and billing practices	Bring criminal or civil charges for fraud, e.g., fraudulent billing practices		
DEA	Controlled Substances Act	Enforcement actions (civil and criminal) against illegal sales, distribution, importation, exportation of controlled substances		Enforcement actions (civil and criminal) against illegal prescribing of controlled substances without a valid medical reason	Enforcement actions (civil and criminal) against illegal dispensing of controlled substances without a valid medical reason	Internet Working Group	
FBI		Enforcement actions (civil and criminal) against fraud (e.g., misrepresentations about a product or about the legal or regulatory requirements of providers)		Enforcement actions (civil and criminal) against fraud, e.g., fraudulent prescribing and billing practices	Enforcement actions (civil and criminal) against fraud, e.g., fraudulent billing practices	Internet Fraud Complaint Center	

Entity	Statutes	Responsibility Over Sales (General)	Responsibility Over Promotion	Responsibility Over Prescribing	Responsibility Over Dispensing Practices	Internet-Related Programs	Other Internet-Related Activities
FDA (CDER, CDRH, CBER, CVM, CFSAN, ORA)	Food Drug & Cosmetic Act	Enforcement actions (civil and criminal) and import alerts against unapproved drugs, adulterated (contaminated or otherwise unsafe) drugs, and misbranded drugs (e.g., misleading promotion, dispensing without a valid prescription) sold in, distributed in, or imported into the U.S.; enforcement actions (civil or criminal) against the reimportation, other than by the manufacturer, of American Goods Returned; enforcement actions (civil or criminal) against the sale, purchase, or trade or the offer to sell, purchase, or trade a prescription drug sample, a prescription drug purchased by a health care entity or a coupon for a prescription drug	Enforcement actions (civil and criminal) against illegal labeling of all drugs (and all other medical products and foods) and illegal advertising of prescription drugs (and restricted medical devices)	FDA does not traditionally regulate the practice of medicine	Enforcement actions (civil and criminal) against dispensing without a valid prescription (interpreted as dispensing without any prescription)	Internet Working Group; participate in FTC Internet "Surf Days"	Enforcement actions (civil and criminal) and import alerts against unapproved medical products, adulterated (contaminated or otherwise unsafe) medical products and foods, and misbranded medical products and foods sold in, distributed in, or imported into the U.S.
FTC	Federal Trade Commission Act		General jurisdiction over any deceptive or misleading statement in any medium over any drug product in or affecting commerce. As a matter of enforcement policy, and in accordance with the FTC's MOU liaison agreement with FDA, FDA has primary jurisdiction for prescription drug advertising and labeling.	Jurisdiction over deceptive or misleading statements in advertising and promotion. As a matter of enforcement policy, FTC does not take action over statements involving the practice of medicine.		Internet Advertising Program; Internet "Surf Days," Rapid Response Team; Consumer Information System (online consumer complaints) and Consumer Sentinel, a complaint database; teaser pages; workshops on Internet and e-commerce issues and other consumer and business education	Online Privacy Initiative, including a Congressionally-mandated rulemaking
Postal Service (Postal Inspection Service; OIG)		Enforcement efforts against fraud, e.g., fraudulent billing practices		Enforcement efforts against fraud, e.g., fraudulent billing practices	Enforcement efforts against fraud, e.g., fraudulent billing practices		

Entity	Statutes	Responsibility Over Sales (General)	Responsibility Over Promotion	Responsibility Over Prescribing	Responsibility Over Dispensing Practices	Internet-Related Programs	Other Internet-Related Activities
States	Individual State's laws	Most states, to varying degrees, have the same or similar enforcement authority as FDA, although some have greater authority, e.g., immediate detention authority, cease and desist authority	Most states, to varying degrees, have the same or similar enforcement authority as FDA, although some have greater authority	Traditionally regulate practice of medicine. Enforcement actions against prescribing without a valid license and prescriber misconduct	Traditionally regulate practice of pharmacy. Enforcement actions against dispensing without a valid license, pharmacist misconduct, and quality standards violations by pharmacies		

Report Date: 06/10/99

Internet Statistics

Total Cases: 57 (including 3 Information Cases)
54 (includes Criminal & Preliminary Cases, excluding Information Cases)

Total Open Criminal Cases: 39
Open Criminal Cases: 37
Open "P" Cases: 2

Total Closed Criminal Cases: 15
Closed Criminal Cases: 9
Closed "P" Cases: 6

Total Open & Closed "P" Cases: 9

Total Arrests: 17
(13 Arrest in Cases presently open)
(4 Arrest in closed cases)

Total Convictions: 9
(6 Convictions in Cases presently open)
(3 Convictions in Cases closed)

Open & Closed Criminal Cases to include Open & Closed "P" broken down by Center

Open Criminal Cases

CDER – 29
CBER – 4
CFSAN – 1
CDRH – 3
CVM – 0

Open "P" Cases

CDER – 2
CBER – 0
CFSAN – 0
CDRH – 1

Closed Criminal Cases

CDER – 7
CBER – 0
CFSAN – 2
CDRH – 0
CVM – 0

CLOSED "P" CASES

CDER – 4
CBER – 0
CFSAN – 2
CDRH - 0

OFFICE OF CRIMINAL INVESTIGATIONS

Active Investigations Involving the Internet

- **Number: 39 Active Investigations**

  Breakdown by number of active investigations under general product type

  Unapproved drug: 25
  Misbranded drug: 6
  Adulterated drug: 1
  Unapproved device: 2
  HIV test kits: 5

- **Anticipated charges:**

  Breakdown by type of violation and number of investigations likely to charge the stated violation

  21 USC 331 – FD&C Act – Prohibited Act: 27
  21 USC 351 – Adulterated drugs: 1
  21 USC 352 – Misbranding: 6
  21 USC 353 – Exemption for drugs, devices, biological products: 1
  21 USC 355 – New Drugs: 3
  18 USC 545 – Smuggling: 5
  18 USC 873 – Blackmail: 1
  18 USC 1001 – False statements: 1
  18 USC 1341 and 1343 – Mail and wire fraud: 17

- **Origin of investigation:**

  Breakdown by source of preliminary information

  Other federal agency: 12
  FDA DO: 10
  Local law enforcement: 8
  OCI: 6
  Foreign law enforcement: 2
  Private individual: 1

Q & A's: Internet Sales of Drugs

Are there any advantages to buying prescription drugs online?

Online purchases offer consumers the opportunity for lower costs and convenience, if the purchase is made from a reputable site.

Are there any disadvantages to buying prescription drugs online?

The downside of buying prescription drugs online is that the consumer can be far less certain about what they are purchasing. Particularly if purchasing from an overseas site, the buyer may not be getting a legitimate, FDA-approved drug. The FDA urges consumers to check with their personal health care providers before purchasing medications from Internet sites.

What agency or department, either state or federal, is the primary regulator of Internet pharmacies?

While no agency is the "primary regulator" of Internet pharmacies, the States have traditionally regulated the dispensing and prescribing of drugs. Pharmacies and pharmacists must be licensed by the States where they dispense drugs. Physicians and other prescribers must be licensed in the State where they practice, and, in some jurisdictions, in the State where their patient is located, as well. Moreover, the States review pharmacy records for accuracy and pharmacy sites for sanitary conditions. In general, FDA regulates drug products and certain promotional activities pertaining to drugs. Other Federal agencies have authority over certain aspects of drug sales, distribution or promotion.

Does online dispensing change the role of pharmacists?

The pharmacist plays an important role in health care, and is often the best-informed professional for the consumer to consult with regarding drug actions and interactions. One drawback to online pharmacies is the absence of the face-to-face contact between pharmacist and consumer that helps ensure that the consumer is properly using these medications.

How do Internet pharmacies deal with issues such as medical records and privacy?

The States generally regulate issues pertaining to medical records and privacy protection.

How do online pharmacies prevent unqualified persons from receiving prescriptions?

Various on-line pharmacies have different policies and procedures relating to this issue. Clearly, many on-line pharmacies do require valid prescriptions, but FDA is very concerned that some pharmacies do not. Consumers should not purchase prescription drugs without first getting a prescription from their health care provider.

Should consumers obtain prescriptions over the Internet?

Unlike the traditional relationship between a patient and their health care provider, online prescribers give the consumer prescriptions in the absence of a physical examination or a medical history tailor-made to the consumer's health needs. By sidestepping these traditional safeguards, consumers are at greater risk for suffering life-threatening adverse events. These risks include side effects from inappropriately prescribed medications, dangerous drug interactions, and the possible ill effects of impure or unknown ingredients found in unapproved drugs. In addition, consumers run the risk that the online prescriber is not a health care provider licensed to prescribe medications. FDA encourages consumers to only obtain prescriptions from their personal health care provider.

Are there certain drugs that should not be ordered from online pharmacies?

Consumers should never order a drug not approved by the FDA. If you aren't sure, ask your local pharmacist, your personal health care provider, your State board of pharmacy, or the FDA. Consumers should also consult with their personal health care provider before ordering prescription medications from Internet sites.

Should consumers buy medications from pharmacies located in foreign countries?

Some of the medications sold on the Internet may be legal in foreign countries but not approved for use in the United States. These products may include addictive and dangerous substances. The system in this country assures that drugs are safe and effective through testing by drug companies and review of that testing by FDA scientists. Products not approved for sale in the United States generally do not conform to good manufacturing practices and quality assurance procedures required by U.S. laws and regulations.

Isn't it legal to buy drugs from overseas for personal use?

It is illegal to bring unapproved drugs into the United States. Under certain circumstances, however, FDA has exercised its enforcement discretion to permit individuals who travel to foreign countries to bring back small quantities of an unapproved drug for their personal use. This policy does not apply to FDA-approved drugs or to unapproved drugs promoted over the Internet or by other means to U.S. residents.

What can consumers do to protect themselves?

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. Check with your 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.

DDMAC Resources for Internet Activities

Current DDMAC Activities

Monitoring

- Companies submit web sites under FDA 2253 as required for promotional labeling and advertisements under 314.81(b). Reviewers review submissions as part of their routine activities

Surveillance

- DDMAC spends .2 FTE to conduct surveillance on web sites that post company press releases.
- DDMAC spends .1 FTE on other web surveillance of pharmaceutical company sites and online sales sites.
- DDMAC staff currently conducts surveillance from PCs through CDER and cannot hide their identity.

Complaints

- DDMAC does not track Internet complaints about pharmaceutical company web sites separately from all complaints received about pharmaceutical company promotion.
- DDMAC receives 5-10 complaints a week regarding online sales site or unsolicited e-mail to individuals advertising prescription drug sales directly to individuals. The complaints are received by phone, through MedWatch, and by e-mail to DDMAC.

Review/Analysis

- Submissions under FDA 2253s and press releases identified under surveillance are analyzed to determine if the press release meets requirements under 21 CFR 201 & 202 or 312.7.
- Complaints on promotion are analyzed to determine if valid and need follow-up action. Complaints about online sales are reviewed for general information and referred to the Office of Compliance if they have not already received the complaint and if the complaint is not about prescription drug promotion.

Case Development

- DDMAC has developed cases and issued letters to pharmaceutical companies for violative web sites.
- DDMAC has not analyzed online sales sites to develop cases.

Enforcement Actions

- DDMAC sent 19 violation letters in 3 years to pharmaceutical companies regarding violative promotion on web sites. Generally in 1 year, DDMAC sends 150-185 violation letters to pharmaceutical companies regarding promotion.
- Untitled letters take 50 hours of staff time from the time a violation is identified to the time close-out letter is sent to indicate all issues are resolved.
- Warning letters take 150 hours of staff time.

Prescription Drug Labeling and Advertisements

Statute - Under the Federal Food Drug and Cosmetic Act	Regulations	Responsibility	Issues and Comments
201(m) - labeling is defined as ". . . all labels and all other written, printed, or graphic material (1 upon any article, . . . or (2) accompanying such article. **502(a)** – "A drug . . . shall be deemed to be misbranded – (a) If its labeling is false or misleading in any particular."	**21 CFR 201** – Labeling Requirements for labeling, including adequate direction for use. **21 CFR 202.1(l)(2)** –"Brochures, booklets, mailing pieces, detailing pieces, file cards, bulletins, calendars, price lists, . . . containing drug information supplied by the manufacturer, packer, or distributor of the drug and which are disseminated by or on behalf of its manufacturer, packer, or distributor are . . . labeling."	The Division of Drug Marketing, Advertising, and Communications (DDMAC) monitors and conducts surveillance of prescription drug labeling and takes enforcement actions, generally untitled or Warning letters to companies. Companies are required to submit labeling to the agency at the time of dissemination.	Does FDA consider online pharmacists to be distributors of prescription drugs? If so, FDA could take enforcement action when distributors' web sites contain violative labeling or advertisements. An online pharmacy's promotion may be the least of its FD&C violations, however. Would it be worthwhile to take actions against promotion when other violations are much more serious? To date, DDMAC has not sent untitled or Warning Letters to online pharmacies.

502(n) – A Rx drug is mis-branded unless its advertisement contains a true statement including the established name, the formula, and information in brief summary relating to side effects, contraindications, and effectiveness.	**21 CFR 202.1** – Prescription Drug Advertisements Requirements for prescription drug advertisements including the brief summary. Sections 202.1(6)&(7) give details on how an advertisement is or may be false, lacking in fair balance, or misleading. **21 CFR 202.1(l)(1)** – Advertisements subject to section 502(n) include those in published journals, magazines, other periodicals, and newspapers,, and broadcast through media such as radio, television, and telephone.	DDMAC monitors, and conducts surveillance of prescription drug advertisements and takes enforcement action. Companies are required to submit advertisements to the agency at the time of publication.	

FOOD AND DRUG ADMINISTRATION

The Federal Food, Drug, and Cosmetic Act (FFDCA or the Act) prohibits certain acts with respect to foods, drugs, devices, and biological products that are regulated by FDA. These prohibited acts are listed in section 301 of the Act (21 U.S.C. 331). For example, under section 301(a) of the Act (21 U.S.C. 331(a)), introduction or delivery for introduction into interstate commerce (which includes importation) of any food, drug, or device that is adulterated or misbranded is prohibited. Section 301(b) prohibits the adulteration or misbranding of any food, drug, or device in interstate commerce. Such prohibited acts may be enjoined under section 302 of the Act (21 U.S.C. 332) and criminally prosecuted under section 303 of the Act (21 U.S.C. 333). A food or drug that is adulterated or misbranded when introduced into or while in interstate commerce or while held for sale (whether or not the first sale) after shipment in interstate commerce may be seized and condemned under section 304 of the Act (21 U.S.C. 334).

Sales of medical products and food products over the Internet may be regulated to the extent the products at issue are adulterated or misbranded under these provisions, or, in the case of human drugs and devices, the products are not approved by FDA. There may also be instances in which the information on the Internet about a product is evidence that the product is misbranded, adulterated, or unapproved, e.g., it may be labeling for the product. In the case of drugs and devices, information on the Internet about a product may be evidence of its intended use.

Human and Animal Drugs

In general, in the case of human drugs, the sections of the FFDCA that are relevant to the issues related to online sales and promotion involve (1) the requirement that (a) a prescription drug be approved by FDA and (b) an over-the-counter (OTC) drug be switched from prescription to OTC status through approval of a supplement to the original new drug application or be subject to an FDA monograph for a particular intended use before its sponsor may market it and (2) the requirement that (a) a prescription or OTC drug's labeling and advertising be consistent with the approved intended use language and (b) that its labeling and advertising, if a prescription drug, or its labeling, if an OTC drug, be consistent with other safety and effectiveness data established through the agency's review process. (Labeling is defined in section 201(m) of the Act (21 U.S.C. 321(m)); section 201(n) of the Act (21 U.S.C. 321(n)) directs how to determine whether labeling or advertising is misleading).

A human or animal drug marketed contrary to the statutory or regulatory requirements regarding approval is deemed to be misbranded and/or adulterated. In addition, a drug whose labeling provides evidence of an intended use not approved by FDA is an unapproved new (human) drug under 505(a) and 201(p) of the Act (21 U.S.C. 355(a) and 321(p)) or an unapproved new animal drug under 501(a)(5) and 201(v) of the Act (21 U.S.C. 351(a)(5) and 321(v)).

Drugs are adulterated under the provisions in section 501 of the FFDCA (21 U.S.C. 351) and regulations that FDA has promulgated thereunder, and they are misbranded under the provisions in section 502 of the FFDCA (21 U.S.C. 352) and the regulations thereunder. For example, a drug is adulterated under sections 501(a)(1) or (a)(2)(A) of the Act (21 U.S.C. 351(a)(1) or (a)(2)(A)) if it is contaminated, or, under sections 501(b) or (c) (21 U.S.C. 351(b) or (c)) if it is past its expiration date, or under section 501(a)(5) (21 U.S.C. 351(a)(5)) if it is an unapproved new animal drug. Under sections 502(a) and (f)(1) (21 U.S.C. 352(a) and (f)(1)), a drug is misbranded if its labeling describes an unapproved use or is false or misleading in any particular or, in the case of a prescription drug, under sections 502(a) and (n) (21 U.S.C. 352(a) and (n)), if its advertising describes an unapproved use or is false or misleading in any particular. An approved prescription drug is also misbranded if it is sold without a valid prescription, under 503(b)(1) (21 U.S.C. 353(b)(1)), which FDA has interpreted to mean sold without any prescription.

Medical Devices

In general, the sections of the FFDCA that are relevant to the issues related to online sales and promotion involve the requirements that a device be granted marketing approval or clearance by the agency for a particular intended use before its sponsor may market it and that its labeling and advertising be consistent with the approved intended use language and other safety and effectiveness data established through the agency's review process. A device marketed contrary to the statutory or regulatory requirements regarding approval or clearance is deemed to be misbranded and/or adulterated.

Devices are adulterated under the provisions in section 501 of the FFDCA (21 U.S.C. 351) and regulations that FDA has promulgated thereunder, and they are misbranded under the provisions in section 502 of the FFDCA (21 U.S.C. 352) and the regulations thereunder. For example, a device is adulterated under section 501(f)(1)(B) of the Act (21 U.S.C. 351(f)(1)(B)) if it is classified as a class III device and it has not been approved by premarket approval, as required by section 515(a) of the Act (21 U.S.C. 360e(a)), or exempt from this requirement under section 520(g) (21 U.S.C. 360j(g)). (Section 513(f) of the Act [21 U.S.C. 360c(f)] provides that any device intended for human use which was not marketed prior to May 28, 1976 is classified into class III unless the agency reclassifies the device into class I or II. Section 520(g) provides an exemption from certain sections of the FFDCA for a device that is being used in clinical investigations designed to determine the safety and effectiveness of the device undergoing investigation.) Under section 501(h) of the Act (21 U.S.C. 351(h)), a device is adulterated if it does not conform to good manufacturing practices specified by regulation. A device is misbranded under section 502(a) (21 U.S.C. 352(a)) if its labeling is false or misleading in any particular, e.g., if it fails to reveal material facts. 21 CFR 801.109 provides that prescription device labeling include certain intended use and risk information, including relevant hazards, contraindications, side effects, and precautions under which the device can be safely used. Under sections 502(q) and (r) (21 U.S.C. 352(q) and (r)) a restricted device is also misbranded if its advertising is false or misleading in any particular or if it is sold, distributed or used in violation of regulations

prescribed under 520(e) (e.g., sold or distributed without a prescription) or if its advertising does not contain certain required intended use and risk information.

Biological Products

All biological products are also regulated as either drugs or devices. Therefore, the sections of the FFDCA and its implementing regulations pertaining to drugs or devices also apply to biological products.

Foods

Foods are adulterated under the provisions in section 402 of the FFDCA (21 U.S.C. 342) and regulations that FDA has promulgated thereunder, and they are misbranded under the provisions in section 403 of the FFDCA (21 U.S.C. 343) and the regulations thereunder. For example, a food is adulterated under section 402(a)(2)(C)(i) of the Act (21 U.S.C. 342(a)(2)(C)(i)) if it is or if it bears or contains any food additive that is unsafe within the meaning of section 409 of the act (21 U.S.C. 348) (food additives are defined in section 201(s) of the act (21 U.S.C. 321(s)). A food is misbranded under section 403(a)(1) of the Act (21 U.S.C. 343(a)(1)) if its labeling is false and misleading in any particular. A food is also misbranded under section 403(q) of the Act (21 U.S.C. 343(q)) if its label or labeling does not bear nutrition labeling as required under FDA regulations (e.g., 21 CFR 101.9), and a food is misbranded under section 403(r) of the Act (21 U.S.C. 343(r)) if, for example, its label or labeling bears a health claim that is not authorized under that section by, for example, regulation (e.g., 21 CFR 101.72-101.81).

Imported Products

All imported products are required to meet the same standards as domestic goods. Imported foods must be pure, wholesome, safe to eat, and produced under sanitary conditions; drugs and devices must be safe and effective; radiation-emitting devices must meet established standard; and all products must contain informative and truthful labeling in English.

Section 801(a) of the FFDCA (21 U.S.C. 381(a)) directs FDA to refuse admission of any article that appears to be in violation. The Act states: "If it appears from examination or otherwise that (1) such article has been manufactured, processed, or packed under insanitary conditions or, in the case of a device, the methods used in, or the facilities or controls used for, the manufacture, packing, storage, or installation of the device do not conform to the requirements of section 520(f), or (2) such article is forbidden or restricted in sale in the country in which it was produced or from which it was exported, or (3) such article is adulterated, misbranded, or in violation of section 505, then such article shall be refused admission."

The FFDCA (21 U.S.C. sections 331(d) and 355(a)) prohibits the importation of unapproved new drugs. Unapproved new drugs are any drugs, including foreign-made versions of U.S. approved drugs, that have not received FDA approval to demonstrate they meet the federal requirements for safety and effectiveness. It is the importer's obligation to demonstrate to FDA that any drugs offered for importation have been approved by FDA.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

JUL 30 1999

The Honorable Thomas J. Bliley
Chairman, Committee on Commerce
House of Representatives
Washington, D.C. 20515-6115

Dear Mr. Chairman:

Thank you for your continued interest in issues relating to the sale of pharmaceutical products over the Internet. This letter completes the response of the Food and Drug Administration (FDA or the Agency) to your letter of June 14, 1999.

As we stated in our previous response of July 9, 1999, a briefing was provided to Lori Wall and Chris Knauer of the Commerce Committee staff on July 1, 1999. During the briefing, we discussed the specific questions posed in your June 14 letter. This letter provides responses to questions 4 and 5. FDA provided responses to questions 1, 2, 3 and 6 in our July 9 letter.

Your question or request is restated, followed by our response.

(4) As part of this response please provide to the Committee the following information regarding the enclosed copies of Internet sites that appear to be selling pharmaceuticals over the Internet:

(a) The physical location of the site, and in what States it sells its products;
(b) A brief description of the pharmaceutical products sold through the site;
(c) The source of all such pharmaceutical products sold through the site;
(d) Whether the site is licensed in the U.S., and if so by what state(s). If not licensed in the U.S., please determine whether the site is licensed by a foreign regulatory authority, or if at all;
(e) Whether the FDA has ever reviewed the sites for any advertising or usage claims made regarding any pharmaceutical product sold;
(f) The accuracy of any such claims made by the site that fall under FDA's jurisdiction.

As per our discussion with Ms. Wall and Mr. Knauer, FDA does not have information on most of the Internet sites provided in your letter. In our discussion, we explained that an attempt to provide all of the information your letter requested would require not only a review of the electronic information on the web sites themselves, but physical investigations of the premises where products are dispensed, including exhaustive records searches. This is particularly true for the source of the product. Given the Agency's current resources and capabilities, this type of full examination of these sites would be a prohibitively time consuming exercise, which would not be the best use of our limited investigative resources.

As agreed to in our discussion with Ms. Wall and Mr. Knauer, various FDA offices checked the web site information enclosed in your letter against existing records to determine if any regulatory or enforcement actions had been taken against any of these sites as are depicted in the enclosures. FDA's Office of Criminal Investigations (OCI) did find one of the sites in their records. An OCI investigator attempted to purchase drugs from the site as part of an investigation of sites that appeared to be selling prescription drugs without a prescription. The site in question did not make such a sale to OCI's investigator, and no further action was taken.

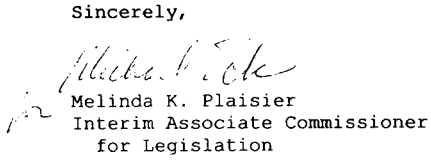
It should be noted that in the past, OCI may have examined other sites you provided. Records have not been kept, however, of these basic site examinations if they revealed no apparent violations.

(5) Finally, if you believe that any single State has already reviewed these numerous Internet sites for the above content, please list the State, and the name of the regulatory authority that conducted the review.

We are aware of only one action by a State regulatory agency regarding any of the sites enclosed with your letter. In is our understanding that the State of Missouri recently obtained a temporary restraining order against the company Pillbox.com.

We hope this information will be useful to you as the Committee explores the various issues presented by drug sales over the Internet. Should you have further questions please let us know. A similar letter has been sent to your co-signers.

Sincerely,



Melinda K. Plaisier
Interim Associate Commissioner
for Legislation

ONE HUNDRED SIXTH CONGRESS

TOM BLILEY, VIRGINIA, CHAIRMAN

W.J. "BILLY" TAUZIN, LOUISIANA
MICHAEL G. OXLEY, OHIO
MICHAEL BILIRAKIS, FLORIDA
JOE BARTON, TEXAS
FRED UPTON, MICHIGAN
CLIFF STEARNS, FLORIDA
PAUL E. GILLMOR, OHIO
JAMES C. GREENWOOD, PENNSYLVANIA
CHRISTOPHER COX, CALIFORNIA
NATHAN DEAL, GEORGIA
STEVE LARGENT, OKLAHOMA
RICHARD BURR, NORTH CAROLINA
BRIAN P. BILBRAY, CALIFORNIA
ED WHITFIELD, KENTUCKY
GREG GANSKE, IOWA
CHARLIE NORWOOD, GEORGIA
TOM A. COBURN, OKLAHOMA
RICK LAZIO, NEW YORK
BARBARA CUBIN, WYOMING
JAMES E. ROGAN, CALIFORNIA
JOHN SHIMKUS, ILLINOIS
HEATHER WILSON, NEW MEXICO
JOHN B. SHADEGG, ARIZONA
CHARLES W. "CHIP" PICKERING, MISSISSIPPI
VITO FOSSELLA, NEW YORK
ROY BLUNT, MISSOURI
ED BRYANT, TENNESSEE
ROBERT L. EHRLICH, JR., MARYLAND

JOHN D. DINGELL, MICHIGAN
HENRY A. WAXMAN, CALIFORNIA
EDWARD J. MARKEY, MASSACHUSETTS
RALPH M. HALL, TEXAS
RICK BOUCHER, VIRGINIA
EDOLPHUS TOWNS, NEW YORK
FRANK PALLONE, JR., NEW JERSEY
SHERROD BROWN, OHIO
BART GORDON, TENNESSEE
PETER DEUTSCH, FLORIDA
BOBBY L. RUSH, ILLINOIS
ANNA G. ESHOO, CALIFORNIA
RON KLINK, PENNSYLVANIA
BART STUPAK, MICHIGAN
ELIOT L. ENGEL, NEW YORK
THOMAS C. SAWYER, OHIO
ALBERT R. WYNN, MARYLAND
GENE GREEN, TEXAS
KAREN McCARTHY, MISSOURI
TED STRICKLAND, OHIO
DIANA DeGETTE, COLORADO
THOMAS M. BARRETT, WISCONSIN
BILL LUTHER, MINNESOTA
LOIS CAPPS, CALIFORNIA

JAMES E. DERDERIAN, CHIEF OF STAFF

U.S. House of Representatives
Committee on Commerce
Room 2125, Rayburn House Office Building
Washington, DC 20515–6115

June 14, 1999

The Honorable Robert Pitofsky
Chairman
Federal Trade Commission
Sixth and Pennsylvania Avenue, N.W.
Washington, D.C. 20580

Dear Chairman Pitofsky:

As you know, the Committee on Commerce has been investigating a number of issues pertaining to the sale of pharmaceutical products over the Internet.

The recent explosion of online sites that are both advertising and selling prescription drugs across state and even international lines clearly challenges the existing regulatory structure. Presently, it is not clear who is responsible for regulating the sale and distribution of pharmaceutical products over the Internet, nor is it clear what actions are being taken to ensure that public health is being protected in this new consumer environment. Although some agency officials have told us that the states are mostly responsible for shouldering this burden, the cross-border nature of most websites, coupled with the sheer volume of Internet activity, makes this a very difficult undertaking for the states, who may not have the resources, expertise, or jurisdiction to adequately oversee this area.

A host of serious regulatory concerns are indeed raised by Internet pharmacies. Patients are often required to submit personal medical data to an online pharmacy before their prescriptions are processed, and it is not clear how all websites will safeguard such personal information. Some online pharmacies could contribute to the problem of drug interactions or other complications in cases where a traditional face-to-face doctor-patient relationship or pharmacist-patient relationship is replaced by online "consultations." Finally, in some cases, it is impossible to determine the source or even the quality of some pharmaceutical products sold online. Without a well-coordinated regulatory system in place, it may become easier to sell improperly stored, illegally manufactured, or possibly tainted drugs to unsuspecting consumers. Moreover, if this area of commerce is allowed to operate with little or no regulatory review, the real possibility exists that the unscrupulous sites could ultimately tar the industry as a whole, thus affecting legitimate businesses.

Committee staff have met with officials from the Federal Trade Commission (FTC), the Department of Justice (DOJ), and the Food and Drug Administration (FDA) in an attempt to determine who is responsible for overseeing and regulating this area of commerce. These discussions have produced – at best – only vague responses as to which federal agency or department is in charge, and what exactly each is responsible for. Thus far, the federal effort (as comprised by FTC, DOJ, and FDA) appears uncoordinated and disorganized.

Both FTC and FDA officials have previously told Committee staff that the regulation of pharmacies has been, and remains, largely a state function. Indeed, states have generally focused on ensuring that pharmacies observe specific guidelines to safely dispense medications to the public, and that they are licensed and operated by qualified and trained staff. State regulators also ensure that any pharmacy under its jurisdiction properly stores and safeguards the pharmaceuticals it sells. Nevertheless, it is not clear that most states have the technology or resources to actively determine who is selling online from their state and thus who should receive scrutiny from that state's regulator(s).

To complicate matters further, in recent Committee staff interviews, some state officials indicated that they believe many Internet sites selling pharmaceutical products in the U.S. are actually foreign-based. Although these sites are readily accessible from any point in the U.S. (and may even display a U.S. mailing address), we have found that several websites are indeed operating from abroad. In the case of foreign Internet sites advertising and selling pharmaceutical products in the U.S., it is particularly important, given the limits on states in the arena of international commerce, that federal agencies or departments assume responsibility for oversight.

Given our concerns in this area, we would like you to address the following:

(1) What specific activities and functions does FTC believe it is responsible for regarding the sale and distribution of pharmaceutical products over the Internet? Please describe both (a) the precise activities (if any), now being conducted by FTC to review Internet sites selling pharmaceutical products online, and (b) the amount of time (in FTEs or another similar measure) dedicated to such efforts.

(2) Does FTC believe it has enough resources to conduct the activities defined in the previous question? If, not, please describe what additional resources (manpower, software/hardware, etc.) FTC needs to enforce its jurisdiction. Please also describe any assessments FTC has done to determine what resources it may need to regulate online pharmacies.

(3) What agencies or departments at either the state or federal level does FTC believe have the primary jurisdiction over Internet pharmacies? For this question, please identify what FTC's understanding is of the responsibilities of each agency identified for this question, and, whether FTC believes other agencies or departments (state or federal) are responsible for regulating online pharmacies. Also, describe FTC's understanding of what each agency or department is doing to address this matter.

(4) Please describe what agencies or departments FTC believes are responsible for regulating online pharmacies <u>selling in the U.S. market, but based outside the U.S. border.</u> As in question (3), please identify and describe what FTC believes are the roles and responsibilities of each agency identified, and what FTC's understanding is of what each agency or department is presently doing to address this matter.

(5) Please detail any efforts FTC has taken with any other identified federal agency or department to <u>define and coordinate</u> the regulation of online pharmacies. This should

include both the domestic and the international component of this matter. Please also describe any efforts to coordinate with any state on this matter. If this is being done, please provide a list of the names and titles FTC is coordinating with. Finally, please list any planned upcoming meetings designed to coordinate such activities.

(6) Does FTC believe that existing laws and regulations, or the present state/federal regulatory structure, can adequately regulate online pharmacies? If not, what discrepancies exist, and what changes, if any, does FTC believe must be made?

(7) Please describe FTC's knowledge regarding the differences between existing online pharmacies. For example, some reports suggest that most online pharmacies only fill prescriptions. Other reports, however, have suggested that some actually provide for a doctor consultation (for example, a quick questionnaire is submitted over the Internet, it is reviewed, and then the prescription is then approved and sent directly to the patient without a doctor ever seeing the patient). How prevalent is this latter operation? Do any trends appear in comparing one form of online pharmacy with another?

(8) What is FTC's understanding of how these websites deal with issues such as medical records privacy/protection, the selling of controlled substances, or drug interactions? How serious are these issues and what shortcomings, if any, do online pharmacies have with regard to these issues? Does FTC have any knowledge of how online pharmacies prevent unqualified persons from receiving prescriptions? Are online pharmacies more susceptible to fraud or deception from FTC's perspective? If so, please explain how?

(9) What quality issues does FTC believe relate to the methods used to ship online pharmaceutical products, and does FTC believe it has jurisdiction in this area?

(10) Please describe what technology challenges the Internet has posed to FTC. Do you believe that FTC has the technology to adequately and efficiently regulate any identified activities under its jurisdiction? Please describe where at FTC the technology to review and track online pharmacy sites resides, and describe that effort.

Thank you for your cooperation and attention to our request. If you have any additional questions about this matter, please have your staff contact Mr. Christopher Knauer, Minority Investigator, at (202) 226-3400. We look forward to working with you on this and other important pharmaceutical integrity and consumer protection issues.

Sincerely,

JOHN D. DINGELL
RANKING MEMBER
COMMITTEE ON COMMERCE

RON KLINK
RANKING MEMBER
SUBCOMMITTEE ON OVERSIGHT
AND INVESTIGATIONS

ONE HUNDRED SIXTH CONGRESS

TOM BLILEY, VIRGINIA, CHAIRMAN

*W.J. "BILLY" TAUZIN, LOUISIANA
MICHAEL G. OXLEY, OHIO
MICHAEL BILIRAKIS, FLORIDA
JOE BARTON, TEXAS
FRED UPTON, MICHIGAN
CLIFF STEARNS, FLORIDA
PAUL E. GILLMOR, OHIO
JAMES C. GREENWOOD, PENNSYLVANIA
CHRISTOPHER COX, CALIFORNIA
NATHAN DEAL, GEORGIA
STEVE LARGENT, OKLAHOMA
RICHARD BURR, NORTH CAROLINA
BRIAN P. BILBRAY, CALIFORNIA
ED WHITFIELD, KENTUCKY
GREG GANSKE, IOWA
CHARLIE NORWOOD, GEORGIA
TOM A. COBURN, OKLAHOMA
RICK LAZIO, NEW YORK
BARBARA CUBIN, WYOMING
JAMES E. ROGAN, CALIFORNIA
JOHN SHIMKUS, ILLINOIS
HEATHER WILSON, NEW MEXICO
JOHN B. SHADEGG, ARIZONA
CHARLES W. "CHIP" PICKERING, MISSISSIPPI
VITO FOSSELLA, NEW YORK
ROY BLUNT, MISSOURI
ED BRYANT, TENNESSEE
ROBERT L. EHRLICH, JR., MARYLAND

JOHN D. DINGELL, MICHIGAN
HENRY A. WAXMAN, CALIFORNIA
EDWARD J. MARKEY, MASSACHUSETTS
RALPH M. HALL, TEXAS
RICK BOUCHER, VIRGINIA
EDOLPHUS TOWNS, NEW YORK
FRANK PALLONE, JR., NEW JERSEY
SHERROD BROWN, OHIO
BART GORDON, TENNESSEE
PETER DEUTSCH, FLORIDA
BOBBY L. RUSH, ILLINOIS
ANNA G. ESHOO, CALIFORNIA
RON KLINK, PENNSYLVANIA
BART STUPAK, MICHIGAN
ELIOT L. ENGEL, NEW YORK
THOMAS C. SAWYER, OHIO
ALBERT R. WYNN, MARYLAND
GENE GREEN, TEXAS
KAREN McCARTHY, MISSOURI
TED STRICKLAND, OHIO
DIANA DeGETTE, COLORADO
THOMAS M. BARRETT, WISCONSIN
BILL LUTHER, MINNESOTA
LOIS CAPPS, CALIFORNIA

JAMES E. DERDERIAN, CHIEF OF STAFF

U.S. House of Representatives
Committee on Commerce
Room 2125, Rayburn House Office Building
Washington, DC 20515–6115

June 14, 1999

The Honorable Janet Reno
Attorney General
Department of Justice
Constitution Ave. and 10th Street, N.W.
Washington, D.C. 20530

Dear Attorney General Reno:

As you know, the Committee on Commerce has been investigating a number of issues pertaining to the sale of pharmaceutical products over the Internet.

The recent explosion of online sites that are both advertising and selling prescription drugs across state and even international lines clearly challenges the existing regulatory structure. Presently, it is not clear who is responsible for regulating the sale and distribution of pharmaceutical products over the Internet, nor is it clear what actions are being taken to ensure that public health is being protected in this new consumer environment. Although some agency officials have told us that the states are mostly responsible for shouldering this burden, the cross-border nature of most websites, coupled with the sheer volume of Internet activity, makes this a very difficult undertaking for the states, who may not have the resources, expertise, or jurisdiction to adequately oversee this area.

