

January 26, 2005

**SENATE SPECIAL COMMITTEE ON AGING**

**Testimony submitted by Jeff Kimmell, RPh  
Vice President, Healthcare Services & Chief Pharmacy Officer  
drugstore.com, inc.**

Mr. Chairman, my name is Jeff Kimmell. I am the Vice President of Healthcare Services and Chief Pharmacy Officer at drugstore.com, inc. I'm a licensed pharmacist and I've been involved in the pharmacy business for more than 30 years. When I was 13, I started working with my father at the drugstore where he worked. During my career, I have been involved in nearly every aspect of pharmacy operations, in settings ranging from mail order to retail to the Internet.

I want to thank you, Chairman Smith and Ranking Member Kohl, for your leadership and for holding this hearing today. We share your concerns about the safety of millions of consumers who purchase prescription drugs over the Internet. There is little doubt that as consumers increasingly bear the burden of paying for prescription drugs, they will turn to the Internet for cost-effective alternatives. It's our job—yours as legislators, and ours as advocates for Internet pharmacies—to ensure that we're doing everything we can to protect consumers in this process.

I am here, and my company is here, to help ensure that consumers have freedom of choice in obtaining their goods and services from the Internet, and that this important tool remains a viable, reliable, safe, secure, private, cost-effective, and trustworthy choice. Congress needs to regulate appropriately, establish clear rules that protect consumers, and prevent Internet shopping for prescription drugs from becoming an uncontrolled free-for-all that ultimately harms consumers. Since its inception, my company, drugstore.com, has taken the high road, imposed high standards and submitted to voluntary third-party review. But too many others have not made an investment in safe pharmacy practice.

There are three sections to my remarks today. First, I'll provide some brief background about drugstore.com and articulate the general benefits of online pharmacies. I will use drugstore.com as a "case study" of the steps that legitimate pharmacies take to add value to, and reduce costs for, consumers. Second, I'll provide additional detail about VIPPS, the voluntary certification standard with which we comply, and how that can serve as the basis for a single national standard for online pharmacies. Finally, I'll offer some insight into how Congress might provide



appropriate enforcement authority to any legislation designed to protect consumers from unscrupulous Internet pharmacies.

Before going into the details of these remarks, I'd like to note that many of these ideas reflect provisions in bills previously introduced in the 108<sup>th</sup> Congress by Senators Judd Gregg and Gordon Smith and Representatives Greg Walden and Tom Davis.

### **Legitimate Internet Pharmacies Can Empower Consumers, Reduce Costs**

The drugstore.com<sup>TM</sup> Web store is a leading online drugstore and information site for health, beauty, vision, and pharmacy products. Our headquarters are in Bellevue, Washington and our 290,000 square-foot distribution center is located in Swedesboro, New Jersey. We offer the convenience of ordering 24 hours a day, seven days a week, with the privacy of both home shopping and home delivery. Since we opened our online store in early 1999, we have served more than 5 million customers and filled more than 2 million prescriptions. From the beginning, we have made a considerable investment in providing our customers with a safe, convenient, private, and informative shopping experience for their prescriptions and over-the-counter consumer products.

Our retail pharmacy is licensed to dispense medications in all 50 states. We undergo a rigorous third-party certification process administered by the National Association of Boards of Pharmacy, in order to assure customers that we have reasonable safeguards in place. From the very beginning, drugstore.com recognized the need for a reputable third-party to develop and uphold standards for online pharmacies in order to ensure consumer safety and confidence.

Licensed online pharmacies, such as drugstore.com, CAN provide a safe, efficient, and cost-effective alternative to more expensive brick-and-mortar pharmacies. For example, filling a prescription at drugstore.com involves quadruple pharmacist checks in the process—many more quality control checks than a retail pharmacist usually conducts. We're able to allocate multiple pharmacists to the same order, which ensures that the checks are made by a different set of "eyes" during each step of the process – again providing more checks than a typical retail pharmacy might deliver.

In addition, we offer our customers online email drug recall alerts in the form of the drugstore.com eMedAlert program. Some of you may remember the most recent Vioxx drug recall. With eMedAlert, drugstore.com Vioxx customers received notice of this FDA recall *within hours* after the FDA made its announcement. This kind of consumer safety alert simply isn't feasible in the brick-and-mortar pharmacy world.



