



NATIONAL ASSOCIATION OF
CHAIN DRUG STORES

Statement
Of
The National Association of Chain Drug Stores

For
U.S. House of Representatives
Energy and Commerce Committee
Subcommittee on Oversight and
Investigations

Hearing on:

Counterfeit Drugs:
Fighting Illegal Supply Chains

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2322 Rayburn House Office Building

National Association of Chain Drug Stores (NACDS)
1776 Wilson Blvd, Suite 200
Arlington, VA 22209
703-549-3001
www.nacds.org

The National Association of Chain Drug Stores (NACDS) thanks the Members of the Subcommittee on Oversight and Investigations for consideration of our statement for the hearing on “Counterfeit Drugs: Fighting Illegal Supply Chains.”

NACDS represents traditional drug stores and supermarkets and mass merchants with pharmacies. Chains operate more than 40,000 pharmacies, and NACDS’ 125 chain member companies include regional chains, with a minimum of four stores, and national companies. Chains employ more than 3.8 million individuals, including 175,000 pharmacists. They fill over 2.7 billion prescriptions yearly, and help patients use medicines correctly and safely, while offering innovative services that improve patient health and healthcare affordability. NACDS members also include more than 800 supplier partners and nearly 40 international members representing 13 countries. For more information, visit www.NACDS.org.

We applaud the Subcommittee for holding this important hearing. The legitimate U.S. drug supply chain inside our borders is highly secure. However, there are threats from outside of the U.S. through bad actors that seek to send counterfeit, adulterated and illegal drug products to U.S. consumers through illicit channels that circumvent U.S. laws. There are many rogue entities, such as illegal online drug sellers, that operate outside the legitimate U.S. drug distribution supply chain, posing risks to U.S. consumers and healthcare practitioners and their patients. Below we discuss policy solutions that we believe would help to address these concerns and educate consumers and others on the risks associated with the illegal supply chain. These include targeting illegal online drug sellers through the chokepoint approach (a website or portal for consumers and Internet entities to use to determine if an online website selling medication is legitimate) and the use of the .pharmacy Internet domain name.

THE SECURE U.S. SUPPLY CHAIN IS STRENGTHENED BY THE NEW DRUG SUPPLY CHAIN LAW

We believe that the U.S. supply chain is one of the safest, if not the safest, in the world. The strength and commitment of U.S. supply chain stakeholders, such as pharmacies and others, are integral to this security. Our members take this responsibility very seriously. They have invested significant resources and efforts towards this goal over many years, including changes in their purchasing practices, actively supporting state legislation that strengthened supply chain integrity, and most

recently supporting enactment of Title II in H.R. 3204, the Drug Supply Chain Security Act. Title II added many new tools and requirements to enhance the security of the U.S. drug supply chain. A number of these responsibilities take effect in just a few months on January 1, 2015. While much work lies ahead to fully implement the new law, the chain pharmacy industry has already begun working with other supply chain sectors and their trading partners to move quickly on implementation strategies and is committed to continuing these efforts to effectively implement the law.

We applaud the leadership and efforts of Congress, the Food and Drug Administration (FDA) and others who worked tirelessly to enact this new law. We also commend the FDA on the efforts the agency has already taken towards implementation of the new law and on future activities. FDA recently released their implementation plan and the published notice of request for information on *Standards for the Interoperable Exchange of Information for Tracing of Human, Finished, Prescription Drugs, in Paper or Electronic Format*, Docket No. FDA-2014-N-0200. We look forward to working with FDA and other supply chain stakeholders on further implementation of the law. As lawmakers, we urge you to consider approaches that will benefit and educate U.S. consumers, healthcare practitioners and others on the threats from illegal supply chains and provide consumers with education and tools to identify the bad actors. Chain pharmacy is committed to working with Congress to protect U.S. consumers and the healthcare system from the risks of counterfeit and adulterated drugs.