A host of serious regulatory concerns are indeed raised by Internet pharmacies. Patients are often required to submit personal medical data to an online pharmacy before their prescriptions are processed, but it is not clear how all websites will safeguard such personal information. Some online pharmacies could contribute to the problem of drug interactions or other complications in cases where a traditional face-to-face doctor-patient relationship or pharmacist-patient relationship is replaced by online "consultations." Finally, in some cases, it is impossible to determine the source or even the quality of some pharmaceutical products sold online. Without a well-coordinated regulatory system in place, it may become easier to sell improperly stored, illegally manufactured, or possibly tainted drugs to unsuspecting consumers. Moreover, if this area of commerce is allowed to operate with little or no regulatory review, the real possibility exists that the unscrupulous sites could ultimately tar the industry as a whole, thus affecting legitimate businesses.

Committee staff have met with officials from the Department of Justice (DOJ), the Federal Trade Commission (FTC), and the Food and Drug Administration (FDA) in an attempt to determine who is responsible for overseeing and regulating this area of commerce. These discussions have produced – at best – only vague responses as to which agency or Department is in charge, and what exactly each is responsible for. Thus far, the federal effort (as comprised by DOJ, FTC, and FDA) appears uncoordinated and disorganized.

FDA and DOJ officials have previously told Committee staff that the regulation of pharmacies has been, and remains, largely a state function. Indeed, states have generally focused on ensuring that pharmacies observe specific guidelines to safely dispense medications to the public, and that they are licensed and operated by qualified and trained staff. State regulators also ensure that any pharmacy under its jurisdiction properly stores and safeguards the pharmaceuticals it sells. Nevertheless, it is not clear that most states have the technology or resources to actively determine who is selling online from their state and thus who should receive scrutiny from that state's regulator(s).

To complicate matters further, in recent Committee staff interviews, some state officials indicated that they believe many Internet sites selling pharmaceutical products in the U.S. are actually foreign-based. Although these sites are readily accessible from any point in the U.S. (and may even display a U.S. mailing address), we have found that several websites are indeed operating from abroad. In the case of foreign Internet sites advertising and selling pharmaceutical products in the U.S., it is particularly important, given the limits on states in the arena of international commerce, that federal agencies or departments assume responsibility for oversight.

Given our concerns in this area, we would like you to address the following:

(1) What specific activities and functions does DOJ believe it is responsible for regarding the sale and distribution of pharmaceutical products over the Internet? Please describe both (a) the precise activities (if any), now being conducted by DOJ to review Internet sites selling pharmaceutical products online, and (b) the amount of time (in FTEs or another similar measure) dedicated to such efforts.

(2) Does DOJ believe it has enough resources to conduct the activities defined in the previous question? If, not, please describe what additional resources (manpower, software/hardware, etc.) DOJ needs to enforce its jurisdiction. Please also describe any assessments DOJ has done to determine what resources it may need to regulate online pharmacies.

(3) What agencies or departments at either the state or federal level does DOJ believe have the primary jurisdiction over Internet pharmacies? For this question, please identify what DOJ's understanding is of the responsibilities of each agency identified for this question, and, whether DOJ believes other agencies or departments (state or federal) are responsible for regulating online pharmacies. Also, describe DOJ's understanding of what each agency or department is doing to address this matter.

(4) Please describe what agencies or departments DOJ believes are responsible for regulating online pharmacies <u>selling in the U.S. market, but based outside the U.S. border.</u> As in question (3), please identify and describe what DOJ believes are the roles and responsibilities of each agency identified, and what DOJ's understanding is of what each agency or department is presently doing to address this matter.

(5) Please detail any efforts DOJ has taken with any other identified federal agency or department to define and coordinate the regulation of online pharmacies. This should include both the domestic and the international component of this matter. Please also describe any efforts to coordinate with any state on this matter. If this is being done, please provide a list of the names and titles DOJ is coordinating with. Finally, please list any planned upcoming meetings designed to coordinate such activities.

(6) Does DOJ believe that existing laws and regulations, or the present state/federal regulatory structure, can adequately regulate online pharmacies? If not, what discrepancies exist, and what changes, if any, does DOJ believe must be made?

(7) Please describe DOJ's knowledge regarding the differences between existing online pharmacies. For example, some reports suggest that most online pharmacies only fill prescriptions. Other reports, however, have suggested that some actually provide for a doctor consultation (for example, a quick questionnaire is submitted over the Internet, it is reviewed, and then the prescription is then approved and sent directly to the patient without a doctor ever seeing the patient). How prevalent is this latter operation? Do any trends appear in comparing one form of online pharmacy with another?

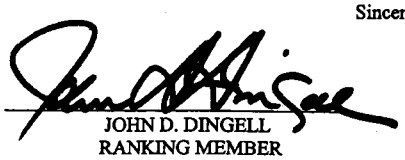
(8) What is DOJ's understanding of how these websites deal with issues such as medical records privacy/protection, the selling of controlled substances, or drug interactions? How serious are these issues and what shortcomings, if any, do online pharmacies have with regard to these issues? Does DOJ have any knowledge of how online pharmacies prevent unqualified persons from receiving prescriptions? Are online pharmacies more susceptible to fraud or deception from DOJ's perspective? If so, please explain how?

(9) What quality issues does DOJ believe relate to the methods used to ship online pharmaceutical products, and does DOJ believe it has jurisdiction in this area?

(10) Please describe what technology challenges the Internet has posed to DOJ. Do you believe that DOJ has the technology to adequately and efficiently regulate any identified activities under its jurisdiction? Please describe where at DOJ the technology to review and track online pharmacy sites resides, and describe that effort.

Thank you for your cooperation and attention to our request. If you have any additional questions about this matter, please have your staff contact Mr. Christopher Knauer, Minority Investigator, at (202) 226-3400. We look forward to working with you on this and other important pharmaceutical integrity and consumer protection issues.

Sincerely,



JOHN D. DINGELL
RANKING MEMBER
COMMITTEE ON COMMERCE

RON KLINK
RANKING MEMBER
SUBCOMMITTEE ON OVERSIGHT
AND INVESTIGATIONS

U.S. Department of Justice
Office of Legislative Affairs

Office of the Assistant Attorney General

Washington, D.C. 20530

July 29, 1999

The Honorable John D. Dingell
Ranking Minority Member
Committee on Commerce
U.S. House of Representatives
Washington, DC 20515

The Honorable Ron Klink
Ranking Minority Member
Subcommittee on Oversight and Investigations
Committee on Commerce
U.S. House of Representatives
Washington, DC 20515

Dear Congressmen Dingell and Klink:

Thank you for your June 14, 1999, letter concerning issues related to online pharmacies. The Department of Justice agrees that the recent increase in online pharmacies presents serious legal and investigative challenges. The Department has, accordingly, begun an analysis of the legal and policy issues raised by such online pharmacies.

Due to the complex character of online pharmacies, this response is necessarily an interim response and does not fully answer your detailed requests for information. Although we are endeavoring to develop more comprehensive answers, we can report to you now only generally about the Department's emerging views on the subject. When we are further along in the process of establishing a government-wide position in response to your detailed questions, we will be able to respond more specifically to your questions.

As an initial matter, we note that some of your questions refer to the "sale and distribution of pharmaceutical products," while other questions refer to the "regulation of online pharmacies." We interpret the term "sale and distribution of pharmaceutical products" to refer to the prescribing of and the actual sale of the drugs. By contrast, we

interpret the term "regulation of online pharmacies" to refer to other issues, such as the labeling and quality of the drugs distributed by the pharmacy.

Several different kinds of online pharmacies exist, each of which presents a different type of concern. The first is where consumers are able to purchase drugs from physicians without the traditional protections built into the doctor/patient relationship, such as an office visit which allows for a physical examination and for the doctor to ask the patient critical questions designed to limit the harm caused by drug allergies and interactions. The second is where consumers purchase drugs which are mislabeled or counterfeit. Finally, there are concerns that certain websites are nothing more than scams, collecting credit cards and cash but providing no products.

Some online pharmacies fill only previously acquired physician prescriptions. Many online pharmacies, however, allow customers with no previously acquired prescription to obtain a "doctor consultation" on the website, which then permits the customer to purchase prescription drugs. A customer undergoes such a "doctor consultation" by completing an online questionnaire, which is then submitted to the online pharmacy via the Internet. These online pharmacies may retain a physician to review completed questionnaires and to prescribe the requested drugs. After the physician orders the prescription, the pharmacy directly mails the drugs to the customer. Drug interactions are a very serious problem amplified by such Internet "doctor consultations." Some of the "doctor consultation" questionnaires that we have seen require the consumer to provide information concerning other medications they are using. Others, however, fail to ask for this information.

The authority to regulate online pharmacies and the online distribution of pharmaceutical drugs involves a balance of jurisdiction between federal and state authorities. States license pharmacies and regulate the practice of medicine, but when pharmacies dispense drugs that are adulterated or misbranded, then the federal government has jurisdiction. The Food and Drug Administration (FDA) inspects pharmacies that dispense drugs and refers cases to the Department of Justice for prosecution. States, as well as the FDA, thus both have authority to regulate online pharmacies and the distribution of pharmaceutical drugs. Moreover, the Drug Enforcement Administration regulates online activities involving controlled substances in the same manner as traditional pharmacies. The determination of which entity has authority to regulate a particular site depends on the specific wrongful conduct that is alleged. In addition, false and misleading claims may be regulated by the Federal Trade Commission (FTC).

The Department of Justice, through its litigating Divisions and the Offices of the United States Attorneys, enforces criminal and civil laws related to the online sale of

pharmaceuticals, including violations of the Federal Food, Drug, and Cosmetic Act ("FDCA"). In general, the FDCA prohibits the manufacture and distribution of misbranded and adulterated drugs, thus requiring drugs to be labeled accurately and handled in ways that prevent them from becoming contaminated or misused. Other federal laws which may be implicated by online sales include the Controlled Substances Act and the Customs laws. Moreover, fraudulent or misleading representations made in connection with online marketing or sales may constitute violations of the federal mail and wire fraud statutes. Prosecutions under these statutes may result from referrals made and investigations conducted by any of a number of federal agencies which have jurisdiction to investigate various aspects of online sales activity, including the FDA's Office of Criminal Investigations, the Federal Bureau of Investigation, the Drug Enforcement Administration, the Customs Service, and the Postal Inspection Service.

The growth of online sales raises several investigatory challenges. For example, the sheer number of internet sites that purport to sell pharmaceutical drugs is staggering. When a particular site is identified as operating in potential violation of federal law, it must be "mirrored" so that, if the site is removed from the web, investigators will, nonetheless, be able to take the necessary investigative steps to ascertain the identity and location of those responsible for the content of and sales being made via that site. It is therefore vital that investigators and prosecutors have the requisite training to successfully conduct internet investigations from their inception.

We are examining issues concerning the extent to which these various categories of online sales activity may raise legal issues under the relevant statutes. In that regard, the Department has participated in interagency discussions to explore the legal and policy issues raised by the marketing and sales of drugs and medical devices on the internet. Those discussions are continuing and we anticipate that they will not only help us in applying existing law to current sales activity on the internet, but will also result in sharing of information about the crime problem and the sharing of investigative techniques to combat it.

We are available to meet with you and your staff to discuss these matters further. If we may be of additional assistance in connection with this or any other matter, we trust that you will not hesitate to call upon us.

Sincerely,

Jon P. Jennings
Acting Assistant Attorney General

ONE HUNDRED SIXTH CONGRESS

TOM BLILEY, VIRGINIA, CHAIRMAN

W.J. "BILLY" TAUZIN, LOUISIANA
MICHAEL G. OXLEY, OHIO
MICHAEL BILIRAKIS, FLORIDA
JOE BARTON, TEXAS
FRED UPTON, MICHIGAN
CLIFF STEARNS, FLORIDA
PAUL E. GILLMOR, OHIO
JAMES C. GREENWOOD, PENNSYLVANIA
CHRISTOPHER COX, CALIFORNIA
NATHAN DEAL, GEORGIA
STEVE LARGENT, OKLAHOMA
RICHARD BURR, NORTH CAROLINA
BRIAN P. BILBRAY, CALIFORNIA
ED WHITFIELD, KENTUCKY
GREG GANSKE, IOWA
CHARLIE NORWOOD, GEORGIA
TOM A. COBURN, OKLAHOMA
RICK LAZIO, NEW YORK
BARBARA CUBIN, WYOMING
JAMES E. ROGAN, CALIFORNIA
JOHN SHIMKUS, ILLINOIS
HEATHER WILSON, NEW MEXICO
JOHN B. SHADEGG, ARIZONA
CHARLES W. "CHIP" PICKERING, MISSISSIPPI
VITO FOSSELLA, NEW YORK
ROY BLUNT, MISSOURI
ED BRYANT, TENNESSEE
ROBERT L. EHRLICH, JR., MARYLAND

JOHN D. DINGELL, MICHIGAN
HENRY A. WAXMAN, CALIFORNIA
EDWARD J. MARKEY, MASSACHUSETTS
RALPH M. HALL, TEXAS
RICK BOUCHER, VIRGINIA
EDOLPHUS TOWNS, NEW YORK
FRANK PALLONE, JR., NEW JERSEY
SHERROD BROWN, OHIO
BART GORDON, TENNESSEE
PETER DEUTSCH, FLORIDA
BOBBY L. RUSH, ILLINOIS
ANNA G. ESHOO, CALIFORNIA
RON KLINK, PENNSYLVANIA
BART STUPAK, MICHIGAN
ELIOT L. ENGEL, NEW YORK
THOMAS C. SAWYER, OHIO
ALBERT R. WYNN, MARYLAND
GENE GREEN, TEXAS
KAREN McCARTHY, MISSOURI
TED STRICKLAND, OHIO
DIANA DeGETTE, COLORADO
THOMAS M. BARRETT, WISCONSIN
BILL LUTHER, MINNESOTA
LOIS CAPPS, CALIFORNIA

JAMES E. DERDERIAN, CHIEF OF STAFF

101

U.S. House of Representatives
Committee on Commerce
Room 2125, Rayburn House Office Building
Washington, DC 20515–6115

June 29, 1999

The Honorable Robert Pitofsky
Chairman
Federal Trade Commission
Sixth and Pennsylvania Avenue, N.W.
Washington, D.C. 20580

Dear Commissioner Pitofsky:

As you know, the Committee on Commerce has been investigating a number of issues pertaining to the sale and distribution of pharmaceutical products over the Internet. As part of this effort, Committee staff have met with Federal Trade Commission (FTC) officials on several occasions to: (1) determine who is responsible for overseeing and regulating this emerging area of commerce, and (2) to determine the precise activities of the state and federal agencies involved in this effort. As indicated in previous correspondence, it remains unclear what agency or department is coordinating this effort. It also remains unclear what specific regulatory tasks are presently undertaken by those agencies and departments that appear to share jurisdiction in this matter. At a minimum this includes the Department of Justice, the Food and Drug Administration, and the FTC.

Recently, we addressed correspondence to you seeking answers to a series of questions about the FTC's regulatory activities in this matter. We presume the issues identified in that letter are being addressed by your staff, and we anticipate your response.

Nevertheless, in addition to that request, we are now submitting for your agency's review approximately100 web sites now apparently selling a range of pharmaceutical products from the Internet which make various claims about the use of different drugs. The volume and rapid emergence of these sites suggest that many sellers are not waiting for the federal and state agencies to formalize a regulatory approach to this problem.

Although the Internet holds great promise as a means of distributing pharmaceuticals, it also imposes considerable challenges to public health and safety and therefore state and federal regulators, particularly when it may place unwary consumers at considerable risk. Our goal is to

work with the FTC to maintain the positive benefits of this new means of commerce, while reducing many of these risks.

Given the serious consumer protection and health consequences of this matter, we are requesting that the FTC review the following attached sites to provide us with the following:

(a) The physical location of each site, and in what States it sells its products;

(b) Whether the FTC has ever reviewed the site for any advertising or usage claims made regarding any pharmaceutical product(s) being sold; and,

(c) The accuracy of any such claims made by the site that fall under the FTC's jurisdiction.

If you believe that any single State has already reviewed these numerous Internet sites for the above content, please list (a) the particular site in question, (b) the State and the name of the regulatory authority that conducted the review, and (c) the date of the review.

Please provide a response by July 29, 1999. If you have any questions on this matter, please have your staff contact Mr. Christopher Knauer at (202) 226-3400.

Sincerely,

JOHN D. DINGELL
RANKING MEMBER
COMMITTEE ON COMMERCE

RON KLINK
RANKING MEMBER
SUBCOMMITTEE ON OVERSIGHT
AND INVESTIGATIONS

Enclosures

UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION
WASHINGTON, D.C. 20580

Office of the Chairman

July 12, 1999

The Honorable John D. Dingell
United States House of Representatives
Washington, D.C. 20515

The Honorable Ron Klink
United States House of Representatives
Washington, D.C. 20515

Dear Representative Dingell and Representative Klink:

Thank you for your letters of June 14, 1999 and June 29, 1999, requesting information about the Federal Trade Commission's role in the regulation of the sale of prescription drug products over the Internet. We are preparing a response to your letters and will forward that information to you shortly. In the interim, we are providing you with an overview of the Commission's jurisdiction and activities relating to the marketing of prescription drugs on the Internet.

The Commission believes that the availability of prescription drugs online offers many potential benefits to consumers, including convenience and value. As your letter indicates, however, the recent expansion of online sites that are selling prescription drugs across state and international borders clearly challenges the traditional regulatory structure that is designed to protect consumers in the sale of prescription drug products.

In general, the Commission's authority derives from the agency's mandate to prevent deceptive and unfair acts or practices in commerce, pursuant to the FTC Act. *See* 15 U.S.C. § 41 *et seq. as amended.*[1] Deceptive or unfair advertising practices by online pharmacies are

---

[1] Pursuant to this general authority, the FTC has devoted substantial resources to monitoring Internet advertising and marketing for various products and services, including health care products. For example, on June 24, 1999, as part of Operation Cure.All, the Commission announced four cases against companies marketing non-prescription health products on the Internet. The Commission's complaints in these matters challenged representations that the four products involved, shark cartilage, Cat's Claw, cetylmyristoleate, and therapeutic magnets, would treat or cure thirty-one different diseases or serious health conditions, including arthritis, cancer, and heart disease. The companies and their respective corporate officers agreed to settle the charges. The settlements prohibit the companies from making the challenged representations or any other representations that their products provide specific health benefits unless the representations are substantiated by competent and reliable scientific evidence.

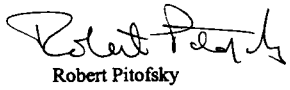
encompassed within this broad mandate, and the Commission has authority to bring enforcement actions where an online pharmacy makes false or misleading claims about the products or services it provides. Thus, for example, if an online pharmacy makes express or implied misrepresentations about the effectiveness or safety of a prescription drug, the Commission could take action.[2] Under our longstanding formal liaison agreement with the FDA, however, the FDA has primary responsibility for the regulation of both labeling and advertising of prescription drugs by a packer, manufacturer, or distributor.[3]

There are some limitations on the Commission's activities in this area. As you are aware, the Commission has traditionally refrained from regulating practices that fall within the doctor-patient relationship, such as communications between doctors and patients about course of treatment decisions. For example, Commission staff has referred matters relating to the practices of doctors who provide online consultations or prescribe drugs online to the appropriate state medical board. Finally, as your letter recognizes, the regulation of pharmacies has traditionally taken place at the state level by state pharmacy boards. While the Commission does not have authority to revoke a pharmacy's license or to enforce the regulations relating to licensing of pharmacies, it can and has assisted state authorities in background investigative work by providing information about the identity and physical location of a pharmacy operating online.

In short, the Commission will continue its efforts to protect consumers by bringing cases challenging the unfair or deceptive acts and practices of online pharmacies, and by assisting other federal and state authorities with their enforcement efforts. Our experience to date indicates that protecting consumers from the practices of some online pharmacies creates significant challenges. More specifically, the jurisdictional limitations of the states make it difficult though not impossible for any individual state to ensure that online pharmacies are following required business practices, including dispensing products only to consumers with valid prescriptions. In addition, limitations in the current registration process for assigning domain names on the Internet make it difficult to determine even in what state(s) the online pharmacies are physically located, hampering the states' ability to effectively deal with this issue.

These issues, along with responses to your specific questions, will be set out in a separate letter in the near future. We would be happy to work with your staff in exploring possible solutions to the concerns raised in your letter.

By direction of the Commission.



Robert Pitofsky
Chairman

---

[2] *See, e.g., FTC v. Pacific Medical Clinics*, 1992-1 Trade Cas. (CCH) ¶ 69,777 (S.D.Cal. April 8, 1992)(defendants' misrepresented effectiveness of prescription drug for treating obesity).

[3] *See* Working Agreement Between FTC and Food and Drug Administration, 3 Trade Reg. Rep. (CCH) ¶ 9.850.01 (1971). The liaison 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.

UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION
WASHINGTON, D.C. 20580

Office of the Chairman

July 29, 1999

The Honorable John D. Dingell
United States House of Representatives
Washington, D.C. 20515

Dear Representative Dingell:

On July 12, 1999 we provided you with an interim response to your letter of June 14, 1999. In that letter, we indicated that we would forward responses to your specific questions in the near future. On June 29, 1999 you forwarded a request for additional information. This letter responds to both requests.

The Internet has become a critical component of health care in this country. According to surveys conducted by Cyber Dialogue, Inc., over twenty million U.S. adults sought health and medical information online as of December 1998. Twenty-nine percent of all Americans looked to the Internet for medical information and nearly seventy percent of that group did so before visiting a doctor's office.

Given the large number of consumers now using the Internet to purchase health care products and services, and the critical role that truthful and accurate information plays in making informed health care decisions, the Commission has devoted substantial resources to monitoring Internet advertising and marketing for health care products and services. In addition to monitoring consumer complaints about specific sites, Commission staff has organized and participated in two "surf days" to identify marketers promoting health care products on the Internet. These efforts, which involved "surfers" from both public and private agencies using common search engines, identified nearly 800 sites making questionable cure and treatment claims for serious diseases, including cancer, heart disease, diabetes, arthritis, multiple sclerosis, and HIV/AIDS.

Following up on our surf days, the Commission announced Operation Cure.All on June 24, 1999, a joint consumer education and law enforcement program targeted at Internet marketers. As part of Operation Cure.All, the Commission announced four cases against companies marketing non-prescription health products on the Internet.[1] Additional

---

[1] *See Arthritis Pain Care Center (APCC) et al.*, File No. 982 3182 (June 24, 1999)(consent subject to final approval challenging arthritis claims for CMO dietary supplement); *Body Systems Technology, Inc.*, File No. 982 3177 (June 24, 1999)(consent subject to final approval challenging claims for treatment/cure of several diseases including cancer and

investigations are underway.

In addition to the Operation Cure.All cases, the Commission has filed other cases against Internet marketers of health care products. On December 8, 1998, the Commission announced a settlement with New Vision International, Inc., a multi-level marketing company, resolving allegedly unsubstantiated claims that its nutritional supplements effectively treated Attention Deficit Disorder and Attention Deficit Hyperactivity Disorder.[2] On March 15, 1999, the Commission filed charges against Rose Creek Health Products, Inc. for making false and unsubstantiated claims that a purported supplement called "Vitamin O" is effective in the treatment of several diseases, including cancer and pulmonary disease.[3]

As indicated in our previous letter, the Commission believes that the availability of prescription drugs online offers many potential benefits to consumers, including convenience and value. Nevertheless, the rapid growth of online prescription sales and online prescribing, across both state and international borders, presents significant technological and logistical challenges to traditional approaches used to protect consumers in the prescribing and dispensing of prescription drugs.

Deceptive advertising practices by online pharmacies are encompassed within the Commission's mandate to prevent deceptive and unfair acts or practices in commerce and false advertising pursuant to the FTC Act. *See* 15 U.S.C. § 41 *et seq. as amended.* The Commission has the authority to bring enforcement actions where an online pharmacy makes false or misleading claims about the products or services it provides or if it engages in unfair or deceptive acts or practices. Thus, for example, if an online pharmacy makes express or implied misrepresentations about the effectiveness or safety of a prescription drug, the Commission could take action.[4]

AIDS for shark cartilage capsules and Cat's Claw herbal supplement); *Pain Stops Here! Inc., et al.*, File No. 982 3175 (June 24, 1999) (consent subject to final approval challenging claims for magnetic therapy to treat cancer, liver disease, arthritis and other conditions); and *Magnetic Therapeutic Technologies, Inc. et al.*, File No. 982 3150 (June 24, 1999)(consent subject to final approval challenging claims for magnetic therapy devices to treat various diseases and conditions including cancer and high blood pressure).

[2] *New Vision International*, FTC Dkt. No. C-3856 (March 3, 1999).

[3] *FTC v. Rose Creek Health Products, Inc.*, CS-99-0063-EFS (E.D. Wash. 1999). This litigation is ongoing.

[4] *See, e.g., American College for Advancement in Medicine*, FTC Dkt. No. C-3882 (June 22, 1999) (unsubstantiated claims for effectiveness of therapy using prescription drug for treating heart disease); *FTC v. Pacific Medical Clinics*, 1992-1 Trade Cas. (CCH) ¶ 69,777 (S.D.Cal. April 8, 1992) (misrepresentation of the effectiveness of prescription drug for treating obesity). As discussed below, individual sites may be involved in other potentially deceptive

There are some limitations on the Commission's activities in this area. As you are aware, the Commission has traditionally refrained from regulating practices that may fall within the doctor-patient relationship, such as communications between doctors and patients about course of treatment decisions. For example, as discussed below, many online pharmacies provide "online medical consultations" to consumers who do not have pre-existing prescriptions. Challenging this practice as an "unfair act or practice" would inevitably involve judgments concerning the appropriateness of certain physician prescribing practices under state law. In such a case, Commission staff would refer the matter to the appropriate state medical board.

Additionally, the regulation of pharmacies has traditionally taken place at the state level by state pharmacy boards. Although the Commission does not have authority to revoke a pharmacy's license or to enforce the regulations relating to licensing of pharmacies and physicians, it can and has assisted state authorities in background investigative work by sharing information about the identity and physical location of a pharmacy or physician providing prescriptions to online consumers.[5]

State authorities, however, face some difficult challenges in attempting to regulate online pharmacies.[6] Specifically, jurisdictional and practical limitations make it difficult for any individual state to ensure that online pharmacies are following required business practices, including dispensing products only to consumers with valid prescriptions. In addition, limitations in the current registration process for assigning domain names to Internet web sites make it difficult to determine in what state(s) the online pharmacies are physically located,

---

practices.

[5] Our preliminary investigation has revealed that at least some of the web sites offering prescription drugs do not themselves belong to licensed pharmacies. Instead, it appears that a number of web sites merely market prescription drugs and arrange with licensed pharmacies to fill the prescriptions.

[6] *See, e.g.*, attached 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.").

further hampering the states' ability to deal effectively with this issue. Thus, we recommend that Congress consider requiring each web site offering prescription drugs for sale to clearly and prominently disclose the following information:

1) the name, business address, and phone number of the pharmacy that will dispense the prescription, and the state or states where such pharmacy is licensed or registered to do business;

2) the name, address, and phone number of each physician providing the online prescribing services, and the state or states where such physician is licensed or authorized to practice medicine, if such service is offered;

3) the name, business address, phone number, and principal officers or owners of the online business offering prescription drugs, if different from the pharmacy or physician; and

4) the state or states from which the web site will accept orders for prescription drugs.

Finally, Congress could consider whether other measures are necessary to assist state pharmacy and medical boards with enforcement of state laws against extraterritorial prescribing practices, including providing states with the authority to bring actions in federal district court.

These relatively straightforward disclosure requirements should provide state pharmacy and medical boards with the information they need to pursue coordinated enforcement actions in this area. Moreover, it will provide Federal law enforcement agencies with the information necessary to assess the need for federal action in the event the states are unable to do so.

Answers to your specific questions are provided below.

1. **What specific activities and functions does FTC believe it is responsible for regarding the sale and distribution of pharmaceutical products over the Internet? Please describe both (a) the precise activities (if any), now being conducted by FTC to review Internet sites selling pharmaceutical products online, and (b) the amount of time (in FTEs or another similar measure) dedicated to such efforts.**

Under Sections 5 and 12 of the FTC Act, 15 U.S.C. §§ 45, 52, the Commission has jurisdiction over unfair or deceptive acts or practices and false advertising in or affecting commerce. As indicated, misrepresentations concerning product efficacy or safety would violate the FTC Act. In addition, some sites offer an online consultation service by a physician for a fee ranging from $50 to $75. If no service is actually provided, *e.g.*, the information is not reviewed by a physician, then the representation would be deceptive. The Commission also has unfairness

jurisdiction.[7] Application of the Commission's unfairness jurisdiction to the practice of online consultations raises difficult issues involving physician practices that the Commission has traditionally refrained from regulating.

The FTC staff has reviewed several web sites selling prescription drugs to determine if those sites are engaged in deceptive or unfair practices or false advertising. Staff has conducted several preliminary investigations and, where appropriate, has referred matters to the relevant state and other federal authorities with primary jurisdiction over the practices identified in our investigations. We estimate that the Commission has spent less than one work year to date on these activities.

2. **Does FTC believe it has enough resources to conduct the activities defined in the previous question? If, not, please describe what additional resources (manpower, software/hardware, etc.) FTC needs to enforce its jurisdiction. Please also describe any assessments FTC has done to determine what resources it may need to regulate online pharmacies.**

The FTC has given a priority to ensuring that it has the technology to monitor and investigate Internet marketing and is continuing to upgrade its current capabilities. It has also given a priority to the development of cases involving online marketing and promotion. At this time, it does not appear that this agency requires additional resources to carry out its limited mission as it relates to online prescription drug sales. However, the increased monitoring and investigative responsibilities resulting from the rapid expansion of the number of web sites offering health care products and services, as demonstrated by the list of web sites you provided, are challenging existing resources. If the FTC were to assume expanded jurisdiction over Internet dispensing practices for prescription drugs, the agency would require additional resources, primarily in the form of additional attorney and investigator positions.

3. **What agencies or departments at either the state or federal level does FTC believe have the primary jurisdiction over Internet pharmacies? For this question, please identify what FTC's understanding is of the responsibilities of each agency identified for this question, and, whether FTC believes other agencies or departments (state or federal) are responsible for regulating online pharmacies. Also, describe FTC's understanding of what each agency or department is doing to address this matter.**

Historically, the states have had primary responsibility for the regulation of pharmacies. The advent of online pharmacies does not alter that traditional jurisdiction. Barring any changes in federal law, the primary responsibility for regulating pharmacies will continue to lie with the states. In addition, it is our understanding that FDA has jurisdiction to take action against the

---

[7] An "unfair" act or practice is defined as one that "causes or is likely to cause substantial injury to consumers which is not reasonably avoidable by consumers themselves and not outweighed by countervailing benefits to consumers or to competition." 15 U.S.C. § 45(n).

selling or dispensing of a prescription drug without a valid prescription.[8] FDA's actions are described in its letter to you dated May 7, 1999. Finally, the Drug Enforcement Agency has jurisdiction over the dispensing of controlled substances, and the FTC has jurisdiction to prevent marketers, including online pharmacies, from engaging in unfair or deceptive acts or practices or false advertising.

A number of states, including Kansas, Colorado, and Washington, among others, have initiated proceedings against physicians who have prescribed drugs based solely on consumers' answers to online questionnaires.

4. **Please describe what agencies or departments FTC believes are responsible for regulating online pharmacies selling in the U.S. market, but based outside the U.S. border. As in question (3), please identify and describe what FTC believes are the roles and responsibilities of each agency identified, and what FTC's understanding is of what each agency or department is presently doing to address this matter.**

It is our understanding that with respect to the importation of prescription drugs, the FDA, DOJ, and U.S. Customs Service all share responsibility. DOJ, for example, is responsible for enforcing many of the FDA's laws and regulations, some of which relate directly to the importation of prescription drugs. FDA's activities relating to foreign sites are described in FDA's May 7, 1999 letter referenced in response to the preceding question.

Under Section 4 of the FTC Act, the FTC would have subject matter jurisdiction over a marketer based outside the U.S. border selling online in the U.S. market. With regard to online pharmacies, that jurisdiction is limited to enforcing Sections 5 and 12, as discussed above.

5. **Please detail any efforts FTC has taken with any other identified federal agency or department to define and coordinate the regulation of online pharmacies. This should include both the domestic and the international component of this matter. Please also describe any efforts to coordinate with any state on this matter. If this is being done, please provide a list of the names and titles FTC is coordinating with. Finally, please list any planned upcoming meetings designed to coordinate such activities.**

Online pharmacies present new and difficult jurisdictional questions that the current regulatory structure appears not to address adequately. On April 26, 1999, an interagency working group, comprised of the FDA, DOJ, DEA, FTC, and other federal and state agencies, met to consider these and other issues relating to the sale of drugs over the Internet. A list of participants in that meeting is attached. One of the group's tasks is to explore enforcement issues and potential jurisdictional gaps. One follow-up meeting has been held. The next meeting has been scheduled for September 9, 1999.

---

[8] 21 U.S.C. §§ 353(b)(1); 331(a), and 333.

In addition, the working group has made several efforts to coordinate with the states. Representatives from the National Association of Attorneys General, the State Attorneys General, and the National Association of Pharmacy Boards, attended meetings of the working group discussed above. FTC staff investigations have resulted in referrals to state regulatory authorities in two states.

On June 8-9, 1999, the Commission held a workshop on international consumer protection issues raised by Internet marketing in general. In addition, for consumer protection in general, the Commission has given a priority to developing cooperative international arrangements.

6. Does FTC believe that existing laws and regulations, or the present state/federal regulatory structure, can adequately regulate online pharmacies? If not, what discrepancies exist, and what changes, if any, does FTC believe must be made?

Our preliminary review suggests that there are clear impediments to the states' ability to enforce existing state standards for professional conduct in this area. For example, it is difficult for states to identify pharmacies or physicians located within their states that are providing online consulting or drug dispensing. It can be even more difficult to identify and locate responsible parties in another state. For example, in one case we investigated, the web site, dispensing pharmacy, and prescribing doctor were all located in different states.

Identifying information provided on web sites or through web site registration entities such as Network Solutions, Inc. is often not reliable. Given current Internet practices, the mere act of identifying and locating regulated parties would require a substantial expenditure of resources.[9] As some of our letters from state regulators indicate,[10] states may find it difficult to enforce their state statutory and ethical standards against physicians and pharmacies located in another state. The lack of disciplinary authority over out of state physicians and the relatively minor penalties attached to the unauthorized practice of medicine in some states may make pursuing actions against out of state physicians impractical. In addition, states may lack the resources to track down and prosecute out of state violators. Moreover, even with regard to physicians located within a particular state, an individual state may not have the incentive to proceed against a physician whose offense is practicing online medicine in another state without a license. All of these factors suggest that legislation may be needed to enhance the states' ability to monitor and regulate online prescribing and dispensing practices.

---

[9] In fact, the only way to find out the identity and location of some online pharmacies is to conduct extensive investigations involving both Internet searches and traditional investigatory techniques. Depending on the circumstances, these investigations can be resource intensive and expensive.

[10] Twelve states and the District of Columbia have contacted the FTC raising concerns about online prescribing practices and, in several instances, their ability to effectively regulate online prescribing and dispensing. See attached letters.

7. **Please describe FTC's knowledge regarding the differences between existing online pharmacies. For example, some reports suggest that most online pharmacies only fill prescriptions. Other reports, however, have suggested that some actually provide for a doctor consultation (for example, a quick questionnaire is submitted over the Internet, it is reviewed, and then the prescription is then approved and sent directly to the patient without a doctor ever seeing the patient). How prevalent is this latter operation? Do any trends appear in comparing one form of online pharmacy with another?**

The Commission staff has identified three types of online sites selling prescription drugs. The first type requires a consumer to fax a prescription from the consumer's treating physician to the prescription dispenser. Like traditional mail order sellers of prescription drugs, these companies appear to be a valuable, useful service to consumers and competition.

The second type of identified online site requires no existing doctor/patient relationship. Instead, the consumer is invited to fill out an online questionnaire that is purportedly reviewed by a physician who then decides whether or not to prescribe the drug.[11] The online "consultation" costs between $50 and $75. This type of web site seems to be directly associated with specific types of prescription drugs, such as Viagra®, Propecia® and Xenical®. The majority of sites Commission staff has reviewed to date fall into this category. Because there appears to be no ongoing doctor-patient relationship between the prescribing physician and the patient, the dispensing of drugs by these sites is very troubling. In one instance, Commission staff was able to order Viagra® from a site even though the "consumer" was identified as being a 260 pound, 6'4" tall, 60 year old male with a medical history of atherosclerosis, heart attack, and bypass surgery. In addition, information submitted to the web site stated that the "consumer" had a family history of heart disease and failed to provide information on current medications.

There have been reports of minors obtaining prescription drugs online. In one complaint filed with the FTC, a parent reported that her minor son obtained Viagra® over the Internet, based solely on an online consultation. She was particularly concerned because her son suffers from bipolar disorder and neurocardiac syncope and was taking blood pressure medication at the time. The State of Kansas recently filed a suit against an Internet company that sold a variety of prescription drugs to a minor using his true age.[12]

The third type of identified online seller makes no pretense of the need for a prescription

---

[11] In fact, it appears that some of these sites will not fill pre-existing prescriptions. The consumer must agree to an online consultation in order to obtain the drug through the site.