Technology allows us to automatically cross-check potential drug interactions and easily screen for health conditions that might be potential contraindications for a prescribed medication. We also provide an extensive drug price index that allows for easy comparison shopping, a detailed drug information database, and other specialized customer care features, including:

- Ask Your Pharmacist. This feature allows customers to browse a database of responses from our pharmacists of over 800 frequently asked questions about medications, dosage, delivery systems, common side effects, and other information about prescription drugs and health-related products. In addition, our customers can ask our pharmacists questions that are not answered in our archive. Our pharmacists seek to provide an initial answer to a non-emergency customer inquiry within one business day.
- Reminders. We have the ability to e-mail a customer when a prescription or non-prescription product on his or her list is scheduled to run out (or in the case of OTC products, is on sale), reminding the customer to order a replacement or a prescription refill.
- Private, Secure Access to Customer's drugstore.com Prescription History. Customers who fill their prescriptions at the drugstore.com pharmacy can access their secure, individual medication profiles at any time. A written patient information document accompanies all medications dispensed to drugstore.com customers. This service enables customers to maintain a record of their prescription purchases for clinical, insurance, and tax reporting purposes.
- Consumer Drug Interaction Checker. Consumers can use this feature to research interactions among prescription drugs, herbal supplements, and dietary supplements, as well as to identify ingredient duplications between drugs. The checker also allows consumers to search for potential interactions between medications and food, alcohol, and tobacco products.
- Generic Insider. We notify customers if a branded drug becomes available in generic form or if a prescription drug becomes available in a non-prescription form over the counter.
- Privacy. When shopping at a physical store, many shoppers feel embarrassed or uncomfortable buying items that may reveal personally sensitive aspects of their health or lifestyle to store personnel or to other shoppers. Shoppers at the drugstore.com Web store avoid these problems by shopping from the privacy of their home or office and are able to



ask a drugstore.com pharmacist questions that they may otherwise feel uncomfortable asking in a public place.

In addition to enhanced service features, we believe that there is an important role for legitimate Internet pharmacies like drugstore.com in reducing health care costs. The Internet business model operates with less overhead than a typical retail chain, allowing us to offer prescription drugs up to an average of 20-30 percent off the prices typically offered by U.S.-based brick-and-mortars. It's also a little known fact that our generic drug prices are significantly better – often 50 percent less – than those of most foreign-based competitors.

### **The drugstore.com Commitment to Quality and Safety**

Legitimate online pharmacies such as drugstore.com are an important part of the daily lives of an increasing number of Americans. We are serving the growing numbers of online consumers by providing a safe, reliable, cost-effective, innovative, interactive, and personalized service features such as those described previously. We are fully compliant with the Health Insurance Portability and Accountability Act of 1996 (HIPAA), which established national standards to protect the privacy and security of personal health information.

We respect and honor the sanctity of the patient-physician relationship, and adhere to American Medical Association policy by requiring patients to see a physician before doing business with our pharmacy.

Our full-service pharmacy stocks more than 4,800 prescription drugs. The pharmacy services at the drugstore.com online pharmacy are provided by experienced professionals using sophisticated information technologies. We accept prescriptions only from licensed health care providers. We do not prescribe medications or otherwise practice medicine. Like traditional retail and mail-service pharmacies, we accept, verify, and cross-check prescriptions. The following outlines some of our extensive protocols:

- **Accepting Prescriptions.** For new prescriptions, customers can mail their prescriptions to us or direct their physicians to call in or fax their prescriptions to us. For transferred prescriptions, customers can direct their pharmacy to transfer their prescription to the drugstore.com pharmacy or request that we contact their pharmacy to transfer the prescription. Customers may order refills from us through our Web site or over the telephone or respond to one of our e-mail prescription refill reminders. For renewal prescriptions, customers may also request that we contact their physician directly to obtain prescription information.



- Verifying Prescriptions. Our pharmacists verify the validity and completeness of prescription drug orders using methods similar to those used by community-based pharmacists. The standard practice for verification of prescription drug orders is for the pharmacist to contact the physician's office by telephone or fax if there is any reason to question the prescription's validity, accuracy, or authenticity. In addition, our pharmacists call and verify the validity of prescription drug orders for controlled substances that we fill. Our pharmacists also verify that all legally required information is recorded on the prescription drug order and, as necessary, use a database of physician-identifying information to confirm the validity and accuracy of the prescription.
- Drug Utilization Review. We ask all customers who use our prescription drug services to provide our pharmacists with information regarding drug allergies, current medical conditions, and current medications. Our pharmacists use technology-aided processes to check and cross-check every prescription against the information we receive from the customer for drug, disease, and allergy interactions.

