

Docket Number 2004N-0115

Peter Neupert, chairman, drugstore.com
Submitted Statement
FDA Drug Importation Hearing
April 14, 2004

Dear Mr. Chairman:

Thank you for the opportunity to speak today. I am Peter Neupert, chairman of drugstore.com, inc. drugstore.com is a leading online provider of health, vision, beauty and pharmacy products. Back in 1999, I testified in Congress regarding options to maximize the benefits of the Internet while protecting consumers. It is in our role as a leading Internet pharmacy that I address you today. I hope you will agree that what I have to say is in the best interest of consumers and helps move the debate between safety versus affordability forward.

To date, you have heard from consumer groups who say that drug importation is already happening. They're right. You have heard from industry representatives who have said the current practice of importation is unsafe. And they're also right.

The Internet has empowered consumers to comparison shop for their prescriptions. For example, drugstore.com was the first to make all of its prescription drug prices available online to any consumer – and that's because we believe that empowerment is a positive thing. However, it is the same medium – the Internet – that has made it so easy for unscrupulous, unregulated and untouchable entrepreneurs to take advantage of and put U.S. consumers at real risk for their health. Whatever you decide about importation, it is crucial that your recommendations include steps to make the Internet safe for pharmacy shoppers. The only way to accomplish that is with uniform verification and certification standards for all online pharmacies, whether foreign or domestic, coupled with restrictions on e-commerce enablers, such as payment systems, search engines and shippers, to help enforce those standards.

Since opening in 1999, drugstore.com has been committed to – and has significantly invested in – making our Internet store a safe, affordable channel for prescription drug delivery. We’ve always wanted to ensure that anyone ordering prescription drugs and submitting sensitive health information over the Internet had confidence in the integrity of our product. Our safety and privacy claims have been substantiated by a thorough audit conducted by a trusted, unbiased, independent organization, the National Association of Boards of Pharmacy. Trusted verification is especially important on the Internet, because the consumer does not have the visual cues available in the physical world – such as neighborhood, cleanliness, orderliness and the like. Because we are certified by the NABP, our customers know that we comply with state licensing and inspection requirements, as well as with other stringent pharmacy practice criteria established by the NABP. Our customers know that they’re getting good drugs.

Consumers don’t have that certainty with many online pharmacies. There is no doubt that serious problems exist with the practices of some Internet pharmacies, and in particular with some sites outside the United States. The FDA’s own studies have shown that some shipments are counterfeit, some sub-potent, some superpotent, some contaminated, some expired. Some online pharmacies ship drugs improperly, others ship without a prescription. Perhaps the risk is small, perhaps not. Not knowing cannot be the right answer when the consequences can be life threatening. Without uniform oversight by a reliable authority, there is no sure way to know who to trust or how great the problem really is.

As the phenomenon of cross-border importation of prescription drugs becomes more popular and widespread, the problems will get only worse – exponentially. This is the nature of the Internet. Trends accelerate at breakneck pace. Consumer demand will create supply while even more marginal players set up shop to tap into a bigger and more lucrative market. Any problems that exist with the current laissez-faire approach of cross-border importation, from therapeutic failures to life-threatening events, will only be exacerbated. An uncontrolled free-for-all without mandatory certification and

enforcement can never claim to put the patient's health interests first. Today, bad actors can too easily set up camp, take advantage of consumers and get out of town before the authorities arrive and the number of illegitimate players will continue to multiply at Internet speed unless we take action.