[12] *See* attached Press Release of the State of Kansas, Office of the Attorney General (6/9/99).

or online "consultation." The FTC has only identified one such site.[13] Dispensing in this manner is a violation of federal law.[14] This site was referred to appropriate criminal authorities.

8. What is FTC's understanding of how these websites deal with issues such as medical records privacy/protection, the selling of controlled substances, or drug interactions? How serious are these issues and what shortcomings, if any, do online pharmacies have with regard to these issues? Does FTC have any knowledge of how online pharmacies prevent unqualified persons from receiving prescriptions? Are online pharmacies more susceptible to fraud or deception from FTC's perspective? If so, please explain how?

The Commission has not performed a comprehensive analysis of how online pharmacies deal with medical records or what steps are taken to protect consumer privacy. Some sites post privacy policies stating that all information provided will be kept confidential. It is clear, however, that consumers consider privacy, and particularly, privacy of medical information, very important. The Commission would consider it a deceptive practice if a company misrepresented its privacy policy.[15]

Pursuant to a requirement in Health Insurance Portability and Accountability Act of 1996 (HIPPA), the Department of Health and Human Services (HHS), in September 1997, submitted to Congress recommendations for standards with regard to privacy of individually identifiable health information contained in medical records.[16] Under Federal law, if Congress does not enact privacy legislation for medical records by August of this year, the Secretary of HHS is required by HIPAA to issue regulations providing protections for medical records. In anticipation, HHS staff is currently drafting a notice of proposed rulemaking that would cover

---

[13] The Commission is also aware of instances where consumers received unsolicited e-mail offering prescription drugs without a prescription. In these instances, law enforcement officials must rely on recipients to report the practice.

[14] 21 U.S.C. §§ 353(b)(1); 331(a), and 333.

[15] *See GeoCities*, FTC Dkt. No. C-3849 (Feb. 5, 1999) (consent)(Commission alleged that company misrepresented that personal identifying information collected would be used only for the purpose of providing to members the specific e-mail advertising offers and other products or services they request); *see also, Equifax, Inc.*, 96 F.T.C. 844 (1980), *rev'd on other grounds*, 678 F.2d 1047 (11th Cir. 1982)(deceptive to represent, inaccurately, that medical information would be released only to specified insurance companies).

[16] In its recommendations, HHS urged Congress to adopt broad Federal medical records privacy legislation covering disclosure and access issues. *See* Recommendations of the Secretary of Health and Human Services pursuant to Section 264 of the Health Insurance Portability and Accountability Act of 1996 (September 11, 1997). (Text available at <http//:www.aspe.os.dhhs.gov/adminsimp/PVCREC1.HTM>.)

health care providers, including online pharmacies, who transmit information electronically to obtain insurance reimbursement for their services. We understand that this proposal would provide a wide range of protections for consumers' medical and health records.

We have not identified any sites selling controlled substances. The DEA and States regulate the dispensing of controlled substances.

The Commission does not collect information concerning adverse consequences of taking a particular drug (adverse incidence reports). Nonetheless, staff has requested Pfizer, the manufacturer of Viagra®, and the states that have contacted us, to provide any information that they have concerning adverse reactions from patients purchasing online. To date, we have received no information.

As noted in our letter of July 12th, online pharmacies offer many potential benefits to consumers. The Commission does not consider that online pharmacies are necessarily more susceptible to fraud and deception than other types of pharmacies. Many online pharmacies operate in essentially the same manner as mail order pharmacies. Nevertheless, as discussed above, a number of the current practices of online pharmacies and of physicians who authorize prescriptions for potentially dangerous prescription drugs based only on information provided in a *pro forma* consultation form raise serious health and safety concerns.

9. What quality issues does FTC believe relate to the methods used to ship online pharmaceutical products, and does FTC believe it has jurisdiction in this area?

As indicated, absent an express or implied claim regarding quality issues related to the shipping of online pharmaceutical products, the Commission does not have jurisdiction over this matter.

10. Please describe what technology challenges the Internet has posed to FTC. Do you believe that FTC has the technology to adequately and efficiently regulate any identified activities under its jurisdiction? Please describe where at FTC the technology to review and track online pharmacy sites resides, and describe that effort.

The Internet has presented a number of technological challenges to effective law enforcement. In addition to the explosion in the number of web sites offering goods and services on the Internet, locating companies and responsible parties can be difficult. Commission staff has identified a number of online pharmacies that operate under names that are not licensed in any state. In addition, many sites do not provide useful contact information identifying their actual address or telephone number. Companies provide contact information in order to register an Internet site, but in our experience, this information is not always reliable. While physical locations and parties can usually be identified eventually, the process may require extensive investigations, and the resources to conduct these investigations, both at the state and federal level, are extremely scarce.

The Commission has the technology to investigate Internet marketing practices that violate the FTC Act. For example, its computer equipment permits staff to locate and preserve web sites for evidentiary purposes. We are continuing to upgrade our hardware and software to take advantage of new technology.

The Commission uses state of the art computer equipment and programs capable of locating and preserving web sites for evidentiary purposes. This equipment is housed at FTC

headquarters and in regional offices. The Commission does not attempt to monitor all Internet pharmacy sites. Commission staff has used available search engines to identify sites marketing popular prescription drugs. Additional sites have been located through advertisements for these drugs in newspapers. These advertisements frequently direct consumers to web sites. Once identified, staff may review the sites and recommend appropriate follow-up action or refer the matter to another federal or state agency with jurisdiction.

In your letter of June 29, 1999, you provided us with a list of ninety-four web sites. As to each of these sites you have asked the following questions:

(a) The physical location of each site, and in what States it sells its products;

(b) Whether the FTC has ever reviewed the site for <u>any advertising or usage claims</u> made regarding any pharmaceutical product(s) being sold; and,

(c) The <u>accuracy</u> of any such claims made by the site that fall under the FTC's jurisdiction.

For reasons articulated above, the actual physical location of a site and the states in which it sells products cannot be determined without an extensive investigation. The physical location of the site, if any, may not be relevant. In its investigations, Commission staff attempts to identify the physical location of the individuals operating the site, the physician authorizing the prescription, if any, and the pharmacy dispensing the drug. The information available on the sites and through sources such as Network Solutions is not necessarily reliable. In a particular case, collection of accurate information about the operators of a site and the identity of participating physicians and pharmacies may require use of Internet and non-Internet resources to (1) collect and verify information, (2) visit physical sites obtained through the web site or other sources to determine what is at a particular location, (3) make undercover purchases to identify pharmacies and physicians; and (4) use access letters, civil investigatory demands, and investigational hearing to collect information about the participants' business practices.

Commission staff has previously reviewed a number of the sites you provided. Where matters were discovered during the course of our investigations relating to possible violations of laws enforced by other federal or state agencies, referrals were made to those agencies.

FTC staff has not had an opportunity to review all of the sites you provided to determine the accuracy of the claims made on those sites. Representations made on a number of the web sites you provided to us raise concerns. A claim that exaggerates the effectiveness of an approved drug could violate the FTC Act. Safety is another concern. For example, a claim that Viagra® is totally safe, or has no, or minimal, side effects could mislead consumers. Commission staff will continue to review these sites for claims that may violate the FTC Act. Nonetheless, we are forwarding as an attachment to this letter the identifying information we have been able to determine to date from a review of the sites you provided to us.

We appreciate this opportunity to respond to your questions on this important issue and look forward to exploring possible solutions to the concerns raised in your letters.

By direction of the Commission.

Robert Pitofsky

ONE HUNDRED SIXTH CONGRESS

TOM BLILEY, VIRGINIA, CHAIRMAN

W.J. "BILLY" TAUZIN, LOUISIANA
MICHAEL G. OXLEY, OHIO
MICHAEL BILIRAKIS, FLORIDA
BARTON, TEXAS
UPTON, MICHIGAN
STEARNS, FLORIDA
PAUL E. GILLMOR, OHIO
JAMES C. GREENWOOD, PENNSYLVANIA
CHRISTOPHER COX, CALIFORNIA
NATHAN DEAL, GEORGIA
STEVE LARGENT, OKLAHOMA
RICHARD BURR, NORTH CAROLINA
BRIAN P. BILBRAY, CALIFORNIA
ED WHITFIELD, KENTUCKY
GREG GANSKE, IOWA
CHARLIE NORWOOD, GEORGIA
TOM A. COBURN, OKLAHOMA
RICK LAZIO, NEW YORK
BARBARA CUBIN, WYOMING
JAMES E. ROGAN, CALIFORNIA
JOHN SHIMKUS, ILLINOIS
HEATHER WILSON, NEW MEXICO
JOHN B. SHADEGG, ARIZONA
CHARLES W. "CHIP" PICKERING, MISSISSIPPI
VITO FOSSELLA, NEW YORK
ROY BLUNT, MISSOURI
ED BRYANT, TENNESSEE
ROBERT L. EHRLICH, JR., MARYLAND

JOHN D. DINGELL, MICHIGAN
HENRY A. WAXMAN, CALIFORNIA
EDWARD J. MARKEY, MASSACHUSETTS
RALPH M. HALL, TEXAS
RICK BOUCHER, VIRGINIA
EDOLPHUS TOWNS, NEW YORK
FRANK PALLONE, JR., NEW JERSEY
SHERROD BROWN, OHIO
BART GORDON, TENNESSEE
PETER DEUTSCH, FLORIDA
BOBBY L. RUSH, ILLINOIS
ANNA G. ESHOO, CALIFORNIA
RON KLINK, PENNSYLVANIA
BART STUPAK, MICHIGAN
ELIOT L. ENGEL, NEW YORK
THOMAS C. SAWYER, OHIO
ALBERT R. WYNN, MARYLAND
GENE GREEN, TEXAS
KAREN McCARTHY, MISSOURI
TED STRICKLAND, OHIO
DIANA DEGETTE, COLORADO
THOMAS M. BARRETT, WISCONSIN
BILL LUTHER, MINNESOTA
LOIS CAPPS, CALIFORNIA

JAMES E. DERDERIAN, CHIEF OF STAFF

U.S. House of Representatives
Committee on Commerce
Room 2125, Rayburn House Office Building
Washington, DC 20515–6115

July 1, 1999

Mr. Carmen Catizone
Executive Director
National Association of Boards of Pharmacy
700 Busse Highway
Park Ridge, Illinois 60068

Dear Mr. Catizone:

The Committee on Commerce has been investigating a number of issues pertaining to the sale of pharmaceutical products over the Internet. Committee staff have met with the Food and Drug Administration (FDA), Department of Justice (DOJ), Federal Trade Commission (FTC), and several state agencies involved in the regulation and sale of pharmaceuticals. These meetings have attempted to determine: (1) the extent of this problem, (2) the jurisdiction of each agency involved and the activities now being undertaken by each in this matter, and (3) specific changes to current law (if any) that might be needed to address this problem.

As you are well aware, pharmacies are regulated by state boards of pharmacies which work in conjunction with the appropriate state agencies to ensure that operating pharmacies are properly licensed and exercise suitable controls and practices over the distribution of pharmaceutical products. Although oversight of these "brick and mortar" pharmacies has been a relatively straightforward process, the emergence of Internet pharmacies poses significant challenges to the existing system. Online drug sites can now be located in almost any state or country having phone lines, yet easily sell to consumers anywhere in the U.S. market. To complicate matters further, some online pharmacies may not have a single location for a state to regulate, but may be located across several states or jurisdictions. For example, an online pharmacy might place its computers and offices in one state, its prescribing doctor(s) in another, and the actual pharmacy filling the prescriptions in a third state, all while the purchaser resides in a fourth state. Clearly, this situation creates significant challenges and risks for both regulators and consumers.

In response to public concern about the safety of these sites, the National Association of Boards of Pharmacy (NABP) has developed the Verified Internet Pharmacy Practice Sites (VIPPS) program. Essentially a "Good Housekeeping" seal of approval, this program is designed

to provide site users some assurance that a pharmaceutical site has received at least some scrutiny and meets certain standards. As NABP's Web site indicates, VIPPS pharmacy sites are identified by the VIPPS hyperlink seal displayed on each site's main page. By clicking on the seal, a visitor is linked to the NABP VIPPS site where verified information about the pharmacy is maintained by NABP.

While we agree that this is a laudable first step to the challenges posed by Internet drug sites, a host of problems still exist, and will probably continue to exist even after the VIPPS program is in place. For example, most sites now operate without any VIPPS seal, and it is unclear when or if the public will ultimately understand what the VIPPS does, or make purchasing decisions because of it. Moreover, some individuals appear to gravitate to fringe sites because of the very activities the VIPPS program is trying to prevent (e.g., the site doesn't require a prescription or the site requires only a dubious online consultation). Because VIPPS is a voluntary program, it is unclear how such an effort would ever address many of these unlicensed fringe sites. Finally, because NABP is not a regulatory authority, it is not clear to us whether NABP will have the resources to provide adequate scrutiny or review of all VIPPS-candidate sites or how it will enforce sanctions against any VIPPS operators should they later engage in bad practices.

Given the rapidly expanding nature of online pharmacies and the significant challenges they are presenting to both state and federal regulators, we are interested in knowing more about what NABP is doing generally about online pharmacies, and particularly more about the VIPPS program. Accordingly, we would appreciate it if your organization could respond to the following questions:

(1) Please describe the NABP standards that an online pharmacy must meet and maintain in order to acquire and keep a VIPPS accreditation.

(2) Please describe the steps each online pharmacy must go through to get a VIPPS accreditation, including: (a) the documents that must be filled out or the types of documents that must be submitted; (b) the components of a company that will be inspected by NABP and what such an inspection will entail; (c) the persons (and qualifications of the persons) conducting such inspections, and (d) the average cost expected for each inspection. Please also include your estimate of the average amount of time the entire application/inspection process will require.

(3) How many online drug sites does NABP currently believe are licensed by any State Board of Pharmacy? How many online sites does NABP estimate are currently selling prescription drugs to U.S. consumers without a license?

(4) How many online pharmacies have applied to the NABP for VIPPS accreditation and how many have you now inspected? Of such applicants, what kinds of VIPPS non-compliance issues has the NABP identified?

(5) Once an online site qualifies for a VIPPS seal, how often will NABP reinspect the site to determine if the Internet site is operating in a manner consistent with the NABP's original requirements? Further, since NABP is not a regulatory body, if a site deviates from NABP's requirements, what actions can or will NABP take to bring the site back into compliance? If a site disagrees with the NABP regarding any aspect of compliance, is there a resolution process? If a disagreement between a site and the NABP persists (e.g. the site remains non-compliant with NABP guidelines), will information about the site be provided to either state or federal regulators?

(6) Please provide a listing of the agencies and organizations that participated in developing the VIPPS program. Please also describe each agency or organization's role in this regard.

(7) Please describe how the individual State Boards of Pharmacy will prepare for this program. Does NABP believe they currently have the trained personnel and finances to implement this program on a state-by-state basis? If not, how long will it take to have such requirements in place?

(8) Will individual medical record privacy be included in the standards developed for accreditation by the VIPPS program? If so, please describe how this will be implemented and enforced.

(9) In cases where sites are offering prescription drugs without a license, what does NABP believe to be the source(s) of such drugs? E.g, are they possibly counterfeit? Are they possibly authentic drugs, but diverted from foreign or other sources? Please explain.

(10) Does the NABP believe there may be threats with hackers stealing the VIPPS seal and placing it on an unapproved site? What will prevent unscrupulous sites from fraudulently linking to the NABP web site or to a dummy site that attests that the web site is accredited under the VIPPS system? How secure will the actual NABP's VIPPS certification database be from outside infiltration by hackers? Are there other related problems you foresee in this area?

(11) When an individual links to the NABP web site through a VIPPS certification seal what exactly will the potential buyer discover? For example, will the user arrive directly at an information screen regarding the particular online web site they linked from, or will it be a general site from which they must search for information about the site in question?

(12) Will NABP be developing any efforts to educate consumers about the VIPPS program and the potential dangers of ordering pharmaceuticals over the Internet? Specifically, for example, how will a user know that a VIPPS certification seal makes an online pharmacy legitimate?

(13) Does NABP have a position on the suitability of so called "online consultations" where a doctor actually "reviews" patient information and then determines through this consultation if the patient should receive a prescription? Does the NABP have specific guidelines/criteria/standards for this type of site?

(14) If so, what guidelines/criteria/standards will you use to prove that there is a "meaningful consultation between a patient and a pharmacists"?

(15) Does the NABP have a position on how doctors' prescriptions should be handled in regard to online pharmacies? For example, what form of communication for a prescription does NABP find acceptable: mail, phone, fax, email, other? How will the authenticity of prescriptions under any of the NABP-approved communication methods be verified?

(16) Does the NABP perceive it as one of the functions of the State Boards of Pharmacy to seek out online pharmacies within the boundaries of their State? If so, how will the Boards carry out this task and what kind of action can they or will they take upon uncertified online pharmacies? If not, whose role is it to find online pharmacy web sites within a State's boundaries?

(17) Finally, how does NABP believe that the U.S. consumer should be protected from foreign online pharmacy sites?

Thank you for your cooperation and attention to our request. We look forward to continuing working with the NABP on these important consumer protection and public health issues. If you have any additional questions about this matter, please have your staff contact Mr. Christopher Knauer of the Commerce Committee minority staff at (202) 226-3400.

Sincerely,

JOHN D. DINGELL
RANKING MEMBER
COMMITTEE ON COMMERCE

RON KLINK
RANKING MEMBER
SUBCOMMITTEE ON
OVERSIGHT AND INVESTIGATIONS

nabp

National Association of Boards of Pharmacy

700 Busse Highway • Park Ridge, IL 60068
Tel: 847/698-6227 • Fax: 847/698-0124
Web Site: www.nabp.net

July 29, 1999

The Honorable Ron Klink
Ranking Member
Subcommittee on Oversight and Investigations

The Honorable John D. Dingell
Ranking Member
Committee on Commerce

United States House of Representatives
Committee on Commerce
Room 2125, Rayburn House Office Building
Washington, DC 20515-6115

Dear Representatives John D. Dingell and Ron Klink:

The National Association of Boards of Pharmacy (NABP) is the professional organization whose membership consists of the state boards of pharmacy in all jurisdictions of the United States, the Virgin Islands, Puerto Rico, Guam, nine provinces of Canada, three states in Australia, and New Zealand. NABP is pleased to respond to the inquiry by the U.S. House of Representatives Committee on Commerce regarding its Verified Internet Pharmacy Practice Sites™ (VIPPS™) program. NABP agrees with your observation that online pharmacies are rapidly expanding in number, services provided, and use by the American public. While the visible emergence of pharmacy practices on the Internet is a relatively new phenomenon, the statutory and regulatory controls of these entities are well established. Mail order pharmacies have operated in interstate commerce under effective regulation by state boards for quite some time. The bulk of Internet pharmacy practices fall under the regulations of mail order pharmacy practices, which has a long history of successful oversight and enforcement. The new challenges of pharmacies operating on the Internet arise from innovative adaptation of the front end of the operations i.e. the electronic interface between patient, prescriber, and pharmacy. The VIPPS criteria for certification address those specific new challenges while solidifying existing laws and regulations into a cohesive consumer protection program.

Though the expansion of pharmacy practices on the Internet has been rapid, the development of the VIPPS program has exceeded that pace. Though currently in the early implementation phase, VIPPS has already had a demonstrable impact on Internet pharmacy practices and their regulation.

- Public awareness has been raised by evidence of the more than 400 media events, which have warned the public of the risks and/or offered VIPPS as a means to minimize risks in obtaining pharmaceuticals through the Internet.

- Established and start up Internet pharmacies are reviewing, adapting, or creating their programs based on the VIPPS criteria as evidenced by the 742 visits to the Web site, 136 visits to the criteria page of our site, and the 96 downloads of the application forms in the last three weeks, as well as the large volume of phone inquiries NABP has received regarding program requirements.

Response to comments of general concerns

"It is unclear when or if the public will ultimately understand what the VIPPS does, or make purchasing decisions because of it."

Early in the development process, the NABP posed that question to consumer focus groups. Using a professional consumer survey company, focus group interviews were conducted employing an experienced discussion moderator and focusing on two primary groups of decision-makers in purchasing pharmaceuticals, mothers with young children and senior citizens. The comments, concerns, and advice from these groups have been incorporated into the fabric of the VIPPS program. They confirmed the need for the program, the credibility of NABP to run the program, and the seal format of the program. They directed us to who they would look to for advice in selecting a pharmacy and what means they would be most likely to hear of and respond to the VIPPS message. The focus groups were so involved they actually redesigned the VIPPS seal to one they would trust and look for. NABP believes that through the input of the focus groups and many others, we have a strategic plan that will educate the public in an easily understood manner on what VIPPS does, what it means to them, and how they can use it.

"Some individuals appear to gravitate to fringe sites <u>because</u> of the very activities the VIPPS program is trying to prevent (e.g. the site doesn't require a prescription or the site requires only a dubious online consultation). Because VIPPS is a voluntary program, it is unclear how such an effort would ever address many of these unlicensed fringe sites."

NABP agrees that it is difficult at best, probably futile, and possibly counter productive to force protective measures on those consumers and providers that adamantly reject it by aggressively seeking each other out to engage in knowingly risky, and sometimes illegal, interchanges. This is especially true in an environment so deeply founded in freedom as the Internet. NABP founded the VIPPS program on the belief that an educated and empowered public will choose wisely to avoid risk. VIPPS is committed to inform the public of the risks and to empowering them with the means to identify regulated sites for their prescription medications. Certain individuals will gravitate to dangerous and sometimes illegal sites regardless of what controls are in place. Our VIPPS program helps to identify those activities for presentation to the appropriate authorities.

"Finally, because NABP is not a regulatory authority, it is not clear to us whether NABP will have the resources to provide adequate scrutiny or review of all VIPPS-candidate sites or how it will enforce sanctions against any VIPPS operators should they later engage in bad practices."

As a professional association, NABP is in a unique position to enforce VIPPS criteria since

- the VIPPS criteria combines mandatory state pharmacy practice acts and expertly developed practice criteria; and
- since the members of NABP are those state boards empowered by law to enforce those practice acts; and
- since NABP's founding mission is to develop uniform standards and to serve the state boards as an enabling mechanism in fulfilling their legal responsibilities to protect the public health, safety, and welfare.

In addition to NABP's membership support in law enforcement, there is emerging support from third party payers and federal entitlement programs that may create a financial imperative as well as the legal imperative. The concept is not without precedence.

A number of successful cooperative programs have brought together professional, technical, and inspection expertise from the private sector with federal and state agencies. For instance, FDA has a memorandum of understanding with HCFA for HCFA to inspect and certify certain health services regulated by FDA. HCFA requires health services to be inspected and certified in order to receive reimbursement from Medicare. However, rather than inspecting all health services themselves, HCFA has entered into deemed status agreements with a number of associations including; Joint Commission on Accreditation of Healthcare Organizations, American Association of Blood Banks, College of American Pathologists and some state health agencies. Third party payers also frequently require providers to be accredited by certain associations as a prerequisite to participating in their health plans. Such agreements evolve over time with trust, legislative support, and collaborative dialogue.

Response to specific questions

1 "Please describe the NABP standards that an online pharmacy must meet and maintain in order to acquire and keep a VIPPS accreditation."

Response: An internet site/pharmacy earning the VIPPS seal must meet and demonstrate compliance with all mandatory licensure, statutory, and regulatory requirements of state pharmacy practice acts. There is no variance from this requirement. NABP's member boards will be responsible for this mandatory, legal aspect of the program. The sites will also adhere to and demonstrate adherence to twenty-one (21) specific criteria. The criteria are listed in "Attachment A." Compliance with current standards of pharmacy practice is assured by verification of licensure in good standing in the state where the pharmacy resides and submission of policy and procedure documents. Prior to inspection the most recent state inspection report is reviewed and continued compliance with corrected deficiencies confirmed as part of the inspection. The criteria are designed to address the unique aspects of interstate pharmaceutical practices through the Internet and are divided into eight categories: Licensure, Prescriptions, Patient Information, Communication, Storage and Shipment, Over-the-Counter Products, Quality Improvement Programs, and Reporting to NABP. Criteria number one requires NABP verification of licensure in good standing as a non-resident pharmacy in each state to which the pharmacy dispenses pharmaceuticals and which has non-resident pharmacy licensure laws.

The development of the criteria was an open, participative, and collaborative process. A wide breadth of organizations lent expertise in reviewing and revising the criteria. Representatives included federal agencies, state agencies, professional associations, trade associations, and representatives from Internet pharmacies. Press releases announced the posting of the criteria on the NABP Web site for a 30-day public comment period. Public comments were reviewed and incorporated into the criteria if warranted.

2 ***"Please describe the steps each online pharmacy must go through to get a VIPPS accreditation, including:***
(a) The documents that must be filled out or the types of documents that must be submitted;
(b) The components of a company that will be inspected by NABP and what such an inspection will entail.
(c) the persons (and qualifications of the persons) conducting such inspections, and
(d) the average cost expected for each inspection."

(e) the estimated average amount of time the entire application/inspection process will require.

Response: Process:

Step 1: Organizations applying for VIPPS certification begin the process by filing a seven page multi-part application. The application collects information about the Web site, the pharmacy, the business ownership, corporate officers, professional staff licensure and facility licensure, addresses and contact information for each facility, and services provided. The application also requires answers to questions regarding compliance with the criteria and description of some pharmacy processes. Examples of written policies, procedures, along with relevant logs and forms are required as evidence of compliance with each VIPPS criteria.

Step 2: NABP staff verifies Licensure in Good Standing for each pharmacy in each state to which they dispense pharmaceuticals. NABP also verifies appropriate licensure in Good Standing for the Pharmacist-in-Charge of each facility. Verifications are obtained directly from the state boards of pharmacy. NABP staff also search NABP national databases for additional unreported licenses and for any history of disciplinary action reported by any state board against the facility or Pharmacist-in-Charge.

Step 3: A team of NABP staff reviews the written policies, procedures, and other material submitted in support of the applicant's claim of compliance with the VIPPS criteria. A review of the Web site online is conducted. A written report of findings is prepared and sent to the applicant for response. Findings address completeness, comprehensiveness, and appropriateness of the procedures in addressing each criteria as well as licensure, and Web site issues. The applicant is asked to respond with revised or additional support documentation within a defined time period. A conference call is an available option if the applicant needs more direction in developing means to meet the intent of the criteria.

Step 4: The applicant's response is received, approved, and the inspection is scheduled. An inspection team is assigned and provided a copy of the last state inspection report, the application form, report of finding from the documentation review, responses, and issues list.

Step 5: The inspection team is generally comprised of an NABP staff member and one contracted inspector. Generally, the inspection will be completed in one day.

Step 6: The inspection report of findings and recommendations is prepared and sent to the applicant for response if any unresolved issues are reported.

Step 7: The applicant returns responses to any unresolved issues. If NABP management final review is satisfactory, the applicant is informed of the decision to award certification and a VIPPS letter of agreement is sent for signature. Finally, upon receipt of the executed letter of agreement, the applicant is given his identity code and password to enter a secure area of the Web site to obtain his coded seal. The verified information regarding the site is posted on the pharmacy's VIPPS data page.

(a) The Application Form and Letter of Agreement must be filled out. Applicant must submit policies, procedures, logs, forms, program descriptions, and release most recent state inspection report directly from the state board.

(b) Components of the company to be inspected depend on the size and organizational structure. The goal of the inspection is to further understand the organization and how the components interact to meet the intent of the VIPPS criteria. The Global approach is to determine if the policies and procedures submitted are readily available to staff. Are the staff knowledgeable of and trained in the policy and procedure, do the staff in fact follow the policy and procedure, and are there contingency plans and processes for problem resolution available for staff and management to follow. A representative sample of functions to be inspected include:

Human Resources	Process for verifying licensure in good standing in the hiring process Enforcement of patient confidentiality policy
Customer service/order entry	processes for assuring authenticity of and integrity of prescriptions Processes for handling calls for pharmacist in event of drug reactions and medication errors Processes for verification of patient, prescriber identity Processes for conducting drug recall notifications Educating patients on disposal of expired and unusable drugs Offer of consultation with pharmacist

Inventory management	Processes for recalls Storage and temperature monitoring Precursor substances control
Pharmacy staff	Medication error reporting and investigation Generic substitution compliance by state Conflict of law resolution Medication profile maintenance Prospective drug utilization review Patient confidentiality Precursor substances control
Shipping	Shipment traceability: Temperature maintenance USP Undue delay policy Recipient identification
Administration	Contracted services review: Confidentiality Quality Improvement Program NABP notification policy Policy on Policy control Contingency planning Ownership and compliance Web site security

(c) Inspection teams consist of an NABP staff member and a trained and experienced pharmacy inspector. Contracted inspectors are qualified healthcare professionals and/or experienced pharmacy compliance inspectors with experience in state or federal inspection programs. NABP staff qualified to inspect are qualified healthcare professionals and/or have experience and training in accreditation or regulatory compliance inspections. All inspectors undergo a minimum of one day standardized and documented training specific to VIPPS inspection procedures and are supervised as a trainee on at least two onsite VIPPS inspections. VIPPS inspectors record and report their observations utilizing standard inspection and investigative techniques and probes. Inspectors have ready access to VIPPS management while in the field and do not make independent judgment calls in the field. The VIPPS Interpretive Guide is always referenced to address issues of acceptable alternative means of compliance with criteria. NABP management determines final decisions on compliance.

(d) The cost for an inspection varies with the type and number of facilities and travel requirements to the site. The cost is $1,000 per day, per inspector plus travel expense. Most inspections can be done in one day, with one or two inspectors.

(e) The estimated average time to complete the application/verification/document review/ report/response/inspection/report/response/approval process is 6-8 weeks.

3 ***How many online drug sites does NABP currently believe are licensed by any state board of pharmacy?***
How many online sites does NABP estimate are currently selling prescription drugs to U.S. consumers without a license?

Response The answer to these seemingly simple questions involve some further definition. First, though the pharmacy supporting a site may be licensed in one state, it may well not be appropriately licensed in the other states that require licensing. Further, one Web site may represent many licensed pharmacies and conversely one pharmacy may support many different Web sites. The former is particularly true of legitimate large mail order pharmacies, the later of entrepreneurs attracting business through a network of sites advertised through broadcast e-mail. Therefore, a Web site count does not equal a pharmacy count. Some important considerations:

- To find a practice site by surfing, requires that the site be listed on one of the search engines or directories using key words. Most clandestine sites do not register in order to avoid detection by authorities and rely on broadcast e-mail to attract customers to a site that may be only a transfer site and only active for a few hours or days before being abandoned.
- Surfing the Web depends on searching for key words. However, most searches to date have focused on English words and ignore large groups of minorities, which, due to cultural differences, may be particularly open to purchasing pharmaceuticals from unverified sources.
- NABP's investigations suggest there are a large number of referral sites, which lead back to a small number of domestic dispensing sites operating outside of good medical practices. Therefore, the magnitude of unethical perveyors of pharmaceuticals on the Web may be grossly overstated.

NABP has identified approximately 150 sites that appear to be operated by legitimate pharmacy practice entities. Most sites are licensed with at least one state board of pharmacy. Many of the sites are licensed/registered in a multiple of states.

4 ***How many online pharmacies have applied to the NABP for VIPPS accreditation?***

Response The program is in its very early implementation phase. The program was opened for applications four weeks ago. It takes considerable time and resources for an organization to gather and submit the quantity of information and documents required. At the time of this writing, four organizations representing over 20 pharmacy facilities have submitted applications. Further, NABP staff receives 2-3 calls per day from organizations involved at some stage in preparation of their application.

How many have you now inspected?

Response None. First inspections are scheduled in two weeks.

5 ***Once an online site qualifies for a VIPPS seal, how often will NABP re-inspect the site to determine if the Internet site is operating in a manner consistent with NABP's original requirements? Further, since NABP is not a regulatory body, if a site deviates from NABP's requirements, what actions can or will NABP take to bring the site back into compliance? If a site disagrees with NABP regarding any aspect of compliance, is there a resolution process? If a disagreement between a site and the NABP persists (e.g. the site remains non-compliant with NABP guidelines), will information about the site be provided to either state or federal regulators?***

Response VIPPS sites will be monitored continuously for disciplinary actions taken by any state and reported through the NABP national Disciplinary Clearinghouse. The information on the disciplinary Clearinghouse periodically updates the licensure status data on the VIPPS Web site data page so the public will be notified within days of the filing of a final disciplinary report. By the terms of the VIPPS Letter of Agreement, NABP may re-inspect a VIPPS facility upon the occasion of the annual renewal of certification, upon receiving a complaint or if NABP becomes aware through its own or any other means that a violation of a VIPPS criteria has occurred, if requested by a VIPPS pharmacy in the process of a seal revocation action, or as part of the VIPPS random inspection program.

The random inspection program involves a drawing at random of one third of VIPPS certified pharmacies to be re-inspected each year. Inspections will be scheduled in advance, but it is NABP's intent that the inspection will be completed no more than three months after the pharmacy is notified. No pharmacy will be inspected more frequently than once every three years based on the random inspection program alone and none will be inspected less frequently than once every three years.

The VIPPS Letter of Agreement prescribes in detail: the terms and procedures to be followed for the decertification of a site, revocation of the seal, and appeal process in the event of an alleged violation of any VIPPS criteria. NABP is committed to taking any and all available legal actions to aggressively defend the VIPPS seal from use on an unauthorized site or continued use by a decertified VIPPS site. In the case of a continued and unresolved violation of a VIPPS criteria which is grounded in the state pharmacy practice act, NABP recognizes its obligation to notify the appropriate member state board of pharmacy and aid in its investigation and disciplinary action procedures. Legal disciplinary actions that state boards of pharmacy can and do exercise include:

Probation—a restriction of pharmacy practice for a specified period of time.
Surrendered—license is relinquished by the licensee and is void.
Suspension—the withdrawal of the license for a specified period of time.
Revocation—the withdrawal of the license. A pharmacy no longer has the privilege to conduct business in the state. The person no longer has the privilege to practice in the state.
Monetary fines
Letters of Reprimand

A state board of pharmacy may take disciplinary action against the pharmacy's license and against license of the Pharmacist-in-Charge. Once a state board reports a disciplinary action to NABP, the action is distributed through the Disciplinary Clearinghouse. The report includes a listing of other state licenses held by the disciplined entity. Frequently, the other state boards from which the entity holds a license then launch their own investigation and also take disciplinary action against the entity.

In cases where an accreditation is granted deemed status and the entity has used the accreditation to satisfy qualifications for licensure or participation in a third-party plan or entitlement program, the revocation or failure to renew the accreditation usually signals the agency awarding the deemed status to suspend payments and initiate independent investigations or inspections.

6 ***Please provide a listing of the agencies and organizations that participated in developing the VIPPS program. Please also describe each agency or organization's role in this regard.***

Response The following list of organizations lent expertise in the development of the VIPPS criteria either through participation at the March Task Force meeting where the proposed criteria were first presented, discussed and debated, and/or by submitting written comments during the open public comment period.

	Meeting	Comments
American Medical Association (AMA)	*	*
CPA WebTrust		*
Drugstore.com	*	*
ePills.com		*
Express Scripts, Inc.	*	
Federal Trade Commission (FTC)	*	
Federation of State Medical Boards of the U.S. (FSMB)	*	
U.S. Food and Drug Administration (FDA)	*	*
Medi-Mail Incorporated		*
Missouri State Board of Pharmacy	*	
National Association of Chain Drug Stores (NACDS)	*	*
National Community Pharmacists Association		*
New Hampshire State Board of Pharmacy	*	
PCS HealthSystems		*
Pharmaceutical Research & Manufacturers of America	*	
PlanetRx.com	*	
Rx.com		*
RxUSA		*
SOMA.com	*	
U.S. Drug Enforcement Administration (DEA)	*	*

7 ***Please describe how the individual state boards of pharmacy will prepare for this program. Does NABP believe they currently have trained personnel and finances to implement this program on a state-by-state basis? If not, how long will it take to have such requirements in place?***

Response Individual state boards need make minimal preparations to support the VIPPS program. NABP believes that the boards already have adequate regulatory authority and resources to carry out their charge of inspection, licensure, investigation and implementation of disciplinary actions as necessary. NABP has staff employed or available on contract to carry out the requirements of the VIPPS

program. VIPPS management includes staff, which have previously created international programs in healthcare improvement, developed inspection and regulatory compliance programs with national scope and served in credentialing programs awarded deemed status by entitlement programs and licensing agencies. Staff currently involved with the program include individuals licensed in pharmacy, attorneys, and trained law enforcement agents. The role of the boards will be to increase communication efforts about identified sites and the initiation of complementary disciplinary actions.

8 ***Will individual medical record privacy be included in the standards developed for accreditation by the VIPPS program? If so, please describe how this will be implemented and enforced.***

Response Yes, one of the central criteria for VIPPS certification is maintain and enforce a procedures to assure patient confidentiality and protect patient identity and patient specific information from inappropriate or non-essential access, use, or distribution. The NABP Guidelines for the Confidentiality of Patient Health Care Information as it relates to patient compliance and patient intervention programs serves as a useful benchmark for addressing the confidentiality and security of patient data. Inspectors will assure that policies and procedures are known to and followed by staff and disciplinary measures are in place for any employee committing a breech of the policy.