These procedures represent the basics of sound pharmacy practice. Consumers can identify whether an Internet pharmacy follows them by looking for the Verified Internet Pharmacy Practice Sites, or VIPPS®, seal. This voluntary program was developed by the National Association of Boards of Pharmacy (NABP) in conjunction with a coalition of state and federal regulatory associations, professional associations, and consumer advocacy groups, and is currently administered by the NABP. The NABP introduced this program in 1999, in response to public concern about the safety of pharmacy practices on the Internet.

To ensure reliability and safety, we strongly support a single, national standard for online pharmacies and advocate that, in order to legally sell pharmaceuticals online, all Internet pharmacies should be required to meet such a uniform certification standard. Based on our experience in complying with the stringent requirements of the VIPPS certification process, we believe that VIPPS can and should be the basis for a federally mandated program. We encourage Congress to move in this direction as soon as possible.

According to the National Association of Boards of Pharmacy, the VIPPS program:

- Provides important quality and credibility information for both Internet search engines and for consumers. The VIPPS Seal signifies to consumers, and to search engine companies, that the Internet pharmacy holds a valid license, that the pharmacy site has



been inspected by NABP-approved inspectors, and that the Internet pharmacy's operations meet stringent Internet pharmacy practice standards;

- Is an additional tool to assist regulators in identifying those online pharmacies, located out-of-state, that are lawfully practicing;
- Receives numerous complaints from consumers who have been defrauded by rogue sites located via Internet searches; investigates a variety of consumer complaints about rogue sites; counsels consumers who have been defrauded by rogue sites; and refers rogue sites to appropriate regulatory authorities;
- Has a long history of collaborating with state and federal regulators to investigate and shut down rogue sites. VIPPS was especially active in 2001, when numerous rogue sites were launched to sell Ciprofloxacin hydrochloride (Cipro®) for treatment of anthrax. NABP worked with its members and states' attorneys to identify and report rogue Cipro sites; and
- Is regularly contacted by the Better Business Bureau and financial institutions to verify unknown online pharmacies.

To be VIPPS-certified, an online pharmacy must comply with the licensing and inspection requirements of not only its own resident state, but also for each state to which it dispenses pharmaceuticals. In addition, pharmacies displaying the VIPPS seal have demonstrated to the NABP compliance with other stringent 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.

The VIPPS certification program administrators conduct an extensive licensure review that asks for a list of states in which the pharmacy is licensed or registered, as well as the license or registration numbers. It also asks for verification that all persons affiliated with the pharmacy site, including those affiliated through contractual or other responsible arrangements, who are engaging in the practice of pharmacy (including pharmacists and technicians), are appropriately licensed or registered in good standing in the state in which they practice. The VIPPS program also ensures that there are written policies and procedures for verifying the licensure or registration of new employee pharmacists and, where applicable, pharmacy technicians. This includes asking for details about any person whose license is not in good standing or whose license has been restricted within the past three years.

Additionally, the VIPPS program reviews a wide range of process controls designed to ensure quality and certifies that policies and procedures are in place that:



- Detail how the pharmacy's policies and procedures are organized, authorized, reviewed, revised, and retired/archived;
- Provide that, in conflicts that arise between individual state laws or regulations and/or between state and federal laws and regulations, the more stringent law or regulation is followed;
- Prevent the prescription drug order from being submitted, honored, and filled by multiple pharmacies;
- Assure that prescription medications are not prescribed or dispensed based upon telephonic, electronic, or online medical consultations without a pre-existing patient-prescriber relationship and an in-person physical examination;
- Assure reasonable verification of the identity of the patient, prescriber, and, if appropriate, caregiver;
- Require patient medication profiles and other related data to be maintained in a readily accessible format organized to facilitate consultation with the prescriber, patient, or caregiver;
- Detail the steps in conducting prospective drug use reviews prior to dispensing of medications or medical devices;
- Ensure patient confidentiality and the protection of patient identity and patient-specific information from inappropriate or non-essential access, use, or distribution while such information is being transmitted via the Internet and while the pharmacy possesses such information;
- Demonstrate that a mechanism is in place for patients to report errors and suspected adverse drug reactions and detailing the pharmacy's response to such reports;
- Provide a mechanism to contact the patient and prescriber if an undue delay is encountered in delivering a prescribed drug or device;
- Inform patients or caregivers about drug recalls;
- Educate patients or caregivers about the appropriate means to dispose of expired, damaged, and for securing and tracing shipments of controlled substances;
- Assure medications and devices are maintained within appropriate temperature, light, and humidity standards, as established by the United States Pharmacopeia, during storage and shipment;