By harnessing the Internet, we think drugstore.com is on to something quite important – and possibly revolutionary. To date, drugstore.com has safely dispensed more than 2.3 million prescriptions to consumers in all 50 states. We leverage the power of the Internet to provide discounts of 20 to 30 percent off the prices of traditional brick-and-mortar pharmacies. Moreover, we are providing important health information that can improve health outcomes. These added value services range from e-mail refill reminders, to an Ask Your Pharmacist question-and-answer page to eMed Alert for more timely announcements. And we do all this while conforming to all applicable federal, state, and local regulatory controls. For the safety of consumers and the viability of the Internet as lower cost drug delivery channel, it is critical that all Internet pharmacies, whether here or outside the United States, play by the same rules. Today, far too few Internet pharmacies follow the regulations designed to protect consumers, thereby putting consumers at risk. drugstore.com is already delivering drugs safely and more affordably than many, if not most, of our domestic counterparts. And generic drugs are already cheaper on the drugstore.com web site than most sites in Canada and other nations with price controls. With respect to branded drugs, however, even our lower prices cannot compete with prices in countries with price controls. But price cannot be the only consideration here. Without appropriate standards and enforcement mechanisms in place, opening our borders undermines confidence in the safety, reliability and affordability of the Internet distribution channel. Our non-verified counterparts outside the United States, even if “legitimate” in their own country, are not required to follow any rules when selling drugs to Americans. Health Canada, for example, does not regulate pharmacies catering to U.S. citizens. And with U.S. pharmaceutical companies increasingly limiting their drug shipments to amounts needed by Canadian citizens, more and more cross-border pharmacies are turning to the illegal gray market – with its illicit operators,

questionable manufacturing conditions, and counterfeit suppliers – to procure the drugs they sell.

A spot check by drugstore.com identified literally hundreds of websites that dispense drugs. Many claim to offer free physician consultations solely for the purpose of selling these drugs. Many appear to be located internationally. I admit, many of these Internet pharmacies may be legitimate. But the average consumer cannot say, with any degree of confidence, which foreign sites are safe and which are not. It's one thing to make a trip on a bus and check it out – it is another to go to the Web, where a store can be built in a day and product shipped from a basement or garage or a site that appears to be located in the U.S. or Canada might actually be operating from Bangladesh or Pakistan. Right now, the situation is buyer beware. Is that the way we want to run our health care system?

With the current practice of drug re-importation, consumers are on their own. But they are not given the right tools or information to help them make health decisions in their best interest. Without a certification standard, there is no reasonable assurance that the people doing business on the other end of the line are honest, reputable or truly concerned about your health. In fact, the General Accounting Office reports that as many as a third of the "pharmacies" operating online appear to have no safeguards to protect the consumer. And if something goes wrong, there's no authority with oversight to help remedy the situation. That is, if you can find an address or phone number in the first place.

According to a recent drugstore.com analysis of pharmacies listed on Google and other popular search engines:

- ?? Many don't provide a company address or phone number.
- ?? Many provide medications without a prescription or with a prescription procured through a short online "consultation"; and
- ?? Many dispense compounds that are either illegal or subject to special controls here in the U.S.

Below is just one example of a suspicious operator:

The image shows a screenshot of the TropicRx.com website. At the top left is the logo for TROPICRX.COM with a palm tree icon. Below the logo is a navigation bar with categories: Weight Loss, Muscle Relaxants, Pain Relief, Sexual Health, and Sleeping Aids. The main content area features a large image of a smiling woman with the text "RELAX WITH SOMA" and a Soma pill. To the right of this image is a list of products with prices and "ORDER NOW" buttons: Soma (Muscle Relaxant) as low as \$79.00, Tramadol (Pain Relief) as low as \$89.00, Fioricet (Migraine Relief) as low as \$99.00, and Ambien (Sleeping Aids) as low as \$149.00. Below the main content is another navigation bar with categories: Women's Health, Men's Health, Migraine Relief, Enhancement, and Skin Care. A banner below this navigation bar states "No Prior Prescription Required" and "RECEIVE A FREE Consultation from our US Licensed Physicians". To the right of this banner is an "FDA APPROVED" logo with a U.S. flag and the text "All FDA Approved Medications are shipped directly from our US Licensed Pharmacies." Below the banner are the words "EASY SAFE PRIVATE" and logos for Visa, MasterCard, Discover, American Express, and FedEx. At the bottom of the page, there is a footer with the text: "ADVERTISEMENT CA-MAIL 207-1425 MARINE DR VANCOUVER, BC V7T1B9 CANADA UNSUBSCRIBE".