9 ***In cases where sites are offering prescription drugs without a license, what does NABP believe to be the source(s) of such drugs? E.g., are they possibly counterfeit? Are they possibly authentic drugs, but diverted from foreign or other sources? Please explain.***

Response NABP has no direct knowledge of the sources of drugs distributed by unlicensed/unregulated sites. In cases where physicians are prescribing and dispensing to patients as part of their licensed practice, the source may be legitimate licensed wholesalers since the physician's scope of practice in many states includes prescribing and dispensing medication to their "patients." International sites or domestic Internet sites using international companies as fulfillment centers may be distributing authentic drugs, counterfeit drugs, stolen drugs, or simply not delivering the goods that have been paid for.

10 ***Does the NABP believe there may be threats with hackers stealing the VIPPS seal and placing it on an unapproved site? What will prevent unscrupulous sites from fraudulently linking to the NABP Web site or to a dummy site that attests that the Web site is accredited under the VIPPS system? How secure will the actual NABP VIPPS certification database be from outside infiltration by hackers? Are there other related problems you foresee in this area?***

Response Due to the public and open nature of the Web, it is not possible to secure text or images that must also be anonymously viewable. The VIPPS seal is simply a graphic display and the Internet affords no means to prevent copying of <u>any</u> graphic display or material. However, NABP has taken steps to secure access to the original logo and image file and to make any unauthorized copying reportable to NABP for legal action to be taken by NABP against the unauthorized user.

The VIPPS seal is not only an image, but also a link to a database maintained by NABP. The message NABP is promoting to the public is "Look for the seal – Click to verify." The following elements are crafted into a security system, which NABP believes, is adequate to protect the integrity of the VIPPS program and protect the public trust.

- The seal posted on certified sites incorporates as an integral part of the design the words "Click to Verify" indicating the significance of the seal image.
- When a cursor passes over the VIPPS seal, a pop-up flag appears telling the visitor to click to verify the credentials of (name of the site).
- HTML code underlying the seal controls the flag and links the user to a unique domain dedicated to VIPPS inquiries from seals.
- The programming at the VIPPS domain captures the URL (Internet address) from which the inquiry came and searches the database for a matching authorized URL. If found, the verified information for that site is displayed. If not found, a message is displayed informing the user that the Web site is not VIPPS certified and the Web site may be fraudulently using the seal. It then invites the user to report the site to NABP and provides an opportunity to report the Web site.
- The NABP domain is programmed to automatically e-mail the URL of the referring site to VIPPS staff and the NABP Web site provider whenever a referral is received from a URL that is not listed in the database as an authorized site. This provides a means for NABP staff to police uncertified Web sites that attempt to link to the VIPPS Web site with or without having modified the underlying HTML code.

An unscrupulous site operator could develop a separate domain which a fraudulently manufactured VIPPS seal on their site would link to and design that domain to look like the NABP Web site domain. This elaborate rouse could be effective for a user who performs only a casual verification. However, NABP has also taken measures to alert the public of this kind of fraudulent activity.

- The NABP domain which the seal links to begins with an introductory page which describes NABP and provides a hyperlink and Web site address for the public to access the NABP Web site where the full VIPPS program Web site is available. The full VIPPS Web site allows users to search the database of VIPPS verified sites to find a pharmacy practice site that meets their needs or to search the database to verify a site's certification or to simply view a list of all certified sites.
- The full VIPPS site contains a feature called Web Watch in which the public is invited to complete a short form to report suspicious or fraudulent Web sites to NABP. NABP will, on a best effort basis, attempt to identify the location and report the suspicious site to the most appropriate regulatory agency. If the site is fraudulently using VIPPS's logo, NABP will initiate legal action against the operator. The VIPPS logo is trademarked.

The NABP Web site and underlying VIPPS database is hosted on a Microsoft Windows NT 4.0 server and published via Microsoft Internet Information Server 4.0. The Windows NT 4.0 is currently undergoing testing by the National Computer Security Center (NCSC) (an arm of the National Security Agency (NSA) Trusted Computer System Evaluation Criteria (TCSEC). Windows NT 4.0, found to meet all requirements will receive "C2" certification, the highest TCSEC evaluation rating that can be obtained by a general-purpose operating system. Windows NT 4.0 is an upgrade version to Windows NT 3.51, which is C2 certified. In order to effectively "infiltrate" the VIPPS database, access to the database would not only need to be gained but modifications and additions would need to be made and then access gained to place the modified information back on the server, which is an even more complicated process. NABP feels that the security provided by the Windows NT 4.0 operating system provides adequate protection against unauthorized access. However, NABP has taken yet an additional step to thwart potential hackers from modifying its verified information database.

The information on the Web site is a subset of the master NABP database. They are two separate unlinked servers in two physically separate locations. NABP periodically refreshes the Web site database from the master database so any unauthorized modification to the information on the Web site database would be short-lived.

NABP believes the above protective steps adequately protect the public's access to accurate verified information via the VIPPS program.

11 ***When an individual links to the NABP Web site through a VIPPS certification seal, what exactly will the potential buyer discover? For example, will the user arrive directly at an information screen regarding the particular online Web site they linked from, or will it be a general site from which they must search for information about the site in question?***

Response By clicking on the seal, the user is linked to a dedicated VIPPS domain. Here, the Web site captures the URL address the user has been referred from and checks against the database for an authorized listing. The welcome screen describes NABP and the VIPPS program and offers a hyperlink to the main NABP Web site, where more extensive information about the program is maintained and a search for a VIPPS site may be conducted. Back on the dedicated VIPPS domain, the user has two option buttons. One brings up the data screen for the site they just came from and one returns them to that site. A sample data page appears in "**Attachment B.**" The data page lists:

- the name and URL of the site,
- name and address of the pharmacy that actually fills the prescriptions,
- name and license information for the Pharmacist-in-Charge,
- name address, date and state of incorporation and CEO of the corporation which owns the Web site/pharmacy,
- the 1-800 phone numbers and e-mail addresses for contacting the pharmacy and corporate offices,
- states of licensure, license number, and automatic reference to the national database for any disciplinary action taken by a board of pharmacy against the registrant, and
- a link to each of the licensing state's board of pharmacy Web site if the user wishes to further inquire about the licensed pharmacy.

When finished reviewing the data, a click on the return button returns the user to the Web site with the seal he originally clicked on.

12 ***Will NABP be developing any efforts to educate consumers about the VIPPS program and the potential dangers of ordering pharmaceuticals over the Internet? Specifically, for example, how will a user know that a VIPPS certification seal makes an online pharmacy legitimate?***

Response NABP has been working with the news media to increase awareness of the risks of purchasing drugs from unverified Internet pharmacy practice sites and to inform the public of the operation of the VIPPS program. Over 400 news pieces have appeared in print or on radio or television as of the time of this writing. NABP will implement its strategic plan for informing the public beginning in the early fall of 1999, after the first seals are awarded and the database is populated. The VIPPS and NABP Web sites are being registered with the ten most active search engines identified from our search for Internet pharmacies. The key word list used to register the NABP and VIPPS sites includes the same words the Internet pharmacy Web sites have been registered under. A conscientious effort is being made to list VIPPS as a link on the most popular and respected healthcare information sites used by the target audience. In addition, NABP will use the information from the VIPPS focus group interviews to identify and recruit the most trusted and influential organizations and individuals to deliver information about VIPPS to the target audience and the general public. Internet information channels, links from state board of pharmacy Web sites, and public service announcements will be added to the ongoing news media support as the first phase of the plan is implemented.

13 ***Does NABP have a position on the suitability of so called "online consultations" where a doctor actually "reviews" patient information and then determines through this consultation if the patient should receive a prescription? Does the NABP have specific guidelines/criteria/standards for this type of site?***

Response NABP supports the position of the AMA and of many state boards of medicine that a valid physician-patient relationship must be established in order to prescribe medication in good practice and that a "face-to-face" interactive consultation is one of the requirements to establish such a relationship. NABP considers the use of questionnaires and cyberspace consultations as invalid patient-physician relationships and the basis for illegal activities.

14 ***If so, what guidelines/criteria/standards will you use to prove that there is a "meaningful consultation between a patient and a pharmacist"?***

Response See response to question 13.

15 ***Does the NABP have a position on how doctors' prescriptions should be handled in regard to online pharmacies? For example, what form of communication for a prescription does NABP find acceptable: mail, phone, fax, email, other? How will the authenticity of prescriptions under any of the NABP-approved communication methods be verified?***

Response NABP requires VIPPS certified pharmacies to follow the requirements of the state of origin of the prescription. Many states accept faxed prescriptions. VIPPS criteria require the pharmacy to have an effective policy and procedure in place that assures the integrity and authenticity of the prescription drug order and seeks to prevent prescription drug orders from being submitted, honored, and filled by multiple pharmacies. NABP recognizes the intent of the criteria may be met by different procedures, and so has not created a limited list of acceptable means at this time.

16 ***Does the NABP perceive it as one of the functions of the state boards of pharmacy to seek out online pharmacies within the boundaries of their state? If so, how will the boards carry out this task and what kind of action can they or will they take upon uncertified online pharmacies? If not, whose role is it to find online pharmacy Web sites within a state's boundaries?***

Response NABP does not view it the requirement of state boards of pharmacy to run active programs to continuously surf the net for unlicensed sites, but to respond to requests for investigation of sites reported to the board as suspicious and operating out of their state or dispensing to citizens within their state. State boards may cooperatively investigate a site within their jurisdiction for another board. Failing appropriate, timely, action by a state board, the complaining board my investigate and discipline a non-resident license independent of the state board of residence. Actions may include fines, and/or license suspension, probation or revocation.

The Missouri Board of Pharmacy recently issued a restraining order for a site/pharmacy located outside of Missouri and not licensed by the Board. The action is pending, but has required the site/pharmacy to post a notice to consumers on its site of its prohibition to dispense pharmaceuticals in Missouri. States will also be using disciplinary data from NABP to take complementary actions that could result in a site/pharmacy being prohibited from dispensing pharmaceuticals in all 50 states.

17 ***Finally, how does NABP believe that the U.S. consumer should be protected from foreign online pharmacy sites?***

Response NABP believes the regulation of pharmaceuticals between countries may best be controlled by cooperative enforcement programs between federal agencies of foreign governments and educating the consumer through our VIPPS program.

If I can be of further assistance, please do not hesitate to contact me.

Sincerely,

NATIONAL ASSOCIATION OF
BOARDS OF PHARMACY

Carmen A. Catizone, MS, RPh
Executive Director/Secretary

CC/gd
Enclosures

cc NABP Executive Committee

Attachment A

VIPPS™ Criteria

Licensure

Qualifying VIPPS Pharmacies (See definitions) will:

- 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;
- Provide NABP with the information necessary to verify that all persons affiliated with the site through contractual or other responsible arrangements and who are engaging in the practice of pharmacy are appropriately licensed or registered and in good standing in all applicable jurisdictions; and
- Agree to comply with all applicable statutes and regulations governing the practice of pharmacy where licensed or registered. When a conflict arises between individual state laws, the VIPPS Pharmacy will agree to comply with the more stringent law or regulation that applies as determined by conflict-of-law rules. Similarly, when a conflict arises between state and federal laws/regulations, the VIPPS Pharmacy will agree to comply with the more stringent law or regulation that applies as determined by conflict-of-law rules.

Prescriptions

VIPPS Pharmacies, in accordance with applicable state and federal laws/regulations, will:

- Maintain and enforce a procedure that assures the integrity, legitimacy, and authenticity of the Prescription Drug Order and seeks to prevent Prescription Drug Orders from being submitted, honored, and filled by multiple pharmacies; and
- Maintain and enforce a procedure that assures compliance with applicable generic substitution statutes/regulations and prohibits unauthorized therapeutic substitutions occurring without the necessary patient or prescriber authorizations and outside of the conditions for participation in state or federal programs, such as State Medicaid.

Patient Information

VIPPS Pharmacies, in accordance with applicable state and federal laws/regulations, will:

- Maintain and enforce a procedure and/or process ensuring reasonable verification of the identity of the patient, prescriber, and, if appropriate, caregiver in accordance with applicable state law;
- 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;
- Conduct prospective drug use review (DUR) prior to the dispensing of a medication or device in accordance with applicable state law; and
- Maintain and enforce procedures to assure patient confidentiality and protect patient identity and patient specific information from inappropriate or non-essential access, use, or distribution. [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

VIPPS Pharmacies, in accordance with applicable state and federal laws/regulations and VIPPS program criteria will:

- Maintain and enforce a procedure for the pharmacist(s) to offer interactive, meaningful consultation to the patient or caregiver;
- Establish a mechanism for patients to report and the VIPPS Pharmacy to take appropriate action regarding suspected adverse drug reactions and errors;
- Maintain and enforce a procedure that provides a mechanism to contact the patient and prescriber, if necessary, if an undue delay is encountered in delivering the prescribed drug/device. Undue delay is defined as an extension of the normal delivery cycle sufficient to jeopardize or alter the patient treatment plan; and
- Maintain and enforce a procedure to inform and educate the patient or caregiver about drug recalls and appropriate means to dispose of expired, damaged, and unusable medications.

Storage and Shipment

VIPPS Pharmacies, in accordance with applicable state and federal laws/regulations and VIPPS program criteria, will:

- Ship controlled substances via a secure and traceable means; and
- Comply with United States Pharmacopeia (USP) standards for the storage and shipment of medications/devices to patients.

Over-the-Counter Products

VIPPS Pharmacies will:

- 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

VIPPS Pharmacies will:

- Maintain a Quality Assurance/Improvement Program.

Reporting to NABP

VIPPS Pharmacies will:

- Provide and maintain a link from the VIPPS Seal on the pharmacy's Web site to the VIPPS Web site in a form and manner acceptable to NABP;
- Notify NABP within 30 days of any change of information provided as part of the verification process or involving data displayed on the VIPPS Web site.
- Notify NABP of any change to the Pharmacist-in-Charge.

Reporting by NABP

VIPPS Pharmacies will receive from NABP:

- A listing on the VIPPS Web site, provided the listing is not deemed an endorsement of the listed pharmacy by NABP for the quality of care provided, and is not utilized by the VIPPS Pharmacy in advertisements inferring such an endorsement; and
- A licensing agreement permitting the VIPPS site to display the VIPPS Seal on its Web site, provided the advertisement or promotion does not imply an endorsement by NABP of the VIPPS Pharmacy, its services, or its products.

Disclaimer

Last Modified: July 26, 1999

TOP

Copyright ©1999 by National Association of Boards of Pharmacy.

Web Business Name
nabp.webitects.com

Pharmacy Name
Pharmacy Name

Web Business Name
Web Business Name

Address
205 West Wacker Drive Suite 513
Chicago, IL 60606

Phone
312.357.1360

Pharmacist in Charge
Sandy Snyder

Corporation
Pharmacy Conglomeration, Inc.

Phone
312.123.4567

Address
One Conglomeration Plaza
Chicago, IL 60606

CEO
Paul Baker

State of Incorporation
IL

Years Incorporated
1

State of Licensure	State License Number	State Board Website	Disciplinary Actions
HI	123-789	None Available	No
IN	4312-22-837	www.ai.org/hpb/isbp/	No
WV	xxmodified	None Available	No
WY	654-321	soswy.state.wy.us/director/boards/pharmacy.htm	No

Services Offered

Provide General Medical / Pharmaceutical Information Via Link
Vitamins and Nutritionals

To report medication / device problems:

Click www.pharmacy.com/drugcompliance/ or call 847.698.6227

To report business compliance problems:

Click www.pharmacy.com/compliant/ or call 847.698.6227

Date First Verified
April 15, 1999

Next Verification Date
April 15, 2000

Disclaimer

Last Modified: June 16, 1999

Welcome to the VIPPS information and verification site of the National Association of Boards of Pharmacy.

The National Association of Boards of Pharmacy (NABP) was established in 1904 to assist state licensing boards in developing, implementing, and enforcing uniform standards to protect the Public Health. Pharmacy boards from fifty states, the District of Columbia, three U.S. territories, nine Canadian provinces, and four Australian states make up the association membership.

In response to public concern of the safety of pharmacy practices on the Internet, the association developed the Verified Internet Pharmacy Practice Sites (VIPPS) program in the spring of 1999. A coalition of state and federal regulatory associations, professional associations, and consumer advocacy groups provided their expertise in developing the criteria which VIPPS certified Pharmacies follow.

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 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. The public is also welcome to access the VIPPS site at www.nabp.net to search for a VIPPS Internet pharmacy, which matches their needs.

We at NABP hope you find the information helpful and invite your comments to continuously improve our service to you.

To verify the **nabp.webitects.com** site click on the link at the bottom of this page.

Disclaimer

Last Modified: June 2, 1999

Copyright ©1999 by National Association of Boards of Pharmacy.

Mr. KLINK. In response, and in the same vein, Dr. Woodcock, on June 14 we sent to Commissioner Henney a letter asking a number of questions, and we finally did get a response. It took a great deal of time, but in the response absent was response to question number 4, and you won't need the letter in front of you. I will read this to you. We asked as part of the response, please provide the committee the following information regarding the enclosed copies of Internet sites—and you saw the stack of sites if you were here earlier—the physical location of the site; what State they sell their products in; a description of the products sold through the site; the source of such pharmaceutical products sold through the site; whether the site is licensed in the U.S.; if so, by what States; if not licensed in the U.S., please determine whether the site is licensed by a foreign regulatory authority; or, if at all, whether the site has ever been reviewed; the site for any advertising or usage claims made in regard to any pharmaceutical product sold, and the accuracy of such claims that were made by the site that fall under FDA's jurisdiction.

Those items were not responded to. I would simply ask if you would work post haste, if you could, when you get back to FDA, to see if we can get some responses to that because this really gets to the guts of the matter that we are dealing with here.

Ms. WOODCOCK. Certainly. I think it also illustrates that a lot of investigative work is required at the current time for any site to get the kind of information that you're talking about for any site that's simply a—a Web site in cyberspace. It requires a fair amount of investigation to see what's actually behind that, and it may be, as other witnesses said, that numerous other corporations or entities may be involved in shipping, billing, obtaining medicine and so forth.

[The following was received for the record:]

The June 14, 1999 letter from the Chairman and various Members of the Commerce Committee asked several detailed questions regarding 104 web sites, primarily selling Viagra, that were enclosed with the letter. In our July 30 response letter, we indicated that FDA had not developed information at that time on most of the Internet web sites. FDA has performed WHOIS searches on domain name registrars to identify the administrators of these operations and their locations. A WHOIS search enables persons to obtain information about or related to a domain name registration record.

The results of these WHOIS searches indicate that 75 of the sites list a domestic address and 28 list a foreign address. Using the basic information obtained from this search, FDA is further evaluating the sites using the process described in our testimony of July 30. The Agency's Internet case assessment team (consisting of representatives from the office of Enforcement and the Office of Criminal Investigations (OCI) within the Office of Regulatory Affairs and a representative from CDER) is reviewing information on the sites and will make referrals for further investigation, as appropriate, to FDA compliance and field offices and to state regulatory agencies and/or pharmacy board representatives. If warranted, such referrals could result in regulatory compliance or civil enforcement actions, professional board disciplinary actions, or criminal prosecution.

We will provide the Committee with additional information as our evaluations and activities proceed.

Mr. KLINK. If I could just interrupt, I know there's a lot of work, I know there's a lot of sites, and we held them up. We sent the same letter to the Federal Trade Commission after we sent the letter to the Food and Drug Administration. They were able to answer, and you weren't, and I am bothered by that. I am troubled.

They showed up, they have their analysis, and we have nothing by the FDA.

Can you tell us what—how many people are being put on the case to determine how many of these sites are and whether or not you believe that any of them have the appropriate State licenses? How many people are looking at that, and do you have any determination as to whether or not any of these sites are licensed and how many there are?

Ms. WOODCOCK. What we have found is 104 sites.

Mr. KLINK. You found 104?

Ms. WOODCOCK. Yes.

Mr. KLINK. We found 200. So apparently we have done a better job of looking for the Easter eggs than you have. Does that bother you? We have got three people on the minority side staff. How many people do you have working at the FDA?

Ms. WOODCOCK. Total people at the FDA?

Mr. KLINK. Yeah, how many total people?

Ms. WOODCOCK. There are 9,000 people.

Mr. KLINK. You have 9,000; we've got three. You found 104; we found over 200, and we're still finding, and we understand there is over 400. That is troublesome. How many of the 9,000 people are working on this?

Ms. WOODCOCK. I can't give you a specific answer.

Mr. KLINK. Do you suppose that you can later on once you go back and check it out?

Ms. WOODCOCK. Yes.

[The following was received for the record:]

At the present time, there are four people reviewing the 104 web sites provided by the Committee. These individuals have been assisted by additional staff at various times, including persons providing technical assistance. It should be stressed that review of these sites is an involved process. A web site is examined and a full check is run on all of the potential links as well as the data known about the web site itself. This entails a complete analysis through various databases identifying all known addresses, credit records, law enforcement records and other comprehensive information. As the review progresses and expands, more people are being involved. The number of people will increase again if the Internet assessment team determines there is a need to pursue additional action with respect to any Internet site.

There are about 10 FTEs (full time equivalent personnel) devoted to the issue of regulating illegal activity in which the Internet may play a role. It is anticipated that this will increase gradually to 20 FTEs as resources are shifted to address the increased activity expected in this area.

Mr. KLINK. I understand that you made an announcement today that you are going to expand your surveillance, and I mentioned before this panel came up, we've had promises before that this is a new day, we have got a new task force, we have got a new initiative. Yet you come here today to say that you have seen 104 sites. How many of those sites are licensed?

Ms. WOODCOCK. I will have to consult with my colleagues.

Mr. KLINK. Of the sites you looked at, of the 104 you found, how many actually have a license?

Ms. WOODCOCK. I'd like to introduce Jeff Shuren if I may.

Mr. KLINK. Jeff, are you sworn in?

Mr. SHUREN. No, I'm not.

Mr. KLINK. Mr. Chairman, would you swear him in, please.

[Witness sworn.]

Mr. KLINK. If you'd introduce yourself, speak into the mike.

Mr. SHUREN. My name is Jeffrey Shuren. I'm a medical officer at the FDA.

The 104 sites we were referring to are the sites that you sent to us, and what we did is——

Mr. KLINK. So you found the sites that we sent to you?

Mr. SHUREN. No. You asked us to look at those sites.

Mr. KLINK. Oh, okay. How many sites are you aware of total then?

Mr. SHUREN. An exact number I can't tell you. We've looked at hundreds.

Mr. KLINK. Hundreds; 200's, 300's, 400's, 900's? There are hundreds. There's a lot of hundreds. Give us an idea, if you would.

Mr. SHUREN. I'd be estimating. I'd say to the 300 to 400's at this point.

Mr. KLINK. 300 to 400. How many of those are licensed?

Mr. SHUREN. I could not tell you the number that are licensed.

Mr. KLINK. Are you looking at how many of them are licensed, and what methodology are you using to determine, A, how many sites there are and, B, whether or not they are licensed?

Mr. SHUREN. Well, in terms of whether the site is licensed as a pharmacy, traditionally the States have regulated that. We do not have authority over the licensing of pharmacies. In fact, under our statute pharmacies are exempt from registering with FDA. What we did do with those sites that you sent to us, is conduct a "who is" search on domain name registrars to try to find out the name of the contact person and the location of those sites. As a result of this search, we found that 75 of those sites are domestic, 28 of those sites are foreign.

Mr. KLINK. Now, where does the consumer go today to determine whether or not it is safe to buy pharmaceutical supplies or pills or whatever else from these sites? We have already heard from the States. They are ill-equipped. These things are coming in from outside the country. They are post office boxes and warehouses that are moving around from one location to another. We have discussed with the FDA, with the Department of Justice, with the FTC all of these problems for many months. Where does the consumer go to find protection? And if we are so concerned about not impeding the growth of the Internet, what about those students that Ms. Egan told us about in the past panel from Philadelphia who acquired the ingredient from cough syrup over the Internet and were injured? And what about the potential for death from taking these drugs? Who is protecting the American public? Which one of your agencies is doing it? What activities have you undertaken in cooperation with the States to make sure that the health and the safety of the American public is, in fact, being protected?

Ms. WOODCOCK. Let me tell you about what actions we will be taking. We have acquired what's called a Web crawler which is a technology that will enable us to rapidly scan sites and locate sites that are illegally selling drugs. We are shifting more of our criminal investigators onto investigating these sites.

Mr. KLINK. How many more? Percentagewise, total number, how many people?

Ms. WOODCOCK. We are doubling our resources from now on.

Mr. KLINK. From what to what?

Ms. WOODCOCK. We estimate we have about 10 people right now working specifically on Internet full time.

Mr. KLINK. Full time, thank you.

Ms. WOODCOCK. So we will double that to 20. We are working, as I said in my testimony, with the States attorney general, with the National Association of Boards of Pharmacy to get to your question of how do consumers know. It is not safe right now probably to purchase drugs from an on-line pharmacy that is not a well-established entity.

Mr. KLINK. So the FDA recommendation today to the general public through the media in this hearing and for anyone else is it is not safe today to be purchasing drugs from an on-line pharmacy unless you have information as to who is the controlling person, and whether they are licensed, and who they are licensed with so that there is, in fact, some verification of the legitimacy of that site?

Ms. WOODCOCK. Yes, through a known entity and a known chain, or some other verification, you know who those people are, because otherwise it could be a foreign site. It could be anywhere, that's correct.

Mr. KLINK. How many of the 400 sites do we know about that are licensed, of the ones that we are expecting that are out there, that are of quality that are licensed? How many do we know that are legitimate, and what is being done about those that may not be?

Ms. WOODCOCK. What's being done about legitimate sites, as you heard, there is a voluntary effort to have a certification program through the National Association of Boards of Pharmacy, the seal of approval that's been talked about, the VIPPS program. The other sites need to be investigated, and many of them are engaged in illegal activities, as other people have said, already other witnesses, and those activities need to be stopped. We have already taken cases and had convictions on Internet cases, but we need to step up this activity.

Mr. KLINK. Thank you.

Mr. UPTON. Mr. Bryant.

Mr. BRYANT. Thank you, Mr. Chairman, and I apologize for my absence. I am running between other subcommittee hearings, and health care is having a hearing on drug addiction and cocaine addiction, interestingly enough, not absolutely totally unrelated to what ultimately we could be talking about here with particularly young people who are venturing out who violate the law to obtain legal drugs and the possibility that could be a gateway ultimately to doing other things, to get illegal drugs and the accompanying addiction.

Ms. Bernstein, I know that in August 1998, complaints were filed with your organization regarding the prescribing and selling over the Internet of Viagra, again without a prescription, and I know you may not be prepared today to tell me the status of those complaints, but I would like to know and I would like for the committee to know the status of those complaints. So if you could add to your testimony later with that information——

Ms. BERNSTEIN. I would be glad to do that.

Mr. BRYANT. [continuing] the status of those complaints.

[The following was received for the record:]

FEDERAL TRADE COMMISSION
BUREAU OF CONSUMER PROTECTION
September 24, 1999

The Honorable FRED UPTON
Chairman
Subcommittee on Oversight and Investigations
Committee on Commerce
House of Representatives
Washington, D.C. 20515

DEAR MR. CHAIRMAN: This letter responds to the Subcommittee's request, made at the July 30, 1999 hearing on the Internet sale of prescription drugs, to provide details regarding complaints filed by Pfizer, Inc. ("Pfizer") with the Federal Trade Commission ("FTC") concerning the online sale of Viagra®.

FTC staff first met with Pfizer representatives on August 25, 1998. Pfizer raised concerns about Internet sites distributing Viagra® without a prescription. Approximately one month later, Pfizer provided staff with specific information on six websites.[1]

Staff's review of Pfizer's submission revealed that each website offered Viagra® to a consumer without a pre-existing prescription. The consumer was invited, for a fee, to fill out an online questionnaire. All of the sites claimed that the completed questionnaire would be reviewed by a physician who would determine whether Viagra® was appropriate for the consumer. If approved, the consumer would be sent the prescription. None of the sites made any express or implied claims about the effectiveness or safety of Viagra®.

Pfizer's principal concern with these websites appeared to be whether the actions of the physicians met the minimum criteria for prescribing Viagra®, However, as we discussed in our July 29, 1999 letter to Representatives Dingell and Klink, and in our testimony before the Subcommittee on July 30, 1999, the FTC has the authority to bring enforcement actions only where an online pharmacy engages in unfair or deceptive acts or practices in commerce.[2] In contrast, the Commission has traditionally refrained from regulating practices that may fall within the doctor-patient relationship, such as communications between doctors and patients about course of treatment decisions. Moreover, the Commission does not have the authority to revoke an individual physician's license or to enforce state licensing requirements. The licensing, revocation of licenses, and regulation of pharmacies has traditionally taken place at the state level by state pharmacy boards. As a result, the FTC believes that the specific concern Pfizer raised is more appropriately addressed by other state and federal agencies with primary regulatory authority over the practice of medicine and distribution of prescription drugs.

Commission staff met with Pfizer representatives again on November 2, 1998. The company reported that it had met with a number of state regulatory agencies who were concerned with the online prescribing of Viagra® without a prescription, and inquired about staff's interest in hearing from those agencies. FTC staff welcomed this contact, and later received letters from twelve states and the District of Columbia raising concerns about online prescribing practices and their ability to effectively regulate online prescribing and dispensing. Copies of those letters were provided to the Subcommittee as attachments to the Commission's July 29, 1999 letter to Representatives Dingell and Klink.

Following the meetings with Pfizer, FTC staff has continued to identify and investigate online pharmacies. By using a variety of web search engines, reviewing Internet "message boards," and traditional newspaper advertisements, staff identified approximately one hundred Internet pharmacies.[3] Staff also made undercover buys from some of these pharmacies to determine if physicians were, in fact, involved in the transaction at the websites represented. While we are continuing to pursue some of these matters independently, staff has also referred matters to the relevant state and other federal authorities with the primary jurisdiction over the particular practices identified in the investigation.

---

[1] FTC staff also requested Pfizer to provide it with information concerning consumers who purchased Viagra® on the Internet who experienced adverse incidents. To date, Pfizer has not submitted any such information.

[2] *See* 15 U.S.C. § 41 *et seq. as amended.*

[3] These websites were identified and reviewed prior to receipt of the ninety-four websites provided to the Commission by Representatives Dingell and Klink on June 29, 1999.

Staff is working closely with other federal and state agencies, and other associations on issues relating to the sale of drugs over the Internet. We look forward to continuing to work with your staff on this difficult and serious public health issue.

Thank you for this opportunity to provide additional clarification on this issue.

Sincerely,

JODIE BERNSTEIN
Director

Mr. BRYANT. Dr. Woodcock, does your agency have jurisdiction over overseas companies that manufacture drugs or that counterfeit drugs and send them over to the United States?

Ms. WOODCOCK. It is illegal to import drugs into the United States unless they are approved by the Food and Drug Administration, prescription drugs.

Mr. BRYANT. What authority do you have over that, and what can you do?

Ms. WOODCOCK. Under the traditional pharmacy system, it was easier, as I have already pointed out, to manage and regulate the distribution of drugs, the coming into the United States. With the ability of consumers to reach out to foreign sites and order drugs that way, our authority starts at our border basically. We work with the foreign governments and the foreign authorities onsites that have been identified. We notify them, and we have gotten cooperation with them and with Internet providers to shut down ads for such sites that are illegally selling drugs.

But as was already said, it's difficult for us to go overseas and actually do something about those sites. We can stop the drugs at the border, and we share that authority with Customs, with the DEA and other Federal agencies.

Mr. BRYANT. I assume your agency has counter or similar agencies, sister agencies so to speak, in other countries, and I assume your best efforts are being used to work with those agencies; is that right?

Ms. WOODCOCK. Countries that have established drug regulatory systems are also struggling with the same issue that you are struggling with today.

Mr. BRYANT. Mr. Fong, from the Department of Justice, I compliment you on agreeing with me in many things in terms of—and that is fairly often that I agree with the current Department of Justice, and sometimes we don't, but I know from your testimony basically you indicate that this is kind of an old problem repackaged, and can I take it by that statement that you feel that existing Federal law is sufficient to handle this problem?

Mr. FONG. That is our current belief based on our analysis. We are actively studying the question, and we are meeting with our Federal agency partners and States, and to the extent we come to the view that additional assistance in the way of legal authority is necessary, we will come back to you, but at this point, as I indicated in my earlier remarks, existing law prohibits the dispensing of a prescription drug without a valid prescription from a licensed physician. We have prosecuted cases of violations of that statute. We will continue to do so.

I want to add, if I might, in response to an earlier question from Mr. Klink about whom does the consumer go to, and this responds in part to your question as well. It depends in part on what the substance is. It's easy to miss the fact that some drugs are pre-

scription drugs, which are governed by certain laws, and others are controlled substances, which are governed by different laws, and as you know, are required by the Drug Enforcement Agency. DEA has a very active investigation and enforcement effort in terms of controlled substances. So many of these problems that we are talking about that involve controlled substances, especially those from abroad, are being quite well, we believe, handled by existing DEA efforts.

Mr. KLINK. Would the gentleman yield for just one moment?

Mr. BRYANT. Mr. Chairman, are we going to have a second round? Okay. Could I have an additional minute based on the fact that he spent time answering Mr. Klink's question?

Mr. KLINK. I would ask unanimous consent for the gentleman to have an additional minute and a half, and I would ask if he would yield just briefly.

Mr. BRYANT. I would be happy to yield, if I am granted that.

Mr. KLINK. On that point about, you know, where does the public go to, and it depends on what it is, how would we expect the general public—and I read some of this. I used to be a professional reader. I used to be paid to read on the television. I was a news anchor. It is hard enough for me to read some of these words, yet alone to know what is over the counter, what is something that would have to have a prescription. How would the average person know that? Where do they go?

You know, the point is, no prescription, no problem, you can get whatever you want. So what are you doing at DOJ? You have already acknowledged the fact that that is illegal. Give us an idea of what you are doing to bust those people that are breaking the law day in and day out. What percentage of the people are you arresting? What percentage of the people are you shutting down? How recently have you shut down the most recent of these couple of hundred sites that Mr. Stupak has in front of him? Have you visited them? Have you actually physically gone to any of those sites?

I thank the gentleman for yielding.

Mr. FONG. Well, you have asked a number of questions, and let me just say I was expressing a view as to the legal structure. I think it's a fair point you make that an average consumer probably would not know. On the other hand, the Internet does offer a wealth of information, and it would be possible, though not—I wouldn't expect that to happen—that there would be mechanisms for determining whom to go to. You know, there are many Internet resources in other—in the area of fraud that the FTC has jurisdiction over.

Mr. KLINK. Excuse me, if the gentleman will suspend, I don't want to take any more of the gentleman's time. When we get back to the second round, I will ask the same question, and this time I hope that you will answer.

Mr. UPTON. I was going to say the gentleman's 30 seconds has expired, and the remaining minute is back to Mr. Bryant.

Mr. BRYANT. Thank you, Mr. Chairman.

Again, you indicate that it is already against the law to sell drugs illegally, but on the other side, the fraud side, I trust that the Federal laws out there, whether they be mail fraud or whatever, are sufficient, in your opinion, to cover the counterfeit, the

people who set up phony Web sites and things like that. But it seems to me—I know you said you met, in your statement, with all the investigative agencies, the FBI, the DEA and your agencies on either side, and the U.S. Attorneys out in the field. The 93 U.S. Attorneys are the ones that I assume do a lot of this prosecution, but it seems to me it would also be a good idea to bring in the individual States, and as General Stovall indicated—from Kansas indicated, they are willing and prepared, as I assume most States are.

Do you agree with her, is my question, that possibly we could enact some legislation that would be similar to what we did in telecommunications apparently to assist the cross-State, cross-boundary efforts of the States and get everybody working on this problem, not only Federal people, because I know they have got limited assets and they have certain criteria before they take cases, to give the States—empower the States with more authority to cross boundaries? Would you agree that some type of legislation, whether it be a uniform law or something, would be beneficial?

Mr. FONG. We would certainly want to seriously consider that proposal, and I know we—to the extent we have experience with the telemarketing provision, we would look to that, but we are very open, I believe, to do those kinds of mechanisms; so, yes.

Mr. UPTON. Thank you.

Mr. Stupak.

Mr. STUPAK. Thank you, Mr. Chairman.

Having been in law enforcement for a number of years that I was, we know it is illegal to sell a controlled substance without a license. We know it is illegal to obtain a controlled substance without a prescription. We know it is illegal to use a controlled substance outside its prescribed use. So do you need a license to sell controlled substance on the Internet? You are shaking your head yes, Doctor, you do?

Ms. WOODCOCK. As we already said, selling prescription drugs on the Internet without a prescription is illegal.

Mr. STUPAK. I asked, though, do you need a license to sell a controlled substance on the Internet? Pharmacy or medical license, do you need one to sell it on the Internet?

Mr. FONG. Again, as I understand the question, it goes to a controlled substance rather than a prescription drug, and as I understand the law, all controlled substances must be, if they are dispensed or delivered—I am not positive because I haven't looked at the statute recently.

Mr. STUPAK. If it is controlled substance, is the person who is selling—the person who is selling must be licensed. The person who is receiving must have a prescription if it is controlled substance. We all agree with that, hey?

Mr. FONG. Regardless of Internet, mail, telephone.

Mr. STUPAK. So then what are you doing to enforce it? That is what we are trying to ask you. January we had 26 sites. Today we got 400. You say the laws are there. Back when I was a police officer many moons ago, they were there. We enforced them. We have a new medium now called the Internet. What we want to know, what are you doing to enforce it? It is proliferating. You go from 26 in January to 400 in July. What are you doing to actually enforce it? Where is the cop on the beat, if you will? Where is the cop

on the Internet to make sure this is being done and administered right?