- Demonstrate compliance with applicable federal and state laws regarding the sale of over-the-counter products identified as precursors to the manufacture or compounding of illegal drugs; and
- Demonstrate implementation of an ongoing Quality Assurance/Quality Improvement (QA/QI) program.

As mentioned previously, the VIPPS certification process is voluntary. Today, about 15 retailers nationwide participate, including drugstore.com and most large national brick and mortar chains with an Internet presence. This, however, is only a small percentage of pharmacies available to consumers through a simple Internet search.

In some cases, non-VIPPS certified pharmacies are indeed bad actors, posing as legitimate online pharmacies, confusing U.S. consumers and providing them with unsafe and illegal prescription drugs, including addictive narcotic drugs. In a June 17, 2004 report presented to the Permanent Subcommittee on Investigations, Committee on Governmental Affairs of the U.S. Senate, the General Accounting Office made clear that many rogue pharmacies are a serious threat to health and public safety. Many bypass the traditional doctor-patient relationship and provide medications without an actual prescription or face-to-face visit. Some provide consumers with pharmaceuticals that are expired, diluted, contaminated, or even counterfeit. At the same time they are jeopardizing public health, these rogue players are taking business away from and diminishing the reputation of legitimate online drugstores like drugstore.com.

### **Enforcement Mechanisms and Governing Authority**

We believe that all Internet pharmacies should be required to meet a uniform certification standard such as VIPPS. We also believe, however, that certification isn't enough to effectively stem the tide of rogue online pharmacies and ensure the integrity of our drug delivery system. Any certification standard must be backed up with clear lines of enforcement authority. The following outlines one approach that, we are convinced, would discourage illegal Internet pharmacies before consumers are put at risk:

- Make it illegal for online pharmacies to advertise on Internet search engines unless they meet the approved certification standard. Prohibit search engines from accepting advertisements from online pharmacies that are not properly certified.
- Stop credit card payment to pharmacies that do not meet the certification standard criteria, to stop funding at the source. The activities of many rogue pharmacies, such as Web sites that offer prescription drugs for sale to consumers without a valid





prescription, are currently illegal under U.S. law, and should be stopped. Requiring all pharmacies to be certified would establish an incontrovertible national standard for legal operation. Stemming the flow of funds to these sites would be similar to efforts by Congress to starve funding of illegal Internet gambling sites, and would largely help to accomplish the goal of putting illegal pharmacies out of business.

- 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 e-commerce enablers (media, payment, and delivery companies) can identify legitimate pharmacies vs. illegal operators.

As a final point, there are multiple layers of jurisdiction regarding oversight and enforcement of our nation's drug delivery system, resulting in confusion over who has ultimate enforcement authority. We suggest consolidation or coordination of efforts.

We encourage you to carefully examine the existing legal and regulatory structure and its adequacy to address the rogue Internet pharmacy problem. Rogue pharmacy Web sites that offer prescription drugs for sale to consumers without a valid prescription, among other questionable practices, are violating *at least* one Federal or state law. Enforcement entities are hampered, however, by a lack of funding and other resources, including state and federal resources for cyber-tracking technology, and a lack of clear jurisdiction over both foreign and domestic operators.

As the U.S. Congress looks for ways to make the Internet a safe place to shop for prescription drugs, drugstore.com stands ready to act as a resource in finding the best solution to this complex issue. U.S. consumers should feel confident that the online marketplace is safe and secure, especially for purchases that are as important to public health as prescription drugs. We are confident that a uniform certification process and the three-tiered approach to enforcement outlined above would most effectively address this growing public health problem.

Thank you for providing us with the opportunity to offer this testimony. I look forward to answering any questions you might have.

Respectfully submitted,

Jeff Kimmell, RPh



Vice President, Healthcare Services and Chief Pharmacy Officer  
drugstore.com, inc.