TARGETING ILLEGITIMATE INTERNET DRUG SELLERS

NACDS believes that addressing the problem of illegitimate Internet drug sellers is an important component of combating illegal supply chains. These illicit online drug sellers target U.S. consumers often by offering to sell drugs without any prescription requirement and seeking to circumvent federal and state laws. These rogue entities lure U.S. consumers often by camouflaging their websites to look like legitimate pharmacy websites. To fool consumers, they frequently modify the website name to closely resemble that of a legitimate U.S. pharmacy website. They operate in clear violation of U.S. state and federal laws and regulations that protect public health and safety.

These illegal Internet drug sellers are often mistakenly referred to as Internet “pharmacies.” They are not pharmacies. They are not licensed as pharmacies by any U.S. jurisdiction, nor do they comply with any of the rigorous state and federal laws governing pharmacy licensure and the practice of pharmacy by pharmacists. Instead, these illegitimate Internet drug sellers are shipping unapproved, counterfeit, mislabeled, or adulterated products within or into the country.

Combat Illegal Internet Drug Sellers - “Chokepoint” Approach and Portal to Check Legitimacy

We support targeting illegal Internet drug sellers through the *chokepoint approach*. Under this approach, Internet service entities and companies such as domain name registrars that issue websites, financial entities that handle payment transactions for online sales, Internet Service Providers that provide information from the Internet, and common carriers that provide the mailing services would have authority to stop illicit transactions at their point of interaction with these bad actors. This approach would be aided by a portal where these Internet entities and companies would have the ability to check to see if an Internet drug seller’s website is valid or illegitimate.

Similarly, this portal would be available to consumers to check to find out if a website selling or offering to sell drugs is illegitimate or legitimate. For example, the consumer could enter the website into a portal and be informed if the “pharmacy” website is illegitimate. Providing consumers and healthcare practitioners with this option would allow them to check before purchasing medication over the Internet so that they can have confidence in the source of their medication.

Target Illegal Internet Drug Sellers with the .Pharmacy Approach

Another approach to aid in combating illegal online drug sellers is the effort by the National Association of Boards of Pharmacy (NABP) to get approval to be the registry that would offer the “.pharmacy” designation to legitimate online pharmacies. For example, an online pharmacy website could be PHARMACYABC.pharmacy.

Currently, “.pharmacy” is not permitted for use on the Internet. However, about two years ago, the global Internet entity¹ that determines what website domain names can be used decided to allow for a broader range of domain names and allowed entities to apply for them. As a result, NABP applied

for “.pharmacy.” NABP recently announced that they have been notified that they may start the initial steps towards being able to offer “.pharmacy” to legitimate Internet pharmacies.

COMMUNITY PHARMACIES – A RESOURCE FOR CONSUMERS

To further address these concerns, community pharmacists are well positioned to serve as a resource for consumers on the risks of illegitimate online drug sellers. They are one of the most accessible healthcare providers in the community and available to help educate their patients on the importance of obtaining medications through legitimate pharmacies where the drugs are sourced through the legitimate U.S. supply chain.

As highly educated medication use experts, pharmacists are also well-positioned to provide their patients with face-to-face, personal interactions. These include meeting with patients to counsel them on their medication therapy, reviewing patients’ drug use, and helping patients comply with their drug therapy regimen to enhance management of their disease states and conditions. Research has shown that an estimated one-third to one-half of all patients in the United States do not take their medication as prescribed. They may fail to take their prescription medications, take their medication incorrectly, or stop taking their medication altogether. These circumstances seriously undermine quality of life and quality of care, patient outcomes and the value of healthcare dollars spent. Poor medication adherence costs the U.S. approximately \$290 billion annually – 13% of total healthcare expenditures. Local, community pharmacists are an excellent resource both to help ensure patients understand the need to get their medications from legitimate sources and to make sure they take all their medications properly.

CONCLUSION

NACDS thanks the Subcommittee for consideration of our comments. We look forward to working with policy makers and stakeholders on these important issues.

¹ The Internet Corporation for Assigned Names and Numbers (ICANN)