I mean, I am hearing promises, we are going to do some things, we are going to do something. Where you been? Do we have to put 100,000 cops on the Internet? Anyone care to answer?

Ms. WOODCOCK. We have been working with the DEA as part of the interagency working group, so——

Mr. STUPAK. Specifically, I mean. I am working with this agency, I am working with that department, I am going to do this. What specifically are you doing to get at this?

Ms. WOODCOCK. As I said, we have purchased a Web crawler. We are going to have surveillance over the Internet. We will be able to refer controlled substances illegally offered for sale to the appropriate enforcement people.

Mr. STUPAK. Do you have a task force or something that decided to do a Web crawler now?

Ms. WOODCOCK. Yes. We have an Office of Criminal Investigation.

Mr. STUPAK. Office of Criminal Investigation. How often have they met about this Internet problem?

Ms. WOODCOCK. The Interagency Task Force has met once, formally.

Mr. STUPAK. Was that after you got notice of this hearing or before you got notice of this hearing?

Ms. WOODCOCK. I believe it was before.

Mr. STUPAK. Okay. So you have met once. From that, have you put any extra resources in trying to do something, or are you still trying to come up with a scheme? You see, while you are taking all this time to do something, next month there will be 500 and then 600, then 700.

Ms. WOODCOCK. As I said in my testimony, the FDA's doubling its resources devoted against this.

Mr. STUPAK. When?

Ms. WOODCOCK. We are now. We have. We have a large number of cases in progress that we are investigating.

Mr. STUPAK. What does a case in progress mean, you looked at the site?

Ms. WOODCOCK. More than that. They're being investigated.

Mr. STUPAK. What does that mean, investigated? What does the investigation consist of? Who, what, when, where, why and how?

Ms. WOODCOCK. Yes. Basic police type of investigational activities, visiting the sites, obtaining evidence, purchasing and documenting an illegal sale by purchasing.

Mr. STUPAK. How many illegal sales have you purchased?

Ms. WOODCOCK. I don't know the answer to that.

Mr. STUPAK. What else have you done?

Ms. WOODCOCK. What else are we doing?

Mr. STUPAK. How many of these are licensed? We gave you 104, you said earlier, and you checked into it, and how many are licensed by the States in those 104 sites?

Ms. WOODCOCK. Again, I think Dr. Shuren said that we can't give you that answer right now. We don't know the answer to that.

Mr. STUPAK. I don't believe there is an investigation going on. I think we are looking at a lot of papers, and that is about it.

Ms. WOODCOCK. We have taken quite a few actions. There have been convictions. People have been put in jail for Internet violations.

Mr. STUPAK. Since January on selling drugs over the Internet, people have been put in jail?

Ms. WOODCOCK. I can't answer that specifically.

Mr. STUPAK. Well, that is what you just said, though, we are putting people in jail.

Ms. WOODCOCK. We have done that. This has occurred.

Mr. STUPAK. For what?

Ms. WOODCOCK. For example, there was a conviction in California, as we have in our testimony, for an individual who offered HIV test kits, a bogus HIV test kit over the Internet. That individual was convicted.

Mr. STUPAK. Is an HIV test kit a controlled substance found under the Controlled Substance Act?

Ms. WOODCOCK. No.

Mr. STUPAK. No, it is not.

Ms. WOODCOCK. That's correct.

Mr. STUPAK. You haven't done anything on this Internet problem. I mean, HIV test kits is not really the subject of this hearing. I mean, I think it is frustrating, having been in law enforcement, you see a problem that is growing leaps and bounds, you are talking about it, but nothing is really being done or were not prepared for the hearing, either one of the two.

I yield back, Mr. Chairman.

Mr. UPTON. The gentleman's time has expired.

Ms. DeGette.

Ms. DEGETTE. Thank you, Mr. Chairman. I would like to follow up some of these questions because we have heard about now a prosecution of someone selling a bogus HIV test kit. We heard a little while ago about some people from South America selling an abortion self-sterilization kit. Neither of those are legal in the United States. And then we heard, Dr. Woodcock, from you about how importing drugs which are not approved in the United States is an illegal act, and here is what I am concerned about, and this is following up on the questions I asked Attorney General Stovall.

I can understand what the States attorneys general are doing and what others are doing to enforce laws that relate to U.S.-based physicians, U.S.-based pharmacies who are dispensing drugs without a prescription, or overseas-based pharmacies and physicians who are trying to send in controlled substances or nonapproved drugs or kits, but it seems to me the real danger we have got lurking out there is overseas-based folks importing drugs that are not controlled substances, that are approved in the United States, but for which there is minimal, if any, pharmacy oversight and medical approval.

First of all, are any of the cases that your agency or the Department of Justice, Mr. Fong, prosecuted involving cases like that, and what are you doing for that set of cases? You know, this is the guy from Denver, Colorado, who decides to order Viagra from a Mexican pharmacy and fills out the little questionnaire, and it is legal in the United States, it is an FDA-approved drug, it is not a controlled substance, but it is an overseas pro forma kind of thing.

Ms. WOODCOCK. Would you like me to start? We have several cases where we have identified sites that were shipping drugs into the United States. We have alerted Customs, and some of the shipments have been detained. Sometimes they are United States importing agents that we are able to go after.

Ms. DEGETTE. And how many times has this happened; do you know?

Ms. WOODCOCK. There are specifics in my testimony. We can get back to you.

Ms. DEGETTE. If you could supplement the record.

[The following was received for the record:]

The Federal Food, Drug, and Cosmetic (FD&C) Act directs FDA to refuse admission of any article that appears to be in violation of the Act and the Agency regularly intercepts such products from foreign sellers at the border through the detention process. Some of these detentions are based on Import Alerts, which identify problem commodities and/or shippers and provide guidance for import coverage. FDA has identified in our Import Alert system several providers of unapproved drugs that utilized the Internet.

Since 1997, FDA has detained the following number of products which were offered for importation into the United States:

Fiscal Year	Number of Detentions
1997	29,420
1998	39,329
1999	*37,389

*(through August, 1999)

These figures are for all FDA-regulated products, including food, drugs, cosmetics, medical devices and other items, and includes entries offered by both commercial and personal importers. Thus, one detention could represent either one package or a shipment of multiple packages. An examination of FDA import data for the twelve months ending in July 1999 indicates that 12.4 percent of detentions are of human drug products (5,067 drug detentions out of 40,855 total detentions). Finally, it should be noted that importations initiated through Internet web sites are not tracked as a separate category.

In a number of cases handled by OCI foreign sellers and importing agents have been implicated. We are unable to determine the number of these cases because the database can not be queried in this manner. Two of these cases, however, are discussed in Dr. Woodcock's written testimony submitted for the July 30 hearing. Additionally, CDER has issued ten Warning Letters to firms in foreign countries concerning violative products that were offered or promoted over the Internet.

Ms. DEGETTE. And are those FDA-approved-type drugs or not?

Ms. WOODCOCK. Generally, I think we have been targeting our efforts by risk.

Ms. DEGETTE. What kind of drugs are they? Are they generally controlled substances or not?

Ms. WOODCOCK. They have generally been unapproved drugs of different kinds, steroids, other kind of unapproved drugs.

Ms. DEGETTE. What about for the approved drugs, that the was the question I had asked.

Ms. WOODCOCK. Yes. We can also do that.

Ms. DEGETTE. Have you done that?

Ms. WOODCOCK. I would have to get back to you.

Ms. DEGETTE. Thank you. If you can supplement your testimony, I would appreciate it.

[The following was received for the record:]

When FDA approves a drug or biologic product for marketing, it is not only approving the formulation of the drug product and its labeling, but also the manufac-

turing facility that will produce the product. Most FDA-approved drugs are manufactured in the United States, but some are manufactured in foreign countries. Thus, the drugs manufactured by foreign companies pursuant to an FDA-approved new drug application (NDA) and shipped into the United States through recognized distribution channels are just as legitimate as FDA-approved drugs manufactured in this country.

A problem arises, however, when consumers import drugs purchased overseas, either through the mail or by personally carrying the drugs across a United States border. Although it is possible that such a drug is FDA-approved (manufactured in an FDA-approved facility pursuant to an approved NDA) this is rarely the case with drugs purchased overseas. Most drugs purchased in foreign countries are not FDA-approved, and as such, are subject to seizure under the FD&C Act.

Ms. DEGETTE. Are you aware of any, Mr. Fong?

Mr. FONG. I am not aware of any. As you know, however, given the questions you've asked, this is a very difficult area. It involves a huge amount of international cooperation.

Ms. DEGETTE. Here's the thing we are all really worried about. Mr. Stupak has that big stack of sites that have proliferated just this year, and I know it is very difficult from your perspective, but this is why we are all so worried. My worry is not just with the nonapproved abortion kits and the AIDS test kits that don't work. I am worried about other drugs that may not seem so risky, but if your doctor doesn't prescribe it and you have got a heart condition, you are going to keel over and die if you use it.

Ms. WOODCOCK. Prescription drugs are prescription for a reason. That's because——

Ms. DEGETTE. That is exactly right.

Ms. WOODCOCK. [continuing] they ordinarily would not be safe in the hand of a consumer even if they were able to self-diagnose the condition. They may still pose considerable risks.

Ms. DEGETTE. I understand all of that. So, Mr. Chairman, may I have unanimous consent for just another 2 minutes because I have to leave?

Mr. UPTON. Go ahead.

Ms. DEGETTE. Thank you.

I have got a chart up there, and this is along these same lines. I know you can really read it about as clearly as I can, but what it says in part is from First Pharmacy On-line, and it says, quote, I understand that the information that I am providing will be transmitted to a physician licensed to practice medicine in Mexico. I understand the Mexican physician is not licensed to practice medicine in my State, and I acknowledge and agree that the Mexican physician is not practicing medicine in my State, and then it says the Xenical I will receive is real and will be sent to me by a pharmacy in Florida which has been in business since 1946. I understand that my credit card will be processed by M.D. By phone.

Now, I guess my question for Mr. Fong and Dr. Woodcock is, number 1, do you know about this site? Number 2, is it legal? And number 3, have you inquired into this site, and what are you doing about the situation?

Why don't we start with Mr. Fong.

Mr. FONG. I am not personally aware of that site.

Ms. DEGETTE. That is one of the ones we gave you according to staff.

Mr. FONG. And I would have to study it to see, to form a legal opinion about it. This is the kind of thing that we have been dis-

cussing amongst ourselves. I know you want us to take action, and we do take this problem very seriously, but we are also concerned about rushing in and doing something with unintended consequences. I don't—I don't mean to minimize at all the fact that we need to do more, but I also think we need to be thoughtful and considerate about what we do, and that's why I want to study it.

Ms. DEGETTE. If you can get back to us and supplement your responses on this particular issue, I'd appreciate it.

[The following was received for the record:]

FDA is evaluating the First Pharmacy Online site as part of its ongoing efforts to regulate the sale of prescription drugs over the Internet.

Ms. DEGETTE. Do you have anything to add?

Ms. WOODCOCK. The activities you've described I would think would be illegal, and we can take action against this. I am sure that if you have given us this site, this is one we're looking into.

Ms. DEGETTE. Okay. If you can follow up and let me know for certain.

Do you have any final comment, Ms. Berstein?

Ms. BERNSTEIN. On this subject?

Ms. DEGETTE. Yes.

Ms. BERNSTEIN. Only this, that I thought that that site was an attempt by a company apparently to get a consumer to agree to violate the law basically, and I think it's our position that a consumer or any other person can't waive State law. So I think it would be an illegal site.

Mr. KLINK. Would the gentlelady yield for one moment?

Ms. DEGETTE. I would be happy to.

Mr. KLINK. Mr. Fong, with all due respect about your rushing in answer, the fact is that you should know, coming from DOJ, you can't waive State law. This is as close to a signed confession as anything I have ever seen. I don't understand where you are rushing in. They are saying that the doctor is not licensed in your State. Everything that you told us in your statement about controlled substances they are admitting to. This is a signed confession. Why would DOJ be rushing in?

Mr. FONG. I meant the comment to apply generally rather than as to this specific site.

Mr. KLINK. What can you do about this site? You are aware of it now. How long will it take you to take some action on it?

Mr. FONG. I can find out whether or not we can investigate, and if so, we will do so.

Mr. KLINK. How would you determine whether you can investigate or not? Is it a jurisdictional question, or is it a question of whether the law has been broken; whether, in fact, a doctor not licensed to practice in the United States can prescribe drugs in the United States? Is that the question, or is the question whether or not you have jurisdiction?

Mr. FONG. I would say that I think it's a matter of—I don't think it's a matter of jurisdiction per se, so I do think once we concluded that it was a potential violation, we would investigate.

Mr. KLINK. Potential violation. I yield back. I thank the lady.

Ms. DEGETTE. Thank you, and I yield back to, Mr. Chairman.

Mr. UPTON. Thank you. Mr. Green.

Mr. GREEN. Thank you, Mr. Chairman. I, like my colleagues, have to admit I didn't bother to look at any of these things until our committee hearing today. I have concerns not only of state law but, for example, prescriptions now where you can—the question is what is currently bothering you now, and I guess you fill it in, and what currently is bothering you about your health, is your body mass index above 25, and you agree to sign the waiver for Phentermine.

I guess I am so surprised to see this, and one of the things I am concerned about is this committee and the full committee and two of our subcommittees are going to deal with hopefully telemedicine, which is, again, a growth industry, and we have a little problem with telemedicine working across State lines, so we will have to deal with that.

But what I am worried about is companies like this, or physicians, no matter where they are at, are really going to hinder us trying to use the Internet and use the technology that we are doing safely. And with what we have, and the numbers we have seen that my colleague passed—although I have to admit they are very good entrepreneurs, because safe Web medical advertised Viagra, along with a Bahamas cruise for $113.

I guess I am surprised that—is there cooperation? I know we had the Attorney General from Kansas, but is the DOJ working with our local State Attorneys General who are aggressively pursuing this? Not only DOJ, but FTC and also the FDA?

Mr. FONG. I understand that representatives of the Department have met with the National Association of Attorneys General on this issue.

Mr. GREEN. Again, my concern is that we have—you can save on your prescriptions if you order them by mail. We have that now. Of course, you have to have a doctor's prescription.

In the next step, it is ordering by Internet, and we are seeing a lot of bad actors who may limit that for the people who really have a prescription, instead of being self-diagnosed by the Web. It worries me we are going to limit—we are going to have to do it by statute, maybe, limiting it; and that way we will lose some of the benefits of what is happening with the revolution in telecommunications.

That is why I guess not only the agencies each of you represent, but the States, need to be as aggressive as they can to prosecute some of these folks who are violating not only State law, but I know Federal law also.

I guess one of the things when I was in the legislature in Texas we passed, and most States did at the urging of the Federal Government, triplicate prescriptions. How would that possibly be effective doing Internet—having prescriptions on the Internet? Can either of you answer that? Comply with any of the prescription laws that we have concerning controlled substances?

Ms. WOODCOCK. Could you restate your question?

Mr. GREEN. Triplicate prescriptions. If I have some type of controlled substance, the doctors—doctors always used to complain about it. How can we possibly ever have any kind of compliance with that law?

Ms. WOODCOCK. Obviously, I would think that for safe Internet prescribing, there may need to be new technologies for things like that, electronic signatures and so forth that were alluded to earlier. There has to be verification. This new field, cybercommerce, is really raising some new challenges.

Mr. GREEN. Okay. I know, Ms. Bernstein, I understand that Pfizer has contacted several States and asked the States to contact the FTC to take action against certain of these sites selling Viagra; is that true?

Ms. BERNSTEIN. We have been in touch with Pfizer, yes.

Mr. GREEN. Was it initiated by Pfizer?

Ms. BERNSTEIN. Yes, it was.

Mr. GREEN. Thank you, Mr. Chairman.

Mr. UPTON. You know, I have heard a lot of things here this morning, and I think a number of us have, have certainly a good number of frustrations. Dr. Woodcock, when we hear you say that you would not advise—when we hear the FDA in essence say we would not advise anyone to use an on-line pharmacy without some personal knowledge of the site, I started looking through a couple of the 100 sites that Mr. Stupak—200 sites that Mr. Stupak offered. I daresay I haven't heard of a single one of them. They have Dr. Welby-like—I know he retired a long time ago, he may be deceased—but when I see pictures of folks that look a lot like he used to, and different businesses on here in terms of looking like they have a real clinic.

I come from a small town, and when my folks and I needed pharmaceutical drugs, we went to a place called Gillespie's. Dr. Gillespie, it was a family held business, and his brother got into it as well, and there are two little shops that are still in business today. People know of the quality of care that you got when you went to Gillespie's, just like you knew your own physician.

And nobody knows, I can't believe anyone on this panel would know or recognize maybe any of these places. You would have no personal knowledge of any of them, probably don't even know a neighbor or friend that might use them. Yet you say that no one should be using these things without some personal knowledge. There is no Good Housekeeping Seal of Approval. There is no way that people can know.

When you hear Mr. Fong testify they stand ready to prosecute, and yet there is really not a single case, other than maybe an AIDS test kit out there, and his statement, too, that they don't want to rush in, yet in fact we hear—one of the bills that this panel began to work on the last couple months, date rape drugs. One of the things that alarmed all of us is their availability over the Internet still today. We were able to pass legislation out of our Health Subcommittee last week, and it looks like—actually it was this week, and it looks like we are going to have a full committee markup on it next week and on the House floor soon. Everyone is on board. It is bipartisan, as it should be, and we are moving forward because we recognized the problem.

Yet we hear the Department of Justice doesn't want to rush in, yet in essence you are not giving the seal of approval to any of these, and it is literally impossible for an individual, a consumer,

to have some knowledge of this, so there really is a gigantic problem.

As we heard from, I believe it was the Attorney General from Kansas, testify a little bit earlier, and particularly the reporters, no one seems to be in charge. The reporter from Philadelphia indicated that they in fact had gone to Federal officials, the DEA, and they said that they would look into it. But nothing has happened.

These are not isolated cases. I have got to believe in every single community we can find abuse. Where are we to turn?

Ms. WOODCOCK. With regard to purchasing drugs over the Internet, I think consumers can go to their pharmacists and get a recommendation for a reputable chain, their physician, their health care provider, their health care insurance company. But consumers should not be purchasing prescription drugs over the Internet from unknown sources, or without a prescription and without having seen and having visited their health care provider.

Mr. UPTON. But it is happening, big time.

Ms. WOODCOCK. Okay. The Agency has taken numerous complaint actions on the Internet. I don't want to give the impression that we haven't. We have had over 60 cases that we have taken on suspected illegal Internet sales, including the first case that we took in 1994.

Mr. UPTON. Is that 60 cases in 5 years? One a month? 12?

Ms. WOODCOCK. I have to stress that our resources are stretched. As Congressman Stupak indicated earlier, we have the Prescription Drug Marketing Act, we have numerous oversight of numerous types of illegal sales, many of which have gone on in non-Internet contexts. What we are going to do is shift resources from our surveillance in that area into the Internet because of the rapid growth in this area.

Mr. UPTON. Mr. Klink.

Mr. KLINK. If I could just ask a basic question, Dr. Woodcock. We are talking about of—what, the actions that you have taken against those people who are distributing over the Internet of what drugs?

Ms. WOODCOCK. I would have to get back to you.

Mr. KLINK. The 60 cases also you are talking about. Those 60 cases, tell us later.

Ms. WOODCOCK. I will.

[The following was received for the record:]

At this time, OCI has 55 ongoing criminal investigations involving on-line promotion and sales of FDA-regulated products. The 60 cases referred to in FDA's written testimony included some non-criminal investigations.

The criminal investigations include six investigations involving sales on the Internet of 17 specific prescription pharmaceutical products, including several which are controlled substances under the Controlled Substances Act. Potential charges include the sale of prescription drugs without a prescription, illegal importation of unapproved new drugs, illegal sale of controlled substances, and wire and mail fraud. All of the six cases were opened in 1998 and 1999. These six cases do not involve the operation of what would be normally recognized as legitimate pharmacies in this country, although they may appear to be pharmacies to the unwary consumer.

The remaining 49 open cases do not involve the sale of approved prescription drugs, but the promotion and sale of a variety of other products falling under FDA's regulatory authority. It is important to stress that in FDA's view, these sales may pose equally significant and, in some cases, possibly greater risk to the public health than the cases described above. We believe the devotion of our limited resources to these cases is essential to protecting the public health.

More than a third of the 49 cases involve the apparent illegal sale of gamma hydroxybutyrate (GHB) or its relative, gamma butyrolactone (GBL), both extremely potent unapproved drugs. These drugs are often used "recreationally" but also have been used in "date rapes." The use of these drugs has resulted in severe respiratory problems, seizures, coma and death. As you know, GHB is currently not scheduled under the Controlled Substances Act, but is the subject of both administrative and legislative activity to accomplish such scheduling.

Other open Internet-related criminal investigations involve the sale of human growth hormone; HIV test kits; adulterated medical-products; fraudulent medical devices; fraudulent unapproved drugs, immune system "boosters," HIV or AIDs "cures," tampered products; and diverted or misbranded drugs. These cases date from 1997 through the present.

FDA has a total of 12 closed criminal cases that involved the sale of drugs in which the Internet played a role. Four of the 12 cases involved resulted in five arrests. Two of these cases were described in FDA's written testimony. The following provides more detail concerning two additional cases.

1. In the first case, a state prosecutor contacted OCI concerning a request for assistance from a therapist concerned about the health of a 16-year-old boy. Through an Internet chat room dealing with transgender issues, the boy had been in touch with an adult male subject in Arizona who was encouraging the adolescent to get a sex change operation and supplying the boy with prescription drugs normally prescribed for presex change patients. To further this objective, the subject had been selling the juvenile Premarin and Progesterone (female hormones) and Aldactone (an androgen suppressant).

OCI contacted the FBI "Innocent Images Squad" to determine whether the man was involved in approaching other children. Later the boy's mother contacted OCI and advised that her son had gone through extreme mood swings and consequently she had searched his room. She found more of the sex change pills and a map showing the way to the subject's home in Arizona. OCI and FBI interviewed the 16-year-old juvenile in his parent's presence. The boy admitted his ongoing relationship with the subject and agreed to cooperate in the investigation. He provided e-mail messages from the subject that clearly confirmed his parent's fears and suspicions. The boy's parents provided the latest shipment of drugs to OCI for testing.

A search warrant was served at the subject's residence in Phoenix, Arizona resulting in the seizure of drugs and documents related to this investigation. The subject admitted going to Mexico to obtain the drugs, repackaging them and sending them to the juvenile across State lines. A Federal grand jury indicted the subject for 12 felony counts concerning misbranded drugs. The subject pled guilty to two counts of delivering misbranded drugs in interstate commerce and was sentenced to six months home confinement, two years probation and $18,000 restitution to the boy's family for therapy costs.

2. In the second case, OCI received information from local police in Texas regarding the sale of GHB kits over the Internet to a juvenile. Investigation determined that unapproved drugs were being mailed from a location in Florida. OCI, working with state authorities, obtained a search warrant for a warehouse in Winter Park and Oviedo, Florida. Evidence was recovered at both locations and a consensual search was conducted at a third location where large quantities of GBL and sodium hydroxide were seized.

State of Florida authorities and OCI arrested two subjects for violations of State controlled substance acts. Later, one defendant died of undisclosed causes and the second defendant was placed on pretrial diversion to include supervised probation for a period not to exceed nine months.

As the Internet assessment team continues its review of web sites, it is anticipated that the reviews and assessments will be converted to more formal investigations.

Mr. KLINK. I don't expect you to have that in front of you, but we really need to have that information. I would also like to know those 60 cases, over what period of time, so that we know from the time that we have been—you know, the Internet is much more explosive today than it was yesterday. It much more explosive this month than it was last month; this year than it was last year.

So as the Internet has gotten more active, as Mr. Stupak pointed out—we have gone from 26 of these sites in January to as many as 400 now—we want to see if your activities have similarly intensified during that period of time.

Mr. Fong, what is the difference, the basic difference, from a law enforcement standpoint, of a person going out on the street with Valium, Percocet, any other kind of drugs that would have a street value, and there are others that we would know about, and selling them on a street corner, on a playground, in an alleyway? Obviously that person is not licensed, he is a common drug dealer. There is a market in those drugs, and always has been.

I remember as a news reporter going out with law enforcement personnel on drug raids all the time. It wasn't always crack cocaine or heroin, a lot of times it was controlled substances. What is the difference between that and what is taking place on the Internet right now, while we speak from a law enforcement standpoint?

Mr. FONG. Legally, there is very little difference.

Mr. KLINK. If there is little difference, what is it, other than volume of business because you have a bigger audience?

Mr. FONG. The difference is investigatory. These sites are difficult to investigate because they can come up and they disappear. Our agents need to be trained to preserve the Web sites for use as evidence in court.

Mr. KLINK. If I can just stop you for a second, because I want to walk through this with you. What is being done, then, to do that and under what kind of timeframe? Because we are not seeing a whole lot of—I am disturbed by Dr. Woodcock's comments that there is an interagency task force that met once. What happened at that meeting, if any of you can tell us? Apparently you didn't even agree to meet again.

Mr. FONG. One of the meetings was, I believe, scheduled for today.

Mr. KLINK. That was coincidental. We would have invited the entire agency task force here, and we could—what is this task force doing? If you have only met once during all of these months, how can there be any coordination with just one meeting? What kind of timeframe? Let's just start with DOJ.

Mr. FONG. If I could respond first to the earlier question, we have an ongoing effort to train our agents and our prosecutors. This is a priority of the Department. We all know that computer crime, the hacking cases, present very difficult challenges, and we are responding to them. This is no different.

As was said earlier, we are trying to keep up with the truly bad actors, and we are doing our best and we can do more.

Mr. KLINK. What kind of dedication of resources do you have? Do you have any idea of the number? If you don't have the number now, you can get it to us later. Any idea of the number of agents within the Department of Justice that are working on this and the number you would expect within a month or year from now? If you can give us those kind of details so we know the kind of resources the DOJ is really putting into the problem.

Mr. FONG. I can give you a general sense. We have a computer crime section within the criminal division. The fraud section has people working on this. The civil division, the Office of Consumer Litigation has responsibility for consumer protection laws. Each U.S. Attorney office has somebody designated as a computer-trained person, and there are often more than one. The FBI has in-

dividuals who are trained. It is such a high-growth area that we recognize the need to dedicate resources to this area.

Mr. KLINK. The pharmaceutical manufacturers seem to be fairly responsible people. I would ask the Department of Justice, FTC as well as the FDA, do you think we could just let them go ahead and self-regulate? Why would we want to inspect them? Why don't we just let them self-regulate themselves, as we are these sites? That has been the suggestion. We kind of don't interfere with e-commerce. Let's let them self-regulate. Is there any kind of a problem? Carry it on——

Mr. FONG. Of course, going back to first principles, we have criminal laws because we don't expect or trust individuals to self-regulate. That is the intersection of two sets of policies that we are currently grappling with.

Mr. KLINK. What is the difference between us regulating how these drugs are manufactured, how they are developed, how safe they are, and then not regulating how they are being dispensed? We don't know when those drugs are shipped, where they were manufactured, where were they manufactured in the case of Viagra. Was it made by Pfizer or is it a knock-off drug? What was the care and custody?

We saw a news report this morning they were repackaged to avoid Customs. During that time were the drugs tainted? How were they handled?

There is no protection. Is FDA doing anything to assure us of this safety? Is the Department of Justice doing anything to prosecute, to see that in fact when these laws are broken, that someone is going to be prosecuted? And in how many cases? We don't have answers. Unfortunately, we have too little time. But we don't have answers to any of these questions. I would say it is unfortunate, Mr. Chairman, and I know we are going to continue to work on this. We have barely scratched the surface on this. We have more questions coming out of today's hearing than we have answers. If you have a response?

Ms. WOODCOCK. We agree it is illegal to perform many of these sales on the Internet. We are trying to get control over this activity. We do not feel that illegal activity should be self-regulated.

Ms. BERNSTEIN. The FTC believes in self-regulation, but not in the face of where laws are being broken. Self-regulation does play a role if there is a basic law in place. That is our view. And it can be effective in carrying out more kinds of controls that you would not want to be in Federal law.

But in this instance, as I said before, we really believe that legislation that would mandate identifying information would be very helpful to law enforcement generally, both to the States and the Federal Government.

Mr. KLINK. Mr. Chairman, the question I have here is we have three agencies in front of us. The FTC came in in their prepared testimony—first of all, they responded in a fairly timely fashion to all questions we asked them, and we appreciate that. The other thing is they walk in saying, Look, basically we need to know who is operating the site, who licenses them, where they are located, and we think there ought to be a law to do that.

Yet the Department of Justice hasn't done that. In fact you started off your testimony saying you are not here to suggest any laws. We haven't heard anything from the FDA. The most commonsense step is to at least let us know who is doing it, who is licensing, who is accountable; and yet the Department of Justice and the FDA to this point in the hearing has not stepped up to the bath, saying we are in favor of taking that preliminary step to assure the public there is some level of safety.

Mr. FONG. May I respond? I will go back to something I said at the very beginning, which is that the same laws that apply in the physical world ought to apply to on-line conduct. If disclosure is required in the off-line world, to the extent State boards require the posting of a license, which States do, that should also apply on the Internet. There should be no distinction, in other words, and the same laws should apply.

Mr. KLINK. Then we should have 50 different State laws to apply? Because that is what it is now. Each State has their own law. You are saying now for these sites, which as the Chairman pointed out—and I thought he did a wonderful job doing it—the pharmaceutical company is headquartered there, the manufacturing plant is there. We are sending the order to Mexico, to a doctor to who may or may not be a doctor. They are shipping the drug from a drop box in Florida. Where do we license it? Do we go with each State having their own set of regulations; or do you recommend from the Department of Justice that, if it would be easier, for law enforcement at the Federal and State level to work together if we had some uniform law that determined how we deal with this display of licensing and the information that went out to the public at these sites?

Mr. FONG. As Attorney General Stovall testified earlier, we have to be very careful not to Federalize what has traditionally been a State responsibility: regulating pharmacies and doctors. We do want to work together in partnership, but we also want to respect our traditional jurisdictions. We enforce Federal law, they enforce those State provisions. We think we can do it together.

Mr. KLINK. In all due respect, and I think we are getting to the point here, no one suggested Federalizing. But I would like you to explain to me what jurisdiction, what amount of manpower any of our States or Commonwealths would have to be able to track down a site in New Zealand, in Singapore, in Mexico, in South America, in Central America, in another State? What enforcement authority would they have to be able to do that? If they are not working with the Department of Justice to have a uniform standard of some kind, is there any evidence that the Department of Justice has been working with the various attorneys general to formulate some method of attacking this problem? Has that begun to occur as we sit here today?

Mr. FONG. We have begun to have some conversations with them.

Mr. KLINK. How far along is the process?

Mr. FONG. I can say I know of meetings that have been held, but I don't know——

Mr. KLINK. Any suggested action from those meetings?

Mr. FONG. I assume we are working together to develop strategies, enforcement strategies.

Mr. KLINK. I would prefer that we don't assume, Mr. Fong. I will ask you to get back to this subcommittee with specifics. I don't want to hear you have had meetings. I have had a lot of meetings, sit down and have a cup of coffee and donuts. That is as specific as it gets. I want to know specifically what has come out of the meetings. Have there been suggested actions? Is the Department of Justice ready to step in and help the States beyond their borders where they don't have jurisdiction? I appreciate your telling us the meetings are occurring.

But this subcommittee wants to know specifically what you have done, because what you are doing for the public has been put at risk. We have not in a timely fashion had the questions that we have asked be responded to, and we are tired in this subcommittee of hearing that you are just having meetings and that you have these interagency task forces that have met once.

I want to know specifically what has been done. We will have a list of questions for you, some of them which I have asked here today, but counsel will get them to you, and we would like to have them responded to.

Mr. Chairman, I thank you for your indulgence, but again, and I hope you will agree, we are going to have to have follow-up hearings to this.

Mr. UPTON. Mr. Bryant, do you have additional questions?

Mr. BRYANT. Mr. Chairman, I do have just a couple of quick comments. I know we have got a vote on right now. I think our panel has received somewhat of a message today that we are very concerned about what is going on, and obviously you are too, and we have just got to get everybody working forward and working together on this.

Certainly I have heard the resources. That is something we hear very frequently on the Hill: Our resources are stressed. Having served as a United States Attorney at one time and having 29 lawyers working for me, and we were prosecuting white collar crime, bank robberies, lots of drug cases and all kinds of Federal issues, I know resources are stretched. That is why I think we have to—you have to take out of this meeting that this has to be a priority, has to go up there, and you have to get the U.S. Attorneys out there, assigning their assistant U.S. Attorneys, making sure their investigative agencies go out there and find these types of cases. Certainly at main Justice, we have to see those international problems worked on. We certainly want to cooperate as much as we can.

I don't want to, again, overlook the fact that we have a great number of State—not only State attorneys general, but State investigative agencies that can be used as much as we did in, I believe, the telemarketing law. Again, if we have to as a Congress work together to pass legislation, then we need to know that, and how to best do that.

I want to stress in closing that we have talked about the bad situations, and there is tremendous potential here for bad. But, on the other hand, there is tremendous potential for good. I think from our first panel, we see those that brought a good case for the

ability to sell legally, in a legal process, drugs over the Internet, and I think that can work. I think it can work, and I think it is part of our jobs to make sure we ferret out the bad so that the good can survive.

I want to hear from the next panel of experts, the people, the good guys out there doing it. I believe there are two companies here that will be represented on the panel that are doing it right. We have got the AMA, we have the Texas Health Department representative, and we have the pharmacy people here. So we need their suggestions. So if I will quit talking long enough, perhaps we will get to that panel after we come back from voting. So I will yield back my time.

Mr. UPTON. I would note that was the warning bells for going back into session. The vote has not yet been ordered. Mr. Stupak?

Mr. STUPAK. If I may, Mr. Chairman. Mr. Fong, if the same laws apply, then why does it take time—and I have heard take time, analyze, study, train, computer section, fraud section, computer section, U.S. Attorneys, FBI—if this is the same laws that apply whether you are selling on the Internet or selling on the street, why do we have to go through all of that?

I mean, I fail to see the difficulty here in doing an investigation. Take the one we have been talking about here. First, Pharmacy On-line. Here is what it says again: I understand that the information I am providing will be transmitted to a physician licensed to practice medicine in Mexico. I understand that the Mexican physician is not licensed to practice medicine in my State, and I acknowledge and agree that the Mexican physician is not practicing medicine in my State. It goes on to say, that Xenical will receive its seal and will be sent to me by a pharmacy in Florida which has been in business since 1946. I understand that my credit card will be processed by M.D. By phone.

So, do we have a reciprocity agreement with Mexico that if you are a licensed physician in Mexico you can practice in the United States?

Mr. FONG. I don't know the answer to that; I am sorry.

Mr. STUPAK. Let me help you. The answer is no. Second, is Xenical a controlled substance? The answer is yes.

The third question: Is it a violation of the law for a Mexican doctor to prescribe controlled substances to a U.S. citizen?

Ms. WOODCOCK. It is a violation of U.S. law for the drug to be brought into the country.

Mr. STUPAK. My question is: Is it a violation of law for a Mexican doctor to prescribe a controlled substance to a U.S. Citizen? Remember, Xenical: Prescription drug, controlled substance.

Ms. WOODCOCK. Is it a DEA-type of controlled substance? It is a prescription drug.

Mr. STUPAK. Right.

Ms. WOODCOCK. Right.

Mr. STUPAK. Same question.

Ms. WOODCOCK. Of U.S. Law, to bring that into this country.

Mr. STUPAK. No. Can a Mexican doctor prescribe a prescriptive drug to a U.S. citizen? Yes or no? I am right here in Washington DC, a Mexican doctor prescribes a substance for me, prescription drugs. He is in Mexico. Is it legal?

Ms. WOODCOCK. No, he continues to send it to you.

Mr. STUPAK. Violation of law, isn't it?

Ms. WOODCOCK. That is correct.

Mr. STUPAK. Is it a violation of law for a Mexican doctor to have a prescription filled by a pharmacy in Florida?

Ms. WOODCOCK. Yes.

Mr. STUPAK. Violation number 2. Is it a violation of the law to have a Mexican doctor, not licensed to practice in Florida or Michigan, prescribe a controlled substance or a prescription for someone in Michigan? I think we already understand it is; right?

Ms. WOODCOCK. Yes.

Mr. STUPAK. When I use the mail, the telephone, or the fax machine to receive or send this prescription without a license, that is also against the law, isn't it?

Ms. WOODCOCK. Yes, okay.

Mr. STUPAK. Sure it is.

Ms. WOODCOCK. I am not a lawyer, sir.

Mr. STUPAK. I haven't done police work in 12 years, but I just found 4 violations there. Now, why do we have to study, analyze, train, do all this stuff? Why don't you just set up a sting operation like the TV people did, don't use a cat or dog because they can't testify in court, but use someone real. Use yourself. You got 400 sites. You have 9,000 people. Go to the Web sites, run them through here, and you are going to get your violations.

Ms. WOODCOCK. We have been doing that. We have been doing investigations, setting up sting operations. These cases are in progress. It is not all of them, but we have been doing that.

Mr. STUPAK. How many buys do you have? How many times have you bought on the Internet?

Ms. WOODCOCK. I can get back to you with that information, I think. We don't have it with us.

Mr. STUPAK. How about a guesstimation? Is it like your task force, one meeting?