I would venture to say that this site is not FDA approved, even though the “FDA approved” logo appears to be making that claim. This site undermines the doctor patient relationship – and patient safety – by requiring no prior prescription. It showcases the U.S. flag, presumably to look like a U.S. company, but the address is in Canada. There are thousands more suspicious sites like this. I would guess that we all have received ads similar to this one in e-mail boxes.

To address the problems that I have described, drugstore.com recommends that, in order to legally sell pharmaceuticals online to U.S. consumers, an organization – domestic or foreign – would have to meet a uniform certification standard. I recommend that we adopt a standard similar to the National Association of Boards of Pharmacy’s Verified Internet Pharmacy Practice Sites, or VIPPS, program. Through VIPPS, drugstore.com customers know that when they do business with us they are dealing with a company that makes safety and health a priority. And that is my point here today. No matter who they are dealing with, consumers should have a reasonable assurance that they are trusting their health to a pharmacy committed to safety; that asks for a physician’s

prescription every time; that treats controlled substances carefully and mitigates any potential for abuse; that checks for drug interactions; that takes the time to collect a health history to identify possible contraindications before dispensing medications; and that protects private, confidential health information. It is one thing to say we are doing this, as every Internet pharmacy claims. It is quite different when a reputable, independent organization with rigorous standards like the NABP says so.

Once such a uniform standard has been adopted and introduced, I recommend the following three-tiered approach to help enforce that standard:

1. Make it illegal for online pharmacies to advertise on search engines unless they meet the approved certification standard and prohibit search engines from accepting advertisements from online pharmacies that are not properly certified.
2. Stop credit card payments to pharmacies that do not meet the certification standard criteria (i.e., illegal pharmacies), to stop funding at the source. This would be similar to efforts by Congress to starve funding of illegal Internet gambling sites. The activities of uncertified pharmacies would be illegal under U.S. law, by definition, and should be stopped. Stemming the flow of funds to these sites will largely help to accomplish that goal.
3. Motivate third party shippers to refuse shipments from pharmacies who do not meet the certification standard. One of the benefits of a clear certification standard is that the e-commerce enablers (media, payment, and delivery companies) can identify legitimate pharmacies vs. illegal operators.

Buying drugs online should be superior experience: convenient, affordable, and private. The Internet enables comparison shopping and empowers the consumer. But in today's world, purchasing drugs online is fraught with peril, because the Internet can serve as a simple disguise for bad actors and unscrupulous hucksters. It is hard to tell the honest from the dishonest; the ethical from the unethical. And without standards and certification, we are asking everyday citizens to make decisions about whether a product

is contaminated or harmful, whether it is counterfeit, or the right dose, dispensed with a proper prescription or delivered with appropriate instructions. Is it reasonable to expect consumers to be able to tell the difference?

Yes, affordability is a big issue. There's no doubt that the Internet is part of the answer. But encouraging consumers to embark on a worldwide shopping spree based on lowest price – without regard to safety – is no solution either. There must be a way to create a system that is appropriately balanced, allowing for innovation and the creation of miracle drugs for our children and grandchildren while allowing tiered pricing for those with special needs, including the nations of sub-Saharan Africa who are fighting the AIDS pandemic, or seniors in our country with limited sources of income.

I do not pretend to have all the answers. I do know that seniors – and all Americans – deserve a system they can trust. This means finding a solution that combines safety with affordability. We deserve to be protected from fly-by-night operations and unscrupulous profiteers who set aside all safety concerns to make a buck. We require a system where Internet pharmacies all play by the same rules and the rules ensure consumer safety is not compromised.

Thank you.