Ms. WOODCOCK. We will get back to you. It is more than one.

[The following was received for the record:]

In regard to the six open prescription drug cases referenced in response to question three above, 12 undercover buys have been made in these cases. With regard to the other cases, we have not tabulated the buys because these cases are not directly related to the topic at hand (internet pharmacy practice). In any case involving sale of an illegal product, undercover buys are a routine practice, and cases in which the Internet plays a role are not an exception. Initiation of such a case typically involves one to three undercover buys to establish a violation prior to execution of search/arrest warrants or other judicially authorized investigative action.

Mr. STUPAK. I mean, again, we start off here in January with 26 sites, we are up to 400. You don't have to be a rocket scientist to figure out how to go after this and approach this problem. We are not here trying to restrict the Internet. We are trying to protect consumers, and nothing is being done, other than we will think about it. That is our frustration up here.

Thank you, Mr. Chairman.

Mr. UPTON. Thank you very much. I think all of you recognize our frustrations with the present system. I think we will be having some additional hearings after the August break.

You will be getting some questions from the two of us to be answered. Hopefully we will try to have a date certain, if you could be fairly quick in turning that around, that would be helpful.

At this point you are now excused. Thank you very much.

Our last panel of the morning—afternoon—will include—no, it will not be evening—Mr. Carmen Catizone, Executive Director of the National Association of Board Pharmacies; Dr. Herman Abromowitz, Member of the Board of Trustees of the AMA; Ms. Cynthia Culmo, Director of the Division of Drugs and Medical Devices from the Texas Department of Health; Mr. William Razzouk, CEO of PlanetRx.com; and Mr. Peter Neupert, President and CEO of Drugstore.com.

As you heard from the earlier two panels, we have a longstanding tradition of taking testimony under oath. Do any of you have objection to that? Do any of you desire to have counsel to protect you in the future?

[Witnesses sworn.]

Mr. UPTON. Thank you. You are now under oath. Mr. Catizone, we will start with you. Again, the rule is your entire testimony is made part of the record. If you could try to limit your remarks to no more than 5 minutes, it would be terrific.

TESTIMONY OF CARMEN A. CATIZONE, EXECUTIVE DIRECTOR, NATIONAL ASSOCIATION OF BOARD PHARMACIES; HERMAN I. ABROMOWITZ, MEMBER, BOARD OF TRUSTEES, AMERICAN MEDICAL ASSOCIATION; CYNTHIA T. CULMO, DIRECTOR, DIVISION OF DRUGS AND MEDICAL DEVICES, TEXAS DEPARTMENT OF HEALTH; WILLIAM RAZZOUK, CHIEF EXECUTIVE OFFICER, PLANETRX.COM; AND PETER NEUPERT, PRESIDENT AND CEO, DRUGSTORE.COM

Mr. CATIZONE. Thank you, Mr. Chairman. I am not sure if the Gillespie Pharmacy is the same Bob Gillespie that I used to interact with, who is a former member of the Michigan Board of Pharmacy and a past president of it.

Mr. UPTON. I am sure that it was.

Mr. CATIZONE. He was an outstanding gentleman and pharmacist.

Mr. UPTON. He also had a brother that was a police chief, so it is good that you stood on the good side.

Mr. CATIZONE. Thank you. Mr. Chairman and members of the subcommittee, I represent the National Association of Boards of Pharmacy, which is the independent and impartial association of State licensing authorities in the United States, the Virgin Islands, Puerto Rico, Guam, 9 provinces of Canada, 3 Australian States, and New Zealand.

NABP's extensive research into this new and engaging area have identified a wide array of legitimate practices as well as unscrupulous and dangerous on-line activities. The Verified Internet Pharmacy Practice Sites program is the beginning of a developing program to support the regulatory efforts of the State boards of pharmacy to better police Internet pharmacies.

VIPPS employs a multifaceted approach that combines the enforcement of laws, regulations, and the recently developed and vali-

dated Internet practice standards with effective consumer education and empowerment.

Of the 400 sites which the committee members have spoken about this morning, we have broken down those sites into additional subdivisions. One hundred eighty-three of those sites are devoted exclusively to the distribution of Viagra; 150 of those sites have been identified as to the registrant State of origin; 30 of those sites are foreign registered; 20 States actually hold licensure.

I would make an offer to Mr. Stupak and other members of the committee that if they would turn over to us that list of 400 pharmacies, or 200 pharmacies, that you have in your possession, within a few weeks' time we will provide to you information as to which sites and which pharmacies are actually licensed by State authorities in the United States.

The practices of those sites, the most egregious sites, to make prescription medications available to consumers without a legitimate patient-prescriber relationship, and thus without a valid prescription order, are not only dangerous but, the opinion of NABP, illegal.

It is NABP's further position that pharmacists and pharmacies dispensing prescription medication also pursuant to an invalid patient-prescriber relationship, are acting illegally and are subject to disciplinary action by the appropriate State board of pharmacy. State boards of pharmacy and medicine are developing the regulatory tools and have in place many of the regulatory tools they need to curb these illegal activities.

The most recent example of such actions occurred in Missouri, when the Missouri Attorney General obtained a temporary restraining order to halt the operations of a pharmacy licensed in Texas, prohibited a physician involved, who was involved in the situation from using on-line consultations to support prescriptions, and enjoined the pharmacy to indicate on its Web site that consumers in Missouri were not able to purchase or obtain prescriptions from that pharmacy.

This recent action by the State of Missouri is significant in many regards. First, it demonstrates the willingness of States to act on the inappropriate action of practitioners and pharmacies located in other States. Second, it demonstrates the ability of these States to take quick and prompt action in these critical situations. Third, the current regulatory powers of the State also provide the means for those pharmacists and pharmacies to be prohibited from practicing in all 50 States.

An Internet site earning NABP's VIPPS must meet and demonstrate compliance with all mandatory licensure, statutory and regulatory requirements of State practice acts. There is no variance from this requirement. NABP will independently verify this compliance directly with the States through its national clearinghouse and data base program and physical onsite inspections of sites and affiliated facilities. The NABP VIPPS seal will inform consumers that the on-line site is a legitimate practice site licensed or registered with a State agency. It will also provide the consumer with important information about the site and how to contact the appropriate governmental agency to record a concern or complaint.

The National Association of Boards of Pharmacy believes that existing State laws and regulations, in conjunction with the VIPPS program and our partnership with the Food and Drug Administration and other Federal agencies, as well as the State medical boards, provide an effective means to regulate and monitor U.S.-based on-line sites. NABP acknowledges that foreign-based on-line sites are outside the jurisdiction of the State boards of pharmacy and operating without restriction or control, and are endangering the citizens of the United States. We support legislation and intensified efforts to curb the activities of these foreign based on-line sites.

We are grateful to the committee for your deliberations on this timely and significant issue, and we offer any assistance we can provide to your deliberations and actions.

Thank you.

[The prepared statement of Carmen A. Catizone follows:]

PREPARED STATEMENT OF CARMEN A. CATIZONE, EXECUTIVE DIRECTOR/SECRETARY, NATIONAL ASSOCIATION OF BOARDS OF PHARMACY

Mr. Chairman and members of the Committee, I am Carmen A. Catizone, Executive Director/Secretary of the National Association of Boards of Pharmacy (NABP). NABP is the professional organization, whose membership consists of the state boards of pharmacy in all jurisdictions of the United States, the Virgin Islands, Puerto Rico, Guam, nine provinces of Canada, three Australian states, and New Zealand. NABP is the international, independent, 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 availability of prescription medications online is a relatively new occurrence, which provides certain benefits, as well as significant risks, to consumers. NABP's extensive research into this new and emerging area identified a wide array of legitimate practices and business operations as well as unscrupulous and dangerous online activities conducted with no apparent regard for laws, regulations, or the personal well being of the individuals accessing the sites. The Verified Internet Pharmacy Practice Sites™ (VIPPS™) program was developed by NABP to support the regulatory efforts of the state boards of pharmacy to better police Internet pharmacies. VIPPS employs a multifaceted approach that combines the enforcement of laws, regulations, and recently developed and validated Internet practice standards with effective consumer education and empowerment.

OVERVIEW OF ONLINE SITES

NABP identified more than 150 pharmacy-based and a comparable number of prescribing-based sites currently available to the public through the legitimate areas of the Internet and the use of conventional search engines. In the context of our research, pharmacy-based sites are defined as those sites that do not offer prescribing services and are associated with an identifiable pharmacy licensed/registered by a state board of pharmacy in the United States. Prescribing-based sites are defined as those online outlets that provide medications to consumers utilizing a cyberspace consultation or questionnaire. Almost without exception, the pharmacy-based sites are located in the United States and its territories and regulated by a state agency. The prescribing-based sites are a complex mix of operations, based both in the United States and its territories and foreign countries. The most egregious and dangerous sites NABP identified are certain prescribing-based sites that operate outside the jurisdiction of the United States with little or no regard for the laws and regulations of the states.

The practices of these sites to make prescription medications available to consumers without a legitimate patient-prescriber relationship, and thus, without a valid prescription order, are not only dangerous but, in the opinion of NABP, illegal.

The prescribing-based sites are often organized into an intricate arrangement of portals and relocator pages designed to increase the accessibility to the services and mislead the consumer into believing that such sites are legitimate simply because of the vast number of similar sites. The system resembles fraudulent "pyramid operations" where a primary operation is often supported by a varying number of referral or access portals. To the unknowing consumer, the referral or relocator pages

appear to be independent and individual sites. In reality, however, such sites are linked and serve only as a means for the primary site to forward sales into its distribution operations.

STATE REGULATION OF U.S.-BASED ONLINE SITES

Online sites located within the U.S. and its territories can be effectively controlled by the state agencies constitutionally empowered to regulate the practices of pharmacy and medicine. It is NABP's position that initiatives to circumvent this authority and assign responsibility for the activities of U.S.-based online sites to federal agencies are unwarranted and preempt the constitutional authority of the states to regulate professionals through the police powers.

Although NABP and its member boards work closely with our counterparts in medicine, it is not appropriate for us to comment on their activities or scope of authority beyond addressing a critical question concerning the online prescribing of medications. It is our interpretation of state medical practice acts that the primary component of the practice of medicine is a valid patient-prescriber relationship. NABP's research into online sites indicates that sites operating illegally are ignoring this requirement and confusing the public by inappropriately defining the use of questionnaires or cyberspace consultations as constituting a valid patient-prescriber relationship.

The Board of Trustees of the American Medical Association, in a report issued in June 1999, challenged the use of questionnaires and online consultations that fail to include: (1) the examination of the patient, (2) dialogue with the patient, (3) establishment of a reliable medical history, (4) providing information to the patient about the prescribed medication, and (5) follow-up with the patient to assess the therapeutic outcome. The report states further that, "Under existing law in the majority of states, prescribing drugs to a patient outside the state where the physician is licensed is considered the unlicensed practice of medicine." It is our belief that state boards of medicine can, and will, effectively regulate these practices and establish appropriate regulations for the prescribing of medications online.

It is NABP's position that pharmacists and pharmacies dispensing prescription medications pursuant to an invalid patient-prescriber relationship are acting illegally and are subject to disciplinary action by the appropriate state board of pharmacy.

The regulation of the practice of pharmacy is rooted in state practice acts and regulations enforced by the state boards of pharmacy. The practice acts and regulations of all U.S. jurisdictions prohibit any entity from operating or representing itself to the public as a pharmacy without licensing/registering with the appropriate state agency, complying with all applicable state and federal laws, and undergoing periodic and/or routine inspections.

Generally, the state boards have the authority to regulate online pharmacies pursuant to existing practice acts under which they presently regulate traditional in-state and out-of-state pharmacies that distribute or dispense drugs within the state borders. Out-of-state pharmacies' regulations focus specifically on this practice sector and provide state boards of pharmacy with the enforcement mechanisms needed to regulate their activities. The NABP *1998-99 Survey of Pharmacy Law* notes that forty (40) U.S. jurisdictions require the licensure/registration of out-of-state pharmacies (Attachment "A"). An example of specific state regulations governing out-of-state pharmacies is included (Attachment "B").

State boards of pharmacy and boards of medicine acting to curb the illegal and dangerous activities of online pharmacies have been effective in closing sites and disciplining practitioners. The most recent example of such actions occurred in Missouri, when the Missouri Attorney General obtained a temporary restraining order to halt the operations of a pharmacy licensed in Texas. The attached press release (Attachment "C") notes that the Texas physician involved is prohibited from using online consultations to support prescriptions and the dispensing pharmacy must include a notice on its Web site alerting consumers that its services are not available to consumers living in Missouri. This recent action by Missouri is significant in many regards. First, it demonstrates the willingness of states to act on the inappropriate practices of online distributors of prescription medications. Second, it demonstrates the ability of states to regulate and discipline pharmacies located in other states.

PRINCIPLES OF UNDERSTANDING WITH THE FDA AND FSMB

NABP has also executed an agreement with the Food and Drug Administration (FDA) and Federation of State Medical Boards (FSMB) to agree in principle to work cooperatively to encourage the enforcement of applicable statutes and regulations,

including the Federal Food, Drug, and Cosmetic Act (FFDCA) and implementing regulations and state statutes and regulations as regards such conduct, and to work towards developing formal agreements to this effect. The parties of the "Principles of Understanding" recognize that a cooperative effort of state and federal authorities is the best means for resolving this problem and ensuring the safety and welfare of the citizens we serve.

COMPLEMENTARY DISCIPLINARY ACTIONS

The Missouri action is also significant because of the ramifications it may hold for the pharmacist and pharmacy. NABP currently maintains a National Disciplinary Clearinghouse and Database. The NABP Clearinghouse and Database contains licensure and disciplinary information on pharmacists, pharmacies, technicians, interns, and wholesale distributors. The NABP Clearinghouse and Database is maintained by the state boards of pharmacy through NABP and utilized by the states to determine the qualifications of individuals and entities seeking licensure in their jurisdictions. It is also used by states to determine when it is necessary to take action against local licensees who hold licenses in other states and are disciplined by another state board of pharmacy. For example, a pharmacist licensed in States A, B, and C commits a serious violation of State A's practice act and, after due process, has his/her license to practice in State A revoked. Once that action is finalized, it is provided to NABP's Clearinghouse and Database and disseminated to the states in which the pharmacist currently holds licensure (as noted by NABP's Clearinghouse and Database) and to all other member states of NABP.

State practice acts and regulations empower the other states where that pharmacist holds licensure to take appropriate action against those licenses based upon the revocation of licensure by State A. In most cases, such severe action by State A will result in States B and C taking similar disciplinary action and revoking the pharmacist's license. These actions are again reported to the NABP Clearinghouse and Database and reported to all states, specifically to states where the pharmacist may be seeking licensure. A pharmacist whose license has been revoked will have little chance of obtaining licensure in a new state until the license in the original state(s) is restored to good standing.

The ability of state boards of pharmacy to discipline licensees based upon the actions of other states where the licensee holds licensure is an important enforcement tool utilized by the state boards of pharmacy to effectively halt illegal and dangerous activities.

NABP'S VIPPS ™ PROGRAM

The NABP VIPPS program is a voluntary program that combines the mandatory requirements of state regulation with Internet practice standards developed by an expert panel of providers, federal agencies, and state regulators. The actual operation of the VIPPS program is detailed in NABP's response to the Committee's questions of July 1 (Attachment "D").

An Internet site earning NABP's VIPPS seal must meet and demonstrate compliance with all mandatory licensure, statutory, and regulatory requirements of state practice acts. There is no variance from this requirement. NABP will independently verify this compliance directly with the states through its Clearinghouse and Database and onsite inspections of the sites and affiliated facilities. The NABP VIPPS seal will inform consumers that the online site is a legitimate practice site licensed or registered with a state agency. It will also provide the consumer with important information about the site and how to contact the appropriate governmental agency to record a concern or complaint. The NABP VIPPS seal will direct consumers to the NABP Web site to confirm the site is legitimate and provide additional information about the online site. Elaborate security measures are being employed to avoid misrepresentation or inappropriate duplication of the NABP VIPPS seal. This information is presented in more detail in our response to the Committee's July 1 questions (Attachment "D").

CONCLUSION

The National Association of Boards of Pharmacy believes that existing state laws and regulations in conjunction with its VIPPS program provide an effective means to regulate and monitor U.S.-based online sites. State boards can be assisted in this regard by the provision of funds and the cooperative efforts of federal agencies. NABP acknowledges that foreign-based online sites may be outside of the jurisdiction of the state boards of pharmacy and operating without restriction or control. Legislation and intensified efforts to curb these activities are desired and needed.

NABP is grateful to assist the Committee in its deliberations for this timely and significant issue of public health. We ask the Committee to carefully consider any action that would preempt state authority by assigning legal responsibility for any aspect of the regulation of pharmacy practice to federal authority. Such an action will not address the serious problems and actions of the foreign-based online sites and only precipitate a regulatory quagmire of conflict and confusion between state and federal agencies. Thank you for providing NABP with this opportunity to testify on this most important subject matter.

[Attachments A-D are retained in subcommittee files.]

Mr. BRYANT [presiding]. Thank you.

Dr. Abromowitz.

STATEMENT OF HERMAN I. ABROMOWITZ

Mr. ABROMOWITZ. Mr. Chairman, members of this subcommittee, my name is Herman Abromowitz, and I am a member of the American Medical Association board of trustees and I'm a practicing family and occupational medicine physician in Dayton, Ohio. We thank you for the opportunity to appear before this subcommittee.

Let's look at the serious problems associated with Internet prescribing. The AMA is concerned that some prescription drugs are ordered and dispensed over the Internet in a manner that clearly constitutes dangerous medical practice. This raises very serious ethical questions and puts patients at great risk.

The American Medical Association's council on Ethical and Judicial Affairs is currently reviewing the entire spectrum of telecommunications, Internet, e-mail telemedicine, and their impact on the overall physician-patient relationship.

Often Web sites request insufficient data to fill a prescription and provide limited information about the prescription, including potential risk. Drugs may be provided without a physician's consultation and, worse, the prescribing physician and may never have obtained or have ready access to a patient's medical history. Further, there is no physical examination or follow-up.

For example, as noted today many times, a typical Web site advertising Viagra will require the patient to waive liability, select a quantity of Viagra, and fill out a very short questionnaire. It is that easy, ladies and gentlemen, and potentially fatal. There is no verification of the accuracy or truth of the patient's statement electronically, and the physician is not able to use clinical expertise and professional judgment to evaluate the appropriateness of this medication for this patient.

Neither is there any discussion of the substantial risk, including death. These Internet prescribing practices are compounded by the fact that some foreign companies, as noted today, are illegally selling prescription drugs in the United States through their Internet Web sites. This may permit patients in the U.S. To obtain non-FDA-approved drugs without a prescription and/or advice of a physician. This could threaten the whole concept of prescription drugs in the U.S., which would be extremely dangerous to patients.

Drugs may be contraindicated and may react to other medications the patient is currently taking; the patient may be allergic to a drug; and the risk, including death, are greatly enhanced, because there has not been any direct physician-patient relationship.

In my personal opinion as a practicing physician for over 30 years, it is vital and in the patient's best interests to have a direct

onsite visit with their physician before taking new or changing medications. Otherwise you are potentially risking your life, as dramatic as it may seem. I ask you: Would any of you take medication not prescribed for you by your own physician? If so, I would like to talk to you after this meeting.

Obviously there is an urgent need to establish medical safeguards to restrict these dangerous prescribing practices. The American Medical Association has several recommendations:

One, a physician must establish or have ready access to reliable medical history, which generally should include a physical examination of the patient. Otherwise this is far below the accepted standard of care.

Two, there must be a dialog between the physician and the patient to discuss treatment.

Three, the physician should inform a patient about a drug's benefits and risks.

Four, the physician should have appropriate follow-up to assess patient outcome.

What can we do to ensure that safety requirements are met with regard to Internet prescribing practices? The AMA will continue to develop principles for appropriate use of the Internet in prescribing medications and will coordinate our efforts with other professional organizations.

As noted today, for example, we are working with the National Association of the Boards of Pharmacy to develop its Verified Internet Pharmacy Practice Sites program. We also expect to work with State and Federal authorities along with State medical societies. States generally have primary jurisdiction over domestic-based Internet prescribing activity, and some States currently are investigating physicians for inadequate on-line prescribing practices.

The Federal Government can build on State efforts. The American Medical Association supports the FDA's principles governing Internet prescribing. The FDA has an important role to play in prohibiting foreign companies from illegally selling unapproved and approved prescription drugs over the Internet.

While State and Federal authorities and professional organizations must all coordinate efforts to assure appropriate Internet prescribing practices, I mention a word of caution: We need to protect and even enhance legitimate electronic prescribing and dispensing practices. For example, a number of licensed Internet pharmacy sites allow computer order entry and on-line transmission of prescriptions "after," after a physician has seen the patient.

Let me conclude by saying that as we discuss this fast-changing world of Internet prescribing and telecommunications, please refer to the time-honored oath of Hippocrates, taken by your physician and myself: Do no harm.

Thank you. I am happy to answer any questions later. Thank you, Mr. Chairman.

[The prepared statement of Herman I. Abromowitz follows:]

PREPARED STATEMENT OF HERMAN I. ABROMOWITZ, MEMBER, BOARD OF TRUSTEES, AMERICAN MEDICAL ASSOCIATION

The American Medical Association (AMA) appreciates the opportunity to present to the Subcommittee its views on prescribing pharmaceuticals over the Internet, and

applauds the efforts of the Chairman and members of the Subcommittee for focusing on this important issue.

The use of the Internet for prescribing and dispensing medications is a practice that has become increasingly prevalent during recent years as the Internet has become more popular and accessible to consumers. The Internet can be an extremely valuable medical resource under certain circumstances, and there currently are many legitimate uses of the Internet for prescribing and dispensing medications. The AMA, however, is gravely concerned about current misuse of the Internet for prescribing purposes. The Food, Drug and Cosmetic Act requires physician involvement in making prescription drugs available. This requirement is part of the safety analysis conducted by the Food and Drug Administration (FDA) prior to the approval of any new drug.

Everyday patients are endangered when they are permitted to receive prescription medications via the Internet without adherence to proper safeguards that ensure good medical practice. Use of the Internet does not obviate the physician's obligation to meet appropriate standards of care when treating any patient.

Recently the AMA considered Internet prescribing issues and set forth its concerns with this matter. Today our testimony addresses the concerns that must be considered in connection with misuse of the Internet for prescribing and dispensing prescription drugs.

In summary, we believe that before prescribing a medication, a physician must—

- Ensure that a medical history is obtained or readily available;
- Provide information to the patient about the benefits and risks of the prescribed medication;
- Generally perform an examination of the patient to determine a specific diagnosis and whether there actually is a medical problem; and
- Initiate additional interventions and follow-up care, if necessary, especially when the drug in question (*e.g.,* Viagra®) may have serious side effects.

These are the requirements that a physician must meet in a setting traditionally used to visit with and treat patients. Treating patients via the Internet is no different, and thus these same requirements must also be met in this context. Web sites that offer a prescription solely on the basis of a simple questionnaire are not sufficient.

The Problem with Internet Prescribing

Internet prescribing has become more prevalent with the advent of certain drugs, such as sidenafil (Viagra®), a prescription drug used to treat erectile dysfunction. Often, the information requested on a web site that is necessary to issue and fill a prescription via the Internet is insufficient, as is accompanying information that should be provided to the patient concerning the prescription.

For example, a typical web site will advertise the advantages of obtaining Viagra® via the Internet. In addition, the web site will require the purchaser to acknowledge a liability waiver, select a quantity of Viagra® to be purchased, and fill out a short questionnaire. An example of such questionnaire is attached as Appendix I.

The questionnaire used does not meet standards that would be considered good medical practice. It usually requests minimal information about the medical history of the purchaser, and some terms used in the questionnaire (*e.g.,* nitrates, arrhythmia, unstable angina, retinitis pigmentosa) are likely to be beyond the level of understanding of a lay person. Further, there is no mechanism to determine whether the purchaser has answered the questions accurately or truthfully. Incorrect answers could be deliberate in order to obtain the medication or could result from a failure to understand the questions. Moreover, some web sites make no attempt to explain the potential risks of a drug, such as Viagra® therapy, for example.

More important, the AMA is very concerned that prescription drugs are being ordered without the benefit of a physical examination, which allows full evaluation of any potential underlying cause of a patient's dysfunction or disease, as well as an assessment of the most appropriate intervention. Clearly, current Internet prescribing practices for the most part do not involve any medical assessment or follow-up to determine whether the medication has been effective or if there are side effects.

This type of prescribing practice can be extremely dangerous for patients. For example, while Viagra® has been beneficial to many men with properly diagnosed erectile dysfunction, it also carries substantial risks for some patients and over 100 deaths have been associated with its use. Without appropriate information and discourse between physician and patient, there is a substantial risk that a drug may inappropriately be prescribed via the Internet that may cause significant harmful side effects and even death.

Without medical standards to serve as a safeguard against these dangerous practices, Internet prescribing could become extremely problematic. Indeed, prescrip-

tions for an increasing variety of prescription drugs may become available to the public through the Internet. Appendix II presents just a few examples of the many Internet prescription and dispensing services, and many more such services exist on the Internet. According to an article published June 16, 1999 in the *Chicago Tribune:* "No one has a clear grasp of the scope of the phenomenon, but some experts estimate that about 400 such instant-prescription Web sites exist, about half based overseas."

Internet prescribing problems are compounded by the fact that some foreign companies are illegally promoting and distributing (selling) prescription drug products in the United States through their Internet web sites. A recent example of this was described in an article published May 11, 1999 in the *New York Times:* "a company based in the Channel Islands of Britain called Direct Response Marketing is selling Xenical over the Internet to just about anybody who electronically fills out a medical questionnaire that is reviewed by a company doctor who then 'prescribes' the drug." "This wonder pill promises to be one of the defining drugs of the 90's along with Prozac and Viagra" the company states on its World Wide Web site. "Most overweight people harbor a sneaking suspicion that somewhere there is a product that will solve all of their weight-loss problems. Well, now that product has arrived."

If this trend continues, a triple problem exists. First, patients in the United States would easily be able to obtain drugs that have not been approved by the U.S. FDA. Second, these drugs would not have been tested in rigorous clinical trials; and third, patients would be receiving these drugs without the advice of a physician. There virtually is no accountability and there are no safeguards that address drugs obtained from foreign web sites. You should not allow this trend to continue. Accordingly, we again emphasize the importance of ensuring that minimum standards of proper medical care are met with respect to prescribing, including Internet prescribing.

Minimum Standards for Proper Medical Care

To avoid the serious problems discussed above, the AMA strongly advocates that diagnostic and treatment decisions made by physicians, including the issuing of a prescription for medication via the Internet or any setting, should be supported by appropriate information. The evaluation leading to diagnostic and treatment decisions generally includes an adequate medical history and an appropriate physical examination. The length and complexity of this evaluation often is dependent upon the problem being presented by the patient. At times, the history and/or the physical examination may not need to be repeated if it is already on record as part of an ongoing relationship between patient and physician.

The AMA strongly believes prescribing practices over the Internet must at least meet the following minimum standards of care—

- There generally must be an examination of the patient to determine a specific diagnosis and whether there actually is a medical problem;
- There must be a dialogue between the physician and patient to discuss treatment alternatives and determine the best course of treatment;
- The physician must establish or have ready access to a reliable medical history;
- The physician must provide information to the patient about the benefits and risks of the prescribed medication; and
- The physician must follow-up with the patient to assess the therapeutic outcome.

AMA Involvement in Ensuring Proper Internet Prescribing Practices

The AMA will continue its involvement in studying the issue of Internet prescribing practices. Recently, the AMA adopted a report on Internet prescribing at our June 1999 annual meeting, and it included a number of recommendations for AMA involvement in ensuring proper medical practice with respect to Internet prescribing practices.

In accordance with these recommendations, the AMA will, among other things, develop principles describing appropriate use of the Internet in prescribing medications. These principles likely will be based on the guidelines discussed in the June report and this testimony, and will support use of the Internet as a prescribing mechanism where appropriate safeguards are in place to ensure standards for high quality medical care.

In addition, the AMA will work with state medical societies in urging state medical licensing boards to ensure high quality medical care by investigating and, when appropriate, taking necessary action against physicians who fail to meet local standards of medical care when issuing prescriptions through Internet web sites that also dispense prescription medications. Finally, as discussed further below, we believe there is a strong role that both state and federal authorities can play in this matter. We wish to work with the Federation of State Medical Boards and others in endors-

ing or developing model state legislation to establish limitations on Internet prescribing, as well as with federal and state regulatory bodies to close down Internet web sites of companies that are illegally promoting and distributing (selling) prescription drug products in the United States.

Finally, we will continue our review of legitimate uses of the Internet and update our recommendations concerning proper standards of practice on the Internet as changes in technology may dictate changes in these standards or even permit additional legitimate Internet prescribing practices.

Legitimate Uses of the Internet for Prescribing and Dispensing Drugs

As discussed above, despite problems with misuse of the Internet for prescribing and dispensing, the Internet can be a valuable source for prescription medications, and a number of appropriately licensed Internet pharmacy practice sites are legitimately dispensing prescription medications pursuant to a valid prescription. Care must be taken to protect and even enhance legitimate electronic prescribing and dispensing practices.

Some examples of the Internet being used for legitimate electronic prescribing purposes are:

- *Computer order entry and on-line transmission of prescriptions.* After a physician sees a patient and performs an adequate medical history and physical, computer order entry and on-line transmission of a prescription to a pharmacy provides an alternative mechanism for prescription transmission. Many experts believe computer order entry of prescriptions can reduce errors that occur from failure to understand handwritten prescriptions. Because technology exists to allow validation of electronic signatures and the encryption of prescription information, even the Drug Enforcement Administration (DEA) is considering allowing this route of prescription ordering, including the ordering of Schedule II drugs.
- *Ordering refills—either patient to pharmacy or physician to pharmacy.* There is a legitimate clinical decision under circumstances where the physician does not see the patient at the time a refill is ordered, but the patient has been and remains under that physician's care and has been seen in person in the recent past. If the refills are authorized on the original prescription, the patient can electronically contact the pharmacy directly and request the refill. This could be a community, mail service, or legitimate Internet pharmacy. When no refills are remaining on the original prescription, the patient could call or electronically contact the physician requesting that a refill be authorized. If the physician believes the refill is needed, the physician can electronically send the renewed prescription to the pharmacy.
- *Electronic consults between physician and patient where the outcome is an ordered prescription.* There can be a legitimate clinical decision under circumstances where the physician does not see the patient at the time a *new prescription is ordered.* This occurs when the patient is under that physician's care, the physician has the patient's medical history and physical information in the medical record, and the patient has been seen in person in the recent past. For example, a patient may inform his or her physician via telephone or electronic mail of a flare up in a seasonal allergy or a documented problem, and the physician may then electronically transmit a prescription for an antihistamine to the pharmacy without an additional office visit. It is critical here that the physician and patient have an ongoing relationship, the patient routinely uses this physician, and the patient's history and physical information are already in the medical record.

In addition to legitimate electronic prescribing via the Internet, there also are appropriately licensed Internet pharmacy practice web sites that provide an alternative consumer option for the dispensing of prescriptions. Recently, the National Association of Boards of Pharmacy (NABP) announced its decision to develop the NABP Verified Internet Pharmacy Practice Sites (VIPPS) program. The VIPPS program will verify the licensure of Internet pharmacy practice sites and inform the public, through a database on the NABP web site, about whether those web sites are licensed in good standing with the appropriate state board(s) of pharmacy or other regulatory agencies. The AMA has participated on a NABP Task Force to develop criteria for the VIPPS program, and will continue to work with the NABP and support their VIPPS program so that physicians and patients can easily identify legitimate Internet pharmacy practice sites.

State and Federal Involvement in Internet Prescribing

The AMA believes that Internet prescribing practices not based on appropriate safeguards to ensure high quality medical care are dangerous and highly inappro-

priate. State authorities, including state medical and pharmacy boards, as well as the federal government have a significant role to play in restricting these practices, but must take care not to interfere with legitimate uses of the Internet.

For the most part, states have primary jurisdiction in these matters, and this is appropriate. Under existing law in the majority of states, prescribing drugs to a patient outside the state where the physician is licensed is considered the unlicensed practice of medicine. Additionally, under most state laws, state medical and pharmacy licensure boards have been delegated jurisdiction, respectively, over medical and pharmaceutical professional practices.

Every state medical board agrees that prescribing drugs without physically examining a patient or reviewing his or her medical records is, in most cases, practicing medicine at a level far below the acceptable standard of medical care. However, at the close of the 1998 state legislative sessions, there were no state laws or regulations directly addressing the issue of Internet prescribing.

Some state licensing boards (Arizona, Colorado, Connecticut, Illinois, Nevada, New Jersey, Ohio, Texas, Washington, and Wyoming) are continuing or initiating investigations into physicians who participate in Internet prescribing. For example:

- On May 3, 1999, the Washington Medical Quality Assurance Commission initiated a licensure action against a Seattle physician for unprofessional conduct for prescribing Viagra® based only on questionnaires completed over an Internet drug-sales site. According to the Commission, the physician was earning $5,000 a month for performing automated online medical reviews.
- On May 5, 1999, the Illinois Professional Regulation Department suspended the license of a physician who was writing Viagra® prescriptions for a pharmacy web site based on a one-page health form and an $85 consultation charge. There was no examination or discussion with the patient. On May 20, the physician's license was reinstated after he agreed to stop prescribing drugs over the Internet or for patients he has not examined. The physician was ordered to pay a $1,000 fine.

These state medical licensure boards are acting well within their authority to uphold the standard of medical care when they investigate physicians who participate in Internet prescribing, and the AMA encourages state boards to investigate any physician or pharmacy that participates in any improper Internet prescribing practices.

Further, as discussed above, the AMA will be working with state boards to establish standards that ensure adherence to proper Internet prescribing practices. In addition, we expect that states will be maintaining their efforts in regulating prescription-selling web sites. It is reasonable to expect that state lawmakers will begin to explore various methods of regulating the manner and in what medium prescription drugs and other medical treatments may be prescribed.

Moreover, the Federation of State Medical Boards (FSMB) is addressing the issue of prescribing medications via the Internet. At a February 8, 1999, meeting convened by the FDA on this issue, a FSMB representative stated that its Committee on Professional Conduct and Ethics had taken a position that it is unprofessional conduct for a physician to provide treatment recommendations, including the prescribing of medications, without taking an adequate medical history and doing a physical examination. It is our understanding, however, that this Committee's final report is not scheduled for consideration and possible adoption by the FSMB until next year.

In addition to state activity, the federal government also has a role to play in ensuring appropriate Internet prescribing practices by assisting and building on these state efforts. Indeed, this is already occurring. For example, Pfizer, the manufacturer of Viagra®, has filed a complaint with the Federal Trade Commission (FTC) asking the FTC to assert authority over Internet prescribing of Viagra® and to proceed against those who dispense Viagra® on-line without adequate safeguards. According to the complaint, Internet sale of Viagra® where a prescription is obtained based on responses to a questionnaire is inadequate for a diagnosis and does not adequately convey the risks of the product, including: (i) risk of concomitant use of nitrates (resulting in possible heart failure from a large and sudden loss of blood pressure when taken in conjunction with heart medication), (ii) underlying medical problems that go undiagnosed because there is no real physical examination, and (iii) risk arising from sexual activity itself.

The federal government, especially the FDA, also has an especially important role to play with respect to addressing web sites of primarily foreign companies that are illegally promoting and distributing (selling) unapproved and approved prescription drug products in the United States, as discussed above. These web sites have multiplied with the growth of the Internet. Typically, these companies will post a price list and advertise that they can sell United States-patented prescription drug prod-

ucts at greatly reduced prices. In many cases, the advertisements state that the medication can be ordered and obtained without a prescription.

Among the concerns with illegal distribution of drugs from foreign sources is the product quality of these "foreign versions" of prescription drugs and whether patients are at risk of harm due to lack of physician oversight and inadequate directions for use. If obtaining prescription drugs from foreign companies without a prescription through the Internet becomes common, it threatens potentially to render the whole concept of legend (by prescription only) drugs meaningless in the United States. While the FDA has used its authority to prevent this illegal activity by some foreign companies, it has been difficult to stop these and other companies from simply continuing these illegal activities from another web site.

In accordance with the above, it is clear that improper and illegal Internet prescribing practices threaten traditional mechanisms that have been long-established to ensure good medical practice when prescribing and dispensing prescription drugs to patients. An FDA-developed document, entitled, *Principles of Understanding on the Sale of Drugs on the Internet,* addresses this concern, and we endorse these principles.

The AMA believes the states and their medical boards must carefully develop standards that continue to ensure such good medical practice when the Internet is used to prescribe and/or dispense prescription drugs, without impeding legitimate use of the Internet. State medical boards must also initiate investigative and enforcement efforts of physicians who violate these standards. These state activities should be accomplished in conjunction with industry organizations, such as the AMA, state medical societies and other professional entities discussed throughout this testimony. Finally, the federal government should coordinate with the states to monitor and facilitate enforcement activity with respect to illegal, domestic-based Internet prescribing activity.

We thank the members of the Subcommittee for your concern and for initiating a review of this important matter. We look forward to working with state and federal authorities to establish standards that assist in the proper use of the Internet for prescribing practices, and stand ready to work with the Subcommittee to further those efforts.

Appendix I

Viagra Fax-Back Form
PRINT, ANSWER ALL QUESTIONS and FAX back to:

Full Name:_____

Street Address:_____

_____

State/Prov: _____ Country _____ Zip/PC:_____

Phone: _____ Fax: _____ E-mail: _____

Date of Birth: _____ Sex: MALE FEMALE **(circle one)**

Height _____ Weight:_____

Known Allergies: _____

Conditions for which you are currently receiving treatment:_____

_____

Current Medications: (Please list all medications you are taking, even occasionally)

_____

Do you take any medication classified as a nitrate in any form?
YES NO (circle one)

Do you have a problem achieving and/or maintaining an erection sufficient for sexual intercourse?
YES NO (circle one)

Have you suffered a myocardial infarction, stroke, or life-threatening arrhythmia within the last two years? Do you have resting hypotension (BP170/100)?
Do you have cardiac failure or coronary artery disease causing unstable angina?
Do you have retinitis pigmentosa?
YES to one or more. NO to all. (circle one)

How did you hear about us? _____

Credit Card: **VISA MASTERCARD AMEX DISCOVER (circle one)**

Name on Card: (if different than above) _____

Cardholder Address: (if different than above) _____

_____

Credit Card Number: _____ Exp. Date: _____

Shipping Address: (if different than above) _____

_____

I would like a prescription for Viagra:
Circle Strength requested or Rx will be for 50mg.

	25mg	50mg	100mg
___ 10 Tablets $105.09			Make Checkmark
___ 20 Tablets $204.69			next to number
___ 30 Tablets $304.39			of Tablets requested.

I certify that I have answered all questions truthfully and that I have read and agree to the Waiver of Liability (http://www._____) agree to the $85.00 consultation fee and I am legally entitled to receive Viagra. I also understand that _____ shipping charges are in addition to my calculated totals and will vary with destination and will range from: **Inside U.S. $9.00 (waived for orders inside U.S. of 20 tablets, or more). Canada $18.00 and Outside the U.S. $50.00 to $79.00, and I am responsible for all import charges.**
Signature: _____ **Date:** _____

Appendix II

NAME DRUGS[1]	WEBSITE COST/ 30 VIAGRA	WAIVER	CONSENT	CONSULTATION
Focus Medical V	www.focus-medical.com $300.00 - 100 mg	YES	YES	$85
KWIKMed V	kwikmed.com $358.50 - 100 mg	YES	NO	$65
Cymedic Health Group Inc. V	www.cymedic.com $358.50 - 100 mg	YES	NO	$50
Worldwide Medicine Inc. V P (World RX	www.worldwidemedicine.com $300.00[2] - 100 mg www.worldrx.com)	YES	YES	$85
Deyarman Medical Group P M	www.drpropecia.com ---	YES	NO	$50
Doctors ASAP V P	www.doctorsasap.com $300.00 - 100 mg	YES	YES	$85
The Net Doctor V P P2	www.net-dr.com $290.00 - 100 mg	NO	NO	$70
MedicalCenter.net V P C (The Pill Box Pharmacy	www.medicalcenter.net $304.39 - 100 mg www.thepillbox.com)	YES	NO	$85
Male Clinic V P P2	www.maleclinic.com $290.00 - 100 mg	NO	NO	$70
Privacy Medical (non-U.S.) V P	www.privacymed.com $290.00 - 100mg	NO	NO	$70
ViaPro V	www.viapro.com $360.00 - 100 mg	YES	NO	$65
MediSource V P Z V2 M2 P3	www.get-it-on.com $300.00 - 100 mg	YES	NO	$35

[1] V = Viagra; P = Propecia; M = Minoxidil; P2 = Proscar; C = Claritin; Z = Zyban; V2 = Valtrex ; M2 = Meridia; P3 = Phentermine

[2] SPECIAL OFFER! "WorldWide Medicine, Inc. is running a special on 50mg doses for a limited time for $4.95 per dose!"

Mr. BRYANT. Thank you, Doctor.

Ms. Culmo. You have a "Mr." in front of your name.

TESTIMONY OF CYNTHIA T. CULMO

Ms. CULMO. That is okay. Thank you. Mr. Chairman and members, thank you for inviting me here today on behalf of Commissioner Archer and the Department. TDH welcomes the opportunity to present comments to the subcommittee.

The Department of Health is involved in the regulation of drugs and medical devices and the manufacture and distribution and possession in the State of Texas, and we are very much involved in the Internet sales and distributions of drugs and medical devices.

Our perspective regarding on-line pharmacies reflects the view of a State regulatory agency. Our intent is not to prohibit, but place some oversight, so consumers are assured of as much safety as possible. We can appreciate the fact that technology is rapidly evolving and the concept of telemedicine on the surface appears progressive and can serve as a method to extend health care and access. The idea and the practices may have merit, but some of the actual practices encountered by State agencies are of concern, and there are difficulties in applying the current laws to these Internet prescribing and dispensing businesses.

The Internet has afforded great benefits which have been particularly manifested in the delivery of information and education to the public and the enhancements of commerce. But such information must be viewed with caution.

The information provided on the Internet is not reviewed or approved by any scientific or regulatory body, and to date no one assumes responsibility for the information provided via the cyberhighway. As an example, we have encountered pseudo-docs, presenting themselves on the Internet as physicians, when in reality they are not licensed medical practitioners. Not only is this a national concern, requiring uniform regulation; the international information should be harmonized and standardized in a manner consistent with international harmonization efforts that are currently being pursued by several regulatory groups around the world for drugs and medical devices.

Should new national regulations prove successful and regulatory actions are initiated as necessary, equal or similar international standards and enforcement, the control of foreign sites, products, and therapies, will need to be addressed to assure international compliance. Once regulatory authority is established, then each entity will then have the same or similar priorities.

We are aware this raises a completely different set of issues, but want to point out we see benefits as well as concerns. We understand that the main benefit of the Internet for health care product access is confidentiality and convenience. Since a number of prescription drugs obtained from the Internet sites are those categorized as lifestyle drugs, those for improved sexual performance, weight loss, the treatment of hearing, et cetera, the Internet purchasing allows one to buy without being seen and affords one the convenience of purchasing from home, office, or on the road. But this benefit could also be recognized as one of the elements which places a customer at an increased risk. The increased risk is due

to one of the checks and balances placed in our health care system being eliminated.

Safeguards to protect patients from injuries resulting from the use of unsafe drugs and devices, unapproved drugs and devices, counterfeit drugs and devices, and the illegal practice of medicine and pharmacy, have been legislatively mandated, both federally and through State legislatures. These mandates have included or implied the requirement that a patient first be seen and examined by a licensed health care practitioner to receive a prescription for prescription drugs and/or devices.

A physician-patient relationship must be established, and until the advent of the Internet, this was understood or specifically noted in State statutes as physical onsite examination. Everyone realizes this is the ideal, and even with these mandates, errors occur in the traditional health care world. There are occasions in the current system when physicians will prescribe for patients without seeing them, but it is not the norm.

The Internet site utilizes questionnaires and/or surveys, is creating a situation where this is the norm. These types of Internet sales circumvent the elaborate controls that our country has placed on dangerous drugs and/or restricted medical devices, and thus its risks are increased. These also result in the majority of complaints.

These controls put in place by Congress and the States establish the physician oversight and physician responsibility for proper use based upon their education, knowledge, experience and best practices, as well as the requirement that a licensed pharmacist dispense the prescribed drug and/or device. There are several pharmacy Web sites which appear to be practicing legitimately and similarly to the currently regulated mail order pharmacies. These sites are of less concern to date.

These are two examples which highlight problems associated with an on-line pharmacy:

We in Texas just recently had a complaint forwarded to us where a pregnant attorney completed a survey and noted on the survey that she was pregnant. She received Propecia, a prescription drug with significant warnings and precautions for women who are or could be pregnant.

Propecia is strictly contraindicated in women of childbearing age, due to causing severe birth defects. The survey was supposedly reviewed by the site's medical director and he approved the cyberprescription for a pregnant consumer. This does not meet the appropriate medical standard of care because they offered a prescription for a patient they have never seen before, and based solely on an on-line survey. The pharmacist also dispensed a prescription and, to our knowledge, did not receive the survey as well.

This demonstrates what happens when safeguards established to address products classified as "dangerous" are bypassed.

Another site, to which there are attachments in the packets submitted earlier, not using a survey cyberform, but they advertise Phen-fen, controlled substances, and steroids as just a few examples, available without a prescription. Phen-fen has been removed from the market in the United States due to its adverse affects. The others on the list are extremely dangerous as well.

There are currently Federal and State drug laws which address specific drug and device regulations, and the consumer protection acts which address deceptive advertising and sales practices. Nonetheless, these are not written to control the Internet sales and deliveries from State, national and international sources. There are limited resources available to the State and Federal regulatory agencies to carry out enforcement actions and the emphasis must be placed on the word "limited." .

Because there is a common element of limited resources between the State and Federal regulatory agencies, interagency cooperation in this arena is of particular importance.

For the sake of time, I will bypass the rest of that.

Many of the owners of the Internet Web sites have advocated a position of opposition to oversight, regulatory oversight. The Internet sites, Soma.com in the "pink sheet" on April 5, 1999, was quoted that several "watchdog organizations" are already reviewing regulation of Internet prescription sales. Of the watchdogs referenced in their list who they believe are providing oversight, FDA was the only one with requisite regulatory authority.

Another on the list, their list, is NABP, a non-regulatory association, the National Association of Boards of pharmacy. To us as a regulatory agency, it is of little consequence that a pharmacy site does not have one of NABP's verified Internet Pharmacy Practice Sites, or the VIPPS. The verification information provided by the VIPPS seal could be obtained by the consumer via other Internet sites and information. The point is, there is no guarantee for the consumers and the self regulatory models being proposed by Soma.com.

At a minimum, if these new prescription drug entrepreneurs are to continue their Internet practices, then a start perhaps would be a consideration given to a Federal requirement that physicians who wish to practice and diagnose and prescribe on the Internet be regulated by the State medical boards at those Internet locations. We should consider their Web sites as a practice location.

Additionally, the same considerations should be given to pharmacists and pharmacies practicing on the Internet. We should require licensing for those sites similar to that of mail order pharmacies. The sites and persons associated with the sites should be required to display their Web-specific licenses on their home page. These should be prominently located on the home page so the consumer and patient would clearly recognize they are conducting business with a legitimate site and licensed health care professionals.

Patchwork enforcement is not effective. Each State has different priorities and resources and Federal uniformity, we believe, is required.

In our view, these practices are not benign. They present a significant threat to public health and they necessitate serious consideration for close standardized and uniform regulatory oversight.

I would like to thank you again for allowing us this time to express our concerns, experiences, and views. And in closing, we too commit to continuing our time, information, and resources in supporting this effort.

[The prepared statement of Cynthia T. Culmo follows:]

PREPARED STATEMENT OF CYNTHIA T. CULMO, DIRECTOR, DRUGS AND MEDICAL DEVICES DIVISION, TEXAS DEPARTMENT OF HEALTH

This is the Texas Department of Health regulatory perspective regarding the on-line pharmacies. In short, it is an issue of great concern and it's an issue in need of immediate attention. The Internet serves as an electronic international hi-way for access to, and sales of both legitimate therapies, products, and practices, as well as untested, unapproved, and unsafe therapies, products, and practices. While the use of the Internet for legitimate treatment modalities has merit, the actual practices and products encountered on "the net" by regulatory agencies are of great public health concern. In addition, we are experiencing great difficulties in applying current "brick and mortar" laws which were not designed to address this technology. The Internet, with standardized and uniform regulation, could serve as a method to extend healthcare and health education. We would recommend new legislation which would require the medical practitioners to license their websites as practice locations. The pharmacists and pharmacies should also license their websites in their respective states. The home page should also be required to display the city and state of the website.

The Texas Department of Health (TDH) welcomes the opportunity to present comments to the Subcommittee on Oversight and Investigations on this important public health issue—Drugstores on the Net: The Benefits and Risks of On-Line Pharmacies. TDH is involved in the regulation of drugs and medical devices manufacturing, distribution, and possession in the state of Texas, and is very much involved in Internet sales and distribution of drugs and medical devices.

TDH's perspective regarding on-line pharmacies reflects the views of a state regulatory agency. We can appreciate the fact that technology is rapidly evolving, and that the concept of tele-medicine on the surface appears progressive and could serve as a method to extend healthcare and access. The idea and practices may have merit, but some of the actual practices encountered by state agencies are of concern, and there are difficulties in applying the current laws to these Internet prescribing and dispensing businesses.

The Internet has afforded great benefits which have been particularly manifested in the delivery of information and education to the public, and the enhancement of commerce. But such information must be viewed with caution. The information provided on the Internet is not reviewed or approved by any scientific or regulatory body, and to date no one assumes responsibility for the information provided via the cyber-hiway. As an example, we have encountered "pseudo-docs" presenting themselves on the Internet as physicians, when in reality they are not licensed medical practitioners. Not only is this a national concern requiring uniform regulation, the international information should be harmonized and standardized in a manner consistent with international harmonization efforts. Should new national regulations prove successful and regulatory actions are initiated as necessary, equal or similar international standards and enforcement, the control of foreign sites, products, and therapies will need to be addressed to assure international compliance. Once regulatory authority is established, each entity will then have the same or similar priorities. We're aware that this raises a completely different set of issues, but did want to point out that we see benefits as well as concerns.

We understand the main benefit of the Internet for healthcare product access: confidentiality and convenience. Since a number of prescription drugs obtained from Internet sites are those categorized as "lifestyle" drugs (those for improved sexual performance, weight loss, and treatment of hair loss, etc.) the Internet purchasing allows one to buy without being "seen" and affords one the convenience of purchasing from home, office or "on the road." This benefit could also be recognized as one of the elements which places a customer at an increased risk.

The increased risk is due to one of the "checks and balances" placed in our healthcare system being eliminated. Safeguards to protect patients from injuries resulting from the use of unsafe drugs and devices, unapproved drugs and devices, counterfeit drugs and devices, and the illegal practice of medicine and pharmacy have been legislatively mandated, both federally and through state legislatures. These mandates have included or implied the requirement that a patient first be seen and examined by a licensed healthcare practitioner to receive a prescription for prescription drugs and/or devices. A physician-patient relationship must be established, and until the advent of the Internet, this was understood or specifically noted as a physical on-site examination. Everyone realizes this is the ideal and, even with these mandates, errors occur in the traditional regulatory world. There are occasions in the current system when physicians will prescribe for patients without seeing them, but it is not the norm. The Internet sites utilizing questionnaires and/or surveys create a situation where this is the norm. These types of Internet

sales circumvent the elaborate controls our country has placed on dangerous drugs and/or medical devices, and thus the risks are increased. These also result in the majority of complaints. These controls, put into place by Congress and the states, established the physician oversight and physician responsibility for proper use based upon their education, knowledge, experience, and best practices, as well as the requirement that a licensed pharmacist dispense the prescribed drug and/or device. There are several pharmacy web sites which appear to be practicing legitimately and similarly to the currently regulated mail-order pharmacies.

Two examples highlight problems associated with on-line pharmacies. We just recently had a complaint forwarded to us where a pregnant attorney completed a survey and noted on the survey that she was pregnant. She received Propecia®, a prescription drug with significant warnings and precautions for women who are or could be pregnant. Propecia® is strictly contraindicated in women of childbearing age due to causing severe birth defects. The survey was supposedly reviewed by the site's medical director and he approved the cyber-prescription for a pregnant consumer. This does not meet the appropriate medical standard of care because they offered a prescription for a patient they have never seen before and based solely on an on-line survey. This demonstrates what happens when safeguards established to address products classified as "dangerous" are bypassed. Another site (see attachments) not using a survey cyber-form, advertises "Phen-fen," controlled substances, and steroids as available without a prescription. "Phen-fen" has been removed from the market in the U.S. due to adverse events.

There are the federal and state drug laws addressing specific drug and device regulations, and the consumer protection acts which address deceptive advertising and sales practices. Nonetheless, these were not written to control the Internet sales and deliveries from state, national, and international sources. There are limited resources available to the state and federal regulatory agencies to carry out enforcement actions. The emphasis must be placed on the word, "limited."

Because there is a common element of limited resources between the state and federal regulatory agencies, interagency cooperation in this regulatory arena is of particular importance. This is not necessarily problematic since interagency cooperation (partnerships, contracts, and memorandums) already exist. For those agencies not already involved in federal/state cooperative relationships, the template has been established and can easily be duplicated. This interagency cooperation should be utilized in all the areas mentioned above, as well as with education. The benefits of the Internet in education outreach must be utilized. Because this regulatory playing field is huge, oversight will be an enormous challenge, and education must be one of the components of that oversight.

Many owners of the Internet websites have advocated a position of opposition to regulatory oversight. The Intent site, "Soma.com," in "*The Pink Sheet*," April 5, 1999, was quoted that several "watchdog organizations" are already reviewing regulation of Internet prescription sales. Of the "watchdogs" referenced in their list, who they believe are providing oversight, FDA was the only one with the requisite regulatory authority. It is of little consequence that a pharmacy site does not have one of the National Association of Boards of Pharmacy's stamp of a Verified Internet Pharmacy Practice Sites (VIPPS). The verification information provided by a VIPPS seal could be obtained by the consumer via other Internet sites and information. The point is that there is no guarantee for the consumers in the "self-regulatory" models being proposed by "Soma.com."

At a minimum, if these new prescription drug entrepreneurs are to continue their Internet practices, perhaps consideration should be given to a federal requirement that physicians who wish to diagnose and prescribe on the Internet be regulated by the state medical boards at these Internet locations. We should consider their web sites as a practice location. Additionally, the same consideration should be given to pharmacists and pharmacies practicing on the Internet. We should require licensing for these sites similar to that of mail order pharmacies. The sites and persons associated with those sites should be required to display their web-specific licenses on their home page. These should be prominently located on the home page so the consumer/patient would clearly recognize they are conducting business with a legitimate site and licensed healthcare professionals.

In our view, these practices are not benign, they present a significant threat to the public health, and they necessitate serious consideration for close standardized and uniform regulatory oversight. I would like to thank you again for allowing us this time to express our concerns, experiences, and views. In closing, we commit to continuing our time, information, and resources in supporting this effort.

Mr. BRYANT. Thank you.

Mr. Razzouk.

TESTIMONY OF WILLIAM RAZZOUK

Mr. RAZZOUK. Mr. Chairman, members of the subcommittee, before I begin, allow me to thank you for giving us the opportunity to share with you what PlanetRx.com believes the on-line pharmacy business is and is not, should and should not be.

My name is Bill Razzouk, the Chairman and CEO of PlanetRx, a pharmacy chain with approximately 70 million branch stores, each of which is on the desktop of a person with computer access to the Internet.

Each of our customers, 70 million branch stores, is a traditional NABP pharmacy. Each one of our branch stores is a place where customers can come to buy over-the-counter products, obtain answers to their questions about prescription drugs and diseases, and have a licensed pharmacist fill the prescriptions issued to them by the properly trained and licensed physicians with whom they have a traditional doctor-patient relationship. In other words, PlanetRx.com is your NABP virtual pharmacy, an on-line pharmacy designed with guidance from leaders of the pharmacy profession.

Like your family's pharmacy, we authenticate all prescriptions before filling them. Like your family's pharmacy, we check to confirm that the prescribing physician is a properly licensed physician with a current DEA number.

Like your family's corner pharmacy, at PlanetRx.com, we do not prescribe drugs; we only dispense them. We do not interfere in any way with the sanctity of the patient-physician relationship. All of which is to say there is very little conceptual difference, but enormous difference, in terms of convenience between PlanetRx, traditional NABP pharmacies, and the mail order prescription services that are used by tens of millions of Americans, many of whom are elderly and housebound.

We fully understand that the concept of on-line pharmacies is new and a bit mysterious to some people. However, discomfort with the concept of e-commerce in general and 3-pharmacies in particular will not eliminate the reality of either. The Internet, as we all know, is now a major positive force in American business, and the legitimate emerging on-line pharmacies are an important part of this new environment.

Mr. Chairman, there is no doubt that we are all concerned about the irresponsible practices of Internet-based prescribers for hire, "doc in a box," doctors whose only contacts with their patient comes in reviewing an on-line questionnaire. Such practices are as abhorrent to us at PlanetRx as they are to our responsible competitors, to the National Association of Boards of Pharmacy, to the American Medical Association, and to you.

The elimination of the Internet equivalent of illicit drug sales does not require new legislation. All it requires is vigorous enforcement of the existing State and Federal laws.

In addition to abiding by all existing laws and regulations, PlanetRx also adheres to a code of principles we have developed for ourselves. We support the VIPPS criteria of the National Association of the NABP. We actively protect the security and confidentiality of our customers' personal information. We provide access to licensed pharmacists 24 hours a day, 7 days a week, including holi-

days. All of these activities meet or exceed traditional requirements for the practice of pharmacy as regulated by the States, and define the next generation of standards followed by responsible on-line organizations.

Quite simply, unlike the NABP pharmacy, we do have some of the most compelling health information on the Internet. A group of disease-specific satellite sites that are designed for sufferers of chronic diseases, including such domains as Diabetes.com, Arthritis.com, Depression.com. We provide easily accessible information on drug interaction as well as a broad range of general medical and personalized medical information. We offer the disabled, injured, and seriously ill an easy way to go to the pharmacy without leaving their homes.

Ultimately, we provide a place where people care about the needs and problems of seniors, the disabled and those who suffer from chronic disease and those who require ongoing follow-up.

The challenge for us as an industry is to manage patient safety, security, and confidentiality while not limiting the creativity that on-line access can offer the millions of Americans who require health care products.

What is needed is an innovative, aggressive effort to enforce existing State and Federal laws that secure legitimate on-line pharmacy distribution. To that end, we would like to use this forum today to call for a national summit meeting of on-line pharmacy industry and technology leaders to address the obvious questions and problems posed by the rogue on-line operators whose practices concern us as much as they do you.

This summit, hosted by PlanetRx, would serve as an opportunity to design tools and establish a system to enhance the enforcement of existing laws and regulations, consider the reliability of the VIPPS seal, and develop innovative ways to promote consumer education regarding responsible on-line pharmacy actions and consider ways that ensure that patients have the choice to fill prescriptions either on- or off-line.

Further, I suggest that the summit should take place within the next 90 days and that the first item on the summit agenda be the establishment of an industry-supported watchdog system that uses technology and trained industry experts to seek out and immediately report to regulatory authorities on the State and Federal level suspected sites that may be selling or prescribing medications without properly sensing.

We believe it is certainly possible to maintain a daily check for unlicensed or otherwise suspect sites in order to immediately report them to the appropriate authorities.

You may ask why you should allow our industry to act as a "neighborhood watch." we are offering to participate in this activity because we know the "neighborhood" well and we know the technology.

Mr. Chairman, we do not believe, however, that knew Federal legislation is necessary at this time. What is necessary instead is the development of innovative ways to apply the laws already in place in an on-line environment that could not have even been imagined when the various laws were written. In the summit we

are proposing, it will allow us together to develop those innovations, beginning with the daily check I just proposed.

Again, thank you for giving us the opportunity to appear before you today. I hope I have clearly explained the practices of our company and provided you some viable solutions to the issues that confront us on this.

[The prepared statement of William Razzouk follows:]

PREPARED STATEMENT OF WILLIAM RAZZOUK, CHAIRMAN & CHIEF EXECUTIVE OFFICER, PLANETRX.COM

Mr. Chairman, Members of the Subcommittee, before I begin, allow me to thank you for giving me the opportunity to share with you what PlanetRx.com believes the on-line pharmacy business is and is not, should and should not be.

My name is Bill Razzouk, and I am the Chairman and CEO of PlanetRx.com, a pharmacy chain with approximately 70 million branch "stores," each of which is on the desktop of a person with computer access to the Internet.

Each of PlanetRx.com's 70 million branch stores is a traditional neighborhood pharmacy. Each of our branch stores is a place where customers can come to buy over-the-counter products, obtain answers to their questions about prescription drugs and diseases, and have a licensed pharmacist fill the prescriptions that have been issued to them by the properly trained and licensed physicians with whom they have a traditional doctor-patient relationship.

In other words, PlanetRx.com is your "neighborhood" *virtual* pharmacy—an on-line pharmacy designed with guidance from leaders of the pharmacy profession.

Like your family's pharmacy, we authenticate all prescriptions before filling them;

Like your family's pharmacy, we check to confirm that the prescribing physician is a properly licensed physician with a current DEA number;

And, like your family's corner pharmacy, at PlanetRx.com we do not prescribe drugs, we only dispense them. We do *not* interfere in any way with the sanctity of the patient-physician relationship.

All of which is to say, there is very little conceptual difference—but enormous difference in terms of convenience—between PlanetRx.com, traditional neighborhood pharmacies, and the mail-order prescription services that are used by tens of millions of Americans, many of whom are elderly and housebound.

We fully understand that the concept of "on-line" pharmacies is new and a bit mysterious to some people. However, discomfort with the concept of E-commerce in general, and E-pharmacies in particular, will not eliminate the reality of either. The Internet, as we all know, is now a major positive force in American business. And the legitimate emerging on-line pharmacies are an important part of this new environment.

Mr. Chairman, there is no doubt that we are all concerned about the irresponsible practices of Internet-based prescribers for hire, doctors whose only contact with their patient comes in reviewing an on-line questionnaire. Such practices are as abhorrent to us at PlanetRx.com as they are to our responsible competitors, to the National Association of Boards of Pharmacy, to the American Medical Association—and to you.

The question before us then, is how to eliminate these unprincipled operators, while fostering the responsible, legitimate on-line pharmacy business in a way that will benefit consumers and protect their health interests.

Eliminating the Internet equivalent of back-alley drug sales does not require new legislation, all it requires is the vigorous enforcement of the existing state and federal laws. For example, PlanetRx.com, as a responsible on-line pharmacy, adheres to all state and federal regulations governing the practice of pharmacy, just as a traditional pharmacy does:

- We only fill prescriptions that are written by authorized prescribers;
- We maintain procedures that verify the authenticity of prescriptions;
- We are licensed to dispense and deliver prescriptions to all 50 states, the District of Columbia, and all U.S. territories;
- We conduct an extensive drug utilization review (DUR) prior to dispensing a medication in accordance with state law to help prevent harmful drug interactions;
- We do not practice medicine—we neither diagnose patients, nor prescribe medications.

In addition to abiding by all existing laws and regulations, PlanetRx.com also adheres to a "code of principles" we have developed for ourselves:

- We support the Verified Internet Pharmacy Practices Sites (VIPPS) criteria of the National Association of Boards of Pharmacy;
- We never sell, trade, rent, or intentionally disclose or access personal data without a customer's consent, except when required to do so by law or legal considerations;
- We actively protect the security and confidentiality of customers' personal information and use the most advanced technology to take orders and to display prescription information. We encrypt all personal information for transactions over the Internet;
- We provide access to licensed pharmacists 24 hours a day, 7 days a week—including on holidays.

All of these activities meet or exceed traditional requirements for the practice of pharmacy as regulated by the states, and define the next generation of standards followed by responsible on-line organizations.

While I've made several references to our similarities to the traditional neighborhood pharmacy, I'd like to outline the numerous differentiators and benefits that PlanetRx.com., an on-line pharmacy, offers consumers.

Quite simply, unlike the traditional bricks and mortar pharmacy:

- We have pharmacists available for private consultation by telephone or e-mail, 24 hours a day, seven days a week, 365 days a year, including all major holidays;
- We are able to carry an enormous array of over 28,000 unique health and beauty items;
- We provide e-mail reminders when it's time to refill prescriptions;
- We have some of the most compelling health information on the Internet, and a group of disease-specific "satellite" sites that are designed for the sufferers of chronic diseases including such domains as Diabetes.com, Arthritis.com, and Depression.com;
- We provide easily accessible information on drug interactions, as well as a broad range of general medical and personalized medical information;
- Because our "stores" are on our customer's desktops, rather than in invested overhead, we can offer lower drug prices to customers, which is particularly important to the millions of seniors who don't have prescription insurance;
- We offer the convenience and privacy of on-line ordering and consultation with a pharmacist, making customers more likely to ask questions they might be embarrassed to ask in the middle of a crowded traditional pharmacy;
- We offer the disabled, injured, and seriously ill an easy way to "go to the pharmacy" without leaving their homes.

Ultimately, we provide a place where people care about the needs and problems of seniors, the disabled, those who suffer from chronic disease, and those who require ongoing follow-up. Using our disease specific "satellite" sites, we are developing a network of patient-oriented communities that provide the emotional and group support many people lack when facing debilitating illness. At PlanetRx.com, we believe that providing care is an essential step in the healing process.

The challenge for us as an industry is to manage patient safety, security, and confidentiality while not limiting the creativity that on-line access can offer the millions of Americans who require healthcare products. What is needed is an innovative, aggressive effort to enforce existing state and federal laws that secure legitimate on-line pharmacy distribution. To that end, we would like to use this forum today to call for a national Summit meeting of on-line pharmacy industry and technology leaders to address the obvious questions and problems posed by the "rogue" on-line operators whose practices concern us as much as they do you. This Summit, hosted by PlanetRx.com, would serve as an opportunity to design tools and establish a system to enhance the enforcement of existing laws and regulations, consider the reliability of the VIPPS seal, develop innovative ways to promote consumer education regarding responsible on-line pharmacy practices, and consider ways to insure that patients have the choice to fill prescriptions either on or off-line.

Further, I suggest that this Summit should take place within the next 90 days, and that the first item on the Summit agenda be the establishment of an industry-supported "watchdog" system that uses technology and trained industry experts to seek out and immediately report to regulatory authorities on the state and federal level suspected sites that may be selling or prescribing medications without proper licensing. If it's possible for an individual to screen his or her own e-mail, and conduct searches across the entire internet, it is certainly possible for an industry as net-savvy as ours to maintain a daily check for unlicensed or otherwise suspect sites in order to immediately report them to the appropriate authorities.

You may ask why you should allow our industry to act as a "neighborhood watch." We're offering to participate in this activity because we know the "neighborhood" well, and we know the technology. We are here to offer our assistance and industry

expertise to the numerous agencies in each of the 50 states, as well as federal agencies who are responsible for law enforcement. As Federal Trade Commission Chairman Pitofsky recently said, when speaking of the on-line privacy issue, "We continue to believe that effective self-regulation is the best way to protect consumer privacy on the Internet . . ." Similarly, we believe that effective self-regulation is the best way to protect consumers using Internet business services.

Mr. Chairman, we do not believe, however, that new federal legislation is necessary at this time. What is necessary instead, is the development of innovative ways to apply the laws already in place, in an on-line environment that had not even been imagined when the various laws were written. And the Summit I'm proposing will allow us together to develop those innovations—beginning with the daily check I've just proposed.

Again, thank you for giving me this opportunity to appear before you today. I hope I have clearly explained the practices of PlanetRx.com, and provided you some viable solutions to the issues that confront our infant industry.

Mr. BRYANT. Thank you.

Mr. Neupert.

STATEMENT OF PETER M. NEUPERT

Mr. NEUPERT. Thank you. My name is Peter Neupert, CEO of Drugstore.com, another of the responsible competitors. Drugstore.com is a legitimate licensed pharmacy. We only ship valid prescriptions from licensed physicians. We comply with all the State and Federal laws required. We have licensed pharmacists that serve our customers. We have been inspected already by the State boards as a part of our ordinary course of business in Texas, and in the State of Washington. Recently—we are now a publicly traded company as of Wednesday.

Rather than talk about our business, I would rather show you. So we have got these two monitors, they are both on. I thought I would walk you through some of the benefits and opportunities of a legitimate licensed pharmacy.

Here you see our home page. The mission of Drugstore.com is to help consumers manage their well-being, using the Web for 5 stores in 1, to make it easy for them to save the trip to the drugstore. At the bottom of the front page you see our privacy policy clearly displayed for anybody to find it.

Mr. BRYANT. Could we stop just a minute here? Could you turn that TV around so people in the audience can kind of see that one? We can probably see it up here on this one. Some of you may have to move to see it better if you want to.

Please proceed.

Mr. NEUPERT. As was previously mentioned, one of the benefits of an on-line drugstore is the readily available, 24 hours a day, information. Solutions is the area where we carry all of our information. You will see complete medical reference, buying guides, ask your pharmacist questions. As our other competitors, we have 24-hour access to our pharmacists and frequently asked questions that have been answered, and one-to-one service for customers to get their questions answered that they can't get answered in any traditional means, because the people in the retail pharmacies or mail order pharmacies don't have enough time.We do significant research to help people with their public health questions.

Next I would like to go to the pharmacy, which is the department where people can learn about their prescription drugs and order their prescription drugs. You will notice that we have partnered here with Rite-Aid to help communicate to customers the trust that

they should get with our facilities, and to get access to the health plans that were mentioned in the first panel that many competitors are having a difficult time.

You can see here that we have a complete drug index which makes it easy for customers to shop and learn about pricing and get all the information that they typically get when the pills are dispensed. I thought I would click on one. I think one of the main benefits of the Web will be able to allow consumers to price shop. Imagine how hard it is to price shop in the retail world today. There is no display of what the pricing is or how to find out. This will help lower costs.

You can see here that we advertise when there is a generic available. You can see what the cost of a brand drug is and what the cost is of a generic. If I had time, you could look and get all of the information about what this was indicated for, what the warnings were for and everything else, available 24 hours a day.

Now, I have here, I am going to go into the prescription summary, which is where I have some information. First I have to log in through our secure server. All of our information is stored in a secure location. Let me see if I can do this to protect the privacy and confidentiality of our patients.

We use industry standard technology to accomplish this.

This is my daughter, Kelly. She has an item ready to order. Another of the benefits of on-line prescriptions is the ability to always manage and know how many refills you have, manage all of your family's needs, know all of the information you may want to know to take care of your own individual health.

You can see here that the number of refills—I can update the patient profile; and in the patient profile is all of the allergy information, all the medical information that you would be required to give to any pharmacy and all of the other things here. People have been wondering, is it hard to get? As you notice, I have down here 1-800-drugstore; customers can always get ahold of us. We're not trying to hide from anybody.

The simplicity of ordering on-line is one of the main benefits, particularly when it comes to refills. One of the key health issues I mentioned, price. The other key health issue is compliance and making sure that it's convenient for people on chronic medications to stay on their drugs.

We use E-mail as an effective communications tool to remind people before they run out. They can come back to the site and simply hit refill and order their drugs. It makes it much easier for them to stay compliant and avoid trips to the hospital or avoid other emergency trips because they've run out of their medication.

I think the core issue that the panel has been discussing is how do you get the benefits that we've—that I've just shown here, the benefits of the on-line word for those legitimate pharmacies while shutting down the illegality or rogue pharmacies. I think the doctor said it well, the first is to do no harm.

There are huge benefits in terms of allowing people the convenience, the information, the price and the selection available on-line. And I think those people who want to do things illegally are going to do things illegally, and customers who know that they're going

to a website and not get a prescription know that they're trying to do something against the law.

There are many laws that we're following today. We support the VIPPS programs, the best industry standard way to communicate that Good Housekeeping Seal of Approval to customers which I think is the real issue.

Thank you.

[The prepared statement of Peter M. Neupert follows:]

PREPARED STATEMENT OF PETER M. NEUPERT, PRESIDENT AND CHIEF EXECUTIVE OFFICER, DRUGSTORE.COM

Good morning Mr. Chairman and Members of the Committee. I am Peter Neupert, President and Chief Executive Officer of drugstore.com. I thank you for inviting me here today, and I am pleased to have the opportunity to speak with you about drugstore.com. We are an Internet drugstore dedicated to providing a convenient, private, safe, and informative shopping experience to our customers.

In my testimony, I will explain to you how drugstore.com operates, and our dedication to providing high quality and safe prescription services through our licensed pharmacy. You will conclude that the drugstore.com pharmacy has many of the attributes of the traditional corner drugstore and the well-established mail service pharmacy with the added capabilities of the Internet. Like community and mail service pharmacies, our customers must have a prescription from their doctor—we do not prescribe medication. What's new here is not the practice of pharmacy, but the way we communicate with and inform customers. Our prescription fulfillment is built on the long-standing procedures and infrastructure of walk-in and mail service pharmacies. The quality control we have established at drugstore.com incorporates the best practices of mail services and community pharmacies.

Our mission is to help consumers manage their well-being using the Web. Our core value proposition is to educate and inform consumers, while saving them time and money. I will have more to say about our drug information and prices later in my testimony.

Full Service Drugstore

Before I describe our pharmacy service, which is the real focus of this hearing, I want to give you a snapshot of our entire site. When we launched our full-service online drugstore in February, 1999, we were responding to the growing trend of consumers taking a bigger role in their health care decisions. That increasing trend is apparent in the number of people seeking health information online. According to recent estimates, the number of consumers accessing the Internet for health and medical information has increased from 3.2 million in 1995 to 22.3 million in 1998, because the Internet provides up-to-date information from a variety of sources along with person-to-person support groups.

drugstore.com is five stores in one with health, beauty, wellness, personal care, and prescription drugs. We focus on those products designed to help people live longer and feel better, including dispensing medications used by consumers on a chronic basis. What is new is that online pharmacies and drugstores offers an exciting prospect for increasing public health by providing more convenient and informative access to health products and information. Our goal is to empower consumers by permitting them to make more informed health-related purchases while saving both time and money.

While we offer the same safety and quality of community drugstores, our online pharmacy has unique benefits:

Information—Our site provides a "Solutions" area where shoppers can find the information they need to make informed purchase decisions. It includes buying guides, a wellness guide, a medical reference, and shopping advisors. We provide comprehensive drug information where consumers can learn about their prescription drugs, including usage, cautions and possible side effects, as well as drug prices. The Web is the only place customers can conveniently price shop for prescription drugs. We also post answers to the questions most frequently asked of our licensed pharmacists. For each product, we display all the information a consumer could read on the package of product—including all the ingredients, directions, and product warnings in a format that is easy to read.

Convenience—Our site permits consumers to shop from wherever they have Internet access, and at anytime. Consumers can receive their products via direct delivery to their home or office. We make it easy for consumers to save time doing this chore,

by saving their personal shopping list and by providing e-mail reminders on prescriptions drugs and other products.

Selection—We offer a broad selection of products so that consumers can obtain products that best suit their health needs.

Communication—Use of the Internet allows drugstore.com to communicate with its customers via e-mail. Our "Ask Your Pharmacist" feature, prescription refill reminders, monthly newsletters and online purchase order tracking information, allows continuing patient/pharmacist communication from the comfort of the patient's home.

Privacy—Customers can shop at our drugstore in privacy, and thus avoid the potential embarrassment of buying personal items or asking personal questions at community drugstores. Because consumers can more freely ask personal questions via e-mail, they will be able to take a more proactive role in managing and promoting their personal health.

Licensed Pharmacy

As I have stated previously, filling prescriptions at drugstore.com works the same way as a community pharmacy and mail service pharmacy. We focus on dispensing medications used by consumers on a chronic basis. For acute care needs, we recommend that customers pick up their prescriptions from a local pharmacy. To fill a prescription at drugstore.com involves the same three steps at any community or mail service pharmacy.

First we are provided with a valid prescription from our customer's physician, customer, or our customer's current pharmacy. The physician calls or faxes in (where permitted by law) the prescription to us at 1-800-drugstore. At the customer's request, we will call the physician for the prescription. The customer may also mail us their original prescription or request a transfer of their prescription from their current pharmacy. If a customer attempts to purchase a prescription drug without providing a valid prescription, the customer will be notified promptly via e-mail that drugstore.com cannot fill the order until we are given a valid prescription. We do not provide prescription medications without a prescription, nor do we prescribe medications.

We also contact the prescribing doctor's office to verify prescription orders for those controlled substances that we dispense. We do not dispense Schedule II controlled substances due to their high potential for abuse.

Before we will fill a prescription, we require each customer to complete an individual patient profile of drug allergies, current medications, medical conditions, and preference for generic substitution. We carefully cross-check all of the information we get from the patient and doctor. We then enter the prescription order into a computer and perform all of the same checks for drug interactions that you expect from your local pharmacist. Once we have received and verified a new prescription, and cross-checked that prescription for interactions we will then fill and mail the prescription.

We use state-of-the-art bar coding at each step of the process to ensure patient safety. We also use automated pharmacy systems to assist with the dispensing of medications. Our pharmacists then recheck each prescription for accuracy before a medication is sent to the customer's home or office. We send drug-specific patient information with each prescription. The shipping method is based on consumer choice and the type of drug. Standard shipping via U.S. Postal Service Priority Mail is provided free of charge to the customer.

Through our partner, RxAmerica, we ship prescription products to every state in the United States. Our recent partnership with Rite Aid will enable customers to order refills of their existing Rite Aid prescriptions on our site, and pick them up at a local Rite Aid store, or receive them through drugstore.com's mail service. To purchase a prescription, the customer provides us with a credit card number for the cash price or copayment and insurance information.

Our prescription drug service saves consumers time. Our vast information on drugs, including drug prices, enables customers to save money and to make more informed decisions. We are committed to giving customers real value. We monitor the prices of products, including prescription drugs, sold at national retail chain drugstores and our cash prices are on average lower than those of the national drug chains. We are leveraging the lower cost structure of the Web to lower costs on drugs.

A hallmark of our pharmacy services is the patient counseling and customer support that we provide to help our customers use medications safely and effectively. Our popular "Ask Your Pharmacist" feature, which I mentioned earlier, is staffed by clinical pharmacists. It allows customers to ask questions online and receive personalized responses from our pharmacists. drugstore.com provides patients with a

toll-free number to access a pharmacist 24 hours a day, 7 days a week. Customers can also access their secure, individual medication profile, which contains a history of their prescription purchases at drugstore.com. In addition, customers receive refill reminders via e-mail, notifying them when they need to place a refill order. This e-mail reminder service helps to promote drug compliance and improved patient outcomes.

The increased convenience of our Internet pharmacy has proven crucial for many of our customers. We continually receive e-mail messages from customers that highlight the advantages of online shopping, as well as commending and thanking us for our innovative and personalized service. For example, one message from a woman housebound with multiple sclerosis told of how she hates asking people for assistance. Our site has enabled her to have the independence she desires in complying with her medical treatment program. A message from another customer emphasized how the consistency of our site permits her to obtain her medication even when she moves. These messages highlight the benefits that online pharmacies can offer consumers.

With respect to patient privacy and the confidentiality of our pharmacy records, drugstore.com will not release any prescription information in connection with any patient identification other than to the patient, our partner RxAmerica which fills the prescriptions, the patient's authorized representative, or the prescribing or authorized practitioner caring for the patient. In addition, all personal information and credit card information are encrypted using SSL encryption technology. We are a licensee of the TRUSTe Privacy Program which is the leading online privacy seal program. The seal is awarded to sites that adhere to established privacy principles and comply with ongoing oversight and consumer complaint resolution procedures.

Finally, because drugstore.com is dedicated to providing safe, legal prescription services to our customers, we have applied for approval into the Verified Internet Pharmacy Practice Sites ("VIPPS") certification program established by the National Association of Boards of Pharmacy. This program will serve to inform the public whether online pharmacies are licensed in good standing with the appropriate state boards of pharmacy and other regulatory agencies, and whether they comply with quality criteria. Such self-regulation provides a means for sites to inform consumers about the site's commitment to compliance with the existing laws and regulations.

Compliance with Existing Laws

drugstore.com complies with all applicable state and federal laws and regulations governing the provision of drugstore products and information over the Internet. For example, we comply with federal and state requirements for pharmacy licensing and registration, and for providing customers with relevant information about their prescription medications. We comply with the laws and regulations governing non-resident pharmacies in every state that has such requirements. We and our distribution partners comply with laws relating to security, recordkeeping, and reporting for pharmaceutical sales, as well as medical record confidentiality. In addition, as mentioned above, we participate in industry efforts to self-regulate online pharmacies.

In keeping with its reputation as a leading online drugstore, drugstore.com will continue to comply with applicable laws and regulations relating to online pharmacies and drugstores. However, we hope that the Subcommittee will consider that there are already extensive laws and regulations in place that affect online drugstores. It is our belief that the number of illegitimate pharmaceutical web sites do not exist due to lack of appropriate existing laws and regulations, but rather to the need for greater enforcement of those laws and regulations.

Legitimate online pharmacies and drugstores are an emerging market which provides an exciting prospect for increasing public health by providing more convenient and informative access to health products and information. We must be careful to distinguish between safe, legitimate online pharmacies and profiteers using the Internet to engage in illegal activities with willing participants. The most practical approach in differentiating the two is by educating consumers and providing them the tools and means to identify the safe, legitimate online pharmacies. As I mentioned above, drugstore.com is looking forward to participating in the VIPPS certification program and displaying its emblem on our web site. drugstore.com will commit resources to educating consumers about the VIPPS certification, so that they will know how to make an informed choice about the sites they utilize.

The reliance on industry self-regulation by legitimate web sites results from the realization that the Internet does benefit consumers as long as they are provided with a means of making intelligent choices. Other examples of such industry self-regulation include the Health on the Net Foundation's code of conduct for medical and health sites, and the Tufts' Nutritional Navigation system which rates nutrition web sites.

I hope that through our mutual dedication to providing consumers with beneficial drugstore services, we can work together to enable legitimate online drugstores to continue providing efficient customer service. Thank you very much for the opportunity to speak with you today. I would be pleased to answer any questions you have.

Mr. BRYANT. I thank all of you.

I think we have another vote and probably our last series of votes coming up within the half hour. So most likely if we can move through this and get everybody's questions answered, it would be good I think if we could finish so that we don't have to take a half hour break and come back this afternoon and everybody can get moving.

So I'm going to yield time to the distinguished ranking member, Mr. Klink.

Mr. KLINK. First of all, I want to thank this panel. I think that you've given some outstanding testimony.

Dr. Abromowitz, that was probably the best bits of testimony I've heard a long time. I think you have to be complimented on that.

The rest of the panel was very good, too.

Mr. ABROMOWITZ. Thank you.

Mr. KLINK. Getting back to the VIPPS—and I will just say from our two industry spokespeople here, if everyone was doing business like drugstore.com and PlanetRx., we wouldn't have to have these hearings. And we appreciate the fact that you want to work with us. It doesn't mean we agree with everything that you said in your testimony.

One of the things that I would question is that Ms. Culmo, who is really in the trenches, has said we really need to have a law on the books that says we identify who we are, we identify whom we're licensed by. And you seem to think that the VIPPS program is fine.

My problem with that, as I said earlier, I don't know if you were in the room, is the VIPPS program may be fine but not a law enforcement agency. Can the VIPPS seal, in fact, be counterfeited and put on another site? What ability does the National Board of Pharmacy have to go out and inspect these sites and do the law enforcement kinds of things?

And so I will just ask, first of all, Ms. Culmo, if you will kind of give a response to the testimony from the two industry spokespeople talking about there are enough laws on the books, in essence, and that they like the VIPPS program and they think that would be fine. What's your reaction to that?

And then I will ask you to respond as well.

Ms. CULMO. From our perspective, we obviously would disagree. We've run into a lot of difficulty in locating persons that are associated with Web sites. And from where we sat, we don't see that the VIPPS program is going to give us a lot more information than we have. The, "rogue pharmacies" are not going to have the VIPPS seal of approval.

The sites so far that would be interested in that are the ones that appear to be more compliant and operating much more similar to a mail order pharmacy. So, right now, they're not our biggest concern.

If we had the information on the home page, we would be able to, one, identify who is associated with that site and the practices of that site, but we would also have a location.

There was a mention earlier about GBL, gammabutyrolactone. We've got quite a bit of activity with those products in the State of Texas, and they're mostly advertised on the Internet. We have several sites, some of which are supposedly located in Texas, and it's been extremely difficult to locate those persons. And one of them we tracked as far as to a public storage establishment, and we can't get the search warrant because we don't have the specific unit.

So it gets very difficult. You sort of get yourself in a vicious cycle with the judicial system and the regulatory perspective.

Mr. KLINK. One thing before I move on and allow the industry spokespeople to give their response, it is unclear from your testimony, to me, and maybe this is because I am a little dim-witted at this time in the day, are you suggesting that each doctor who is issuing a prescription and each pharmacy who is filling a prescription on the Internet be licensed in each State in which that is done?

Ms. CULMO. In each State, yes. Essentially that's what it comes down to.

There is already similar requirements, and if I'm not mistaken, I believe that drugstore.com has obtained licenses in all 50 States, and they're already doing that. So one of the things there they have those licenses, they can just display those on their home page already.

Mr. KLINK. As long as it's displayed on the home page so the consumer is informed who the licensee is and where they're licensed, then at least we're dealing with—we can deal with some information. Then if you have a site which is not displaying it, then we know it's an outlaw site?

Ms. CULMO. That's our assumption, yes. And in Texas, for instance, we have the ability to actually go in on the Internet and check the status of a physician and—to see if there's been any sanctions. If a license was actually posted on the Web site, the consumer could verify that automatically—in Texas, it's not in all States.

But if there were a Federal requirement that they must license in every State, the boards of pharmacy already have those requirements, as do the medical boards for practicing physicians and pharmacists, to license with them. So it would just be an extension of that license.

Mr. KLINK. Mr. Razzouk.

Mr. RAZZOUK. You know, we agree that the States already require, if you're going to practice pharmacy, that you have to be licensed in every State; and PlanetRX. Is licensed in all 50 States, District of Columbia and all U.S. Territories, so we've gone through that rigorous screen, if you will, to become licensed that way.

The VIPPS protocol—in order to be a VIPPS-approved pharmacy, you have to be a licensed pharmacy and you have to be a licensed pharmacy in all the States you do business in. So, theoretically, the VIPPS seal could act just as effectively as people having to post every license that they've got all over their Web site as a screen

to legitimate sites versus not legitimate sites as we go forward to try and identify who the bad guys are.

Mr. KLINK. If you yield, though, the VIPPS is voluntary?

Mr. RAZZOUK. The VIPPS is voluntary.

Mr. KLINK. What if we just chose not to volunteer?

Mr. RAZZOUK. You can choose not to volunteer and you would pop on the screen and you would get looked at on a regular basis.

Mr. KLINK. By whom?

Mr. RAZZOUK. I think I made the suggestion today about how we might be able to proceed to try and put together technology and people in a way to do that that could help support the agencies that testified here a little bit earlier today who just finally brought a Web site——

Mr. KLINK. What authority? That's the question. How often and what authority? Unless we have a government regulatory agency with authority to go in and do the inspection, to what benefit, what assurance do we have?

Mr. RAZZOUK. I think, based on what I understand, and I may not have all of it, that we've got effective Federal and State laws on the books today that can do that.

Mr. KLINK. If you've already gone to the trouble, and I'm sure to some trouble, to be licensed in each of the 50 States and the District of Columbia——

Mr. RAZZOUK. Yes, it is.

Mr. KLINK. [continuing] Drugstore.com as well, why don't you want all of the people that are competing with you to do the same thing and to display that information proudly as called for by law?

Mr. RAZZOUK. We definitely want them to have to be licensed. We definitely do not subscribe to these prescribers on-line, people, you know, buying prescriptions through consultations, you know, all the things we talked about here today. We think you have to be——

You know, we practice—I will point out here, Peter, a legitimate pharmacy, and you do that by being licensed and having licensed pharmacists and by not having doctors on staff and not by writing prescriptions for people, but by filling them. So we have no informal—we fully support the fact that any on-line pharmacy should have to be a licensed pharmacy, and that's incorporated in the VIPPS protocol as well.

Mr. KLINK. Well, I have no problem with the VIPPS protocol, that it's voluntary. But why shouldn't they, if you say there's no problem that they should be licensed, you think they should be licensed, then what's the problem with causing that to be displayed on the home page so that the consumer knows that that's done?

Mr. RAZZOUK. Do you want to take it, sir?

Mr. KLINK. Let Peter have a shot so we're not dwelling on Mr. Razzouk.

Mr. NEUPERT. I will help him out.

The practice of pharmacies is founded on trust, and for those of us in the legitimate pharmacy business we would love to have trust be assured in the marketplace. I don't know that—I don't understand how creating yet another regulation will assure that those people who want to avoid the law will follow a new law. We can—the VIPPS program says we will put a seal up. They created a data

base and a security architecture that says, hey, this is a way to be sure the Good Housekeeping Seal of Approval, that these people are licensed. If you just put up a license—understanding a web design, it's going to be supereasy for anybody who wants to create a copy of a license and to forge a license.

I don't know that applying or demonstrating—displaying a license on a Web page solves any real problem. The issue is, you're going to have to enforce against those people who are breaking the law, today's laws or any new laws. And what the industry is proposing, I think, is a reasonable rule or a reasonable way to move forward to say we will validate that these people are indeed licensed, and if consumers want to only deal with licensed people, they will be able to do that.

There will still be consumers who, we've heard this morning, who will want to break the law, as there will be proprietors who will want to break the law. The issue of enforcement remains the same.

Mr. KLINK. My problem with your proposition is simply this, that I think probably what bothers me most about this is exactly what you said, Mr. Neupert, that the pharmacists I think in almost every poll that I've ever seen taken of Americans are among the most trusted people in America. We trust other pharmacists. We really do and for good reason.

Every pharmacist that I know when I walk in the pharmacy they have displayed behind them their license. They're licensed by the State. All we're asking is that, as we go into this new E-commerce, you post your license. And if you post a false license—if it's in a bricks and a mortar pharmacy and somebody goes in and finds it out, Ms. Culmo is going to see that that you are arrested. They will come down on you. And if you post a false license on the Internet, then we can come after you right away.

It helps us. It's an expeditious way of us finding out what's going on.

And you're right. We can counterfeit licenses, driver's license. We can counterfeit a lot of things. We can counterfeit the VIPPS seal. We can counterfeit a lot of things.

But if we just ask from the E-commerce sites the same thing we're asking from everybody else, post your license, let the public know that they can check you out, if the license number is on there, we can check with the State of Pennsylvania, we will call Harrisburg, or we will call the other State capitols around the country. We can check on you.

But if it's a VIPPS seal, who do we check with and how do we find out if and when the last time was when they were expected and what authority the inspectors had? That's the difficulty that I think I have with your answer.

I think Mr. Catizone wants to step in.

Mr. CATIZONE. Please.

As part of the VIPPS program, each facility will have to be currently inspected by a State board of pharmacy, so that will be an official regulatory, mandatory action. And that report becomes available to the VIPPS program.

Mr. KLINK. How often?

Mr. CATIZONE. At this point, it will be at the point of the first issuance of the seal and then every year or 2 years thereafter de-

pending upon complaints, depending upon the regulatory schedule of the State and also the renewal cycle for the VIPPS.

Mr. KLINK. I see as many leaks as a sieve in this, but I will jump over to Ms. Culmo because I think she wants to jump in.

Mr. CATIZONE. Can I finish my response?

Mr. KLINK. Please do, and I will get to the Ms. Culmo.

Mr. CATIZONE. I not disagreeing with posting the license on the Web sites. That might be a good idea for the consumers. But it won't be independently verified. I can provide you with a list of States in which the consumers would not be able to reach that agency within 2 to 3 months and obtain a verification of whether or not that practitioners was licensed simply because they are under understaffed, don't answer the phone. They can contact a Web site. We have people working to answer the phone to verify that licensure. It's a problem there for the consumer to have some sort of independent verification that information on that site is truly legitimate and real.

Mr. KLINK. First of all, I don't know what agency you're talking about. Because the board of pharmacy, it's a board, and I imagine they're different in each State, and therein would lie a problem, also.

By the way, Mr. Catizone, I want to thank you. I understand—I had to leave the room for a second—that you said that you would help us get information on some of these sites and you can tell us who were legitimate and who weren't. I appreciate your offer of help with that, and I think it's amazing that you all at the National Association of Boards of Pharmacies are able to do and the FDA was not able to do that. And I think it shows a great willingness on your behalf to work through this problem.

Ms. Culmo, let me ask you to jump in here. Then I think my time is expired.

Ms. CULMO. Thank you.

The only thing I was going to point out is that if you counterfeit a license, be a pharmacist, a pharmacy license or a medical practitioner, which are also required to display their licenses at their practice sites, you've broken the law, and there's consequences and penalties for that. If you counterfeit a VIPPS seal, there would be no consequence for that. It's a common legal requirement.

Mr. BRYANT. Thank you.

Just very quickly. If you were to go to some type of system that you've talked about, Mr. Catizone, could each State have its own site with a listing of certified people with their number, and then if a person wanted to go to pharmacy X, they could go to pharmacy X, see the seal, see the number, and then go back into another site and make sure it's properly licensed in Tennessee or Pennsylvania and then go back and make the purchase?

Mr. CATIZONE. Part of the security provision of the VIPPS program is that, when a consumer clicks on the VIPPS seal, they are brought to a Web site that provides all that information about the site as well as the States where they were licensed and a direct link to that State's Web page to verify independently that licensure, as well as additional information for the consumer about other pharmacies or other States where that may be licensed.

Mr. BRYANT. In that system, where does it break down?

Mr. CATIZONE. We're not aware of anyplace where it breaks down. We're certain that hackers can duplicate the seal, as they can anything else, but our security system always focuses on the consumer getting independently verified information from the direct sources.

Mr. BRYANT. And it seems to be education would be a big factor here, much as the Good Housekeeping seal. You know, if consumers are taught you need to be—especially in this arena you need to be looking for that seal, and then if we can get a verification process in place, you know, it seems to be that would be logical.

But let me move on to my colleague from Michigan, Mr. Stupak.

Mr. STUPAK. Thank you, Mr. Chairman.

Mr. Abromowitz, you quote in your testimony of June 16 a Chicago Tribune article and it says, no one has a clear grasp of the scope of the Internet prescribing phenomena, but some experts estimate that about 400 such prescription Web sites exist, about half based overseas.

It appears that number of sites seems to go larger each month. Would you agree?

Mr. ABROMOWITZ. Yes, sir, I certainly agree to that; and that's been determined by the AMA staff.

Mr. STUPAK. Where are all of these sites getting their drugs from?

Mr. ABROMOWITZ. I'm sorry?

Mr. STUPAK. Do you have any idea where they're getting their drugs from?

Mr. ABROMOWITZ. No, I don't.

Mr. STUPAK. If we have all of these sites coming up monthly, just popping up, where do they get the Viagra, all the other stuff that they're selling out there, Propecia and all?

Mr. ABROMOWITZ. Mr. Stupak, that's an excellent question. And, very frankly, as a practicing physician, you know, it just amazes me that they can, very frankly, can purchase this, these medications. And I think we have to address that question with the pharmaceutical industry. I personally don't know where they're getting all of these drugs, but it amazes me that these drugs are being able to be dispensed like that.

I mean it's—it's against patient care. It's—the stories we heard today, the anecdotes we heard throughout the country. And before I leave, I want to compliment the Commerce Committee, especially the subcommittee. The American Medication Association is proud to participate in this because we think this is a gigantic problem in American medicine today and for our patients that we all serve.

Mr. STUPAK. Sure.

Does anyone else have any comments on that, where they're getting these drugs? You have the manufacturer, you have the wholesaler, you have the pharmacist, and you have the person with the prescription. Those are the four links, and there should be a flow here that you should be able to track.

Then somehow we get this fifth link, the Internet; and, boom, as I said earlier, a number of times, we had 26 of them in January, we're up to about 400 now, how are they getting access to all of these drugs?

Mr. ABROMOWITZ. What I would fear, to answer that personally is, that many of these drugs that they're sending out to the doorsteps do not—would not pass inspection, you know, or U.S. Pharmaceutical standards of care. I mean, I don't know where the drugs are made, in the back room of some garage someplace or something else, so I would question the fact where many of these drugs do not meet the standards for what they've been prescribed for.

That would be my question, you know, and I would challenge that, if I were the person ordering those drugs.

Mr. STUPAK. Mr. Catizone, it looks like you wanted to jump in there.

Mr. CATIZONE. If these pharmacies and distributors are obtaining these from legitimate manufacturers, there is a paper trail that must exist to trace those drugs back. By Federal and State requirements, a manufacturer cannot ship prescription drugs to anything but a licensed wholesaler or a licensed pharmacy; and, therefore, there has to be a paper trail of both invoices in order to bill for those drugs and the fact that that is a licensed or a registered site that can't accept and receive prescription drugs.

Mr. STUPAK. And I agree with you. I wrote the 1993 Chemical Diversion Act to get ahold of ephedrine, which is being used to make methcathinone, cath as we call it. We got that one pretty much stamped out. And myself and Chairman Upton, we've been working on the GAP problem and, again, we're putting precursors, we're putting the tracers on it, so we have some good idea.

But then could not FDA and the others really look at this paper trail and try to make some determination from it?

Mr. CATIZONE. Yes.

Mr. STUPAK. Just for the record, we need more than a nodding of the head, we need a yes or no.

Mr. CATIZONE. I'm afraid to say anything. Representative Klink is gone. I can speak then. Otherwise, I would say, yes, that paper trail should exist.

Mr. STUPAK. Ms. Culmo.

Ms. CULMO. Being involved in the manufacture and distribution of drugs, the paper trail should exist, but it's probably not the paper trail that you envision. And what we encounter is the manufacturers—it's easier, because it's the start of the process. And—so it's easier for them to document where their product goes initially.

Once it leaves their facility, then it's out of their control again. It goes to a wholesaler. And from the wholesaler, it can go to a numerous number of entities, some authorized to possess and some not authorized to possess. And what we encounter a lot of times, if the wholesaler is not automated, then it's extremely difficult to have that paper trail to show where it went to the next location.

The other thing is lot numbers are not tracked. The controls for prescription drugs are not the same as what's required for controlled substances. So it would not be difficult for a lot of these products to go out back doors of overnight storage sites. You have drop centers when there's mass quantities being trucked or trained to different locations. We have diversion problems through physicians' offices and hospitals. You have huge purchasing groups that also warehouse their drugs. So it's not exactly as black and white as the four entities, and it's difficult to track.

Mr. STUPAK. Yeah, right. And in the legislation we've always drafted it was always precursors, which is a little easier to track than the final product which gets shipped around quite a bit.

Doctor, if I may, in your testimony, you quote a May 11 New York Times article, and that reads, "a company based in the Channel Islands of Britain called Direct Response Marketing is selling Xenical over the Internet to just about anybody who electronically fills out a medical questionnaire that is reviewed by a company doctor who then prescribes the drug."

You then add the following: If this trend continues, a triple problem exists. First, patients in the United States would easily be able to obtain drugs that have not been approved by the U.S. FDA. Second, these drugs would not have been tested in rigorous clinical trials. And, third, patients would be receiving these drugs without the advice of a physician.

Can you expound on that for us? Can you describe what the present regulatory system is designed to do and why and elaborate on how it might be undermined by some of these instant prescription Web sites?

Mr. ABROMOWITZ. Well, the drugs, you know, manufactured and prescribed here in the U.S. and controlled by the U.S. Standards have to meet the pharmaceutical industry standards. You know, the drugs in the foreign market—and I'm no world expert on this, but to the best of my knowledge probably would not have to meet those standards. Xenical, you know, is a drug used basically to, you know,—which blocks fat absorption, weight loss, lowering cholesterol and things of—the various lipids and things of that sort, so it's a hot-ticket item.

And the only thing I know—and I personally have refrained from prescribing this drug until I see what the side effects are, which is—as a family physician for a number of years, I don't really prescribe all the new drugs initially until I see what the side effects are, and Xenical has some very significant ones like diarrhea. But the fact is—for some patients.

So U.S. Drugs have a certain standard, a very rigid standard to meet, as my associates here at the table have told you from the pharmaceutical level. I'm not quite sure whether the foreign companies will meet those standards. And, again, that's either a legislative or a regulatory situation. I fear that, very frankly, Mr. Stupak, they don't meet those standards.

Mr. STUPAK. The AMA, they've been recently come out pretty harsh on these instant Web sites, have they not?

Mr. ABROMOWITZ. Absolutely. AMA feels that there must be an establishment—you take—for example, you're taking a symptom, you're taking a symptom of, I don't know, obesity and then you're putting a prescription drug, you're missing the interchange between the physician, you're missing a diagnosis, you're missing a treatment, you're missing a history, you're missing a physical examination, you're jumping from one arena to another, and you're missing the whole aspect of good medical practice.

Mr. STUPAK. For our other two witnesses—and, again, your Web sites look like they're trying to take all the health and concerns and safety of your consumers in mind, but do any of the consumers ever call you back up and say, hey, this drug didn't work right or,

geez, I want a refund, it isn't doing what I want, or I have a question? Do you get—your consumers call you back?

Mr. RAZZOUK. We certainly get questions from consumers, and they get to talk to our pharmacists with their questions. But I don't have perfect knowledge of this, but I'm not aware yet of an instance where consumers tried to return a prescription medication to us, I mean, that was prescribed by the doctors, which are the only ones that we fulfill. But we certainly answer questions for consumers. Our pharmacists intercede in the fill-in process if they see a drug-to-drug interaction. They have the patient's history. They call the patient and say, did you—you know, to ensure—perhaps call the patient's doctor to say there's going to be interaction here you're not aware of. You need to change this prescription.

So we proactively, you know, get engaged that way. But we don't, and I'm sure Peter doesn't either, we don't accept—we don't take return prescriptions. You can't do that. That's illegal.

Mr. NEUPERT. We only buy quality approved drugs, No. 1. We have a lot of customer contact. We've answered over 20,000 ask-your-pharmacist questions by E-mail since our launch on February 24. That's 20,000 customers whose questions otherwise wouldn't have gotten answered. That's just the E-mail questions. We answer hundreds of questions a day from customers trying to find out—I want to place my order, this is where I want to go, this is how I'm going to do it, and we respond.

And absolutely, when we have questions about a customer's prescription order, we verify with a doctor, just like a traditional neighborhood or a mail-order pharmacy would. And we have, as I plastered on our site, 1-800-drugstore to make it superconvenient for people to make sure that they can get ahold of a pharmacist 24 hours a day if they need to.

Mr. STUPAK. Well, that's one of the concerns we had when we went through all of these Web sites. There's no way to contact them if you have a question. How do you follow-up? Is there any follow-up back with the patient? And your two companies and maybe one or two others at least had a phone number and an address you could at least track to.

Thank you. I have nothing further, Mr. Chairman.

Mr. BRYANT. Thank you.

Let me just kind of wind this thing down little bit. I have a couple of questions.

Mr. Razzouk, this weekend the Wall Street Journal discussed the issue of pharmacy benefit managers or PBMs. You briefly mentioned this issue of PBMs in your testimony as well. Can you explain more about the issue of PBMs and how it affects your companies and others like you?

Mr. RAZZOUK. It's a very complicated area in managed care. PBMs are pharmacy benefit managers, that's what PBM stands for, and they are entities that are either hired by health care organizations or provide health care services themselves who put together retail, put together a network of brick and mortar retail pharmacies that their members can have their prescriptions filled at and be covered by insurance. And the major pharmacy benefit management companies also have their own pharmacies that are mail order pharmacies that they own and that they operate.

And to date, with very few exceptions, they have been very adamant about not allowing the legitimate on-line pharmacies to act as a retail pharmacy, as Peter and I have described retail pharmacy and neighborhood pharmacy today, and be part of the bricks and mortar equivalent of a retail network where a patient could come and get their prescription filled and be covered by insurance.

And the reason they have decided not to do that is they view us as a potential competitor somewhere down the road, so they have all proactively said they're not going to let any of us into their network. Whereas if I was a neighborhood pharmacy, community pharmacist, if I was a RiteAid store, if I was a CVS store, if I was a Walgreens, if I was a Gilespie's, I would have a heck of a chance being in that network, because they wouldn't view me as a competitor, and that's exactly what is going on today, and it's wrong.

Mr. BRYANT. Thank you.

Mr. Neupert, in your written statement you indicated that you would be willing to commit resources to educating consumers about the VIPPS certification. What do you have in mind on that?

Mr. NEUPERT. Well, as I said before, the practice of pharmacy is based on trust, and it's important to our business to separate ourselves from those rogue sites. And we spend significant dollars to educate consumers about our brand name and about our services and about the convenience of ordering on-line. And we would certainly be willing to commit to spend some of those resources to promote VIPPS and what it means and that we're VIPPS certified.

And I think that's generally how things work when you have a voluntary, industry-supported seal of approval. It's in the industry's best interests to communicate its benefits to customers. Otherwise, that means nothing. And so we would take some of those marketing funds and communicate to customers in all the vehicles that we do, whether it's on our Web site, whether it's on web advertising or whether it's in our television advertising, the benefits of being a VIPPS member. And that's how they would learn how to use it and why it's a good thing.

Mr. BRYANT. I have no additional questions.

And certainly, as someone who has practiced law a long time, I learned not to do this, but let me, before we close, ask if any of you have any closing comments. You all came a long way to be here, and you don't have to say anything, but if anyone would like to get in one final word, you're welcome to do it now or forever hold your peace.

Thank you very much for all being here, and we appreciate your very able assistance. This hearing is adjourned.

[Whereupon, at 1:50 p.m., the subcommittee was adjourned.]

[Additional material submitted for the record follows:]

PREPARED STATEMENT OF S. LAWRENCE KOCOT, SENIOR VICE PRESIDENT, GOVERNMENT AFFAIRS AND GENERAL COUNSEL, NATIONAL ASSOCIATION OF CHAIN DRUG STORES

INTRODUCTION

Mr. Chairman and Members of the Subcommittee, the National Association of Chain Drug Stores (NACDS) appreciates the opportunity to submit a statement to the Subcommittee on issues relating to obtaining prescription pharmaceutical products through the internet.

Founded in 1933 and based in Alexandria, Virginia, the National Association of Chain Drug Stores membership consists of 136 retail chain community pharmacy companies. Collectively, chain community pharmacy comprises the largest component of pharmacy practice with over 97,000 pharmacists. The chain community pharmacy industry is comprised of more than 19,000 traditional chain drug stores, 7,000 supermarket pharmacies and nearly 5,000 mass merchant pharmacies. The NACDS membership base operates more than 31,000 retail community pharmacies with annual sales totaling over $158 billion including prescription drugs, over-the-counter (OTC) medications and health and beauty aids (HBA). Chain operated community retail pharmacies fill over 60% of the more than 2.73 billion prescriptions dispensed annually in the United States. Additionally, NACDS membership includes nearly 1,400 suppliers of goods and services to chain community pharmacies. NACDS international membership has grown to include 105 members from 26 foreign countries.

Pharmaceutical internet websites allow consumers to order new and refill prescriptions, obtain important information regarding the prescriptions they are taking, receive medication refill reminders, or access their complete medication profile. Better use of medications, improved health outcomes, reduced health care costs, and convenience for the consumer can result.

Internet pharmaceutical sites represent another electronic medium for ordering prescriptions - such as the commonly-used fax or telephone. For example, just like a patient takes a prescription to a pharmacy, a physician calls in a prescription, or the patient calls in a refill, internet pharmacy sites are alternative ways to order prescription medications. After verification by the pharmacist that the prescription order is legitimate, the pharmacy prepares and delivers the prescription that was ordered through the site.

Many of these pharmacies are the same ones that prepare prescriptions for consumers that are obtaining prescriptions through traditional sources. These pharmacies and pharmacists are licensed by state boards of pharmacy, and must comply with a comprehensive set of laws and regulations.

There are, however, certain questionable and unethical pharmaceutical prescribing and dispensing practices occurring through some internet pharmaceutical sites. For example, some pharmaceutical sites focus solely on the prescribing and dispensing of certain "lifestyle" drugs. These prescriptions are often provided without the benefit of complete medical information about the patient, and it may be questionable whether the dispensing pharmacy is licensed.

Moreover, some sites allow pharmaceutical products to be ordered, but the products are actually shipped from sites that are "off shore." There are potential quality of care and legal concerns with the pharmaceuticals that are imported into the United States.

These situations raise legitimate concerns about quality of care and safety issues regarding the prescribing and dispensing of prescription drugs through certain pharmaceutical internet sites. However, while the use of the internet may have brought these issues more into public focus, the concerns raised have been successfully handled for many years within current oversight structures to assure the quality and integrity of the prescribing and dispensing process.

NACDS PERSPECTIVES ON INTERNET-BASED PHARMACEUTICAL SERVICES

- **Legitimacy of Internet Pharmaceutical Sites should be Acknowledged:** Policymakers should recognize the consumer and health care benefits of "legitimate" licensed internet pharmaceutical sites. These sites should be contrasted with sites whose only goal is to promote or sell a certain "lifestyle" pharmaceutical outside the context of a professional-patient relationship, or import pharmaceuticals from other countries.
- **Physician-Patient Relationship should Exist:** NACDS believes that prescribing pharmaceutical products through the internet should only occur within the context of an established physician-patient relationship. That is, a physician or other health professional licensed to prescribe should be making the judgement concerning the prescribing of a drug based on reliable, complete information required within the scope of practice, including a physical assessment of the patient and diagnosis of the medical condition.
- **Existing Oversight Structures Provide Protections:** NACDS believes that sufficient Federal and state oversight already exists that can continue to adequately protect the consumer from unsafe pharmaceutical prescribing and dispensing practices, including those that occur over the internet:
  - *State boards of pharmacy* are responsible for regulating all pharmacies operating in their state, including internet and mail service pharmacies. Some

states also require pharmacies that operate outside of their state but ship products to consumers within their state, to be licensed. The development by the National Association of Boards of Pharmacy (NABP) of a certification program for those online pharmacies that voluntarily wish to post this seal of approval on their site lends one additional safeguard to the system. This seal is known as VIPPS - Verified Internet Pharmacy Practice Site.

- *State boards of medicine* regulate medical practice within their state. Prescribing privileges are granted by the state. If physicians engage in prescribing for patients with whom they have no valid relationship, the state medical boards are responsible for taking appropriate disciplinary action.
- *Food and Drug Administration (FDA)* has authority over pharmaceutical importation. Offshore sources of prescription drugs, whether accessed by the patient via telephone, mail or internet, that ship to U.S. consumers are within FDA's jurisdiction. NACDS has worked with the FDA to identify "off shore" pharmacies that are sending pharmaceuticals into the United States. FDA should enforce, with the assistance of the U. S. Customs Service and possibly the Drug Enforcement Administration, the prohibition of foreign sources' ability to ship these drugs into the United States.

- **Consumer Education Component Important:** As with any health care service, the consumer needs to be well informed about the benefits and risks of obtaining pharmaceuticals through various methods, including the internet. NACDS believes that it will be important to fully educate consumers about using the internet for pharmaceutical services and the types of questions they should ask. Moreover, consumers need to be educated about the potential hazards of obtaining pharmaceuticals from "off shore" sites, given the potential problems with the quality and integrity of these products.

CONCLUSION

NACDS does not believe it is necessary to expand the jurisdiction of federal agencies to regulate online sales of prescription drugs. Rather, there are provisions in current state and federal laws that will adequately protect the consumer from unsafe internet practices.

Mr. Chairman and Members of the Subcommittee, NACDS looks forward to working with you, consumers and other interested parties to assure the quality and integrity of the pharmaceutical distribution system, including for pharmaceuticals obtained through legitimate internet sites.